4.2 局所画像によるナビゲーション

ここでは局所画像を用いてナビゲーションを行った30 例のうち,基準となる肋骨頭(①)と基準より1 肋間上のレベルの肋骨頭(②),①と②の中間になる椎骨上の点(③)の3点でレジストレーションを行ったとき23 例の結果について述べる.これらの点を選択できない場合の誤差については、文献[2]を参照されたい.

23 例の症例の内訳は手術者 A が 12 例, 手術者 B が 7 例, 手術者 C が 4 例であった. 図 8 に基準点を横軸にとったときのレジストレーション誤差について, 3 人の手術者を比較した結果を示す. 基準とした肋骨頭を横軸とし, 縦軸にレジストレーション誤差を示した. グラフを見ると, 19 例で目標精度とした 5.0mm 以下となっており, 精度は安定している. 肋骨間が 1 肋間であれば, 身体の捻転の影響も受けにくく, 背骨のレベルによらず誤差はほぼ一定となったと考えられる.

また,図9に施行の順番を横軸にしたときのレジストレーション誤差について,3人の手術者の比較した結果を示す.手術者Aに関しては,全例で5.0mm以下のレジストレーション誤差となっており,2.0mm以下に抑えている場合もある.手術者B,Cについては最初のうちは7.0-9.0mmの誤差となっているが,回数を重ねることで誤差が減少する傾向にある.大動脈瘤の走行によっては探索が難しいところを手探りで探索することになるため,手術者にある程度の解剖学的なイメージがなければ難しい作業であることが示唆された.

4.3 外科医のコメントと手術成績

画像を用いたナビゲーションによって,立体的な画像を用いて,患者の重要な肋間動脈の位置を特定し,走行を把握することができるようになったことは,次の 2 点を可能にしたとのコメントを得た.1)執刀医がこれまで経験と勘をもとに下していた決断に客観的な情報を加えることができるようになった.2)執刀医の頭の中だけにあったイメージを画像によって助手との情報共有できるようになった.これより,執刀医も自信を持って自分の判断が下せるようになった.

さらに、本システムを利用した30例の臨床例では、院内での死亡が1例あったが、対麻痺の発生はゼロであった.現在、東京女子医科大学で行われる胸腹部大動脈瘤の手術では、必ずナビゲーションを利用している.そして、手術における外科医の安心と患者のQOL向上させるためのツールのひとつとなっている.

5 今後の展望

今後,このシステムが他の医療機関でも利用されるようになるためには次の3点の問題を克服すべきである. すなわち,1)レジストレーション方法の簡易化,2)ベッドの移動による再レジストレーション,3)作業効率の向上 である。

1)レジストレーション方法の簡易化については,4.2 で示したようにレジストレーション点として解剖学的特徴点を正確に選択すること自体にスキルを要することがわかった.オリエンテーションがつけられない場合には,肋骨そのもののレベルを間違うこともあり得た.そこで,解剖学的特徴点を簡単に探し出すために,大局画像を取り入れたナビゲーションを行っており,肋骨のレベルを同定するのには十分の精度であった.大局画像では大動脈の走行までは確認できても肋間動脈の走行までは描出できない.そこで現在,大局画像と局所画像を融合させて,開胸前にレジストレーションした結果をそのまま用いたナビゲーションへの改良を行っており,画像の補正アルゴリズムについても検討をしている[9].

2) ベッドの移動による再レジストレーションについては、開胸前に行ったレジストレーションを開胸後も利用したい場合には考慮しなければならない問題となる. レジストレーションした結果を利用するためには、3 次元位置測定装置と患者の相対位置が動かないことが前提となる. しかし、通常臨床では手術野を確保するために患者のベッドを動かす機会が多い. 患者と計測器の位置関係がずれた場合には、再レジストレーションをすれば、ナビゲーションを再開できるが、レジストレーションの時間がかかるため、ベッドの動きを追跡し、補正する機能も追加した[10].

3)ナビゲーション施行において、最も労力がかかるのがセグメンテーションの作業である. CT の画像から 3D サーフェスデータを作成する工程には、膨大なデータから大血管と分枝・骨を精密に抽出する作業が必要である. 多くを人力に頼る作業であり、現在手術前には 1日がかりで準備をしている. 画像データから半自動的に血管・骨を抽出するために、予め骨や血管の構造をテンプレートとして読み込み、画素値と同時に解剖学的構造を考慮した領域抽出を行う方法を確立したい.

6 まとめ

本論文では、30 例の大動脈瘤手術に対して手術ナビゲーションを利用し、システムの有用性を論じた. そこで、以下の3点を満たすことを確認した. 1)ナビゲーションを用いて、重要な肋間動脈の位置を臨床上十分な精度で特定できた. 2)手術中に患者の体内で見えない血管の走行も CT 画像から血管・骨などの CG モデルを作成して呈示することで容易に把握できた. 3)手術後の対麻痺の発生率がゼロであった.

また、医師の熟練度によって、局所画像を用いたのみのレジストレーションは特徴点探索が難しいことがあるとわかった。そこで新しい試みとして、大局画像を用いたナビゲーションで予め解剖学的イメージを把握した上で、局所画像を用いたナビゲーションを施行するシステ

ムへと改良した.

今後は、これまでの成果を活かし、大局画像のレジストレーションのみでナビゲーションが行えるよう、発展させていきたい.

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胸腹部手術ナビゲーションのための重み付き特徴点レジストレーション

Registration using weighted feature points for a surgical navigation in thoracoabdominal surgery

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Key words: Navigation, Registration, Model Experiments

置はじめに

正確な手術ナビゲーションには、画像空間と手術空間の精度よい位置合わせが求められる。 胸腹部手術では、位置合わせ エマーカの配置ができないため、手術者が選択した解剖学的 特徴点を基準にレジストレーション(位置合わせ)する。 現在臨 株応用中のシステムは、体内の特徴点を利用するため、特徴点 の探索に労力を要する。 そこで、 体表上の特徴点を利用し、 各 特徴点の特性に応じて誤差を補正するレジストレーションを提 案する。 今回、 各特徴点の特性を調査したので報告する。

2. 方法

プレジストレーションは解剖学的に特徴のある形状をもつ骨上の点について、術前の CT 画像上で計測した点と術中に 3 次元位置計測装置で計測した点とを一致させることにより行う. この際, 生じる誤差は主に次の 3 つの要因:1)形状, 2)皮下組織原, 3) CT 画像(撮影体位等)による. そのうち, 1), 2)は, 特徴点周りの構造に由来するため, 人体模型(Fig.1)を用いて、

製差を推定する.

人体模型は骨格モデル(3D Scientific, Inc.)と皮下組織を模擬した2種のシート: A)シリコン, B)ソルボセイン(Sorbothane, Inc.)により構成される. 解剖学的特徴点は臨床経験より次の3意点: a) 恥骨稜, b) 腸骨突起, c) 胸骨角とし, それぞれ, シート厚は点 a (0mm, 10mm, 20mm, 30mm), 点 b (0mm, 1mm, 5mm, 10mm, 15mm), 点 c (0mm, 3mm, 6mm, 9mm)とした. これらのまデル上の特徴点を被験者が指し示した時の位置を計測し,特徴点形状, 皮下組織厚の変化に伴う計測値の平均と分散を算出する.

たこで、シート厚と実際のヒトの皮下組織厚との対応をとるため、ヒトの皮下組織の平均厚(点 a:33.7mm, 点 b:11.8mm, 点 に6.6mm)と比較する.

