

図4 主要脳腫瘍の全脳腫瘍に対する割合の年次変化 全脳腫瘍における疾患別のパーセントの変化を示す.神経膠腫は相対的 に減少し、髄膜腫、下垂体腺腫が大幅に増加していることを示す.シュワン細胞腫は変動が少ないが徐々に増加している.

腫の遺伝的付加の生物的指標になる可能性があるとの報告がされているが、実証されるまでには時間がかかるものと思われる<sup>21)</sup>.

そのほか,胎児と関係して,母体の受けた因子あるいは出産時に用いた薬剤が子供の脳腫瘍発生に関係するとの国際的研究報告がある.この研究は,case-control study として行われたものであるが,出産時麻酔ガスを用いると,子供が $0\sim4$ 歳までに星細胞腫に罹患するリスクが高くなるとしている $^{20}$ .

以上,幾つかの報告を紹介したが,脳腫瘍のリスク因子に関する報告は散発的であり,腫瘍そのものが発生頻度が少ないことや,発生までに長期間要することなど,解決に難題も多く疫学的研究の成果はまだ十分ではない.

#### 5. 脳腫瘍全国統計による主要脳腫瘍頻度 の年次推移

それぞれの脳腫瘍の発生頻度が変化していることから、各種脳腫瘍の全脳腫瘍に対する割合が著明に変化してきている。この変化を示したのが図4である。髄膜腫が著明な増加を示している。下垂体腺腫も前述した理由により、1979年代から急増しその後平坦化している。図の割合はいずれも全脳腫瘍に対する相対的頻度(%)

を示している.

#### 6. 細分類にみる各種神経膠腫の割合

神経膠腫の組織別分類とその分布の変化は, 膠芽腫は,調査年度前半1969~83年では神経 膠腫全体の28.7%,退形成性星細胞腫は15.1% であったが,後半1984~90年では,前者は31.4 %,後者は17.4%と増加している.逆に星細胞 腫,髄芽腫は減少の傾向にある.

#### 7. 年齢分布の変化

年次別に脳腫瘍の発生年齢の推移をグラフにしたものが図5,6である.図5は全原発性脳腫瘍の発生年齢を示しているが,そのピークが1969~78年では45~49歳であったが,1989~96年では55~70歳に大きな山を示し,60~64歳に最大の山を示している。全体的には15~20歳の高齢化がみられる。図6は,髄膜腫,シュワン細胞腫,星細胞腫,膠芽腫のそれぞれの治療開始時の年齢を示している。高齢化社会になって,腫瘍患者の年齢構成も高齢化してきている。特に著しい変化は,成人の良性腫瘍の代表である髄膜腫,逆に最も悪性の脳腫瘍である膠芽腫の高齢患者の増加である。

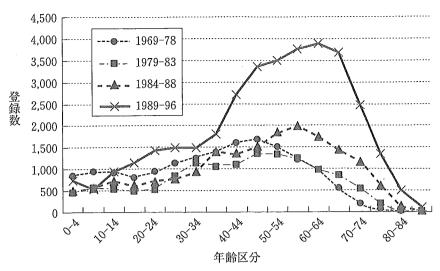


図 5 原発性脳腫瘍の年齢別登録数の年代別変化 全脳腫瘍では約10歳の高年齢層への変化がみられる.

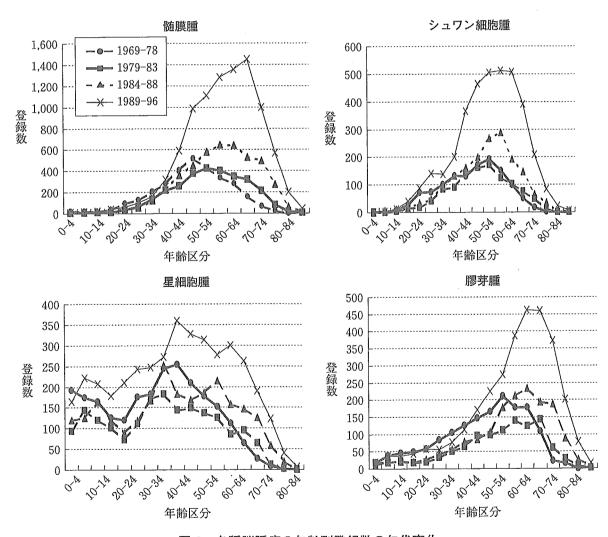


図 6 各種脳腫瘍の年齢別登録数の年代変化

髄膜腫,膠芽腫においては,著しい好発年齢の高齢化がみられる.両者ともピークが  $60\sim70$  歳代にある.この両者が,高齢者の腫瘍として代表的であることを示している.星細胞腫は  $40\sim70$  歳までに大きなピークを認める.1970 年代では  $30\sim50$  歳代にピークを認めたが, $10\sim15$  歳ほど高年齢層側にシフトを認める.

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#### 特 集



特集: 手 術 支 援 環 境

#### 術中MRI手術環境

#### 1. はじめに 一術中情報の可視化一

精密かつ安全な手術を遂行する上で最も重要な事項の一つは、患者・病変に関しての質の高い情報をいかに確保するかということである。「敵を知り已を知れば百戦党からず」とは孫子の言葉であるが、手術においてもまさしくこの言葉が当てはまる。すなわち、対象となる病変の情報を多く獲得し、かつ自分が手術という一連のプロトコルの中で現在どういう状態にあり、これから何をするべきかを決断するための情報を獲得することが、よりよい手術結果を獲得するために必要なことである。

肉眼で確認できない患者体内の病変についてのより質の高い情報を獲得するための試みが古くより多くの医学者・科学者によりなされてきた。Röentgen が1895年11月8日にX線を発見し12月22日に夫人の手指骨の透過写真を撮影したのが、非侵襲的な(切開等の直接的侵襲を伴わない)体内情報の画像化の最初であるり、その後、Hounsfield による X線 CT の開発 (1968)、和賀井敏夫らによる超音波診断装置の開発、そして Lauterbur・Mansfield らにより開発された核磁気共鳴画像 (MRI) (1971) の登場により、体内の多品質・高品質な画像情報の獲得が可能となった。

またこれら画像診断装置の登場によりもたら された画像による生体情報の提示, すなわち体 内情報の可視化は, 情報処理における以下の大 中 村 亮 一\* 村 垣 善 浩\* 伊 関 洋\*

きな特徴を医療のフィールドにもたらした.

