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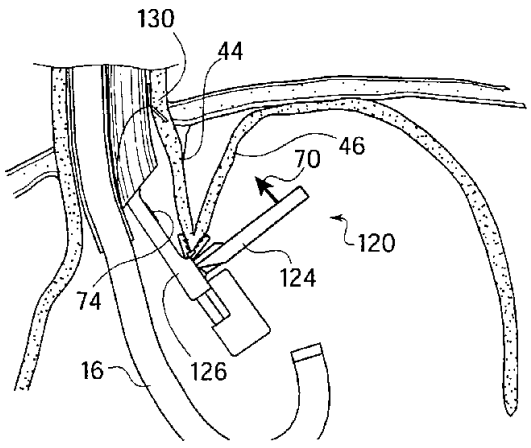
(54)【発明の名称】管腔内底皺壁形成実行方法及び該方法を使用するための装置

(57)【要約】
本発明は、管腔内底皺壁形成を実行する方法及び装置に関する。胃腸食道接合部の一部分を掴み胃腸内に引き込むために用いられるユニット、及び底の一部を食道に向けて動かすユニットを含む装置は患者の胃腸に食道を通じて挿入され、個所に取り付けられる。装置は又、胃腸壁と食道壁を一緒に保持するために用いられ、食道及び胃腸間のバルブを形成するるファスナーを配置することができる。前記二つの壁の縫合を安定させるために接着化合物を使うことができる。



【特許請求の範囲】
【請求項１】
患者の食道及び胃腸の管腔内底皺壁形成を実行する下記を具備する方法：
前記食道の選択された部分を前記胃腸に引き入れ、及び前記胃腸の底部を前記食道に置換えることで前記食道の前記胃腸への重積陥入を形成し；
重積陥入間の留め具を定置させることにおいて、前記留め具は互いに隣接した重積陥入を形成せうる食道壁及び胃壁を維持し；
前記重積陥入を癒着させるために前記食道壁及び前記胃壁間に癒着液を注入する。
【請求項２】
さらに前記重積陥入癒着後に前記留め具を除去することを備えた請求項１に記載された方法。
【請求項３】
さらに下記の事前ステップを備えた請求項１に記載された方法：
内視鏡装置を前記食道を通して導入し及び胃食道接合部に近接して定置し；
前記食道の開口部を掴み及び引っ張るために適用される把握装置を前記内視鏡装置から延長し；及び
前記胃腸の底部を置換するために適用される上皮組織置換装置を前記内視鏡装置から延長する。
【請求項４】
さらに下記を備えた請求項１に記載された方法：
留め具届け装置を前記食道を通して導入し及び希望する堅牢化個所の重積陥入に近接して定置し；
前記食道壁を胃腸壁に付着させるために前記留め具を前記届け装置から届ける。
【請求項５】
さらに下記を備える請求項４に記載された方法：
前記留め具届け装置から前記重積陥入を形成する前記食道壁及び前記胃腸壁を通してハイポ管を延長し；
前記留め具の引出しを負前記具ために前記留め具の遠端を配置し；
前記重積陥入から前記ハイポ管を引出し；及び
前記食道壁を前記胃腸壁に近接して保持するために前記留め具の近端を配置する。
【請求項６】
さらに前記定置及び届けステップを選択した回数だけ繰り返すことを備える請求項４に記載された方法。
【請求項７】
さらに継続的に前記届け装置を配置し及び前記重積陥入の周囲の選択した個所に前記留め具を届けることをさらに備えた請求項４に記載された方法。
【請求項８】
前記配置ステップはさらに前記留め具の遠端及び近端に配置された袋状物を膨張させることを備えることを特徴とする請求項５に記載された方法。
【請求項９】
前記配置ステップはさらにさらに前記留め具の遠端及び近端に配置された変形可能部分を延長させることを備えることを特徴とする請求項５に記載された方法。
【請求項１０】
前記注入ステップはさらに粘着性及び硬化液の少なくとも一つを注入することを備えることを特徴とする請求項１に記載された方法。
【請求項１１】
前記重積陥入を形成し及び前記留め具を配置するステップは、さらに下記を具備することを特徴とする請求項１に記載された方法：
把握部分及び上皮組織置換部分を有するファスナー装置を前記食道を通して導入し及び胃腸食道接合部に隣接して配置し；

前記把握部分で前記食道の開口部を把握し、及び前記開口部を前記胃腸に引き入れ；
前記上皮組織置換部分を前記ファスナー装置のきぬた骨部分に向けて旋回して、前記胃腸壁及び前記食道壁が前記きぬた骨部分及び前記旋回した上皮組織転置部分の間になるように、前記胃腸の底部分を前記食道に向けて動かし；
前記胃腸壁及び前記食道壁を通して前記上皮組織転置部分上に配置されているファスナーの有刺部分を作動させ；及び
前記ファスナーの前記有刺部分を前記きぬた骨部分上に配置されている前記ファスナーの合致するウォッシャー部分に対して確保する。

【請求項１２】
管腔内底皺壁形成を実行する下記ステップを具備する方法：
患者の食道を通じて前記患者の胃腸に内視鏡を挿入し；
前記食道を通じて把握装置を胃腸食道接合部に隣接する位置に挿入し；
前記食道を通じて上皮組織置換装置を胃腸食道接合部に隣接する位置に挿入し；
食道壁を形成するために、前記把握装置により前記食道の選択された部分を把握し及び前記胃腸内に動かし；
胃腸壁を形成するために、前記上皮組織置換装置により前記胃腸の底部を前記食道壁に向けて置換し；
前記食道を通じて接合装置を前記胃腸食道接合部に隣接する位置に挿入し；及び
前記食道壁を前記胃腸壁に付着させるために、前記接合装置からファスナーを配置する。

【請求項１３】
さらに前記胃腸壁と前記食道壁の間に粘着及び硬化液の一つを注入するステップをさらに備える請求項１２に記載された方法。

【請求項１４】
前記把握装置、上皮組織置換装置、及び接合装置の少なくとも一つの挿入経路を定めるために、前記食道上に覆管を挿入するステップをさらに備える請求項１２に記載された方法。

【請求項１５】
選択された回転により前記接合装置を回転し、及び前記配置ステップを繰り返すステップをさらに備える請求項１２に記載された方法。

【請求項１６】
前記回転ステップは前記接合装置を約３０度回転させることを備えることを特徴とする請求項１５に記載された方法。

【請求項１７】
前記食道壁に対して前記胃腸壁を付着した後に前記ファスナーを除去するステップをさらに備える請求項１２に記載された方法。

【請求項１８】
患者の食道及び胃腸の管腔内底皺壁形成を実行する下記を具備する装置：
前記患者の食道を通じて前記胃腸に内視鏡を挿入するために遠端に適用された柔軟管；
前記食道の選択された部分を把握するために適用される前記柔軟管の遠端に配置された上皮組織把握装置；
前記胃腸の底部を前記食道に向けて動かすために適用される前記上皮組織把握装置に隣接して配置される上皮組織置換装置；及び
前記上皮組織置換部分に対して旋回可能なきぬた骨部分であって、前記上皮組織置換装置及び前記きぬた骨部分は着脱可能であってファスナーの付属部分を保持し、前記底部分が前記食道に向かって動いたときには前記付属部分は結合する、ことを特徴とする。

【請求項１９】
前記食道の選択された個所を動かすために適用される前記柔軟管の有刺部分をさらに具備する請求項１８に記載された装置。

【請求項２０】
前記上皮組織把握装置は前記上皮組織置換装置とは独立して操作可能な一組のはさみ口を

具備することを特徴とする請求項１８に記載された装置。
【請求項２１】
前記ファスナーは有刺部分及び合致するウォッシャー部分をさらに具備する請求項１８に記載された装置。
【請求項２２】
前記上皮組織置換装置及び前記きぬた骨部分の旋回により、前記食道の前記選択された個所及び前記胃腸の前記動かされた底部を前記上皮組織置換装置及び前記きぬた骨部分の間に配置することを特徴とする請求項１８に記載された装置。
【発明の詳細な説明】
【０００１】
［発明の分野］
本発明は、一般に、胃腸の食道に対する底皺壁形成技術に関する。とくに、本発明は、そのような底皺壁形成を管腔内で実行する方法、及び食道に底を保持する装置に関する。
【０００２】
［発明の背景］
底皺壁形成は、胃腸食道接合部（ＧＥＪ）の変形、及び／又は機能不全の下部食道括約筋の結果しばしば生じる疾病であって、典型的に、胃腸食道逆流（ＧＥＲ）状態の治療に使われる。ＧＥＲに関連する普通の兆候は、胃腸の内容物の食道への嘔吐又は逆流である。底壁皺形成処置は、食道への逆流を防ぐためのＧＥＪのバルブを形成するために、食道及び胃腸の上皮組織を操作することに向けられている。バルブは胃腸を陥入させるように食道を操作し、それから食道の遠端の周りの胃腸の底を包み込み、及びその包んだ位置で胃腸を保持することにより形成される。
【０００３】
最も普通に使われる底皺壁形成では、包み込み及び保持が実行できるように、腹部又は胸部の切開が必要になる。このような手術は非常な侵襲性の性格をもつことから、合併症や死亡もかなりのケースで発生する。さらにこれらの処置は実行するのに何時間も要するように長時間がかかり、切開が施された場所に醜い傷口を残す。
【０００４】
他の最近開発された底皺壁形成処置は、腹腔内視鏡下手術用口又は経皮内視鏡胃フィステル形成（例えば米国特許番号５，４０３，３２６及び５，０８８，９７９、これらの内容を参照して以下説明する）を利用することにより、幾分、大掛かりな手術切開をする必要を限定している。これらの処置は、大掛かりな腹部及び胸部切開が絡むものより侵襲性は小さいが、とはいえ侵襲することには違いは無く、それらの侵襲的手術に伴うコスト及びリスクを負う。例えば、これらの処置の最中に一般的な麻酔が施されるが、それはこれらの処置の費用に加えられ、及び周知のリスクを伴う。
【０００５】
現行の底皺壁形成方法の侵襲的性格に伴う合併症、リスク及びコストに加えて、これらの方法には他の問題もある。一つのそのような問題は、底部包みのずれと呼ばれる底の包みが解けることである。現行の方法ではずれはしばしば生じ、適切に皺にした底部を保持することができなくなる。
【０００６】
［発明の要約］
本発明は、まず胃腸食道接合部の付着部分を見つけるために柔軟内視鏡を使う管腔内底皺壁形成方法に関する。そして上皮組織把握装置が内視鏡の遠端に配置され、見つけられた身体上皮組織付着個所に取り付けられる。次に上皮組織置換装置が内視鏡の遠端に配置され、食道の上皮組織重積を胃腸内腔に形成する目的で、胃腸の底部を置換するために使われる。そして、ファスナー配置装置が第１の望んだファスナー配置位置に隣接して配置され、望んだファスナー配置位置に重積を形成する上皮組織と通して第１のファスナーを配置するために使われる。第１のファスナーは食道の胃底の第１の部分を保持する。そしてファスナー配置装置は追加的に望んだファスナーの複数の位置に追加的ファスナーを配置