結果と考察

愛頭足方向に着目した結果を Fig.2 に示す. 縦軸は誤差値, 横軸はシート厚をヒトの皮下組織厚で割った無次元量である. つまり, 横軸の1という値はシート厚とヒトの皮下組織の平均厚とが変することを示す. 胸骨角の平均誤差および分散が頭足方原がmm 以下であった. 恥骨稜は平均誤差が 5mm 以下であったが, 分散が 10mm を越えることもあった. 腸骨突起は平均値, が散値共に大きく, 組織厚が厚いと 10mm を超える誤差も計測された.

本システムでは頭足方向について精度 10mm を目標として いため、レジストレーション誤差は 5mm 以下が望ましい. これ り、肋骨角は信頼の高い解剖学的特徴点と考えられる. 一方 によって変動する可能性が高い.

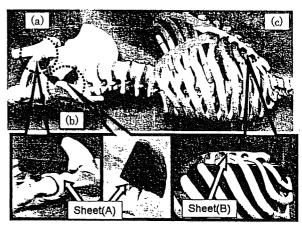
基とめと今後の展望

体表上からレジストレーション点を計測した際の特徴点ごとの 性を調査した. 胸骨角は信頼性の高い点であった一方で, 腸 は計測者によってばらつきの大きい点であった.

とジストレーション点として利用できる解剖学的特徴点は限ら ないるため, 信頼性の高い点と低い点を混合して用いること になる. 解剖学的特徴点ごとに信頼性を考慮した重み付けをすることがよりレジストレーションの精度を向上させると考える.

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(a)Public crest (b) Anterior superior iliac spine (c)Stemal angle

Fig.1 Anatomically specific points (model)

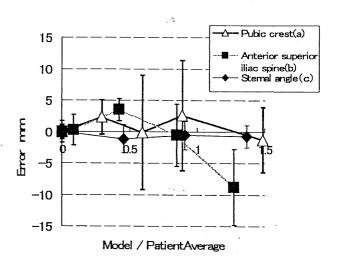


Fig.2 Errors corresponding to thickness of tissues (n=35)

機械学会[No.09-55]第22回バイオエンジニアリング講演論文集('10-1.9〜10 岡山)



体内構造を透かし見て 目標血管を特定する ~大血管ナビゲーションシステム~

国立医薬品食品衛生研究所 療品部 植松美幸

WITE A LICA & TITE OF



現在、私たちはGoogle Earth¹⁾を使って、地球上の様々な場所を空から地上からありとあらゆる角度で眺めることができる。それは私たちが幼い頃に地球儀を使ってくるくる回しながらいろいろな国を探したのとはまた違う感覚である。例えて言うなら、スモールライト*1を使って、自分自身の大きさを大きくしたり、小さくしたりして、いろいろな土地を訪れたような感覚である。このように今はコンピュータを使えば、全地球規模の情報も自由に操作できる時代になったのだと考えていいのかもしれない。

実はこれに似た技術はGoogle Earthが出る ずっと前から医療の世界にも応用されている²⁾。 この場合、上記例の地球に当たるのがヒトの身体である。地球の場合は、宇宙を周回する衛星から、あるいは道路情報を走る車から、計測した地球の画像と位置情報をもとに立体的に再構築したデータの集まりを扱っている。一方、医療では、X線CTやMRIといった画像診断機器によって撮影され、デジタル化された画像情報を用いる。

この画像データは3次元的な広がりをもつ情報の集まりで、血管や骨・臓器の構造を精密に表現可能である。本来なら身体を切開した後に見える世界が、身体に一切メスを入れることなく取得される。この情報は多くの場合、病状を診断するために用いられる。しかし、そればかりでなく、患者の身体を3次元的に表現する画像情報を手術中に医師の理解を助ける地図とし

^{※1} ドラえもんが4次元ポケットから出すひみつの道具の1つ。懐中電灯のような形をしている。スイッチを押して光を出し、物体に当てると、物体が小さくなる。

て用いることもできる。治療 しようとする目的の血管や腫 傷の位置をこの地図によって 医師が把握するのである。こ れを可能にするシステムを手 術ナビゲーションシステムと いう。本稿では、手術ナビゲー ションシステムの大血管外科 領域への応用の取り組みにつ いて紹介する。

手術リスクの高い 大血管外科手術

大血管とは、心臓の左心室 から全身に血液を送る重要な 血管、大動脈をいう。身体の ほぼ中心を頭から足の方向に 走る。大動脈の壁が薄くなり、 膨れたものを大動脈瘤とい う。瘤が破裂すると、死に至 る危険性が高い。そのため破 裂を未然に防ぐよう、人工血 管に置換する手術が行われ る。国内における胸部大動脈 瘤の手術は2005(平成17)年

に8,907件行われており、うち1割がステント 治療である3)。大動脈の人工血管置換術におけ る手術リスクは低下したとはいえ、死亡率が7 ~11%あり、手術合併症の下半身麻痺の発生率 は2~27%ある4)。そこで、手術リスクを回避 するための方法が諸施設で検討されている。

下半身麻痺の原因は、人工血管への置換後に 脊髄へ血液が十分に送られないためだと言われ ている。予防法の1つに、脊髄への多くの血流

図1(a) どれが大事な血管かな? 血管の開口部



を確保している前間動脈のみを手術中に同定し て温存し、人工血管置換後にも十分な血流を確 保することが有効であるとの考えがある。しか し、大動脈から分岐する肋間・肋下動脈は10 対あり、大動脈切開後に内壁側から見えるそれ ら動脈の開口部は、図1(a)に示すように5本 程度ある。その中から脊髄につながる重要な1 本の肋間動脈の開口部を同定し、血管壁の裏側 にある肋間動脈の走行を把握する作業は手術者

の経験と技術に大きく依存する。

ここで求められる技術は手術前に頭の中に思い描いた立体像と実際に目の前に広がる患者体内の解剖学的情報とが正確に一致することである。図1(b)に示すように、手術者は患者の予後を左右する1本の血管の位置を決定する。しかし、限られた時間の中で行わなければならず、手術者にとって大きな精神的負担となる。

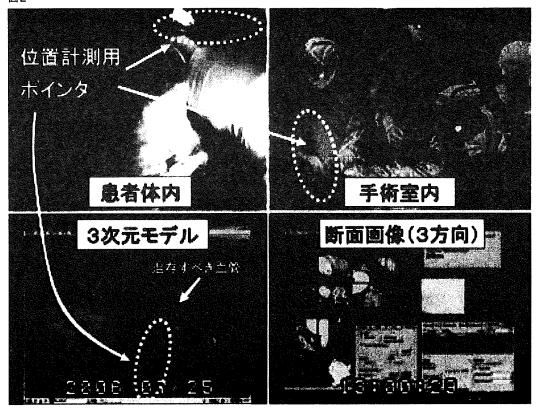
3 大血管手術ナビゲーション

われわれは、大血管手術ナビゲーションシステムを開発した⁵⁾。このシステムは、手術前の画像を地図としてモニタ画面に表示し、温存す

る肋間動脈の位置・走行を即座に把握するため のものである。医師が手に持っている術具の位 置を画面上に同時に指し示すことで、目標との 位置関係を確認できる。

本システムでは、地図となる画像に、患者体内の情報として手術前の3次元CTの画像を使用する。図2に示すように詳細な情報を確認するために3方向から見た断層画像を表示するほか、事前に血管や骨を部位ごとに分け、輪郭を抽出して3次元再構築したモデルを使用する。3次元モデルは、色・透明度に関して可変で見たい部位を見たい方向から自由に見ることができる。これにより、術者が術中に、いつでも容易に術野の空間的な位置関係を把握することができる。