- (1) 情報の客観性:聴診や触診といった,診断を行う医師の技量・経験に基づく診断と異なり,人間の能力に依存しない結果の提示がなされる.
- (2) 情報の共有化:上記の診断では診断情報はそれを行った医師のみが情報をもつ.情報を可視化することにより、それを得る人間すべてが同じ情報を客観的に共有することが可能である。

このように、診断装置の開発はそれまで得られなかった体内情報の獲得が可能になったということのみならず、情報の可視化を通じこれに客観性と共有化をもたらしたという点で、非常に大きな意味を持つ.

このような診断機器の開発の一方で, 一種の 特殊環境である手術室内で、手術中に患者の情 報を取ることにはまた様々の障壁が存在してい る, 常に対象の形態的・機能的状態が変化する 生体を対象とする場合には,必然的に術中にこ れらの画像情報をアップデートしなければなら ない. 比較的装置に自由度が多く存在するCア ーム等のX線装置や超音波診断装置は広く術中 での利用が行われてきたが、装置が大掛かりな CT や MRI の手術場での利用には術式・装置 双方において多くの技術開発が必要となった. 本稿ではわれわれが運用しているインテリジェ ント手術室 一術中 MRI を中心とした高度術中 情報集約手術室一 の紹介を通じ, 術中 MRI装 置による術中情報の可視化のもつ臨床的有用性 ・可能性について紹介する.

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#### 2. 術中 MRI 誘導下脳腫瘍摘出術

悪性脳腫瘍は手術,放射線,化学,免疫療法を含めた様々な集学的治療によっても満足すべき治療成績が得られない治療抵抗性の疾患であり,手術治療の意義にも疑問がなされていた.しかし日本脳腫瘍全国統計(1969~1993)の結果によると,悪性神経膠腫(グリオーマ)に対する6,395例の検討では,外科的に腫瘍の摘出手術を行っても摘出量が95%(体積)以下の場合,術後5年生存率において生検群・未手術群との有意差はなく10~15%程度であるが,95%以上の摘出を行った場合には22%,全摘出では40%にまで上昇する<sup>2</sup>.

このことからわかる事実は、「全摘出が達成できれば手術治療の意義はある(5年生存率が20%以上向上)が、完全摘出が達成できる症例は少ないため結果として疑問が生じている」ということである。ではなぜ完全摘出が難しいかといえば、理由として大きく以下の3つがあげられる。

- (1) 神経膠腫(グリオーマ)と正常脳との間に明瞭な境界が存在せず, 術者の肉眼および触覚によっている現在の手術ではその区別はきわめて困難である.
- (2) 脳は場所により機能が異なること(機能 局在)が知られているが、言葉や運動などの大 切な機能の中枢付近に腫瘍がある場合、大切な 機能を残すために腫瘍の摘出を不十分にせざる をえない.

(3) Brain Shift や術中の手術作業に伴う脳の変形・移動<sup>3)</sup>, また腫瘍の発生に伴う機能領域の移動(圧排)により, 術前情報や解剖学的知識のみで腫瘍および機能領域の境界を術中に正確かつ明確に同定することは不可能である.

われわれは 2001年 3月13日より開放型 MRI (AIRISII 日立メディコ社製) を手術室に導入 し、術中 MRI 情報を利用した脳腫瘍完全摘出 手術の実現に取り組んできた(図1). 術中MRI の多断面・多種類のシーケンスで撮像された画 像は、脳神経外科医を長年悩ましてきた Brain Shift および手術操作による脳の変形・移動に 対応しながら、腫瘍と正常組織の境界を明確に 提示することが可能である4.5、また、拡散情報 の画像化が可能なため、形態的に差異のない組 織群において、機能による差異を画像化するこ とも可能である. しかし診断室での使用と異な り,手術室内で手術中の患者を対象に MRI の 撮像を行うためには様々な制約が存在するため、 手術室での運用に適した機器の開発, 術式の最 適化が必要となる

#### 3. 術中 MRI 手術室の基本環境

AIRISⅡは永久磁石による垂直磁場方式の開放型 MRI で磁場強度は 0.3 T, 共鳴周波数 12.7MHz, 前方開放部が 210 度, 開放部磁石間ギャップが 43cm となっている。垂直磁場方式による広い開放部と低漏洩磁場を実現しており, 磁石中心より左右 2.0m, 前 2.2m, 上 2.5m の位置で磁場強度が 5 ガウスまで低減する。MRI



図 1 術中 MRI 手術室での脳腫瘍摘出手術

#### (10) 医器学 Vol. 75, No. 5 (2005)

を手術室内に導入することにより、その高磁場に影響を受けない手術室内設備の整備が必要となる。われわれの施設では非磁性体で構成された窒素ガス駆動手術顕微鏡(三鷹光器製)、MRI対応手術台(瑞穂医科工業製)、MRI対応無影灯(山田医療照明製)、MRI対応麻酔器・モニタ(Dräger Medical 製)を導入している。MRI 撮像時には電磁的ノイズの撮像を避ける必要があるため、麻酔器・モニタを除きすべての電子機器・照明を停止する。

術中 MRI のパイオニアである米国 Brigham & Women's Hospital や滋賀医科大学などでは 超伝導コイル方式の開放型 MRI (Signa SP, General Electric 製)を使用した術中 MRI 手 術室を運用している<sup>6,7</sup>。こちらでは患者をMRI 内に常時置いた状態で術式を行っており、治療 のどの局面においても迅速かつ容易に MRI 画 像の獲得が可能である、一方で超伝導コイル型 の術中 MRI では作業空間の狭さ、漏洩磁場の 大きさおよび術中患者移動の難しさから, 手術 に利用する全ての機材を MRI 対応にする必要 がある. われわれが対象とする悪性脳腫瘍的手 術においては, 開頭後 Brain Shift が起こった 後は治療対象が大きく変形移動することがない ため,リアルタイムでの MRI 撮像の必要性は 高くない. そこでわれわれは AIRIS II の漏洩磁 場の低さの特徴を生かし、手術は MRI の外部 (5 ガウスライン外)で行い,必要に応じて患者 を MRI 内に導入し撮像を行う Pit-in 方式を 採用している(図2)、この方式では先に述べ た施設での方法と比較すると、リアルタイム での撮像が不可能という 弱点 はあるものの、 MRI 対応手術設備・機器は先に述べた顕微鏡・ ベッド・無影灯・麻酔器・モニタのみでそれ以 外の手術器具等は一般の手術と同じものが使用 できる. また, MRI 装置による術者作業空間の 制約もまったく受けないため、一般の手術室と 全く同じ手術を行いながら,必要に応じ適宜 MRI の撮像が可能である. 外科医の技量はト レーニング・手術経験により培われたものが大 きい点を鑑みると、MRI の設置に伴う手術器 具の変更・患者体位の変更・術者作業空間の制 約が少ない Pit-in方式は、治療の安全性と信頼 性を担保する上で有効なものであると考えられ