するために使われ、胃腸底部を食道の周りに保持する。一つの実施態様では、ファスナー配置装置、上皮組織把握装置、及び上皮組織置換装置は単独のユニットに統合されている。

【０００７】

最後に、内視鏡の遠端に注入装置が配置され、癒着液を重積を形成する上皮組織に注入するために使われる。例えば、癒着剤は線維性固着剤又は接着液である。

【０００８】

一つの実施態様では、本発明は、患者の食道及び胃腸の管腔内底皺壁形成を実行する下記を具備する方法：前記食道の選択された部分を前記胃腸に引き入れ、及び前記胃腸の底部を前記食道に置換えることで前記食道の前記胃腸への重積陥入を形成し；重積陥入間の留め具を定置させることにおいて、前記留め具は互いに隣接した重積陥入を形成せうる食道壁及び胃壁を維持し；前記重積陥入を癒着させるために前記食道壁及び前記胃壁間に癒着液を注入する。

【０００９】

もう一つの実施態様では、本発明は、患者の食道及び胃腸の管腔内底皺壁形成を実行する下記を具備する装置：前記患者の食道を通じて前記胃腸に内視鏡を挿入するために遠端に適用された柔軟管；前記食道の選択された部分を把握するために適用される前記柔軟管の遠端に配置された上皮組織把握装置；前記胃腸の底部を前記食道に向けて動かすために適用される前記上皮組織把握装置に隣接して配置される上皮組織置換装置；及び前記上皮組織置換部分に対して旋回可能なきぬた骨部分であって、前記上皮組織置換装置及び前記きぬた骨部分は着脱可能であってファスナーの付属部分を保持し、前記底部分が前記食道に向かって動いたときには前記付属部分は結合する、ことを特徴とする。

【００１０】

［発明の詳説］

本発明の方法は、例えば、好ましくは上皮組織把握装置１８（図１に示す）、上皮組織置換装置２２（図２に示す）、ファスナー配置装置２４（図３に示す）、及び注入装置２８（図４に示す）を備えた柔軟内視鏡１６により実行することができる。内視鏡は、好ましくは様々な装置が通過可能な一つ以上の覆鞘を有する。例えば、内視鏡は、覆鞘の内腔を通る上皮組織置換装置を備え、内視鏡操作者により内視鏡の遠端を通って管理可能に延長できる。さらに内視鏡は好ましくは、ファスナー配置装置が通過し及び注入装置がその遠端で操作可能な第２の覆鞘の経路を有する。内視鏡操作者は、上皮組織把握装置、上皮組織置換装置、ファスナー配置装置、及び注入装置を含んで内視鏡を、内視鏡の近端から操作できる。

【００１１】

この処置には異なるタイプの内視鏡を使うことができる。必要であれば、追加的な道具の挿入を円滑にするために、一つ以上の経路を有する覆管を底皺壁形成場所に内視鏡上から差し入れることができる。例えば、図１５ａには、水路、吸入路、光源、ビデオ・フィードバックを提供する幾つかの経路を有する内視鏡１６を表す。この例示内視鏡１６は一つの作業用経路Ａを含む。追加道具の挿入を円滑にするために、覆管２０を使い、内視鏡１６の遠端に達する追加的作業経路Ｅ及びＦを画する鞘を形成する。同様に、図１５ａは、二つの作業経路Ａ及びＢをもつ内視鏡１６‘を表す。この場合は、覆管２０’は一つの追加的作業経路Ｆを単に提供しなければならない。ここでの話では、「内視鏡装置」とは一般に内視鏡及び、必要なときは、追加的作業経路を画する覆管を指すために用いられる。

【００１２】

一つの実施態様では、患者の腹部は治療を円滑にするために空気を吹き込まれている。患者は又、処置の間、静脈麻酔注射により鎮静されている。

【００１３】

本方法では、柔軟内視鏡１６はまず患者の口に差し込まれ、図１のとおり食道１０を通り腹部に入る。そこで挿入された内視鏡１６は、胃腸食道接合部の付着個所１４を見つけるために使われる。処置を施す内視鏡操作者又は他の実施者は、内視鏡でＧＥＪを覗くこと

で場所を見つけることができる。内視鏡により目標個所を見つけるこれらの方法は公知で、従来技術でよく用いられている。

【００１４】

上皮組織把握装置１８は見つけられた個所に配置され、図１に示すようにその上皮組織を把握して保持するために使われる。上皮組織把握装置１８は、内視鏡１６の内腔を通り、実施者により内視鏡１６の近端で操作可能である。好ましくは、実施者は装置１８の着脱のみならず装置１８が当該個所に適用する力もコントロールすることができる。この力は装置１８延ばしたり、内視鏡１６の遠端に向けて装置１８を引っ込めることでコントロールできる。上皮組織把握装置１８が取り掛かり、又は把握し、上皮組織を保持する手段は、鉤、引っ掛け具、把握具、それらの組合せなど、従来技術で公知である。

【００１５】

ＧＥＪの上皮組織が把握された後は、食道１０の重積２２が効果的に胃腸３２内に形成されるように、図２に示すように、胃腸底１２を置換するために上皮組織置換装置２２が使われる。上皮組織置換装置２２は、内視鏡１６を囲む覆管２０の内腔を通り、内視鏡１６の遠端の位置に押し付けられたり又は旋回させたりすることができる。装置２２は、好ましくは、硬いケーブルかナイチノル・バンドの遠端に位置する球体端２３を具備する。実施者は、上皮組織置換装置２２を、例えば、押したり又はそれを胃腸底に向かって旋回させることで操作することができる。

【００１６】

一端、胃腸底１２に対する位置が決まると、上皮組織置換装置２２は、胃腸底１２に対して押したり、再配置したりするためにさらに押し付けられたり、旋回したりする。同様に、上皮組織把握装置１８は、付着個所１４の上皮組織を保持し、上皮組織置換装置２２により供給される力に対抗して力を掛ける。これらの相反する力の正味の効果により、胃腸底１２は、参照番号３４により正確に彼と特定されている角度を為し、食道に極めて近い位置に運ばれる。胃腸底１２の置換は上皮組織片３０を形成し、それは有効に食道１０が胃腸３２に入った重積となる。一つの実施態様では、上皮組織片は長さ約１から３センチになる。

【００１７】

実施態様では、上皮組織把握装置１８により上皮組織を引っ張り、上皮組織置換装置２２により底を置換するステップは、重積の周囲の幾つかの位置で繰り返される。例えば、この処置は食道の周囲の４つから１２の等間隔の個所で実行される。

【００１８】

彼３４の角度の縮小及び重積３０の形成は、胃内容物の食道１０への逆流の程度を減少させる。胃腸と食道の間に実質的にバルブが構築される。胃腸内腔３２、さらに詳しくは胃腸底１２にガスが溜まるに従い、食道１０の包まれた部分に圧力が掛かり、それを胃腸から閉じる。さらに胃内容物は、胃筋肉の収縮及び一般的な身体の動きにより胃腸内腔３２内で顫動する。重積３０により、胃内容物が食道１０に達するために通過しなくてはならない障害のようなバルブを作ることにより、ＧＥＲが和らげられる。

【００１９】

重積された食道３０は、その配置を固定するために次に胃腸底１２の壁に縛りつけられる。ファスナー配置装置２４は胃腸及び食道上皮組織をその個所に保持するために重積３０内にファスナー２６を挿入する目的で使われる。典型的には操作を施す上皮組織には神経や血管が通っているので、実施者は、ファスナー２６を挿入する前に、神経や血管を見つけてそれらを傷つけないようにしなければならない。とくに、実施者は、食道、大動脈、及び様々な胃血管を通じる迷走神経束を見つけておかなければならない。このような解剖学的特徴を見つける様々な方法は、超音波、光学顕微鏡及びＸ線を含む従来技術で公知である。

【００２０】

一端、前述の特徴が見つかると、実施者はファスナー２６をファスナー配置装置２４に付けて、装置２４を配置装置２４の操作端が望むファスナー挿入場所に配置されるまで第２

の鞘経路２５を通じて挿入する。そして装置２４は、図３のように望む場所にファスナーを配置するために使われる。ファスナー２６は、好ましくは新しく作られた上皮組織縁３０の先１４の１ｃｍ及び２．５ｃｍ上に重積を通して挿入され、胃腸内腔３２に伸長する。ファスナー２６はまた、上皮組織縁の長さに沿って他の場所にも挿入することができ、実施態様では長さは約１及び３ｃｍである。

【００２１】

ファスナー配置装置２４は、食道の全周囲にファスナーを挿入するために、食道及び胃腸内腔ないで旋回することができる。好ましくは、ファスナーは３０度離して挿入される。例えば、初めの挿入個所から、装置２４は一つの方向に旋回し、初めの場所から３０度、６０Ｄ０，１２０度及び１８０度と旋回する。そして装置２４は、初めの挿入個所に戻り、反対方向へ、再び例えば３０度間隔で、重積の全周囲が縫合されるまでファスナーを挿入する。

【００２２】

好ましくは、重積は３６０度全部、すなわち食道の全周囲に伸長すべきである。重積により形成されるバルブは、「胃腸食道反射疾病（ｇｅｒｄ）標準」又は腹腔手術、組立て式かまぼこ型底皺形成と同様である。しかし、全３６０度は内腔アプローチでは達成不可能であるかもしれない。その場合は、鬘状（ｔｏｕｐｅｔ）底皺形成で、食道の周囲約２７０度範囲が実行することができる。