図2



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4

システムの臨床応用

2006 (平成18) 年7月から2008 (平成20) 年8月までに東京女子医科大学で行われた胸部下行大動脈瘤および胸腹部大動脈瘤の人工血管置換術全30例で本システムを利用した。いずれも、手術中に重要な血管の位置を同定するのに役立っており、安心して手術ができると医師からコメントをもらっている。

技術的な側面からいうと、ナビゲーションを 行うには患者の画像と実際の患者の解剖学的情 報とが一致することが重要である。画像を手術 前に撮影することから、手術中の患者の体位と は異なっており、完全に一致させることは難し い。そこで、初期の21例については、動きの 小さい部位を精度よく合わせることでナビゲー ションを行っていた。しかし、開胸後に広い手 術野を確保できない場合は画像で見るように明 瞭にレジストレーションの位置を特定すること は難しく、限られた局所の領域を見て、手探り で特徴点を探すことになった。そこで、最近の 9例については、開胸前に体表上から体内の骨 や血管の立体的位置関係を把握し、作業を進め ることができるよう画像全体を用いたナビゲー ションを導入している。。

ちおりに

手術は低侵襲化の方向に進んでおり、なるべく切らずに治す傾向にある。今回紹介したような開胸を伴う手技は、未来の医療においては少なくなるに違いない。しかし、ステントやコイルを用いた治療、エネルギー照射することによ

る療法にしても、ある目的に対してどのように アプローチするのかというプロセスは重要であ る。またさらに、実際に身体を開けて見ること ができずに治療するからこそ、目的とする治療 域へのナビゲーションという技術は重要な治療 支援技術となるであろう。画像の情報も事前に 撮影したものだけでなく、リアルタイムに取得 したデータを融合させた情報を用いるようにな るであろう。そのためには、実際の身体とコン ピュータ上の画像データとの正確かつ迅速な位 置合わせが求められる。

6

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Anatomical Pattern of Feeding Artery and Mechanism of Intraoperative Spinal Cord Ischemia

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Background. We evaluated correlation between anatomical pattern of the spinal cord feeding artery, detected by preoperative multidetector row computed tomography, and the mechanism of spinal cord ischemia during aortic surgery.

Methods. One hundred sixteen patients underwent multidetector row computed tomography before descending or thoracoabdominal replacement. Segmental arteries feeding the spinal cord were detected in 92 patients (79%), and were classified into "critical" (isolated hairpin shaped) or "supplemental" (confluenceshaped or multiple). Spinal cord ischemia was monitored together with distal aortic perfusion in 53 of them by motor-evoked potentials, evoked spinal cord potentials, or both. The relationship between monitoring results and operative management to the detected feeding arteries was analyzed.

Results. When no feeding segmental artery was involved in the extent of replacement (n = 18), spinal cord

ischemia was detected in 1 (6%), which was due to cross-clamping the subclavian artery. When a supplemental feeding artery was involved (n = 15), ischemia was detected in 7 patients (47%), and was reversed by stopping back-bleeding. When a critical feeding artery was involved (n = 20), ischemia was detected in 6 (30%). In 3 of them, ischemia was reversed by stopping back-bleeding, whereas it was reversed only after reconstruction of the critical feeder in the remaining 3. Paraparesis occurred in 1 of the latter 3, and the incidence of spinal cord injury was 2% (1 of 53).

Conclusions. When the involved feeding artery is a supplemental one, the steal phenomenon is the predominant mechanism of ischemia. Conversely, blood flow interruption to the critical feeding artery may cause spinal cord ischemia without steal phenomenon.

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Ischemic spinal cord injury is a devastating complication of aortic surgery. Although it is a multifactorial event, there is no doubt that anatomical characteristics of the spinal cord blood supply play a pivotal role. Spinal cord blood supply has multiple feeders and rich collateral networks both inside and outside the spinal canal, and is not dependent upon any single artery [1]. However, several anatomical studies have pointed out that the anterior spinal artery is sometimes hemodynamically discontinuous at its junction with the radicular artery [2, 3], which may be a cause of insufficient collateral blood flow to this area.

With the recent advance in the imaging technologies, noninvasive visualization of the spinal cord feeding arteries has become reliable, either by magnetic resonance imaging (MRI) [4–6] or multidetector row computed tomography (MD-CT) scan [7, 8]. We have been using MD-CT scan for this purpose [8]. Based on this experience, we hypothesized that anatomical pattern of the

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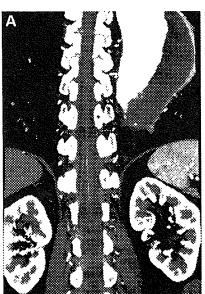
spinal cord feeding arteries, visualized by MD-CT scan, reflects hemodynamic continuity of the anterior spinal artery and is related to the prevalence and mechanism of intraoperative spinal cord ischemia. The study aim was to test this hypothesis in our clinical experiences.

Material and Methods

We retrospectively analyzed a total of 116 patients who underwent MD-CT scan to detect spinal cord feeding arteries, as a part of preoperative evaluation, from September 2001 through January 2009. There were 39 descending and 77 thoracoabdominal lesions, and 36 of the latter had Crawford I or II extent. Forty-eight had aortic dissection. The imaging system used had 64 detector rows. This study was approved by the Institutional Review Board. All the patients gave informed consent.

Segmental arteries that fed the spinal cord were detected in 92 patients (79%), and were multiple in 34 patients (29%). Their anatomical pattern was classified into the "hairpin" shaped and the "confluence" shaped (Fig 1). The latter were frequently accompanied by a more proximally located hairpin-shaped feeding artery. Distribution of these feeding arteries is shown in Figure 2, with respect to each anatomical pattern. The hairpin-

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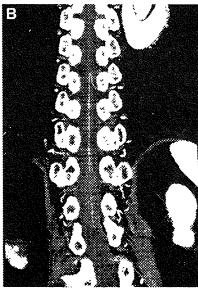


Fig 1. Anatomical patterns of the spinal cord feeding artery detected by multidetector row computed tomography (MD-CT) scan: (A) confluence-shaped, (B) hairpin-shaped. The confluence-shaped arteries were frequently accompanied by a more proximally located hairpin-shaped artery, as in this Figure.

shaped ones were arising from T7 to L1, predominantly in the left. This finding is consistent with our current knowledge of the great radicular artery. On the other hand, confluence shaped ones were distributed more distally, in accordance with a previous anatomical study [9].

For the following study on the prevalence and mechanism of intraoperative spinal cord ischemia, isolated hairpin-shaped feeders were classified as "critical" and confluence-shaped ones or hairpin-shaped ones that were accompanied by distal confluence shaped ones (multiple feeders in continuity) were classified as "supplemental," based on the assumption that multiple feeders were not clamped simultaneously.

Study on Prevalence and Mechanism of Intraoperative Spinal Cord Ischemia

Among the 92 patients in whom spinal cord feeding arteries were detected, 28 without electrophysiologic monitoring, 10 undergoing deep hypothermic operation, and 1 without distal aortic perfusion were excluded from

the study. Therefore, the study subjects consisted of the remaining 53 patients who underwent surgery with monitoring and distal aortic perfusion. There were 17 descending and 36 thoracoabdominal lesions, and 18 of the latter had Crawford I or II extent. Sixteen had aortic dissection, and none had acute presentation.