Pit-in 方式を採用する上で重要な点は、患者移動時の室内機器の迅速かつ安全な移動と、患者の安全・清潔確保である。前者においては特に滅菌された手術器具類を清潔を確保しながら移動する点に工夫が必要である。これを解決するための方法として、吸引システム・モノポーラ・バイポーラの設備を下部に統合した器械台を開発し、迅速かつ安全に患者・ベッドからの分離を可能にしている。後者においては、ビニール製の透明ドレープを採用することにより、清潔性の担保と同時に患者体位・輸液ライン・挿

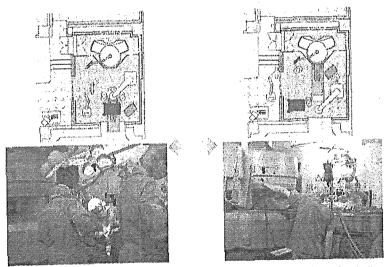


図 2 Pit-in 方式による手術. 左:手術施行(5 ガウスライン外), 右:撮像

管ライン・ヘッドフレーム状態の視認による安全性の確保を実現している.

#### 4. 術中 MRI 用 RF 受信コイル

前章で術中 MRI 手術室の基本設備について解説したが、術中 MRI においてもっとも大きな問題となるのが RF 受信コイルである. MRI の診断用 RF コイルは当然のことながら手術中での(患者に侵襲的作業を行っている間での)使用を想定していないため、手術中での利用は困難である.

開頭手術において患者頭部は、杉田式フレー ムなどの頭部固定具を利用しベッドに固定され ている状態であり、QD コイルを利用すること はそもそも空間的に不可能である. 腹部用フレ キシブルコイルをドレープの上から設置する方 法を当初は採用していたが、 画質の点で QD コ イルに大きく劣り、また設置の操作性および安 全性に難があった、そこでわれわれは術中MRI に対応し, 手術器具として従来から使用されて いる頭部固定用フレームと一体となった専用手 術コイル (Head Holder Coil) を開発した(図 3). 手術用の頭部固定ヘッドフレームとコイ ルを一体化することで, 従来のコイルと同等以 上の性能と手術操作性および撮像時の作業性を 向上することができた. AIRIS II が垂直磁場方 式であることからこの Head Holder Coil がRF 受信コイルとして利用でき, かつ水平磁場方式 で用いられるサドル型受信コイルに比して高感

度であるため高い画質を得ることができた.

#### 5. 拡散強調画像撮像による白質 神経線維の可視化

術中画像の有用性については,絶えず作業対象の状況が変化する手術という作業の特徴から明らかであるが, 術中 MRI が他の術中画像モグリティに比して優位な点は,撮像プロトコルの多様性により実現された,多様な画像である. 代表的には T1 強調画像と T2 強調画像があるが,体内の拡散情報を利用した画像の取得も可能である.

先に述べたように, 脳腫瘍の完全摘出が難易 度の高い手術である理由の一つは, 脳機能の局 在の問題である. 患者の QOL を担保するため には手術作業による運動や言語などの重要な脳 機能の領域を同定する必要がある. 現在われわ れは術中に運動誘発電位(Motor Evoked Potentials, MEP) などの電気牛理学的モニタ リングを利用して運動野そして運動野からの 神経軸索(顚体路)の温存を図っている. しか し、この方法では鍾体路が保存されているかど うかの指標にはなるが, 鍾体路の位置, 形状の 空間的把握は困難である. MRI の拡散強調画 像 (Diffusion Imaging) は大脳皮質での拡散 の異方性を元に神経束を画像化することがで き. 拡散テンソル情報を基に神経走行方向の トラッキングを行うことにより神経線維画像 (Tractgraph)を作成することも可能である.

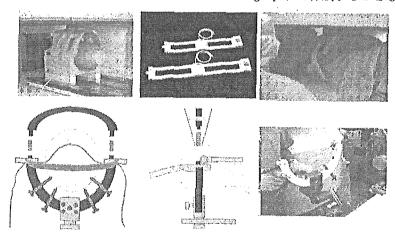


図 3 MRI用コイル 左上:診断用 QD コイル 中央上・右上:腹部用フレ キシブルコイルによる衛中 MRI 撮像, 下: Head Holder Coil

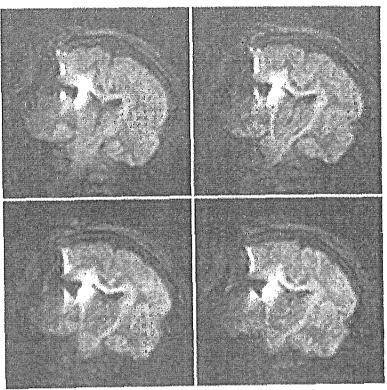


図4 拡散強調画像による錘体路の可視化

一方 Diffusion 画像の撮像は外来電磁ノイズや磁場の不均一性による画質の劣化がT1/T2FSE 撮像などに比して大きいため、手術室という特殊環境での低磁場 MRI では困難な点が多いが、われわれはプロトコルの最適化とコイルの改良により、診断用 1.5 T 機には及ばないものの高画質な拡散強調画像 (Diffusion Weighted Image) の獲得に成功している(図4). 現在、拡散強調画像と電気生理学モニタリングを併用した機能温存腫瘍摘出術の確立を目指し、拡散強調画像により画像化された錘体路の精度について検証している<sup>6</sup>.

## 6. 術中画像を利用したナビゲーションシステム

術中 MRI の導入により商品質な体内情報の可視化が可能となった。しかし画像としてフィルム・ディスプレイ上に表示された情報を基に治療を行う場合には、その画像が術前・術中いずれの画像であっても、必ず行わなければならない作業が存在する。データの 3 次元再構成と

座標系統合 (レジストレーション) である.

従来, 術者はこのような画像データを下に体 内情報の3次元的把握と手術計画を行い治療を 行うが、連続した2次元画像として表現される CT/MRI 等のデータを 3 次元再構成し、さらに 実空間に存在する手術対象(患者)とそのデー タの位置を一致させる作業は, 術者自身の頭の 中での作業である. すなわち, 診断時には客観 性と共有性をもった情報として提供されている 医用画像は,いざ実際の治療を実行する時点で は術者の3次元再構成能力・空間座標系統合能 力に依存した主観的情報に変換されてしまう. 全ての術者および手術に携わる人間が、術中画 像によりもたらされた客観性・共有性をもつ正 確な情報を治療に反映するための手助けとなる 技術がここで必要とされる. これがナビゲーシ ョンシステムである.