【００２３】

したがって、内腔処置では、食道の裏側約６０度の半円範囲は、一般に実行できない。食道周囲の残余の部分には、ファスナーは例えば３０度間隔で付着させることができる。

【００２４】

図５はファスナー配置装置２４を通って挿入され、さらに進み食道及び胃腸壁、それぞれ４４および４６の両方の上皮組織を貫通する斜角のハイポ管４０を表す。ハイポ管４０は、例えば、皮下注射針套管か、又は好ましくはステンレス製の薄い管の他のタイプで可能である。

【００２５】

公知技術のＴファスナー４２は、ファスナー４２の遠端が重積の胃腸側に適用されるまでハイポ管４０を通じて挿入することができる。そしてハイポ管４０は、鞘２４に向けて引き抜かれ、Ｔファスナーの適用された遠端が、図６に示すように、ハイポ管４０が引き抜かれるに従って胃腸壁４６に噛み合うようにする。図７のように、ハイポ管４０は、さらにＴファスナーの近端が、Ｔファスナーの遠端から行使される圧力によりハイポ管をから抜け出るまで、鞘２４内に引き抜かれる。そしてＴファスナー４２の近端は、食道の内壁に対して着地し、胃腸壁及び食道壁の両方を一緒に保持する。Ｔファスナーの縦中心部分の長さは、食道の内壁及び底の内壁の間の最大長を決定する。

【００２６】

図９－１１は食道及び胃腸壁を保持するするために使われるＴファスナーの様々なコンフィグレーションを表す。伝統的なＴファスナー４８は、各端に簡単なＴバーを有する。このファスナーにより、変形後位置での胃腸及び食道上皮組織を保持する力は、ファスナー各端のＴバーにより担われ、力を分散するための小部分を有する。このタイプのＴバーは胃腸及び食道のいずれかの壁を通して引くことができる。したがって、上皮組織を保持する力を分散させるより広い場所と合わせて、本発明と共にＴバー・コンフィグレーションのＴファスナーを利用することが望ましい。図９は、各端に二つのＴボルスタを有するＴファスナーを表す。さらに、上皮組織を保持する力を分散させる場所は、例えば三つ股、４股、または６股（それぞれ図１０，９，及び１１に示す）のＴファスナーを利用することにより増大させることができる。

【００２７】

図１２は、本発明に従って胃腸及び食道上皮組織を保持するために使うことのできる代替的なファスナー５６を表す。ファスナー５６は、各端に膨張可能袋５８を備えた縦中心部分を有する。このファスナー５６は、Ｔファスナー挿入に関して上述したと同様のやり方

で、胃腸及び食道上皮組織を通して挿入することができる。一端ファスナー５６の位置が定まると、空気、水または他の物資を膨張可能端５８に挿入することができ、端５８を膨らませて、胃腸及び食道上皮組織を保持することができる。膨張可能端は球形または円盤状である。

【００２８】

一つの実施態様では、袋は図１２のようにファスナー４２の遠端に作られ、壁４４，４６への挿入中、ハイポ管４０内に納められる。ハイポ管４０が引出されると、ハイポ管４０内に作られた膨張管を通して流体が通り、袋が膨張する。ハイポ管４０からの分離の前に、ファスナー４２の近端の袋を膨らますために同様のプロセスが実施される。公知デザインのシールを膨張した両方の袋の保持に使うことができる。

【００２９】

図１３－１４は、本発明に従った胃腸及び食道を保持するために使うことのできるもう一つの代替的ファスナー６０を表す。ファスナー６０は、近端及び遠端近くに変形可能部分６２，６４を伴った縦要素部品で、好ましくは、ポリプロピレインまたは他のバイオ並立耐性材料により作ることができる。

【００３０】

変形部分６２，６４は、好ましくは、ファスナー６０がもう一つに押し付けられたときに、例えば、撓むことにより、放射状に拡張することのできるメッシュ状構造を有する。ファスナー６０は、図５－７のように、Ｔファスナー挿入に関して先述したのと同様なやり方で、胃腸及び食道上皮組織に挿入することができる。近端及び遠端が食道及び胃腸のそれぞれで望む位置になると、端は拡張される。

【００３１】

一つの実施態様では、ファスナー６０は、図１３ｂのように、変形された位置に向かって通常傾きがあるように形成することができる。このタイプのファスナー６０は、減少された直径コンフィグレーションに維持され、一方、ハイポ管４０内に保持され、及びそこから解き放たれると自然の傾きにために拡張される。変形可能部分６２及び６４は、配置装置２４を通し及び胃腸及び食道上皮組織の両方を通じてファスナーの挿入を可能とするように圧力を掛けられる。そしてファスナー６０は、遠位の変形可能部分６４がハイポ管４０の遠端を抜け出るまでハイポ管４０を通って進み、その通常放射状に拡張された位置に再び戻る。そしてハイポ管４０は、引っ込み、近位の変形可能部分６２がその通常の放射状に拡張された位置に拡張することを許容する。そこで変形可能部分６２及び６４は、胃腸及び食道上皮組織を適切な位置に保持するためのボルスタとして作動する。

【００３２】

代替的に、変形可能部分６０を有するファスナー６０は、図１３ａのように、通常上方変形部分として作ることができる。通常上方変形ファスナーは、通常変形実施態様に関して上述したのと同様のやり方で胃腸及び食道上皮組織を通して挿入できる。通常上方変形ファスナーはそこで、食道及び胃腸上皮組織の範囲のなかで望む位置に配置された後に、図１３ｂに用に変形された位置に操作される。内視鏡内腔を通して挿入される皺寄せ装置がこのような処置をするために用いられる。この装置はリベット挿入に用いられる公知のメカニズムに似ている。当業者には明らかなように、変形部分を撓ませるためにファスナー６０の端に圧力を掛けることができ、内視鏡の内腔を通して挿入できるいずれの装置であっても、皺寄せ装置として使うことができる。

【００３３】

ファスナー６０はまた、挿入を支援するための遠端の針状ポイントにより作ることもできる。このような遠端により、ファスナー６０を直接胃腸及び食道上皮組織を通して挿入することが可能になり、ハイポ管４０の必要がなくなる。

【００３４】

図１６に示すように、図５－７との関係で先述したハイポ管４０は、ファスナー１０２を適用する挿入装置１００に換えることができる。図１６ａのように、挿入装置１００が食道及び胃腸壁４４，４６を跨いで配置されたときは、内視鏡１６の長さに延長された活性

ワイア１０４が引かれ、図１６ｂのように遠位ステント１０６が適用される。挿入装置１００が引き抜かれたときには、活性ワイア１０４は、図１６ｃのように再び引かれ、近位ステント１０８が適用され、及び壁４４，４６は図１６ｄのようにステント１０６，１０８の間に挟み込まれる。

【００３５】

本発明に従った、異なる実施態様では、図１４のように、有刺タック７０及び合致ウォシャー７４を具備する二葉ファスナーを採用することができる。有刺タック７０は、有刺コネクタ７２をもつ円盤部分７１を構成する。有刺コネクタ７２は、合致ウォシャー７４を通して挿入でき、コネクタ７２はウォシャー７４とかみ合う。コンポーネント７０及び７４の両方は、好ましくは、弾力ポリマー材料から作られる。

【００３６】

本発明に従った装置の代替的なもう一つの実施態様では、有刺タック７０及び合致ウォシャー７４は、図１７ａから１７ｅまでに示されるように、皺壁形成装置１２０を使って挿入される。図１７ａは、食道１０を通じて患者の胃腸３２に挿入される柔軟管１２１の端の装置１２０を表す。手順を監視するために内視鏡１６を導入することもできる。一端配置されると、装置１２０は図１７ｂのように、胃腸底１２に向けて位置を動かす旋回可能上皮組織置換部分１２４を適用する。

【００３７】

装置１２０の把握部分１２８は、図１７ｃのように、胃腸食道接合部の付着個所１４を把握するために使われ、装置１２０の下方運動により食道１０の領域を胃腸３２内に引っ張る。この手順を容易にするために鉤１３０も使うことができる。一端食道開口部が適当な位置に配置されると、上皮組織置換装置１２４が装置１２０のきぬた骨部分に向けて旋回し、底１２が食道に向けて押されて、重積を形成する。

【００３８】

上皮組織置換部分１２４がきぬた骨部分１２６に到達すると、図１７ｄのように、上皮組織置換部分１２４上に搭載されたファスナーの有刺部分７０は、胃腸壁４６及び食道壁４４を貫き、きぬた骨部分１２６上に搭載された合致ウォシャー７４を保持する。この処置の結果、上皮片１３２が形成される。本発明に従った他の実施態様について前述したように、この処置は、図１７ｅのように、食道１０から胃腸３２を分離する、望んだ形のバルブを形成するために、食道の周囲の異なる周辺場所で繰り返すことができる。

【００３９】

最後に、図４のように、接着液が重積の上皮に注入され、皺壁形成の胃腸及び食道上皮組織を保持する線維性反応が生じる。例えば、モルイン酸ナトリウムは胃腸及び食道上皮間に形成される上皮包に注入される公知の液で、胃腸底を食道に永久に粘着させる線維性反応を生じさせる。

【００４０】

接着液として幾つかの化合物を使うことができる。例えば、シアン化アクリル酸塩だけでなく、フィブリン密封剤、筋肉硬化プロテイン、成長要素変化ベータ、プララミン・ジェル、ゼラチン‐レソシネル‐フォルマル・ジェル及びヒストアクリルなどを使うことができる。硬化剤化合物としては、モルイン酸ナトリウム、ナトリウム四化硫酸塩、エタノラミン・オレイン酸塩、エアゾル剤及び滅菌ブェオミチン硫酸塩を使うことができる。

【００４１】

このような接着液が使われたときには、ファスナーは、液により生じた反応がその位置の上皮を保持するまで上皮を保持する必要があるだけである。そして使われたファスナーは生分解又は生吸収性物質で形成され、または除去することができる。