Our surgical technique, which we call the multisegmental sequential repair, has been reported previously [10]. Briefly, the distal one third of the descending thoracic aorta, where spinal cord feeding arteries were usually present, was opened in two or more sequences, and segmental arteries, usually one pair from each segment, were reattached sequentially by separate tube grafts. Presence of mural thrombus did not preclude the use of this technique as long as the aorta could be clamped and blood flow through distal aortic perfusion could effectively be blocked. The rationale of this technique was to expect collateral blood flow through the neighboring segmental arteries during reattachment of a segmental artery, and to minimize the steal phenomenon in opening the aorta. In this technique, we always noticed

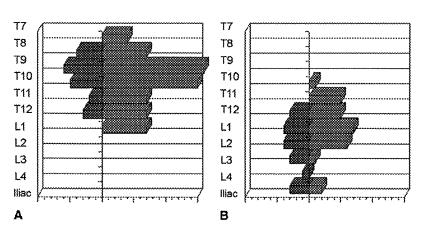


Fig 2. Distribution of the spinal cord feeding arteries with respect to each anatomical pattern: (A) hairpin shaped, and (B) confluence shaped.

active back-bleeding from the patent segmental arteries, reflecting the presence of rich collateral blood flow. We usually used a specially designed occlusion balloon catheter (A shield; Asahi Intecc, Nagoya, Japan) to stop back-bleeding during reconstruction. In addition, mild hypothermia and cerebrospinal fluid drainage, to maintain its pressure at 13 cm $\rm H_2O$, were also employed.

Intraoperative spinal cord ischemia was monitored by transcranial motor evoked potentials, evoked spinal cord potentials, or both, using a Neuropack MEB-2204 system (Nihon Kohden, Tokyo, Japan). For motor evoked potentials, myogenic responses of tibialis anterior and abductor hallucis muscles were recorded, together with the abductor pollicis muscle as a control. In order not to interfere with motor evoked potentials monitoring, total intravenous anesthesia was used and the anesthetic depth was controlled by bispectral index level. Muscle relaxants were not used except for anesthetic induction. Evoked spinal cord potentials were monitored using two epidural electrodes, one for stimulation and one for recording. The detail of monitoring technique was reported elsewhere [11, 12].

The relationship between monitoring results and operative management to the detected feeding arteries was analyzed.

Results

There was 1 hospital death (2%) of a patient with Crawford I nondissection aneurysm and 1 patient with paraparesis (2%) with Crawford I postdissection aneurysm. Intraoperative spinal cord ischemia was detected in 12 patients. When no feeding segmental artery was involved in the extent of replacement (n=18), spinal cord ischemia was detected in 1 patient (6%); it was due to cross-clamping the subclavian artery and was reversed by selective perfusion. When supplemental feeding arteries were involved (n=15), ischemia was detected in 7 patients (47%) and was reversed by stopping backbleeding. When a critical feeding artery was involved

Table 1. Prevalence of Intraoperative Spinal Cord Ischemia Versus Extent of Repair and Feeding Artery Involvement

Postant of		Involved Feeding Arteries			
Extent of Repair	Dissection	No	Supplemental	Critical	Total
Descending	Yes	1/3	1/1		2/4
	No	0/6	1/3	0/3	1/12
Crawford I	Yes		_	2ª/4	2/4
	No	0/2	1/4	1/3	2/9
Crawford II	Yes	******	0/1	2/4	2/5
Crawford III	Yes	_	0/1	0/1	0/2
	No	0/2	1/2	_	1/4
Crawford IV	Yes	0/1	_	_	0/1
	No	0/3	2/2		2/5
Safi V	No	0/1	1/1	1/5	2/7
Total		1/18	7/15	6/20	14/53

^a One patient with paraparesis.

(n = 20), ischemia was detected in 6 patients (30%). In 3 of them, ischemia was reversed by stopping back-bleeding, whereas it was reversed only after reconstruction of the critical feeding artery in the remaining 3. Paraparesis occurred in 1 of the latter 3, and the incidence of spinal cord injury was 2%. Ischemic monitoring changes started to recover right after these maneuvers.

When extent of repair was taken into account, critical feeding arteries were involved in 11 patients with Crawford I or II extent and in 9 patients with less extensive repair. Prevalence of intraoperative ischemia was higher with Crawford I or II extent, and all the 3 patients in whom ischemia was not reversed by stopping backbleeding had Crawford I or II extent (Table 1).

Comment

The results of present study showed that anatomical pattern of the spinal cord feeding arteries, detected by preoperative MD-CT scan, is related to the prevalence and mechanism of intraoperative spinal cord ischemia. Although similar classification of the anatomical pattern was proposed by Kawaharada and colleagues [5] using MRI, its relationship with the mechanism of ischemia has not been reported. While steal phenomenon was the most frequent mechanism of intraoperative ischemia, comprising two thirds (10 of 14) of them in the present series, blood flow interruption to the critical feeding artery, defined as an isolated hairpin-shaped one, may cause spinal cord ischemia without the steal phenomenon, especially when extensive Crawford I or II repair was performed.

These results not only are consistent with the collateral network concept proposed by Griepp and Griepp [13], but also may improve our understanding as to when collateral blood flow fails to maintain spinal cord perfusion within a viable range. Namely, visualization of a hairpin-shaped feeding artery means that there is a great discrepancy between the diameter of the anterior spinal artery above and below the junction, and spinal cord perfusion proximal to this point is vulnerable to ischemia even with the use of distal aortic perfusion, as pointed out by Svensson and colleagues [3] in 1986.

The prevalence of intraoperative ischemia in the absence of steal phenomenon was 6% (3 of 53) in this series, which seemed higher than that reported by the Griepp group [1, 14]. However, it is not different from the incidence of postoperative spinal cord injury reported by the groups who do not reattach segmental arteries [15, 16] or that after thoracic endovascular aneurysm repair [17, 18]. The difference from the Griepp series may be explained by their technique of sequentially dividing segmental arteries before opening the aorta.

The clinical implication of the present results is clear. When no spinal cord feeding artery is involved in the extent of repair, there is no need for segmental artery reattachment, which has also been shown by previous studies [19]. When an isolated hairpin-shaped feeding artery is involved in the extensive Crawford I or II lesion, it may be better to consider the segmental artery reat-

tachment, using a more aggressive method of spinal cord protection than that depending upon collateral flow, such as active segmental artery perfusion or deep hypothermia. For the remaining cases, segmental artery reattachment, using our optimized surgical technique that maximally takes advantage of collateral blood flow, seems at least not detrimental. Therefore, we will continue to use this strategy, expecting that it will reduce the risk of delayed-onset injury resulting from the postoperative hemodynamic deterioration [20].

Study Limitations

One may argue against the accuracy of MD-CT scan to detect the spinal cord feeding arteries, especially those with confluence shape arising from distal aortic segment. Nijenhuis and colleagues [6], using MRI with two consecutive dynamic phases, have reported that such a vessel is the great anterior radiculomedullary vein, and reported its validation in the postmortem examination of 1 patient [21]. However, Hyodoh and colleagues [22], using MRI, have reported that spinal cord drainage vein merged at T9 to L2 levels, which suggests that distally located vessels detected in the present study were not necessarily veins. In contrast to the four-row machine and fixed scan delay used in the Nijenhuis series [6], we used a 64-row machine and an automated trigger system to acquire images in the arterial phase. In our experience, change from the four-row machine to the 64-row one dramatically improved the imaging quality. In addition, most recent series have reported the use of 64-row machines, suggesting that image resolution in our series is accurate enough, although machines with 128 or 256 rows may further improve the imaging quality. Because the anatomy of the spinal cord drainage vein has not been extensively studied, further works will thus be required on this issue.

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ACQUIRED CARDIOVASCULAR DISEASE

Hybrid endovascular aortic arch repair using branched endoprosthesis: The second-generation "branched" open stent-grafting technique

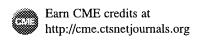
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Objective: We advanced the open stent-grafting technique with a branched endoprosthesis, which reconstructs simultaneously the cervical branches and descending aorta within an acceptably short interval of deep hypothermic circulatory arrest. In this study, we evaluated the efficacy of this new technique and assessed the early and midterm results.