手術におけるナビゲーションシステムの基本 的理念・効果は、一般的に知られるカーナビゲー ションと同じである、書店で購入した道路地図 を元に自動車の運転を行う場合には、地図の情 報を実空間に一致させ、自分が今地図上のどこにどの方角を向いて存在し、目標との空間的位置関係がどうなっているかを認識する能力をどの程度有しているかによって、目的地に無事に効率的に到達できるかが決まる。カーナビゲーションは GPS 等のセンサの情報を基に自分が今地図上のどこにどの方角を向いて存在しているかを正確に表示することで、この能力を補助し誰でも自分と目的地の状態がわかるようになっている。

手術ナビゲーションシステムとは、今術者が 治療を行っている部位が、地図である医用画像 上のどこに相当し、どういう方向でアプローチ しているかを位置センシング情報を基に表示す る。カーナビゲーションシステムとの違いは、 道路という 2次元情報と患者という 3次元情 報との違いであり、提示の仕方などに工夫が必 要となる.

われわれの開発したナビゲーションシステ ムは,光学式3次元位置計測装置 (Polaris, Northern Digital Inc.)を用いて患者と術具の 空間位置を測定し、この実空間の座標系と術中 MRI 画像の座標系をコンピュータによりレジ ストレーションし、術具先端の術中 MRI デー タ上での位置・方向を術者に提示する (図5). 表示は Axial・Coronal・Sagital の 3 断面 (2 次元)と、レンダリングボード (Volume Pro 1000, 旭エレクトロニクス製) を利用した高速 3次元ボリュームレンダリング像による. 術中 MRI によるナビゲーションは、いわば最新の 地図情報と道路情報をリアルタイムにアップデ ートしているカーナビゲーションであり、術野 の形状変化・移動に対応して正確な診断情報を 医師に提供することを可能にする.

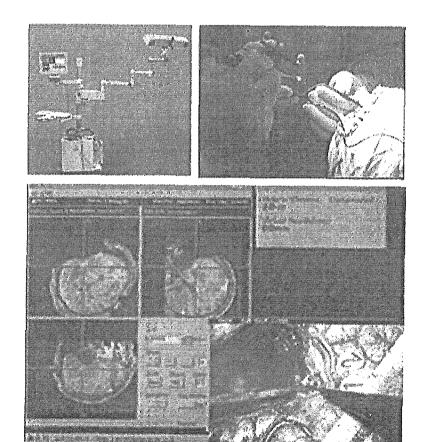


図 5 ナビゲーションシステム 左上:システム全体,右上:光学式 マーカを取り付けた術具,下:ナビゲーション画面

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#### 7. おわりに 一術中情報の可視化と 統合に基づく高品位医療の実現に 向けて一

手術を遂行する上で必要とされる情報を、術者個々の情報把握能力に左右されずに高品位の状態で利用するにおいて重要なことは、情報が正確で、現在を反映し、客観性を担保したまま治療へ直接利用できることである。術中MRIにより可視化された高品質で客観的な腫瘍と錘体路の情報は、ナビゲーションシステムにより客観性を失わずに治療情報へと変換される。誰の目に見ても明らかに区別のできるような情報の可視化を実現することは、まさしく Evidence Based Medicine の実現に他ならない.

術中 MRI を中心としたわれわれのインテリジェント手術室は、「高品位な術中情報の可視化」による高品位な手術の実現を目指した施設である。現在の取り組みとして、術中 MRI を含む手術室内の診断情報・画像情報・音声情報を統合提示することにより、手術室内外のスタッフ全員に手術の現在状況を容易に認識可能にするシステムの整備を行っている(図6)、従来術野で何が行われているかについては術者自身にしか認識できなかったが、これをはじめ術場内の全ての情報を手術にかかわる全ての人間で共

有することにより、真のチーム医療を実現する ことが初めて可能になると考える.

高品位な情報の可視化を実現する術中 MRI 装置は, 医療サービスを提供する上で必須の装置になる可能性を秘めている. 医療サービスを提供する側, 享受する側双方において,「誰が見てもおかしくない手術」が実現されていることを証明することのできる術中情報可視化システムは, 21世紀の高度先端医療社会において一翼を担うものになると考える.

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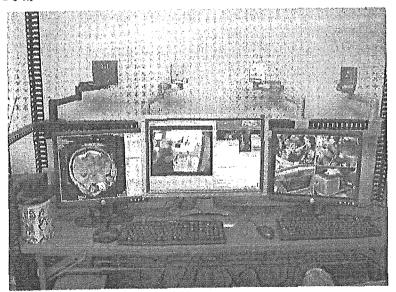


図 6 術中情報統合提示システム「手術戦略デスク」 手術室内の映像・音声 情報, 術中 MRI 装置コンソール画面をネットワークを介して配信する.

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# A Flexible Endoscopic Surgical System: First Report on a Conceptual Design of the System Validated by Experiments

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**Background:** Surgery is a standard diagnostic and therapeutic procedure. However, its technical difficulty and invasiveness pose problems that are yet to be solved even by current surgical robots. Flexible endoscopes can access regions deep inside the body with less invasiveness than surgical approaches. Conceptually, this ability can be a solution to some of the surgical problems.

**Methods:** A flexible (surgical) endoscopic surgical system was developed consisting of an outer and two inner endoscopes introduced through two larger working channels of the outer endoscope. The concept of the system as a surgical instrument was assessed by animal experiments. **Results:** Gastric mucosa of the swine could be successfully resected using the flexible endoscopic surgical system, thereby showing us the prospect and directions for further development of the system.

**Conclusion:** The concept of a flexible endoscopic surgical system is considered to offer some solutions for problems in surgery.

Key words: surgical robot - endoscopic surgery - surgery - robotics - endoscope

#### INTRODUCTION

We recently reported a new concept for endoscopic mucosal resection of gastric cancer with the use of a magnetic anchor. The anchor consisted of microforceps and a magnetic weight in order to grasp, stabilize and pull up the gastric mucosa (1). During the experiments, we thought that the procedure would be easier if one more endoscope was present to hold and stabilize the mucosa instead of the magnetic anchor.

Concerning flexible endoscopes, there are some ultrathin endoscopes that can be inserted into the working channels of standard endoscopes, such as gastrointestinal endoscopes. If the outer endoscope is able to contain larger and multiple working channels, several thin endoscopes could be inserted through the outer endoscope. This would allow for the resecting procedures. Such a system could also be applied to the fields where current surgical robots are targeting.

One of the problems with current surgical robots is inaccessibility to regions located deep inside the body, particularly regions reached through narrow and winding routes, such as the digestive tracts and blood vessels. However, some early gastric cancers can be resected endoscopically with much less

invasiveness than surgery. These surgeries cannot be performed by current surgical robot systems because those regions were not originally considered places for the systems to operate.