【図面の簡単な説明】

本発明は添付図面を参照し、以下の詳説を通してより容易に理解することができるが、その中で、図１から４は、本発明に一つの実施態様に従った管腔内底皺形成方法を表す。

【図１】

内視鏡を食道を通して胃腸内腔に挿入し、及び上皮組織把握装置を胃腸食道接合部の個所

に付着させた、食道の遠端及び上部胃腸壁の横断面を表す。
【図２】
図１の横断面と同様に、さらに、食道の重積を胃腸内腔に形成するために置換された上皮組織置換装置と胃腸底部を表す。
【図３】
図２の横断面と同様、さらに、上皮組織ファスナー装置と重積に配置されたファスナーを表す。
【図４】
内視鏡を食道を通して胃腸内腔に挿入し、上皮組織把握装置を胃腸食道接合部の個所に付着させ、二つのファスナーを重積内に配置し、及び重積に挿入した注入装置と共に、食道の遠端及び上部胃腸壁の横断面を表す。
【図５】
ハイポ管を食道及び胃腸壁の両方に挿入し、食道の重積を胃腸内腔に入れた横断面を表す。
【図６】
図５の横断面と同様、適用されたＴファスナーの遠端と共に示す。
【図７】
図５の横断面と同様、身体上皮組織内から引っ込めたハイポ管と共に、及び適用されたＴファスナーの近端及び遠端の両方と共に表す。
【図８】
各端のＴバー当て物と共にＴファスナーの立体図を表す。
【図９】
各端の四つ股当て物と共にファスナーの立体図を表す。
【図１０】
各端の三つ股当て物と共にファスナーの立体図を表す。
【図１１】
各端の曲がった六股当て物と共にファスナーの立体図を表す。
【図１２】
各端の膨張可能当て物と共にファスナーの立体図を表す。
【図１３ａ】
変形していない位置でのファスナーと共に、各端近くの変形可能部分を有したファスナーの縦面を表す。
【図１３ｂ】
変形した位置でのファスナーと共に、各端近くの変形可能部分を有したファスナーの図１３ａと同様の縦面を表す。
【図１４】
有刺タックを有する部分、及び合致するウォッシャーを有するもう一つの部分をもつ本発明のもう一つの実施態様の等積図を表す。
【図１５ａ】
一つないし二つの覆管を有する内視鏡の二つの実施態様の一つの横断面を表す。
【図１５ｂ】
一つないし二つの覆管を有する内視鏡の二つの実施態様の一つの横断面を表す。
【図１６ａ】
本発明のもう一つの実施態様に従ったファスナー用の適用装置の側面を表す。
【図１６ｂ】
本発明のもう一つの実施態様に従ったファスナー用の適用装置の側面を表す。
【図１６ｃ】
本発明のもう一つの実施態様に従ったファスナー用の適用装置の側面を表す。
【図１６ｄ】
本発明のもう一つの実施態様に従ったファスナー用の適用装置の側面を表す。

【図１７ａ】
底皺壁形成装置を含む本発明に従ったシステムの異なる実施態様の操作ステップを表すダイアグラムを示す。
【図１７ｂ】
底皺壁形成装置を含む本発明に従ったシステムの異なる実施態様の操作ステップを示すダイアグラムを表す。
【図１７ｃ】
底皺壁形成装置を含む本発明に従ったシステムの異なる実施態様の操作ステップを示すダイアグラムを表す。
【図１７ｄ】
底皺壁形成装置を含む本発明に従ったシステムの異なる実施態様の操作ステップを示すダイアグラムを表す。
【図１７ｅ】
底皺壁形成装置を含む本発明に従ったシステムの異なる実施態様の操作ステップを示すダイアグラムを表す。

【図１６ａ】

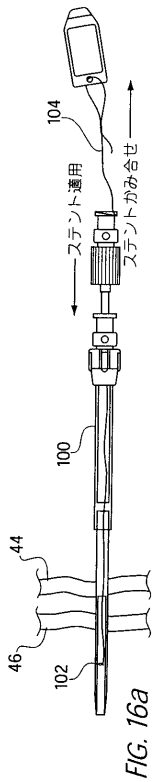


FIG. 16a

【図１６ｂ】

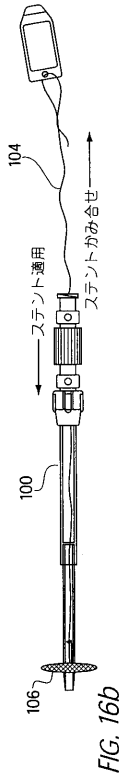


FIG. 16b

【図１６ｃ】

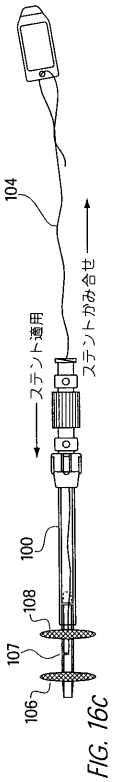


FIG. 16c

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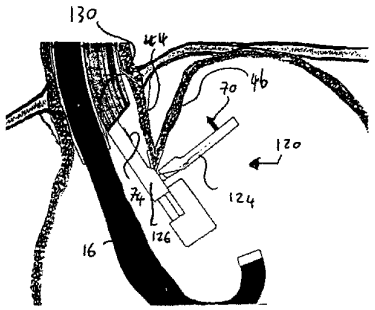

(57) Abstract: A method and device for performing endoluminal fundoplication are described. A device is inserted in the patient's stomach through the esophagus, including an unit adapted to grasp and pull a portion of the gastroesophageal junction into the stomach, and an unit adapted to move a portion of the fungus towards the esophagus. The device also can place fasteners to hold the gastric wall and the esophageal wall secured together, thus forming a valve between esophagus and stomach. An adhesive compound can be used to stabilize the juncture of the two walls.

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METHOD FOR PERFORMING ENDOLUMINAL FUNDOPLICATION AND APPARATUS FOR USE IN THE METHOD

Field of the Invention

The present invention relates generally to the art of fundoplicating the stomach to the esophagus. More specifically, the present invention relates to a method for performing such a fundoplication endoluminally, and to an apparatus for securing the fundus to the esophagus.

Background of the Invention

Fundoplication is a surgical procedure which is typically used to treat Gastroesophageal Reflux (GER) condition, a malady often resulting from a deformity of the gastroesophageal junction (GEJ), and/or a dysfunctional lower esophageal sphincter (LES). One symptom commonly associated with GER is regurgitation or reflux of stomach contents into the esophagus. Fundoplication procedures are directed towards manipulating esophageal and gastric tissue so as to form a valve at the GEJ which limits reflux into the esophagus. The valve is formed by manipulation of the esophagus so as to invaginate the stomach, then wrapping the fundus of the stomach around the distal end of the esophagus and securing the stomach in that wrapped position.

The most commonly used fundoplication procedures require abdominal or thoracic incisions through which the abdominal wrapping and securing can be performed. Due to the highly invasive nature of such surgery,1 complications and morbidity occur in a significant percentage of cases. In addition, these procedures are lengthy, often taking a number of hours to perform, and may leave disfiguring scars where the incisions were made.

Other recently developed fundoplication procedures somewhat limit the necessity of making large surgical incisions by utilizing laparoscopic ports or

percutaneous endoscopic gastrostomy. (See, e.g. United States Patent Nos. 5,403,326, and 5,088,979, the contents of which are hereby incorporated by reference). Although these procedures are less invasive than those involving large abdominal and thoracic incisions, they are invasive nonetheless, and have costs and risks associated with such invasive surgery. For example, general anaesthesia is typically used during these procedures which adds to the expense of these procedures and entails well known risks.

In addition to the complications, risks, and costs associated with the invasive nature of current fundoplication methods, these methods have other problems as well. One such problem is unwrapping of the fundus, also referred to as slippage of the fundal wrap. Slippage frequently occurs with current methods, as they fail to adequately secure the plicated fundus.

Summary of the Invention

The present invention is directed to a method for endoluminal fundoplication in which a flexible endoscope is first used to locate an attachment site at the gastroesophageal junction. A tissue grasping device is then positioned at the distal end of the endoscope, and attached to the body tissue at the located attachment site. Next, a tissue displacement device is positioned at the distal end of the endoscope and used to displace the fundus of the stomach, so as to create an intussusception of the esophagus into the gastric lumen. A fastener delivery device is then positioned adjacent to a first desired fastener delivery location and used to place a first fastener through the tissue which forms the intussusception at the desired fastener delivery location. The first fastener secures a first portion of the gastric fundus to the esophagus. The fastener delivery device is then used to place additional fasteners at a plurality of additional desired fastener locations, thus securing the gastric fundus around the esophagus. In one exemplary embodiment, the fastener delivery device, the tissue grasping device, and the tissue displacement device can be incorporated into a single unit.

Finally, an injection device is positioned at the distal end of the endoscope and used to inject a bonding agent into the tissue which forms the intussusception. For example, the bonding agent can be an agent for fibrotic fixation or adhesion.

In one embodiment, the invention is a method for performing endoluminal fundoplication of a patient's esophagus and stomach, having the steps of forming an intussusception of the esophagus into the stomach by pulling a selected portion of the esophagus into the stomach, and by displacing a fundus portion of the stomach towards the esophagus, placing a fastener across the intussusception, said fastener maintaining an esophageal wall and a gastric wall forming the intussusception adjacent to one another, and injecting a bonding agent between the esophageal wall and a gastric wall to bond the intussusception.

In another embodiment, the invention is a device for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising a flexible tube having a distal end adapted for insertion in the stomach through the esophagus, a tissue grasping device disposed at the distal end of the flexible tube, adapted to grasp a selected portion of the esophagus, a tissue displacement device disposed adjacent the tissue grasping device, adapted to move a fundus portion of the stomach towards the esophagus and an anvil portion, pivotable relative the tissue displacement portion, wherein the tissue displacement device and the anvil portion releasably carry complementary portions of a fastener, such that said complementary portions are joined when the fundus portion is moved towards the esophagus.