Methods: From January 2004 to September 2007, the branched open stent-grafting technique was performed in 69 cases (55 men, average age 66.2 years, 36 degenerative aneurysms and 33 aortic dissections, 13 [18.8%] in emergency, 7 [10.1%] redo cases). Under deep hypothermic circulatory arrest, the branched endoprosthesis was delivered through the opened proximal aortic arch, and total arch repair was completed. To avoid cerebral embolism, retrograde cerebral perfusion was performed at the end of deep hypothermic circulatory arrest.

Results: Average time of operation, cardiopulmonary bypass, and deep hypothermic circulatory arrest was 417, 130, and 36 minutes, respectively. A total of 124 cervical stent grafts were inserted and successfully delivered in 121 (97.6%). Operative mortality within 30 days was 3 (4.3%). The major postoperative complications involved 4 (5.8%) strokes and 2 (2.9%) spinal cord injuries. No aorta-related death was observed after discharge from hospital, and the survival was 90.9%, 88.8%, and 88.8% at 1, 2, and 3 years, respectively. Six (5.0%) cervical stent grafts showed endoleak; however, all these cases were successfully treated by additional endovascular repair.

Conclusion: Aortic arch repair with branched open stent grafting is an effective technique with satisfactory early results. In midterm analysis, cervical branch events were acceptably rare and controllable. This technique could be an attractive alternative to conventional total arch replacement.



Open stent grafting is a hybrid aortic arch repair method that involves stent grafting in conventional aortic arch surgery. With this technique, surgeons can complete total arch repair by inserting a stent graft into the descending aorta through the opened proximal arch, which eliminates the difficulty of direct distal anastomosis in the deep portion beyond the left subclavian artery. The feasibility of this procedure as an alternative to elephant trunk technique was described, and also the long-term durability was reported. 1.2 The most outstanding results were presented when open stent grafting

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was applied to total arch repair in acute type A dissection, because it provided not only easy management of distal anastomosis but also excellent clotting formation of the false lumen in the descending thoracic aorta. These results suggested that open stent grafting could be a powerful method to complete total arch repair in acute type A dissection; however, it is still a far more complex procedure than hemiarch replacement because it still requires cervical branch reconstruction of the same sort of conventional arch repair.

With the intention to make total arch repair a much simpler procedure, we modified the stent graft to the second generation and developed branched endoprosthesis. The branched endoprosthesis was designed to reconstruct the descending aorta and cervical branches simultaneously in a single circulatory arrest period through the opened proximal aortic arch, thus completing total arch repair by the same aortic incision line as hemiarch repair.

In this study, we describe the efficacy of aortic arch repair using the branched open stent-grafting technique by evaluating the early and midterm results.

MATERIAL AND METHODS Patients

The branched open stent-grafting technique and the retrospective review of the records for publication were approved by the Institutional Review Board. From January 1994 to September 2007, 195 patients with aortic

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Abbreviations and Acronyms

3DCT = 3-dimensional computed tomography

BCA = brachiocephalic artery

DHCA = deep hypothermic circulatory arrest

LCCA = left common carotid artery LSA = left subclavian artery

RCP = retrograde cerebral perfusion

TEVAR = thoracic endovascular aortic repair

arch pathologies were operated using open stent-grafting technique in 2 centers (Osaka University Hospital, Osaka General Medical Center). Among them, 69 consecutive operations after April 2004 were the second-generation branched open stent-grafting technique. Informed consent was required in each case. The mean patient age was 66.2 years (range, 33–85 years), and preoperative comorbidities of the patients are listed in Table 1. The operation was performed for 36 (52.2%) degenerative/atherosclerotic aneurysms and 33 (47.8%) aortic dissections, including 13 (18.8%) emergency status (6 ruptured aneurysms and 7 acute type A dissections).

The selection criteria for branched open stent grafting were aortic arch/proximal descending aortic aneurysm and aortic dissections that necessitated aortic arch replacement to close the primary intimal tear. All these aortic pathologies were excluded from indication for thoracic endovascular aortic repair (TEVAR), mostly because an adequate proximal landing zone was not provided even by covering the left subclavian artery. Regarding the patient's condition (eg, instability, age, or comorbidities), inclusion criteria were the same as that of conventional ascending aortic repair. The aortic characteristics are listed in Table 2, and the specifics are indicated as follows.

Type A dissection. In acute (within 14 days from onset) type A dissection, we selected hemiarch repair or total arch repair with branched open stent-grafting technique to accomplish complete resection of the intimal tear. Patients in all 7 cases of branched open stent grafting had intimal tears in the aortic arch, which were unable to be resected by hemiarch replacement. Six patients with chronic type A dissection were operated with the branched open stent-grafting technique; all of these were redo cases (status of post-ascending aortic replacement/aortic root replacement in acute phase).

Type B dissection. All type B dissections had complicated status, which had been the indication for primary intimal tear closure (eg, aneurysmal enlargement of false lumen, malperfusion, intractable pain). In our institution, when proximal sealing was adequate, TEVAR with or without subclavian coverage was the first choice to close the intimal tear. When proximal sealing was not adequate (eg, tight arch angulation, aneurysmal dilatation of the arch), arch replacement with the branched open stent-grafting technique was performed. In this period, primary entry closure of type B dissection was performed by TEVAR in 28 cases and by branched open stent grafting in 20 cases.

Degenerative/atheroscleritic aneurysm. These aneurysms were also excluded from indication for TEVAR with cervical debranching because of lack of adequate proximal landing zone. In patients with extended aortic aneurysms (involving aortic arch and descending thoracic aorta more distally than 10 cm from left subclavian artery), 2-stage repair was performed (branched open stent grafting with distal flotage and delayed aneurysm exclusion, with extensional TEVAR in the next day).

Description of the Device

The branched endoprosthesis used in this study was a homemade device. It was made of a noncoated polyester fabric graft (main body: WSL graft, cervical branch: WST graft; Ube, Japan) with Gianturco stent (William

TABLE 1. Preoperative patient profiles

Demographic	
Gender	
Male	55
Female	14
Age (y)	
Mean	66.2
Range	33-85
Marfan syndrome	3 (4.3%)
Preoperative complications	
Stroke	7 (10.1%)
Spinal cord injury	2 (2.9%)
Coronary artery disease	10 (14.5%)
Chronic obstructive pulmonary disease	2 (2.9%)
Chronic renal failure (creatinine > 2.0 mg/dL)	7 (10.1%)
Hepatic failure	2 (2.9%)
Iliac artery malperfusion	3 (4.3%)

Cook Europe A/S, Biaeverskov, Denmark) for the main body and a Palmatz stent (Cordis Endovascular Systems, Miami Lakes, Fla) for cervical branches (Figure 1). The main body was composed of a suturing portion and a stented portion, and corresponding to the number of reconstructing cervical artery, 1 to 3 branches were attached. Normally, 2 branches (left subclavian artery [LSA] branch, left common carotid artery [LCCA] branch) were attached. The size of each part was determined by the measuring results using preoperative 3-dimensional computed tomography (3DCT). The diameter of each landing zone (descending thoracic aorta and cervical arteries) was calculated by tracing the intimal circumference, and an oversized graft (10%-15% in aneurysms, 5%-10% in dissections) was selected. The length of each part and distance between the branches were also designed according to 3DCT measurement. The stented portion of the main body was composed of self-expandable Giantruco Z stent and mounted on a balloon catheter (20F Silicon nephrostomy balloon catheter) with restraining silk string. The branches involved the Palmatz stent, and these were fixed on a balloon catheter (Powerflex, Cordis endovascular System; Figure 2). Assembly of the stent graft and preparation for insertion (mounting to the balloon catheter) were performed at the side table in