An experimental flexible endoscopic surgical system was developed to cope with these problems of accessibility, consisting of a flexible outer endoscope with two working channels through which two inner flexible endoscopes could be inserted. These inner endoscopes were designed to have similar functions as flexible gastrointestinal endoscopes allowing for performance of standard endoscopic procedures even when introduced through the outer endoscope.

The uses of the flexible endoscopic system as a surgical instrument, as well as its functionality, were confirmed during gastric mucosal resection of the swine. This is in contrast to the current limitations for surgical robotics in terms of lesion access.

#### MATERIALS AND METHODS

FLEXIBLE SURGICAL ENDOSCOPE

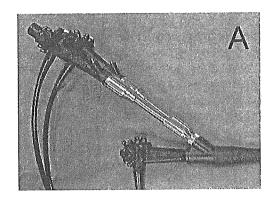
As shown in Fig. 1, the flexible surgical endoscope consists of an outer flexible endoscope and two inner flexible endoscopes inserted into the working channel of the outer endoscope. The specifications of these endoscopes are listed in Table 1.

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The outer endoscope also has a 2.8 mm working channel and a charge coupled device (CCD) enabling the endoscope to operate in a similar fashion as standard gastrointestinal endoscopes. The endoscopic images are observed on cathode ray tube (CRT) monitors in the same manner as video-endoscopes.

Each of the inner endoscopes has a 2.0 mm working channel allowing accessories such as forceps and an electrocautery tip to be introduced and used. Unlike the outer endoscope, the inner endoscopes have optic fiber bundles for image visualization, instead of a CCD. These endoscopic images are also observed on CRT monitors. However, a video-adaptor, i.e. a small CCD video camera, must be connected onto each eye



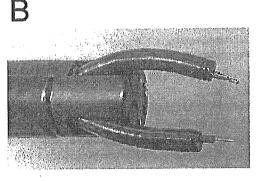


Figure 1. The flexible endoscopic surgical system. (A) The inner endoscope is inserted through a telescopic connecting device, which connects to the opening for the working channel of the outer endoscope near its control section. (B) At the tip of the outer endoscope two inner endoscopes protrude laterally, obtaining a certain distance between the two endoscopes.

Table 1. Specifications of the flexible endoscopic surgical system

	Outer endoscope	Inner endoscope
Total length (mm)	975	1395
Working length (mm)	665	1050
Insertion portion diameter (mm)	20	4.9
Tip bending (degree) (up/down, right/left)	210/120, 120/120	210/120, 120/120
Field of view (degree)	140	120
Depth of field (mm)	4–100	3–50
Channel diameter (mm)	7, 7, 2.8	2

piece of the inner endoscopes in order to view the image on the monitors.

These combined endoscopes are manipulated manually by three physicians together with the help of several assistants. The system, as a whole, operates similar to surgical robotic systems.

#### PHYSICIANS

Two series of experiments were conducted. The first series was performed by a senior endoscopist and three resident physicians in order to assess the system with consideration to its endoscopic nature. The senior endoscopist was trained within the specialty of internal medicine, whereas one of the resident physicians was in training for internal medicine and the other two were for surgery.

The purpose of the subsequent series was to assess the concept of the flexible surgical endoscope from the viewpoint of surgeons. Consequently, the procedure was performed by two senior endoscopists, one having more than 15 year experience as a surgeon and the other having some surgical training, in addition to two residents who were in training for surgery.

These two series were performed on separate occasions, with none of the physicians performing in both series.

#### TEST SUBJECT

Three female swine, under intravenous anesthesia, were laid on an examination table in the left lateral position. Within the first experiment, a 35.6 kg and a 34.1 kg swine were used. In the following experiment, a 41.8 kg swine was used. During these experiments, the law for the humane treatment and management of animals was observed.

#### PROCEDURE

The procedure was similar to standard endoscopic mucosal resection with the exception of one more endoscope for stabilization of the gastric mucosa.

First, an incision was made in the mucosa surrounding the region of stomach intended for resection (2,3). The outer endoscope was inserted through the esophagus into the gastric cavity. Subsequently, using the telescopic connecting devices (Fig. 1), the inner endoscopes were inserted into the working channels of the outer endoscope and introduced into the gastric cavity.

The outer endoscope was placed near the region in which the first incision was made. Thereafter, the resecting procedure was performed using an electrosurgical knife through one of the working channels of the inner endoscopes, whereas the other contained forceps. Within the procedure, the operator decided which side of the working channels would use the electrosurgical knife.

These procedures were observed on three CRT monitors, each of which was connected to its endoscopic counter part.

The resecting procedures were performed on the anterior wall of the gastric angle, the anterior wall of the middle gastric body and the greater curvature of the middle gastric body in the first series for the assessment of endoscopic features. Within the following series, the resecting procedures were performed on two regions adjacent to the greater curvature of the lower gastric body.

#### RESULTS

Concerning insertion of the outer endoscope through the esophagus into the gastric cavity, some difficulties were encountered owing to the large diameter of the outer endoscope and the relatively small size of the swine in both experimental series. However, the outer endoscope was introduced into the gastric cavity.

As for insertion of the inner endoscopes through the working channels of the outer endoscope, there were no difficulties experienced, even when the outer endoscope was bent due to insertion through the esophagus. Access to regions of the gastric wall was limited to the greater curvature due to the rigidity of the outer endoscope.

Maneuverability of the flexible endoscopic surgery system was satisfactory regarding the experiments were the first experiences for the physicians involved, despite some problems to solve.

The images from the outer endoscope were similar to those of standard gastrointestinal video-endoscopes due to the CCD system used in the outer endoscope. However, the images from the inner endoscopes were inferior to those of the outer endoscope. This inferiority was attributed to the limited number of optical fibers within the inner endoscope and deterioration of the image caused by conversion from optical images to electrical images through the use of a video-adapter. Consequently, during most of the procedure, endoscopic images were mainly observed using the monitor for the outer endoscope.

Some differences in use of the inner endoscopes for the resecting procedures between the first series and the second series were noticed. In the first series, the physicians appeared to have difficulties in some of the procedures such as accessing the mucosa, stabilization of the mucosal flap and resection procedures. These procedures were considered standard techniques for actual surgery, which means surgical experiences are required even to maneuver the flexible endoscopic surgical system.