Brief Description of the Drawings

The invention will be more readily understood through the following detailed description, with reference to the accompanying drawings, in which:

Figures 1 through 4 illustrate the method of endoluminal fundoplication according to one embodiment of the present invention;

Figure 1 shows a cross-sectional view of the distal end of an esophagus and the upper gastric wall, with an endoscope inserted through the esophagus and into the gastric lumen, and a tissue grasping device attached to a site on the gastroesophageal junction;

Figure 2 shows the cross-sectional view as in Figure 1 and, in addition, shows a tissue displacement device and the gastric fundus displaced so as to form an intussusception of the esophagus into the gastric lumen;

Figure 3 shows the cross-sectional view as in Figure 2 and, in addition, shows a tissue fastener device and a fastener placed through the intussusception;

Figure 4 shows a cross-sectional view of the distal end of an esophagus and the upper gastric wall, with an endoscope inserted through the esophagus and into the gastric lumen, two fasteners placed within the intussusception, and an injection device inserted into the intussusception;

Figure 5 shows a cross-sectional view of an intussusception of the esophagus into the gastric lumen with a hypotube inserted through both the esophageal and gastric walls;

Figure 6 shows the cross-sectional view as in Figure 5, with the distal end of a T-fastener deployed;

Figure 7 shows the cross-sectional view as in Figure 5, with the hypotube retracted from within the body tissue, and with both the proximal and distal ends

of the T-fastener deployed;

Figure 8 shows an elevation view of a T-fastener with a T-bar bolster at each end;

Figure 9 shows an elevation view of a fastener with a four-pronged bolster at each end;

Figure 10 shows an elevation view of a fastener with a three-pronged bolster at each end;

Figure 11 shows an elevation view of a fastener with a six-pronged bolster at each end, in which the prongs are curved;

Figure 12 shows an elevation view of a fastener with inflatable bolsters on each end;

Figure 13a. is a longitudinal view of a fastener with deformable portions near each end, with the fastener in the undeformed position;

Figure 13b is a longitudinal view of the fastener shown in Fig 13a, with the deformable portions near each end in the deformed position;

Figure 14 is an isometric drawing showing another embodiment of a fastener according to the invention, having a portion with a barbed tack, and another portion with a mating washer;

Figures 15a and 15b. are cross sectional views showing two embodiments of an endoscope, with one and two overtubes;

Figures 16a, 16b, 16c and 16d are side views showing the deployment device for a fastener according to another embodiment of the present invention; and

Figs 17a to 17e are diagrams showing the steps of operation of a different embodiment of a system according to the present invention, which includes a fundoplication device.

Detailed Description of the Invention

The method of the present invention can be performed, for example, using a flexible endoscope 16, which is preferably equipped with a tissue grasping device 18 (shown in Figure 1), a tissue displacement device 22 (shown in Figure 2), a fastener delivery device 24 (shown in Figure 3), and an injection device 28 (shown in Figure 4). The endoscope preferably has one or more oversheath channels through which various devices may pass. For example, the endoscope may be equipped with a tissue displacement device which passes through the lumen of an oversheath channel, and can be controllably extended past the distal end of the endoscope by the endoscopist. In addition, the endoscope preferably has a second oversheath channel through which a fastener delivery device passes and an injection device operable at its distal end. The endoscopist can operate the endoscope, including the tissue grasping device, tissue displacement device, fastener delivery device, and injection device from the proximal end of the endoscope.

Different types of endoscopes can be used for this procedure. If necessary, an overtube with one or more passages can be slipped over the endoscope to the location of the fundoplication, to facilitate insertion of additional tools. For example, Figure 15a shows an endoscope 16 having several channels 15 that provide irrigation, suction, illumination and video feedback. This exemplary endoscope 16 includes one working channel A. To facilitate insertion of additional tools, an overtube 20 can be used, forming a sheath that defines

additional working channels E and F that reach the distal end of endoscope 16. Similarly, Figure 15b shows an endoscope 16' having two working channels A and B. In this case, an overtube 20' only has to provide a passage for one additional working channel F. In this discussion, an "endoscopic device" is used to generally indicate and endoscope and, when required, an overtube defining additional working channels.

In one embodiment, the patient's stomach is insufflated to facilitate the operation. The patient can also be sedated with an intravenous anesthesia injection during the procedure.

Using the present method, the flexible endoscope 16 is first inserted into the patient's mouth, passed through the esophagus 10 and into the stomach, as shown in Figure 1. The inserted endoscope 16 is then used to locate an attachment site 14 at the gastroesophageal junction. The endoscopist, or other practitioner performing the procedure, can locate the site by viewing the GEJ through the endoscope. These methods for endoscopically locating target sites are well known and widely used in the art.

The tissue grasping device 18 can be positioned at the located attachment site 14, and engaged so as to grasp and hold that tissue, as shown in Figure 1. The tissue grasping device 18 passes through a lumen of the endoscope 16 and is operable from the proximal end of the endoscope 16 by the practitioner. Preferably, the practitioner can control the engaging/disengaging of the device 18, as well as the tension which the device 18 applies to the engaged tissue. This tension can be controlled by extending the device 18 past or retracting the device 18 towards the distal end of the endoscope 16. The means with which the tissue grasping device 18 engages, or grasps, and holds the tissue can consist of a hook, clamp, grasper, a combination thereof, or the like, as is known in the art.

After tissue at the GEJ has been grasped, the tissue displacement device 22 is used to displace the gastric fundus 12 so as to effectively create an intussusception 30 of the esophagus 10 into the stomach 32, as shown in Figure

2. The tissue displacement device 22 passes through a lumen of an overtube 20 which surrounds the endoscope 16, and can be pushed or rotated to a position distal to the distal tip of the endoscope 16. The device 22 preferably comprises a spherical tip 23 located at the distal end of a stiff cable or Nitinol band. The practitioner can operate the tissue displacement device 22, for example, by pushing and rotating it into position against the gastric fundus.

Once in position against the gastric fundus 12, the tissue displacement device 22 is further pushed and rotated so as to press against and reposition the gastric fundus 12. Simultaneously, the tissue grasping device 18 holds the tissue at the attachment site 14, applying a force which opposes force supplied by the tissue displacement device 22. The net effect of these counteracting forces is that the gastric fundus 12 is brought in closer proximity to the esophagus, which makes the angle of His, identified at reference numeral 34, more acute. The displacement of the gastric fundus 12 creates a tissue flap 30, which is effectively an intussusception of the esophagus 10 into the stomach 32. In one preferred embodiment, the flaps of tissue can have an approximate length between 1 and 3 cm.

In a preferred embodiment, the steps of pulling the tissue with the tissue grasping device 18 and displacing the fundus with the tissue displacement device 22 are repeated at several positions around the circumference of the intussusception. For example, the procedure can be performed at four to twelve equidistant locations around the circumference of the esophagus.

The reduction in the angle of His 34 and formation of an intussusception 30 reduces the degree to which stomach contents can reflux into the esophagus 10. A valve is essentially built between the stomach and the esophagus. As gases build up in the gastric lumen 32 and, more specifically, in the gastric fundus 12, pressure is brought to bear on the wrapped portion of the esophagus 10, closing it off from the stomach. In addition, stomach contents move around within the gastric lumen 32 due to contraction of the stomach muscles, and body

movement in general. The intussusception 30 alleviates GER by creating a valve like barrier which stomach contents must pass through in order to reach the esophagus 10.

The intussuscepted esophagus 30 is then fastened to the wall of the gastric fundus 12 to fix the arrangement. The fastener delivery device 24 is used to insert fasteners 26 within the intussusception 30 to hold the gastric and esophageal tissue in place. Since a number of nerves and blood vessels typically run through the tissue being manipulated, the practitioner should, before inserting the fasteners 26, locate the nerves and blood vessels, so as not to damage or sever them. In particular, the practitioner should locate the Vagus nerve bundle which runs alongside the esophagus, the aorta, and the various gastric blood vessels. Numerous methods for locating such anatomical features are well known in the art, including use of ultrasound, fluoroscopy and x-ray.

Once the aforementioned features are located, the practitioner loads a fastener 26 into the fastener delivery device 24 and inserts the device 24 through a second sheath channel 25 until the operating end of the delivery device 24 is positioned at a desired fastener insertion site. The device 24 is then used to place a fastener at a desired site, as shown in Figure 3. Fasteners 26 are preferably inserted through the intussusception at 1cm and 2.5 cm above the tip 14 of the newly-formed tissue flap 30, which extends into the gastric lumen 32. The fasteners 26 can be inserted also at other locations along the length of the tissue flap, which in the preferred case has a length of between about 1 and 3 cm.

The fastener delivery device 24 can be rotated within the esophagus and gastric lumen so as to insert fasteners around the entire circumference of the esophagus. Preferably, fasteners are inserted at locations approximately 30° apart. For example, from an initial insertion site, the device 24 may be rotated in one direction, inserting fasteners at 30°, 60°, 120°, and 180° from the initial site. The device 24 is then returned to the initial insertion site and rotated in the

opposite direction, again inserting fasteners at, for example, 30° intervals, until the entire circumference of the intussusception has been fastened.

Preferably, the intussusception should extend a full 360 degrees, i.e., the entire circumference of the esophagus. The valve formed by the intussusception is similar to the "gerd standard" open or laparosopic procedure, a Nissen Fundoplication. However, a full 360 degrees may not be achievable with an endoluminal approach. In that case, a Toupet fundoplication, spanning approximately 270 degrees of the circumference around the esophagus can be performed. The endoluminal procedure thus cannot generally be performed on an arc of approximately 60 degrees, on the back side of the esophagus. In the remaining portion of the esophagus circumference, fasteners can be attached, for example, at 30 degrees intervals.

Figure 5 shows a hypotube 40 with a beveled edge which has been inserted through the fastener delivery device 24 and further advanced so as to penetrate tissue of both the esophageal and gastric walls, 44 and 46 respectively. Hypotube 40 can be, for example, an hypodermic needle cannula, or another type of thin tubing, preferably of stainless steel.

A T-fastener 42 of the type known in the art can be inserted through the hypotube 40 until the distal end of the fastener 42 is deployed on the stomach side of the intussusception. The hypotube 40 is then retracted towards the sheath 24 so that the deployed distal end of the T-fastener engages the gastric wall 46 as the hypotube 40 is retracted, as shown in Figure 6. As shown in Figure 7, the hypotube 40 is further retracted into the sheath 24 until the proximal end of the T-fastener is pulled out of the hypotube 40 by the tension exerted from the distal end of the T-fastener 42. The proximal end of the T-fastener 42 then seats against the inner wall of the esophagus, thereby holding the gastric wall and the esophagus together. The length of the longitudinal center portion of the T-fastener determines the maximum distance between the inner wall of the esophagus and the inner wall of the fundus.

Figures 9-11 illustrate various configurations of T-fasteners which may be used to secure the esophageal and gastric walls. The traditional T-fastener 48 has a simple T-bar at each end. With this fastener, the forces of securing the gastric and esophageal tissue in the post-deformation position are borne by the T-bars at each end of the fastener, which have a small area over which to distribute the forces. This type of T-bar may pull through either the gastric or esophageal wall. Thus, it may be desirable to utilize T-fasteners in conjunction with the present invention which have T-bar configurations with increased area over which the forces of securing the tissue will be distributed. Figure 9 shows a T-fastener with two T-bar bolster at each end. In addition, the area over which the forces of securing tissue are distributed can be increased by, for example, utilizing a T-fastener with three prongs, four prongs, or six prongs. (Shown in Figures 10, 9, and 11 respectively.)