TABLE 2. Aortic characteristics

Pathology	
Aneurysm	36 (52.2%)
Atherosclerosis	35
Aortitis	1
Dissection	33 (47.8%)
Type A	13
Acute	7
Chronic	6
Type B	20
Acute	5
Chronic	15
Diameter of aneurysm (mm)	61.2 ± 10.6
Status of operation	
Emergency	13 (18.8%)
Rupture	6
Acute type A dissection	7
History of aortic repair	
Ascending/aortic root	7 (10.1%)
Descending/thoracoabdominal	4 (5.7%)
Abdominal	7 (10.1%)

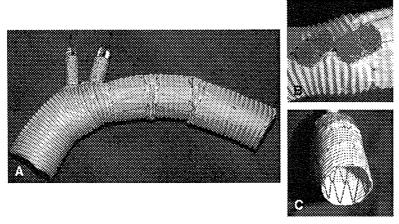


FIGURE 1. A, Whole image of the branched endoprosthesis, made up of a main body and cervical branches. B, The cervical branch is composed of a balloon-expandable stent. C, Stented portion of the main body. It is composed of self-expandable Z stent.

parallel with surgery. It could be completed within about 60 minutes, which was shorter than the time to establish deep hypothermic circulatory arrest at 20°C.

Surgery

After endotracheal intubation with a single lumen tube, the patient was positioned on the operating table in supine position with the right arm abducted on an armrest. The left arm was secured at the side, with rotation outward to expose the brachial artery. The left brachial artery was isolated with small incision, and a sheath introducer (Radiforcus introducer II, 5F, 10 cm; Terumo, Japan) was cannulated. The femoral artery was also cannulated by puncture with the same sheath introducer, and after administering heparin (100 U/kg), guide wires (0.035 inches, 260 cm, Radifocus guide wire) were advanced through these sheath introducers to the ascending aorta under the guide of fluoroscopy. Arterial pressure monitoring was also performed with these sheath introducers.

A median sternotomy was made, and the pericardial space was entered. Heparin (300 U/kg) was then administered. The right axillary artery and femoral artery contralateral to the sheath introducer were isolated and cannulated with a 16F or 18F cannula for blood return. Both venae cavae were

cannulated separately through the right atrium, and cardiopulmonary bypass was established with right axillary artery perfusion. Perfusion cooling was initiated to bladder temperature of 20°C; the ascending aorta, brachiocephalic artery (BCA), and predetermined aortic incision line between BCA and LCCA were exposed.

In distal arch repair, with circulation arrest at bladder temperature of 20°C, aortic transection was made between the BCA and LCCA. Cardioplegic solution was administered antegradely using a balloon catheter. The guide wires from the femoral artery and left brachial artery were pulled out from aortic transection and led into the balloon catheter of the stent graft's main body and LSA branch, respectively. After inserting the branched endoprosthesis carefully, the LSA branch and LCCA branch were deployed by inflating the Powerfelx (Cordis Endovascular System) balloon with inflation device (8 atm, 5 seconds). Next, the main body was deployed by releasing the restraining silk string, and the stented portion was dilated with the balloon catheter to confirm the full opening of the stent graft. The suturing portion of the main body was trimmed and sutured to the transected aorta in inclusion fashion with continuous 3–0 polypropylene suture. Before finishing the suture, to flush out the air and debris in the cervical branches, retrograde cerebral perfusion (RCP) through the superior vena

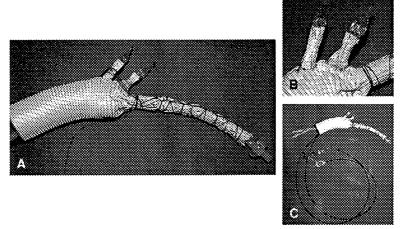


FIGURE 2. Delivery system. A, The stented portion of the main body is restrained with a silk string. B, The cervical branch is mounted on a balloon catheter. C, Whole image of the delivery system.

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TABLE 3. Device size

	Average	Range
Main body		
Diameter (mm)	29.9 ± 5.9	20-40
Length (mm)	92 ± 18	75-145
Cervical branch diameter		
LSA	11.5 ± 1.1	8-14
LCCA	10.0 ± 1.0	8-12
BCA	13.0 ± 1.1	12-14

LSA, Left subclavian artery; LCCA, left common carotid artery; BCA, brachiocephalic artery.

caval cannula was initiated for 2 to 3 minutes at a flow of 600 to 900 mL/min, maintaining a central venous pressure of less than 25 mm Hg. RCP was also used when deep hypothermic circulatory arrest (DHCA) time exceeded more than 30 minutes. Then the descending thoracic aorta was flushed out by femoral blood return at a flow of 500 to 1000 mL/min for less than a minute, and finally antegrade reperfusion by axillary blood return was restarted.

In total arch repair, the ascending aorta and the root of the BCA were resected at the beginning of DHCA. After inserting the endoprosthesis, the suturing portion of the main body was sutured to the transected stump of the aorta with buttressing Teflon felt, and subsequently continuous anastomosis to a woven Dacron graft with 2 side branches (UBE Shield graft, UBE, Japan) was made.

Rewarming was initiated to rectal temperature of 35°C, and during this period, reconstruction of the BCA and proximal suture of the ascending aortic replacement were performed in total arch repair. Hemostasis was affected, and the patient was weaned from cardiopulmonary bypass.

Statistical Analysis

All data were reviewed retrospectively. Continuous variables are expressed as mean \pm standard deviations and categorical variables as percentages. Survival and freedom from endoleaks and from aortic intervention were estimated by the Kaplan-Meier method. Data analysis was performed using SPSS 11.0 for windows (SPSS Inc, Chicago, III).

RESULTS

Operative Records

In this series, 41 (59.4%) total arch repairs and 28 (40.6%) distal arch repairs were performed. Nine (13.0%) patients required 2-stage repair. Other concomitant procedures included 2 (2.9%) aortic root replacements, 4 (5.8%) coronary artery bypass grafts, 4 (5.8%) tricuspid valvoplasties, 1 (1.4%) mitral valve replacements.

The branched endoprosthesis had 1 branch in 14 (20.3%) patients, 2 branches in 51 (73.9%), and 3 branches in 4 (5.8%). The size data of the device are listed in Table 3. A total of 124 cervical branches (1.79/case) were inserted, and 121 (97.6%) of them were successful. There were 3 (2.4%) branch insertion failures: 1 LSA branch slipped out from the orifice of LSA, 1 LSA branch did not fully open, and 1 LCCA branch was obstructed by unintended involvement to the aortic inclusion anastomosis. The 2 cases of failed LSA branch insertion required bypass grafting to LSA.

The overall average operation time was 417 minutes. In distal arch repair, operation time was shortened to an average 325 minutes (shortest time: 191 minutes). The mean du-

ration of DHCA including terminal RCP was 36 ± 4 minutes (range 26–49 minutes).