Within the second series conducted by endoscopists with surgical experience, the resecting procedures were satisfactory, despite the fact this was their first experience using the system (Fig. 2). Through cooperation between the operator and assistants using verbal commands, manipulation of the inner endoscopes and the outer endoscope could be achieved. The functions of the inner endoscopes could be modified by changing the instruments inserted into the working channels. The flexible nature of the inner endoscopes allowed additional functions such as stabilization of the gastric wall by the longitudinal flank of the endoscope, as shown in Fig. 2C.

Within all the experiments, resecting procedures were completed without any complications such as perforation of the gastric wall. Consequently, five mucosal pieces, with sizes of

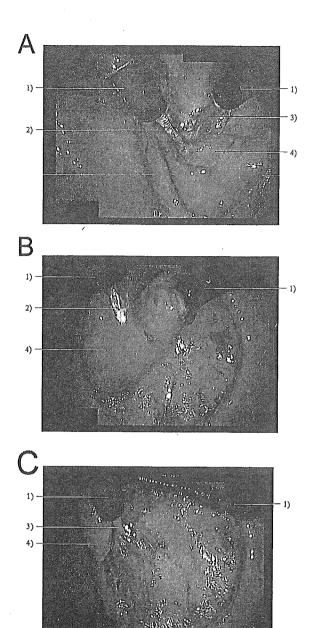


Figure 2. Images of the resecting procedures. (1) Inner endoscope, (2) forceps, (3) electrosurgical knife and (4) mucosal flap. (A) The right inner endoscope, with an electrosurgical knife introduced through its working channel, was maneuvered by the operator. The left inner endoscope, with forceps, was maneuvered by an assistant. (B) The tip of the right inner endoscope is holding up the mucosal flap in order to assist the forceps of the left inner endoscope to grasp the mucosal flap. (C) The right inner endoscope is pulling up the mucosal flap using forceps concealed in this image. In addition, using the flexibility of the endoscope, the gastric wall is stabilized by the longitudinal flank of the inner endoscope.

 $2.8 \times 1.6 \text{ cm}^2$ ,  $2.8 \times 2.7 \text{ cm}^2$  and  $2.6 \times 2.0 \text{ cm}^2$  in the first series, and  $3.2 \times 2.7 \text{ cm}^2$  and  $4.0 \times 3.4 \text{ cm}^2$  in the second series were each resected in a single piece.

#### **DISCUSSION**

Surgical procedures are good options for diagnosis and treatment providing several advantages over non-surgical

approaches, especially in cases of malignant diseases. Although surgery is well accepted as a standard procedure in medicine there are still some problems left unsettled.

The technical difficulty of surgery is a common problem particularly for trainees, but even for experienced surgeons who have some technical limitations. Surgical procedures are difficult for regions deep in the body because the visual field for surgeons is limited, the number of surgical instruments which can be introduced is limited and the movements of these instruments are limited. One of the exemplary regions of this problem is the pelvic cavity, which includes surgery of rectal and prostate cancers.

Invasiveness is an inherent drawback to surgery, discouraging patients to undergo surgical treatment even when it is appropriate. It is true that surgery should be avoided when there are other less invasive alternatives.

Surgical robots such as the da Vinci system and the Zeus system are highly advanced medical instruments allowing for fine movements when appropriately manipulated by surgical experts. These systems are expected to solve some surgical problems such as invasiveness and the difficulty (4–8). Thus far, the systems have been able to solve some of the problems associated with surgery.

As for the invasiveness of surgery, endoscopic surgeries such as laparoscopy can be performed with robotic systems, utilizing smaller incisions than those of other standard open surgical approaches. The precise movements of surgeons are facilitated by robotic systems. However, laparoscopic procedures can be performed even without the robotic systems with the same amount of invasiveness.

Current robotic systems may also pose problems (4–8), such as the limited number of surgeons who can manipulate the system, which is usually one. Additional training for the specific manipulating methods of the systems is another problem, as well as introduction costs. Consequently, it is currently not clear what the benefits of these robotic systems are, especially when assessed from the patient side. Moreover, problems which even surgical experts suffer from have not been solved.

Flexible endoscopes have been developed to cope with the problems of accessing regions through narrow tracts such as the esophagus and the tracheobronchial tree. Even in these regions flexible endoscopes can perform surgical procedures similar to standard surgery. Therefore, endoscopes are naturally considered functional even in other cavities such as the abdomen and pelvic cavities.

It would be easier and more functional to perform an operation using several endoscopic instruments introduced through the end of one endoscope, rather than conducting resection using only one endoscopic instrument introduced into one endoscope, as done in standard endoscopic procedures. The simplest model for this concept is the flexible endoscopic surgical system we developed and examined within these trials.

We assumed that there would be several problems with the flexible endoscopic surgical system when used clinically as it is merely a conceptual model to confirm its feasibility of use. However, despite those problems, the system was able to perform surgical resection. In addition, the problems encountered within the first experiment were inherent in all technical procedures.

Of interest, these problems showed us that, when indicated for resecting procedures, the flexible endoscopic surgical system is easier to manipulate by surgeons and not by endoscopists despite its endoscopic appearances.

The images of the inner endoscopes were not satisfactory because a CCD was not used in these endoscopes. Consequently, resecting procedures were monitored by images from the outer endoscope which contained the CCD. In this situation, the operator had to control the inner endoscope via observations on the monitor of the outer endoscope. This is different from standard endoscopic procedures in which images are observed on the monitor of the endoscope which the operator is controlling.

In general, it is not easy for trainees to understand appropriate surgical procedures, i.e. where to cut and where to stabilize. Verbal communication during operation is important to facilitate appropriate assistance, which was not adequately utilized in the first series. These issues are to be learned through years of experience and cannot be achieved instantly.

As mentioned above, the difference between the two experiments may reveal that for these flexible endoscopes, surgical experience is an important factor, when the system is indicated for surgical procedures. The limitation of the inner endoscopes, not having CCD may have emphasized this issue. Consequently, the next system is to consist of two inner endoscopes with a CCD for each. This would allow the operators to control the inner endoscopes in such a manner as used for standard gastrointestinal endoscopic procedures.

Furthermore, we think that there should be two styles of design for future flexible endoscopic surgical systems; one with increased surgical maneuverability designed particularly for the techniques of surgeons, the other preserving flexible endoscopic maneuverability for endoscopists. Although it has not been decided yet which design is more appropriate for a future surgical system, endoscopists may be able to become accustomed to the flexible endoscopic surgical system with surgical maneuverability when the system is popularized.

In addition to the merits mentioned above, flexible endoscopic materials can theoretically be made compatible with X-ray systems such as fluoroscopes and computed tomography (CT) systems, exemplified by such procedures as X-ray guided bronchoscopy. In the future, the materials used for flexible endoscopic constructions are expected to acquire compatibility with the magnetic fields of magnetic resonance imaging (MRI) systems.