Figure 12 shows an alternative fastener 56 which can be used to secure gastric and esophageal tissue according to the present invention. The fastener 56 has a longitudinal center portion with inflatable balloons 58 at each end. This fastener 56 may be inserted through the gastric and esophageal tissue in the same manner as that described above with respect to T-fastener insertion. Once the fastener 56 is in place, air, water or other material may be introduced into the inflatable ends 58, thereby inflating the ends 58 and securing the gastric and esophageal tissue. The inflatable ends may be spherical or disk-shaped.

In one exemplary embodiment, the balloon can be formed on the distal end of fastener 42, as shown in Figure 12, and can be stored in hypotube 40 during insertion through walls 44, 46. As hypotube 40 is retracted, the balloon can be inflated with a fluid passing through an inflation tube formed within hypotube 40. A similar process can take place to inflate a balloon at the proximal end of fastener 42, before separation from hypotube 40. Seals of known design can be used to maintain both balloons inflated.

Figures 13-14 show yet another alternative fastener 60 which may be used

to secure gastric and esophageal tissue according to the present invention. The fastener 60 is a longitudinal member with deformable portions 62, 64 near the proximal and distal ends, and may preferably be made of polypropylene or other biocompatible durable material.

The deformable portions 62, 64 preferably have a mesh-like structure which may be expanded radially by, for example, buckling when the ends of the fastener 60 are compressed toward on another. The fastener 60 is inserted into the gastric and esophageal tissue in the same manner as described above with respect to T-fastener insertion, as shown in Figures 5-7. When the proximal and distal ends are in desired positions within the esophagus and the stomach respectively, the ends are expanded.

In one exemplary embodiment, the fastener 60 may be formed such that it is normally biased toward the deformed position, as shown in Figure 13b. A fastener 60 of this type can be maintained in the reduced diameter configuration while contained within in the hypotube 40, and would expand due to its natural bias upon release therefrom. The deformable portions 62 and 64 are compressed so as to allow insertion of the fastener through the delivery device 24 and through both gastric and esophageal tissue. The fastener 60 can then be advanced through the hypotube 40 until the distal deformable portion 64 exits the distal end of the hypotube 40, and regains its normally radially expanded position. The hypotube 40 can then be retracted, allowing the proximal deformable portion 62 to expand to its normally radially expanded position. The deformed portions 62 and 64 then act as bolsters which secure the gastric and esophageal tissue in place.

Alternatively, a fastener 60 with deformable portions 60 may be formed such that it is normally in the un-deformed position, as shown in Figure 13a. The normally un-deformed fastener would be inserted through the gastric and esophageal tissue in the same manner as described above with respect to the normally deformed embodiment. The normally un-deformed fastener must then

be manipulated into the deformed position shown in Figure 13b after being placed in the desired position spanning the esophageal and stomach tissue. A crimping device, inserted through the lumen of the endoscope, can be used to perform such manipulation. This device may resemble a known mechanism used for inserting rivets. As would be understood by those skilled in the art, any device which may be inserted through the lumen of an endoscope and which can compress the ends of the fastener 60 so as to buckle the deformable portions may be used as the crimping device.

The fastener 60 may also be formed with a needle-like point at its distal end to aid insertion. Such a distal end would enable insertion of the fastener 60 directly through the gastric and esophageal tissue, eliminating the need for the hypotube 40.

As shown in Figure 16, the hypotube 40 previously described with reference to Figures 5-7 can be replaced with an insertion device 100 that deploys a fastener 102. When insertion device 100 is in position across the esophageal and gastric walls 44, 46, as shown in Figure 16a, an actuating wire 104 that extends the length of endoscope 16 is pulled, so that a distal stent 106 is deployed, as seen in Figure 16b. As the insertion device 100 is withdrawn, actuating wire 104 is pulled again as shown in Figure 16c, so that proximal stent 108 is deployed, and the walls 44, 46 are sandwiched between stents 106, 108, as shown in Figure 16d.

In a different embodiment according to the invention, a two-piece fastener comprising a barbed tack 70 and a mating washer 74, as shown in Figure 14, may be employed. The barbed tack 70 consists of a disk portion 71 with a barbed connector 72. The barbed connector 72 can be inserted through the mating washer 74 such that the connector 72 is engaged by the washer 74. Both components 70 and 74 can preferentially be made of a resilient polymeric material.

In one alternative exemplary embodiment of a device according to the

invention, the barbed tack 70 and mating washer 74 may be inserted using a fundoplication device 120, that is described in Figures 17a to 17e. Figure 17a shows a device 120 at the end of a flexible tube 121, that is inserted through esophagus 10 into the patient's stomach 32. An endoscope 16 can also be introduced, to visually monitor the procedure. Once in position, device 120 deploys a pivotable tissue displacing portion 124, shown in Figure 17b, that is moved in position towards the gastric fundus 12.

A gripping portion 128 of device 120 is used to grasp an attachment site 14 at the gastroesophageal junction, as shown in Figure 17c, so that downward movement of device 120 pulls that region of the esophagus 10 into stomach 32. A spike 130 can also be used to facilitate this procedure. Once the esophagus opening is in the proper position, tissue displacement portion 124 is pivoted towards an anvil portion 126 of the device 120, so that fundus 12 is pushed towards the esophagus, forming an intussusception.

When tissue displacement portion 124 reaches anvil portion 126, as shown in Figure 17d, the barbed portion 70 of the fastener, mounted on tissue displacement portion 124, pierces the gastric wall 46 and esophageal wall 44, and is secured to mating washer 74, mounted on anvil portion 126. This procedure results in formation of a flap of tissue 132. As previously discussed for other embodiments according to the invention, this procedure can be repeated at different circumferential locations around the esophagus, to form a valve of desired shape separating stomach 32 from esophagus 10, as shown in Figure 17e.

Finally, a bonding agent can be injected into the tissue of the intussusception, as shown in Figure 4, causing a fibrotic reaction which secures the gastric and esophageal tissue of the fundoplication. Sodium morrhuate, for example, is a known agent that may be injected into the tissue fold formed between the gastric and esophageal tissue, so as to create a fibrotic reaction that adheres the gastric fundus to the esophagus permanently.

Several compounds can be used as bonding agents. For example, among the adhesive compounds, cyanoacrylate can be used, as well as fibrin sealant, muscle adhesive protein, Transforming Growth Factor Beta, Prolamine gel, Gelatin-Resorcinol-Formol glue and Hystoacryl. Among the sclerosant compounds, Morrhuate Sodium, Sodium Tetradecyl Sulfate, Ethanolamine Oleate, aerosol-tale and sterile Bleomycin Sulfate can be used.

When such a bonding agent is used, the fastener need only secure the tissue until the reaction caused by the agent has sufficiently secured the tissue in place. The fastener used may then be made of a biodegradable or bioabsorbable material, or can be removed.

What is claimed is:

1. A method for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising:

forming an intussusception of the esophagus into the stomach by pulling a selected portion of the esophagus into the stomach, and by displacing a fundus portion of the stomach towards the esophagus;

placing a fastener across the intussusception, said fastener maintaining an esophageal wall and a gastric wall forming the intussusception adjacent to one another; and

injecting a bonding agent between the esophageal wall and a gastric wall to bond the intussusception.

2. The method according to claim 1, further comprising removing the fastener after bonding the intussusception.

3. The method according to claim 1, further comprising the preliminary steps of:

introducing through the esophagus and positioning an endoscope device adjacent a gastroesophageal junction;

extending from the endoscope device a grasping device adapted to grasp and pull the opening portion of the esophagus; and

extending from the endoscope device a tissue displacement device adapted to displace the fundus portion of the stomach.

4. The method according to claim 1, further comprising:

introducing through the esophagus and positioning a fastener delivery device adjacent to the intussusception at a desired fastening location;

delivering the fastener from the delivery device to attach the esophageal wall to the gastric wall.

5. The method according to claim 4, further comprising;
extending a hypotube from the fastener delivery device through the esophageal wall and the gastric wall forming the intussusception;
deploying a distal end of the fastener to prevent withdrawal of the fastener;
withdrawing the hypotube from the intussusception; and
deploying a proximate end of the fastener to maintain the esophageal wall adjacent to the gastric wall.

6. The method according to claim 4, further comprising repeating the positioning and delivering steps a selected number of times.

7. The method according to claim 6, further comprising successively positioning the delivery device and delivering the fastener at selected positions around a circumference of the intussusception.

8. The method according to claim 5, wherein the deploying steps further comprise inflating bladders disposed at the distal and at the proximate end of the fastener.

9. The method according to claim 5, wherein the deploying steps further comprise extending deformable portions disposed at the distal and proximate ends of the fastener.

10. The method according to claim 1, wherein the injecting step further comprises injecting at least one of an adhesive and a sclerosant agent.

11. The method according to claim 1, wherein the forming an intussusception and the placing a fastener steps further comprise:
introducing through the esophagus and placing adjacent a

gastroesophageal junction a fastening device having a gripping portion and a tissue displacing portion;

gripping an opening portion of the esophagus with the gripping portion, and pulling the opening portion into the stomach;

moving a fundus portion of the stomach towards the esophagus by pivoting the tissue displacing portion towards an anvil portion of the fastening device, such that the gastric wall and the esophageal wall are between the anvil portion and the pivoted tissue displacing portion;

driving a barbed portion of a fastener disposed on the tissue displacing portion through the gastric wall and the esophageal wall; and

securing the barbed portion of the fastener to a mating washer portion of the fastener disposed on the anvil portion.

12. A method for performing endoluminal fundoplication comprising the steps of:

inserting an endoscope through a patient's esophagus into the patient's stomach;

inserting a grasping device through the esophagus to a position adjacent the gastroesophageal junction;

inserting a tissue displacement device through the esophagus to the position adjacent the gastroesophageal junction;

grasping and moving into the stomach a selected portion of the esophagus with the grasping device, to form an esophageal wall;

displacing a fundus portion of the stomach towards the esophageal wall with the tissue displacement device, to form a gastric wall;

inserting a fastening device through the esophagus to a position adjacent the gastroesophageal junction; and

deploying a fastener from the fastening device, to attach the esophageal wall to the gastric wall.

13. The method according to claim 12, further comprising injecting one of an adhesive and a sclerosant agent between the gastric wall and the esophageal wall.

14. The method according to claim 12, further comprising inserting an overtube over the endoscope, defining a channel for insertion of at least one of the grasping device, tissue displacement device, and fastening device.