Mortality and Morbidity

Operative mortality within 30 days was 3/69 (4.3%). The causes of deaths were 1 multiorgan failure, 1 acute subdural hematoma by accidental in-hospital fall over injury, and 1 massive progression of unfounded rectal cancer. There were 2 other hospital deaths (overall in-hospital mortality 5/69 [7.2%]); 1 was secondary aortoesophageal fistula and the other was drug-induced thrombotic thrombocytopenic purpura. The aortoesophageal fistula had occurred in a 67year-old man who presented rapid expansion (>60 mm) of subacute type B dissection. The true lumen of the lower descending aorta was severely compressed, and as a consequence, malperfusion of the lower extremity and hepatic failure were observed. To repair the whole descending aorta, we planned to perform distal arch repair with branched open stent grafting and secondary TEVAR with visceral debranching for thoracoabdominal lesion. The postoperative course of the distal arch repair was uneventful; however, the thoracoabdominal aorta ruptured while waiting for the next surgery, and fatal aortoesophageal fistula developed.

Postoperative complications include 4 (5.8%) strokes, 2 (2.9%) spinal cord ischemias, 2 (2.9%) acute renal failures, 2 (2.9%) tracheotomies, 2 (2.9%) reexplorations for bleeding. Among 4 strokes, 2 were small multiple infarctions in both cerebral hemispheres in degenerative aneurysms with massive mural thrombosis. One was in the cerebellar hemisphere, and this patient also had severe mural thrombosis. One was observed in a patient with acute type A dissection with dissecting left subclavian artery, which showed infarcted left posterior cerebral artery lesion.

In our series, there were 7 (10.1%) cases of reoperative total arch repair and the results were satisfactory; mortality 0%, stroke 0%, spinal cord ischemia 0%, tracheostomy 0%.

Survival and Aortic Events

In average 20.3-month follow-up (range 1-41 months, 100% completion), there were 2 late deaths: 1 pneumonia and 1 malignant melanoma. No aorta-related death was observed, and actuarial survival estimates 1, 2, and 3 years after the procedure were 90.9%, 88.8%, and 88.8%, respectively.

There was no endoleak from the distal end of the main body, and also no new intimal tear creation by the edge of the stent graft. Four patients having dissection (3 chronic dissections and 1 acute dissection with Marfan syndrome) required intervention to control other intimal tears in the remaining dissected aorta (3 TEVAR of descending/thoracoabdominal aorta and 1 graft replacement of abdominal aorta). No patient with degenerative aneurysm required intervention for aortic pathology. The freedom from aortic

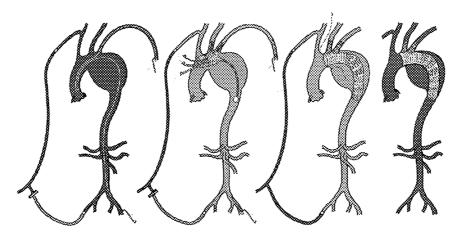


FIGURE 3. Distal arch repair with branched open stent-grafting technique.

intervention was 95.6%, 92.8%, 87.4% at 1, 2, and 3 years, respectively.

There were 8 (6.4%/branch, 11.6%/case) cervical branch events. Six showed endoleak from the distal end of cervical branches (5 in the LSA branch and 1 in the LCCA branch); however, all 6 patients underwent additional endovascular repair successfully (endovascular repair success: 6/6 [100%]). The freedom from endoleaks was 92.0%, 92.0%, and 84.4% at 1, 2, and 3 years, respectively. The remaining 2 patients had stenosis at the edge of LSA branch. One patient developed hypotension and coldness of left arm, so endovascular repair with bare stent was performed.

DISCUSSION

The branched open stent-grafting technique is an evolutionary hybrid aortic arch repair procedure that combines conventional aortic surgery and endovascular repair with branched endoprosthesis.

The outstanding point is that the branched open stent-grafting technique provides total arch repair without performing direct surgical reconstruction of the descending thoracic aorta and cervical branches. The distal aortic incision line is almost the same as in the hemiarch repair, and the branched endoprosthesis completes arch repair within an acceptably short interval of DHCA. In our series, all the maneuvers (insertion of the branched endoprosthesis, de-

ployment, balloon attachment, inclusion anastomosis of the suturing portion and terminal RCP) took on average 36 minutes of DHCA. Terminal RCP was performed when DHCA time exceeded more than 30 minutes, which was also performed with the intention to eliminate debris and air in the cervical branches. We believe the duration of DHCA and addition of RCP was appropriate for brain protection, ^{6,7} and satisfactory results were achieved. In our series, the rate of stroke was 5.8%, which is acceptable when compared with previous arch replacement series reporting 3.0% to 7.0%. ⁸⁻¹¹

The branched open stent-grafting technique is best indicated in total arch repair for acute type A aortic dissection with intimal tear in the transverse arch or proximal descending aorta. It is emphasized that intimal tear resection is mandatory for better long-term results ^{12,13}; however, whether to include transverse arch in surgical resection in the acute setting is a long-lasting issue. ¹⁴ This means the increment of risk and complexity could be larger than that of benefit if the surgeon selects conventional total arch repair instead of hemiarch repair.

Our results suggested that the branched open stent-grafting technique could reduce the risk and technical difficulties of total arch repair to close to those of the hemiarch repair, although further controlled trials would be necessary to prove it. Also, excellent clotting formation of the false lumen

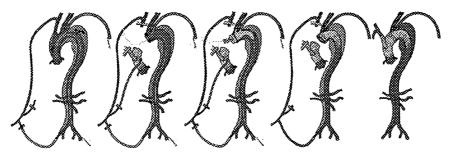


FIGURE 4. Total arch repair with branched open stent-grafting technique.

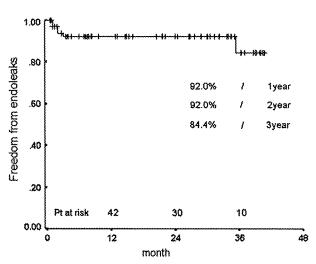


FIGURE 5. Freedom from endoleaks.

in descending thoracic aorta is expected. In this series, all 7 acute type A dissections showed complete thrombus formation in the false lumen at the level of stent graft distal edge; this result would be compatible with that of first-generation open stent grafting. ³⁻⁵

Another good situation for the branched open stent-grafting technique is reoperative total ach repair. Operation of an enlarged residual dissection in the aortic arch after graft replacement of acute ascending aortic dissection is a formidable situation. Tight adhesion makes all the maneuvers (exposure, suture) in conventional aortic arch repair very difficult and subsequently has high mortality. 15 However, the branched open stent-grafting technique requires only median sternotomy, exposure of right atrium for establishment of cardiopulmonary bypass, and exposure of distal anastomosis site of the ascending aortic graft. Arch repair can be completed by inserting the branched endoprosthesis from the opened distal anastomosis site of the ascending graft during DHCA. Our results in reoperative cases were excellent, which suggests that branched open stent grafting can be a very attractive option in this situation.

On the other hand, branch open stent grafting should be used with discretion for degenerative/atherosclerotic aneurysms that have massive mural thrombosis around the cervical branch orifice. In this series, 3 patients with stroke in degenerative aneurysms had severe mural thrombosis in the ascending aorta and transverse arch. We think the technical advantage to prevent embolic events in this operation is to use adequate terminal RCP to eliminate embolic agents from cervical branches.

Cervical branch event would be a topic of discussion in comparison with conventional total arch repair. There were a total of 6 cervical branch endoleaks, and 5 of them were from the LSA branch. The LSA tend to have angulation, and its orifice is further than the LCCA from the aortic transection line, so it was technically not easy to insert the

LSA branch. However, insertion became easier by using the guide wire, a minor modification of the device, and our learning. Also, it was not difficult to make additional endovascular repair when endoleaks were detected, and actually all endoleaks of the cervical branches were treated successfully by endovascular repair in this series.

The LSA is an important blood supply source not only of posterior cerebral circulation through the vertebral artery but also of anterior spinal circulation. ^{16,17} This would mean that sacrifice of the LSA could raise the risk of spinal cord injury, so we think LSA branch reconstruction during circulatory arrest is important.