As mentioned before, limitations in visualization pose surgical problems even for experienced surgeons. This may only partially be solved by the subjective ability of surgeons to presume the identity of invisible objects using their tactile sense and their intuition. Actually, the compatibility with imaging systems was one of the important requirements for the design of the flexible endoscopic surgical system,

allowing visibility of anatomical information invisible to the surgeon's eyes.

In order to make one more step towards the future for less invasive and more effective medical treatments, we believe that future surgical systems should acquire the accessibility to narrow regions located deep inside the body together with the compatibility of imaging systems such as CT and MRI. Thus, from the flexible nature and structural characteristics of a nonjointed, smooth outer sheath, we selected the flexible endoscope as the conceptual basis of development for our system. It is the combination of these and the aforementioned aspects that allows for minimization in invasiveness, through the use of pre-existing natural structures and tracts for lesion access to deep regions, and with the presence of multiple interchangeable inner-scopes, an increase in distal tip functionality at the surgical site. Although there are several factors still to discuss and develop, the concept of the flexible endoscopic surgical system is considered an appropriate development for a future surgical robotic system with this current system being a successful step towards that furture.

#### Acknowledgments

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### **Technical Innovation**

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## Vascular Virtual Endoluminal Visualization of Invasive Colorectal Cancer on MDCT Colonography

**OBJECTIVE.** The purpose of this study was to assess the utility of vascular views for visualization of invasive colorectal cancers on contrast-enhanced MDCT colonography.

**CONCLUSION.** By means of Hounsfield-transparency settings, we obtained virtual endoluminal images that show vascular structures and delineate invasive cancers of the colorectal wall, and we call these images "vascular views." Using this technique for contrast-enhanced MDCT colonography, we found that the increase in flow and pooling of blood related to angiogenesis of cancerous lesions is easy to identify and that this finding is useful in the detection of invasive colorectal cancers.



T colonography, a technique for visualizing colorectal lesions using 3D volumetric data generated by helical CT, has developed rapidly

over the past several years [1, 2]. This method has been reported to be useful for improving the diagnosis of colonic polyps and is now being considered for colorectal cancer screening in the United States [3, 4]. This potential has been markedly enhanced by the advent of MDCT, which allows acquisition of entire images of the colorectum during a single breathhold [5]. A major merit of MDCT is its high acquisition speed that can be used to cover large volumes with thin collimation, resulting in good spatial resolution and reduction of the partial volume effect artifact [6]. The thinness of the reconstructed axial CT slices has allowed an increase in the image quality of CT colonography to depict colonic tumors more accurately. Furthermore, in contrast-enhanced studies with MDCT, the ability to scan through the entire abdomen in 20 sec or less means that data for the whole colon can be acquired within the time generally regarded as the arterialdominant phase.

Detection of lesions on CT depends on lesion size, slice thickness, and contrast differentiation [7]. By means of Hounsfield-transparency set-

tings, we obtained virtual endoluminal images that show vascular structures and delineate invasive cancers of the colorectal wall, called "vascular views," on contrast-enhanced MDCT colonography. Using this technique, we found that the increase in flow and pooling of blood related to angiogenesis of cancerous lesions is easy to identify and that this is useful in the detection of invasive colorectal cancers.

The purpose of this study was to assess the utility of vascular views for the visualization of invasive colorectal cancers on contrast-enhanced MDCT colonography.

#### Materials and Methods

From January to March 2002, 28 consecutive patients presenting with 30 invasive colorectal carcinomas underwent contrast-enhanced MDCT examinations at our hospital for preoperative staging. The series included 15 men and 13 women, ranging in age from 37 to 77 years (median, 60 years). Of these patients, 22 (78.6%) underwent MDCT after preoperative colonoscopic examinations with standard bowel preparation of up to 3 L of a polyethylene glycol–electrolyte solution, and the remaining six patients (21.4%) with advanced colorectal carcinomas underwent MDCT without preparation. Patients with rectal cancers underwent MDCT in the prone position, whereas a supine position was used for those with colon cancers. Before treatment, patients re-

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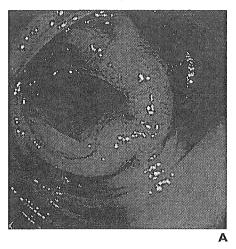
ceived muscular injection of anticholinergic drugs, and room-air insufflation via the anus was performed just before each scan.

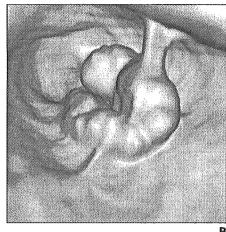
Pathologic diagnosis with endoscopic biopsy or surgically resected specimens was confirmed in each

case. All colonic tumors had been initially diagnosed at colonoscopy, and the presence and site of the lesion were known at the time of the CT examination.

CT colonography was performed on an MDCT scanner (Aquilion, Toshiba Medical Systems). The

scans were obtained through the abdomen and pelvis with the following parameters: 120 kV, 250–350 mA with automatic exposure control [8], 4 rows  $\times$  2-mm collimation, and helical pitch of 5 (pitch factor, 1.25). All patients received an IV bolus injection of 150 mL





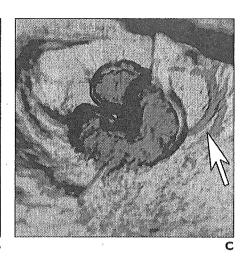
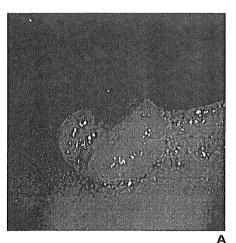


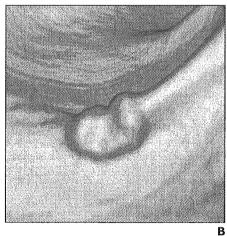
Fig. 1.—Colonoscopic view and surface and vascular virtual endoluminal images for representative case of advanced colorectal cancer in 60-year-old woman.

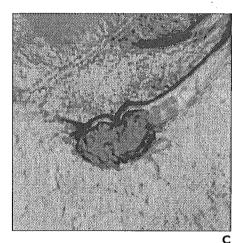
A, Colonoscopic view shows advanced cancer in sigmoid colon.

B, Surface virtual endoluminal image shows lesion.

C, Vascular virtual endoluminal image clearly shows blood pooling of tumor and vessels (arrow) in colorectal wall.







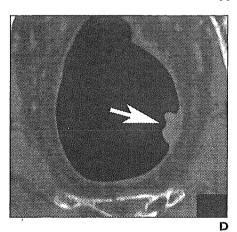


Fig. 2.—64-year-old man with colorectal cancer who underwent MDCT after colonoscopy. A, Colonoscopic view shows small sessile lesion with central depression in lower rectum.