15. The method according to claim 12, further comprising rotating the fastening device by a selected rotation, and repeating the deploying step.

16. The method according to claim 15, wherein the rotating step comprises rotating the fastening device by about 30 degrees.

17. The method according to claim 12, further comprising removing the fastener after bonding of the gastric wall to the esophageal wall.

18. A device for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising:

a flexible tube having a distal end adapted for insertion in the stomach through the esophagus;

a tissue grasping device disposed at the distal end of the flexible tube, adapted to grasp a selected portion of the esophagus;

a tissue displacement device disposed adjacent the tissue grasping device, adapted to move a fundus portion of the stomach towards the esophagus; and

an anvil portion, pivotable relative the tissue displacement portion, wherein the tissue displacement device and the anvil portion releasably carry complementary portions of a fastener, such that said complementary portions are joined when the fundus portion is moved towards the esophagus.

19. The device according to claim 18, further comprising a barbed portion of the flexible tube adapted to move a selected portion of the esophagus.

20. The device according to claim 18, wherein the tissue grasping device comprises a pair of jaws operable independently of the tissue displacement device.

21. The device according to claim 18, wherein the fastener comprises a barbed portion and a mating washer portion.

22. The device according to claim 18, wherein pivoting motion of the tissue displacement device and the anvil portion places the selected portion of the esophagus and the moved fundus portion of the stomach between the tissue placement device and the anvil portion.

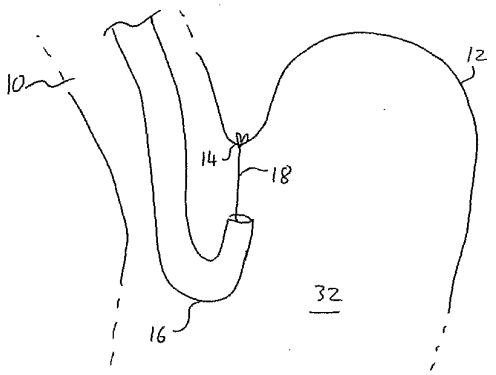


Figure 1

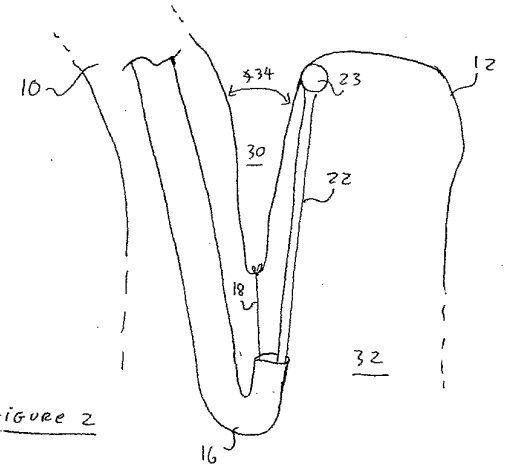


Figure 2

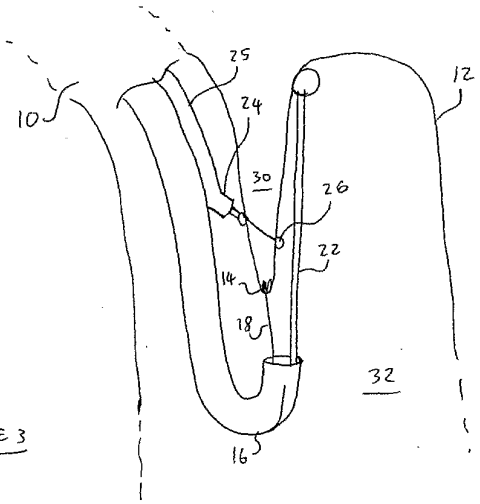


FIGURE 3

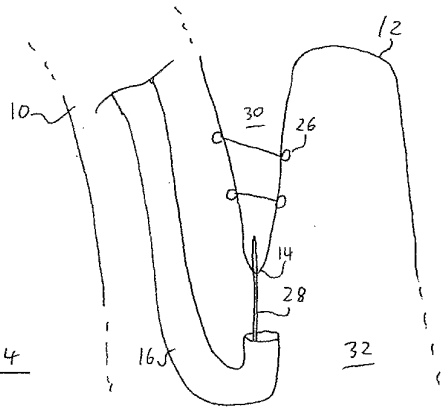


FIGURE 4

FIGURE 5

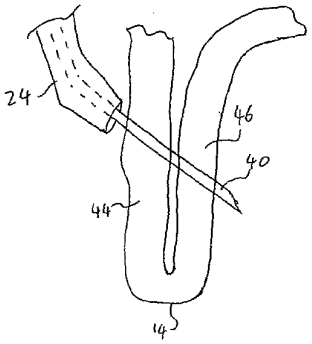


FIGURE 6

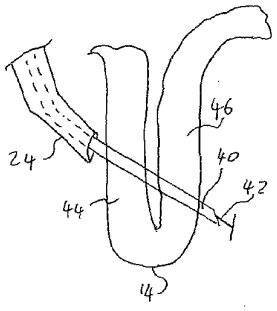
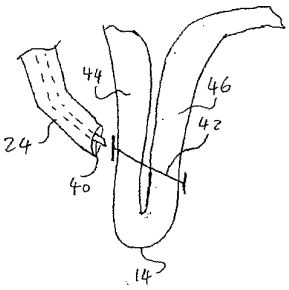


FIGURE 7



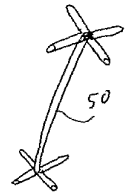


FIGURE 9

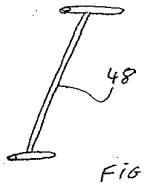


FIGURE 8

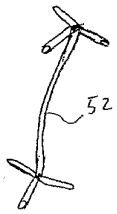


FIGURE 10

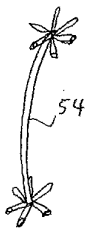


FIGURE 11

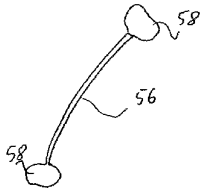


FIGURE 12

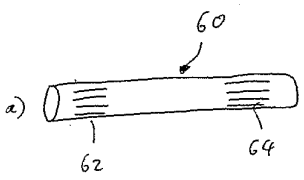
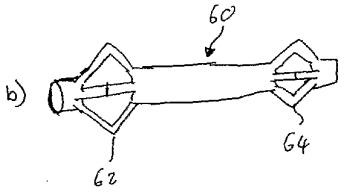


Figure 13



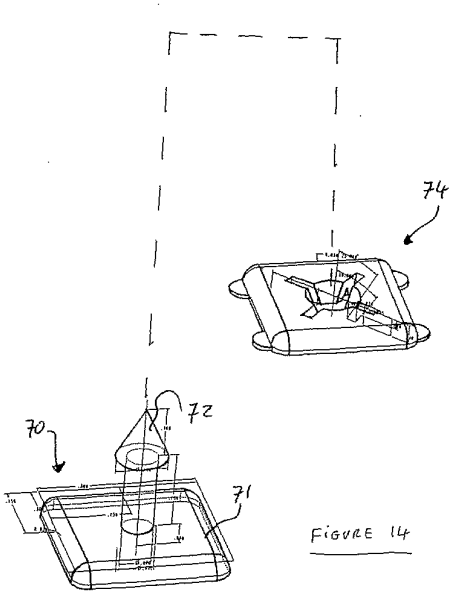
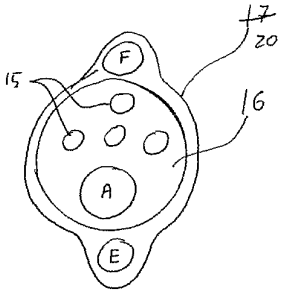


FIGURE 14

a)



b)

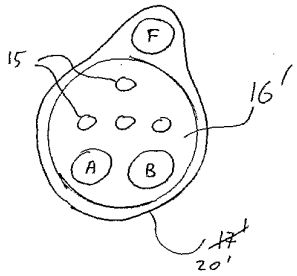
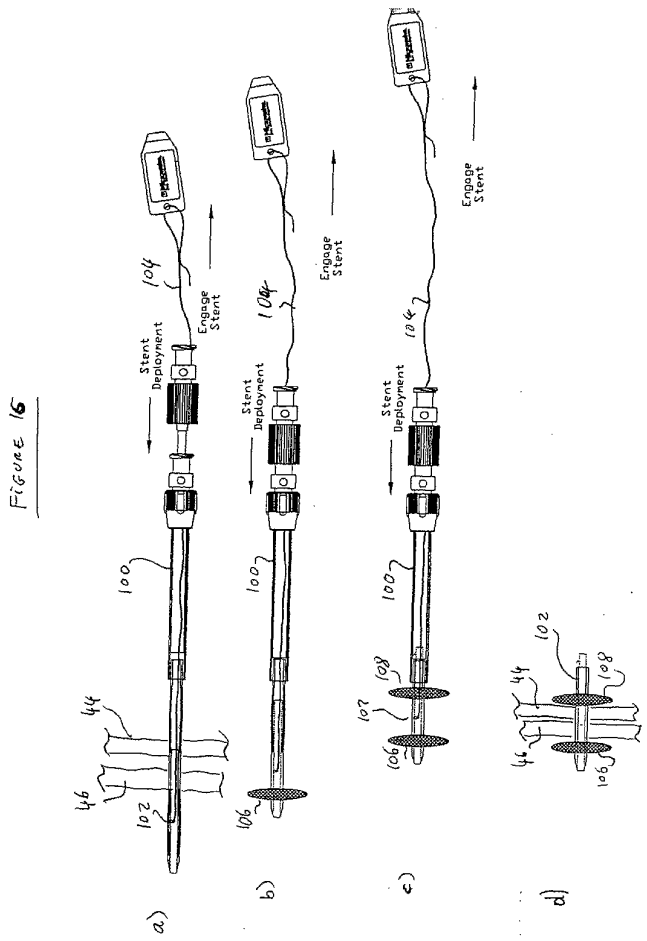