There was no cervical branch occlusion in our study, but 2 stenoses were observed (2/124 [1.6%]). One was repaired in endovascular fashion. Of course, further observation is mandatory to argue about the patency of these cervical branches; it is expected to be satisfactory because simple endovascular stenting for cervical branch provides satisfactory patency (LSA stenting, 72%–89%/5 years 18,19, carotid stenting, 84%/4 years 20), even in stenotic/obstructive pathologies.

Total endovascular arch repair with branched/fenestrated stent graft or TEVAR with arch debranching²¹ would be another option to repair aortic arch pathologies. These can be performed off-pump, so would be less invasive than branched open stent grafting. We also performed these procedures in high-risk patients for cardiopulmonary bypass surgery. However, there were several problems. First was how to achieve proximal sealing. Aortic arch disease is often associated with diseased (dissected or atheromatously changed) ascending aorta, which is then not appropriate for use as a proximal landing zone. Second was how to prevent embolism in the cervical/cerebral artery. Protection methods such as using temporary balloon occlusion or using a filter protection device would be necessary; however, these technique are still not established in TEVAR.

Total arch replacement with branched open stent-grafting technique uses surgical graft replacement of the ascending aorta and direct anastomosis to secure proximal sealing and circulatory arrest with retrograde cerebral perfusion to prevent cerebral embolism. These methods are well established and time tested, so we believe branched open stent grafting has an advantage over totally endovascular arch repair with branched/fenestrated stent graft or TEVAR with arch debranching.

This study was a retrospective cohort study and the lack of concurrent control group restricts direct comparison with conventional total arch replacement. In order to elucidate the precise advantage of this technique, prospective casecontrol study would be required.

In conclusion, the branched open stent-grafting technique is an effective hybrid procedure using branched endoprosthesis to complete aortic arch repair, and it provides satisfactory early results. In the midterm, cervical branch events are observed; however, these are successfully treated with additional endovascular repair. This technique could be an very

attractive alternative to conventional aortic arch surgery, especially for aortic dissections.

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Discussion

Dr Heinz G. Jakob (Essen, Germany). I would like to congratulate Dr Shimamura and colleagues from Osaka for a great idea to facilitate and to horten aortic arch surgery by refining their own method of open stent grafting of the distal arch and the descending aorta, already published in the mid 1990s. Dr Kato's work certainly influenced my group as well as other European and probably American groups in adopting the principle of combining classical surgical methods with evolving interventional technologies to reduce the surgical dimension on one side but to simultaneously gain the treatment option for the descending aorta. Again, it is your group who demonstrates durability and low reintervention rates long term for this first-generation approach.

The inclusion of cervical branches into this concept seems logical, and you demonstrate how to securely place your main body graft as well as the left subclavian artery graft using a 2-wire guiding technique to guarantee landing within the true lumen in aortic dissection and to overcome kinking of the proximal subclavian artery. The procedural success rate of over 97% is impressive, as is your hospital mortality of 7.2% and your stroke rate of 5.8%, especially in light of the mean age of 66 years of your patient population. In addition, no aorta-related deaths occurred during a mean follow-up of 20 months, and reported survival is 88% at 3 years. I have 3 questions for you.

First, the construction of your "homemade" branch stent graft has to be done based on 3-D computed axial tomographic scan measurements and probably takes 30 minutes or more, either before surgery or at an early stage of the operation. What are you doing in the very acute situation of acute type A aortic dissection, for example, with pericardial tamponade? Can you use this method in this situation, too?

Dr Shimamura (Osaka, Japan). Thank you for your very important question. I think we can use this technique even in that situation, because the insertion of the branched endoprosthesis is provided after establishing deep hypothermic circulatory arrest, and it required about 30 or 40 minutes to achieve core cooling to 20°C in the blood temperature. During this time we can make the stent graft in the side dish, and it is possible to do this procedure even in such a situation, I think so.

Dr Jakob. You state in your article that you don't oversize beyond 10% to 15% when designing the stent-graft dimension, and you are applying 8 atm balloon pressure over 5 seconds to deploy the cervical stent grafts. Is it the same balloon pressure in the descending aortic true lumen, and what about back bleeding during the reperfusion period and early after discontinuation of extracorporeal circulation, especially when you have tears in the aortic arch?

Dr Shimamura. We use a self-expandable type of stent for the main body. So we do not inflate at such a high pressure for the descending thoracic aorta. We only use the spontaneous opening of the self-expandable stent. In dissections, we insert very carefully and avoid the neointimal tear creation by overinflating. And we use the balloon-expandable stents for the cervical branch. Only in

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the cervical branch do we use the inflation device to achieve 8 atm pressure.

Dr Jakob. So you don't have back-bleeding problems?

Dr Shimamura. Because we do this procedure during deep hypothermic circulatory arrest, we do not have such a problem doing this procedure.

Dr Jakob. And not in the reperfusion period either? No bleeding problems during reperfusion?

Dr Shimamura. Oh, yes.

Dr Jakob. Probably not.

And a final question. You had 6 cervical endoleaks and 2 stenoses, which could be successfully treated by reintervention. You do not see persistent or distal descending aorta leaks, but you report freedom from endoleak is 84.4% after 3 years. Could you please explain this discrepancy?

Dr Shimamura. All the endoleaks were from the cervical branches, and there were no endoleaks from the distal end of the main body. All these endoleaks were detected in the primary computed tomography scan, and we think this is related to our technical immaturity to deliver the stent graft in our early experience.

Dr Jakob. But you state in the article that after 3 years, you have an 84% freedom from endoleaks. This means that you have 16% rate of endoleak.

Dr Shimamura. That may be because the number of cases is only 69 cases, and this is calculated by the Kaplan-Meier method. So the overall freedom from endoleak is calculated by that number.

Dr Jakob. Okay. Thank you. I think it is an important contribution.

Dr Shimamura. Thank you very much for your question.

Dr Jean E. Bachet (Abu Dhabi, United Arab Emirates). I might fall in the category of the old conservative surgeons denounced this

morning by Marko Turina, but I observed that in your method the length of the procedure was about 7 hours, that the duration of deep hypothermic circulatory arrest was also rather long, and that those lengths are clearly over the lengths observed, at least in my experience, in straightforward conventional replacement of the aortic arch. So my question is either naive or provocative, but what are the advantages of your method as compared with conventional replacement of the aortic arch, considering that your follow-up is quite short, that the procedure is not validated, and that the long-term outcome is somewhat uncertain?

Dr Shimamura. I think the biggest advantage of this procedure is that you can complete aortic arch replacement without manipulating distally to the left common carotid artery. So you do not need to perform anastomosis on a profound lesion, and you do not have an opportunity to make a recurrent laryngeal nerve injury. So this is the strongest point of this technique. However, as you pointed out, this technique should be more sophisticated, because the average deep hypothermic circulatory time is 36 minutes. So we have to improve the technique or the device to shorten the time of circulatory arrest to complete this procedure.

Dr Bachet. I have another question of the same kind. Considering now that it is highly demonstrated that antegrade selective cerebral perfusion and moderate hypothermia are much better than deep hypothermic circulatory arrest, why do you stick to this old technique of cooling down the patient to less than 20°C?

Dr Shimamura. Because to insert the cervical branches under direct visualization, we do need deep hypothermic circulatory arrest, but we are going to attempt selective cerebral perfusion, as you mentioned, after opening the cervical branches, and this could reduce the time of operation by raising the temperature of the circulatory arrest.

Dr Bachet. Thank you.