 $\textbf{B}, \textbf{Surface virtual endoluminal image clearly shows lesion, although it is less than 2\,cm in diameter.}$ 

C, Vascular virtual endoluminal image dramatically shows blood pooling of lesion in colorectal wall.

**D**, Axial MDCT image also shows lesion (*arrow*) as polypoid mass in insufflated rectum.

#### **MDCT of Invasive Colorectal Cancer**

of iohexol 350 (Omnipaque, Daiichi Pharmaceutical) with a power injector at a rate of 3 mL/sec through a 20-gauge plastic IV catheter placed in an antecubital vein, and the whole abdomen was scanned 50 sec after this introduction of contrast material during the arterial phase. All images were reconstructed at a thickness of 1 mm, and the slices were transferred to an image workstation (M900/Pegasus, AMIN) for generation of 3D images of each patient.

We used virtual endoluminal images obtained with Hounsfield-transparency settings in MDCT colonography to show a surface or vascular view of the colorectal wall on a videotape monitor (Figs. 1-5). Hounsfieldtransparency settings are based on Hounsfield units, which are the CT attenuation values. First, we adjusted the CT monitor's transparency and opacity setting to a value of 1 to display only the contour of the lumen and the mucosa. Next, we adjusted the transparency and opacity setting to a value of 2 to display only the arterial-dominant blood with contrast medium. Third, we adjusted the spatial parameters to display only to a depth of 3 mm surrounding the lumen and the mucosa, which corresponds to the thickness of the intestinal wall. Fourth, we overlaid the data displayed in steps one through three to produce a surface and vascular view of the colorectal wall, and then we reduced the surface opacity to produce an unobstructed vascular view.

The workstation was also equipped with navigation software for virtual colonoscopy, and the two types of virtual endoluminal images were displayed on the monitor. Two radiologists retrospectively evaluated primary lesions using the virtual endoluminal images with or without the Hounsfield-transparency settings—first, with a conventional surface view and then with a vascular view. Consensus interpretations were rated against all clinical information, including the results of colonoscopy; pathologic findings from biopsy and surgically removed specimens served as the gold standard.

#### Results

In the 28 patients, a total of 30 invasive carcinomas were confirmed by the preoperative colonoscopic examinations. Of the 30 lesions, 18 were in the rectum, five in the sigmoid colon, four in the transverse colon, and three in the ascending colon. The number of lesions over 2 cm in diameter was 21 (70.0%). Of the total, 19 (63.3%) were well differentiated and 11 (36.7%) were moderately differentiated on histologic diagnosis.

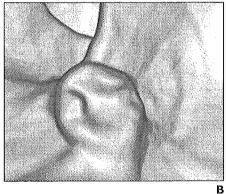
Lesions showing invasion limited to the submucosal layer were defined as early invasive colorectal cancer, whereas invasion farther than the submucosal layer was characterized as advanced colorectal cancer. Among the 30 lesions, 23 (76.7%) were advanced colorectal cancer lesions and seven (23.3%) were early invasive colorectal cancer lesions. Invasive lesions larger than 2 cm are generally of more advanced stage, but four (44.4%) of nine small lesions, 2 cm or smaller, were found to be advanced colorectal cancer.

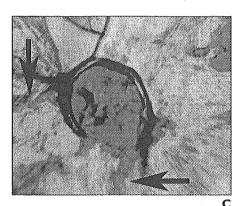
Of the 30 confirmed cancerous lesions, 22 were revealed on conventional surface virtual endoluminal images, whereas 28 could be identified with vascular views (Table 1). The respective figures for lesions 2 cm or smaller were 44.4% (4/9) and 77.8% (7/9). Of lesions larger than 2 cm, three (14.3%) of 21 were missed on surface virtual endoluminal images,

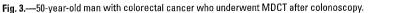
# TABLE I Detection of Colorectal Lesions Using Conventional Surface Versus Vascular Views for Virtual Endoluminal Imaging with Lesions Categorized by Size No. (%) of Lesions Detected on Virtual Endoluminal Images

Size of Lesion	No. (%) of Lesions Detected on Virtual Endoluminal Images		
Size of Lesion	Conventional Surface View	Vascular View	
≤ 2 cm	4/9 (44.4)	7/9 (77.8)	
> 2 cm	18/21 (85.7)	21/21 (100)	
Total	22/30 (73.3)	28/30 (93.3)	







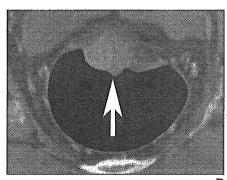


A, Colonoscopic view shows irregularly shaped sessile lesion with central ulceration in lower rectum.

B, Surface virtual endoluminal image shows polypoid lesion.

C, Vascular virtual endoluminal image clearly depicts blood pooling and small vessels (arrows) in colorectal wall.

**D**, Axial MDCT image shows lesion (arrow) as enhanced mass in wall.



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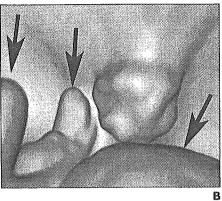




Fig. 4.—59-year-old man with colorectal cancer who underwent MDCT without preparation.

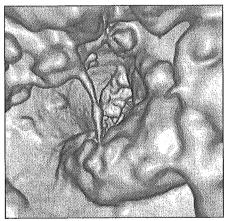
A, Colonoscopic view shows nodular protrusion in lower rectum.

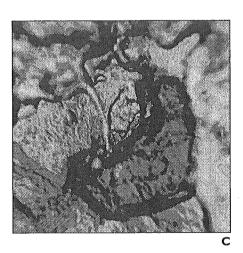
B, It is hard to recognize lesion in residual stool (*arrows*) on surface virtual endoluminal image.

C, Vascular virtual endoluminal image successfully shows lesion as mass having blood pooling in colorectal wall.

D, Axial MDCT image shows lesion (*arrow*) as enhanced mass in colorectal wall.







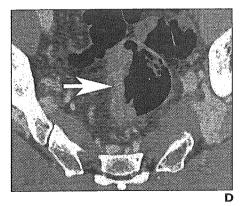


Fig. 5.—63-year-old man with colorectal cancer who underwent MDCT without preparation.

A, Colonoscopic view shows large mass with central ulceration in upper rectum.

B, Because of stool material, lesion cannot be identified on surface virtual endoluminal image.

C, Vascular virtual endoluminal image dramatically distinguishes lesion from stool.

D, Axial MDCT image shows lesion (arrow) as irregular thickening of rectal wall.