Fig. 15

Figure 16



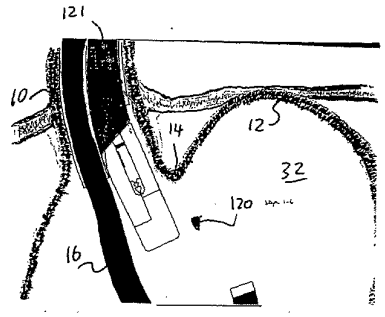


FIG. 17a

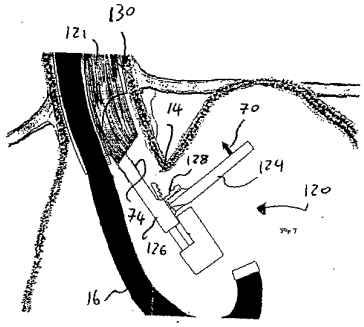


FIG. 17b

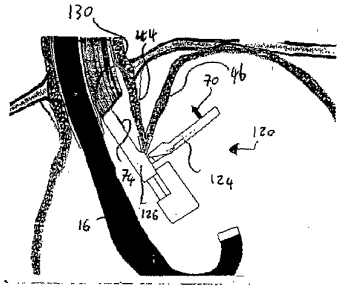


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FIG. 17c

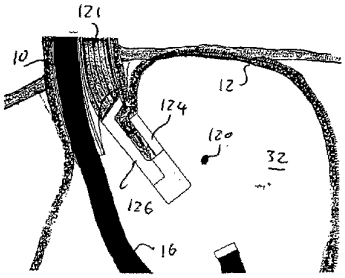

FIG. 17d

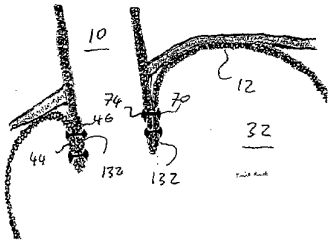

FIG. 17e

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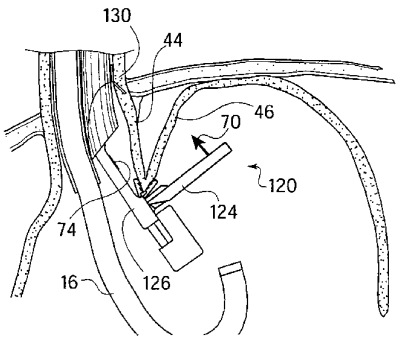
(54) Title: METHOD FOR PERFORMING ENDOLUMINAL FUNDOPLICATION AND APPARATUS FOR USE IN THE METHOD



(57) Abstract: A method and device for performing endoluminal fundoplication are described. A device is inserted in the patient's stomach through the esophagus, including an unit adapted to grasp and pull a portion of the gastroesophageal junction into the stomach, and an unit adapted to move a portion of the fungus towards the esophagus. The device also can place fasteners to hold the gastric wall and the esophageal wall secured together, thus forming a valve between esophagus and stomach. An adhesive compound can be used to stabilize the juncture of the two walls.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD FOR PERFORMING ENDOLUMINAL FUNDOPLICATION AND APPARATUS FOR USE IN THE METHOD

Field of the Invention

The present invention relates generally to the art of fundoplicating the stomach to the esophagus. More specifically, the present invention relates to a method for performing such a fundoplication endoluminally, and to an apparatus for securing the fundus to the esophagus.

Background of the Invention

Fundoplication is a surgical procedure which is typically used to treat Gastroesophageal Reflux (GER) condition, a malady often resulting from a deformity of the gastroesophageal junction (GEJ), and/or a dysfunctional lower esophageal sphincter (LES). One symptom commonly associated with GER is regurgitation or reflux of stomach contents into the esophagus. Fundoplication procedures are directed towards manipulating esophageal and gastric tissue so as to form a valve at the GEJ which limits reflux into the esophagus. The valve is formed by manipulation of the esophagus so as to invaginate the stomach, then wrapping the fundus of the stomach around the distal end of the esophagus and securing the stomach in that wrapped position.

The most commonly used fundoplication procedures require abdominal or thoracic incisions through which the abdominal wrapping and securing can be performed. Due to the highly invasive nature of such surgery,1 complications and morbidity occur in a significant percentage of cases. In addition, these procedures are lengthy, often taking a number of hours to perform, and may leave disfiguring scars where the incisions were made.

Other recently developed fundoplication procedures somewhat limit the necessity of making large surgical incisions by utilizing laparoscopic ports or

percutaneous endoscopic gastrostomy. (See, e.g. United States Patent Nos. 5,403,326, and 5,088,979, the contents of which are hereby incorporated by reference). Although these procedures are less invasive than those involving large abdominal and thoracic incisions, they are invasive nonetheless, and have costs and risks associated with such invasive surgery. For example, general anaesthesia is typically used during these procedures which adds to the expense of these procedures and entails well known risks.

In addition to the complications, risks, and costs associated with the invasive nature of current fundoplication methods, these methods have other problems as well. One such problem is unwrapping of the fundus, also referred to as slippage of the fundal wrap. Slippage frequently occurs with current methods, as they fail to adequately secure the plicated fundus.

Summary of the Invention

The present invention is directed to a method for endoluminal fundoplication in which a flexible endoscope is first used to locate an attachment site at the gastroesophageal junction. A tissue grasping device is then positioned at the distal end of the endoscope, and attached to the body tissue at the located attachment site. Next, a tissue displacement device is positioned at the distal end of the endoscope and used to displace the fundus of the stomach, so as to create an intussusception of the esophagus into the gastric lumen. A fastener delivery device is then positioned adjacent to a first desired fastener delivery location and used to place a first fastener through the tissue which forms the intussusception at the desired fastener delivery location. The first fastener secures a first portion of the gastric fundus to the esophagus. The fastener delivery device is then used to place additional fasteners at a plurality of additional desired fastener locations, thus securing the gastric fundus around the esophagus. In one exemplary embodiment, the fastener delivery device, the tissue grasping device, and the tissue displacement device can be incorporated into a single unit.

Finally, an injection device is positioned at the distal end of the endoscope and used to inject a bonding agent into the tissue which forms the intussusception. For example, the bonding agent can be an agent for fibrotic fixation or adhesion.

In one embodiment, the invention is a method for performing endoluminal fundoplication of a patient's esophagus and stomach, having the steps of forming an intussusception of the esophagus into the stomach by pulling a selected portion of the esophagus into the stomach, and by displacing a fundus portion of the stomach towards the esophagus, placing a fastener across the intussusception, said fastener maintaining an esophageal wall and a gastric wall forming the intussusception adjacent to one another, and injecting a bonding agent between the esophageal wall and a gastric wall to bond the intussusception.

In another embodiment, the invention is a device for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising a flexible tube having a distal end adapted for insertion in the stomach through the esophagus, a tissue grasping device disposed at the distal end of the flexible tube, adapted to grasp a selected portion of the esophagus, a tissue displacement device disposed adjacent the tissue grasping device, adapted to move a fundus portion of the stomach towards the esophagus and an anvil portion, pivotable relative the tissue displacement portion, wherein the tissue displacement device and the anvil portion releasably carry complementary portions of a fastener, such that said complementary portions are joined when the fundus portion is moved towards the esophagus.

Brief Description of the Drawings

The invention will be more readily understood through the following detailed description, with reference to the accompanying drawings, in which:

Figures 1 through 4 illustrate the method of endoluminal fundoplication according to one embodiment of the present invention;

Figure 1 shows a cross-sectional view of the distal end of an esophagus and the upper gastric wall, with an endoscope inserted through the esophagus and into the gastric lumen, and a tissue grasping device attached to a site on the gastroesophageal junction;

Figure 2 shows the cross-sectional view as in Figure 1 and, in addition, shows a tissue displacement device and the gastric fundus displaced so as to form an intussusception of the esophagus into the gastric lumen;

Figure 3 shows the cross-sectional view as in Figure 2 and, in addition, shows a tissue fastener device and a fastener placed through the intussusception;

Figure 4 shows a cross-sectional view of the distal end of an esophagus and the upper gastric wall, with an endoscope inserted through the esophagus and into the gastric lumen, two fasteners placed within the intussusception, and an injection device inserted into the intussusception;

Figure 5 shows a cross-sectional view of an intussusception of the esophagus into the gastric lumen with a hypotube inserted through both the esophageal and gastric walls;

Figure 6 shows the cross-sectional view as in Figure 5, with the distal end of a T-fastener deployed;

Figure 7 shows the cross-sectional view as in Figure 5, with the hypotube retracted from within the body tissue, and with both the proximal and distal ends

of the T-fastener deployed;

Figure 8 shows an elevation view of a T-fastener with a T-bar bolster at each end;

Figure 9 shows an elevation view of a fastener with a four-pronged bolster at each end;

Figure 10 shows an elevation view of a fastener with a three-pronged bolster at each end;

Figure 11 shows an elevation view of a fastener with a six-pronged bolster at each end, in which the prongs are curved;

Figure 12 shows an elevation view of a fastener with inflatable bolsters on each end;

Figure 13a. is a longitudinal view of a fastener with deformable portions near each end, with the fastener in the undeformed position;

Figure 13b is a longitudinal view of the fastener shown in Fig 13a, with the deformable portions near each end in the deformed position;

Figure 14 is an isometric drawing showing another embodiment of a fastener according to the invention, having a portion with a barbed tack, and another portion with a mating washer;

Figures 15a and 15b. are cross sectional views showing two embodiments of an endoscope, with one and two overtubes;

Figures 16a, 16b, 16c and 16d are side views showing the deployment device for a fastener according to another embodiment of the present invention; and

Figs 17a to 17e are diagrams showing the steps of operation of a different embodiment of a system according to the present invention, which includes a fundoplication device.

Detailed Description of the Invention

The method of the present invention can be performed, for example, using a flexible endoscope 16, which is preferably equipped with a tissue grasping device 18 (shown in Figure 1), a tissue displacement device 22 (shown in Figure 2), a fastener delivery device 24 (shown in Figure 3), and an injection device 28 (shown in Figure 4). The endoscope preferably has one or more oversheath channels through which various devices may pass. For example, the endoscope may be equipped with a tissue displacement device which passes through the lumen of an oversheath channel, and can be controllably extended past the distal end of the endoscope by the endoscopist. In addition, the endoscope preferably has a second oversheath channel through which a fastener delivery device passes and an injection device operable at its distal end. The endoscopist can operate the endoscope, including the tissue grasping device, tissue displacement device, fastener delivery device, and injection device from the proximal end of the endoscope.

Different types of endoscopes can be used for this procedure. If necessary, an overtube with one or more passages can be slipped over the endoscope to the location of the fundoplication, to facilitate insertion of additional tools. For example, Figure 15a shows an endoscope 16 having several channels 15 that provide irrigation, suction, illumination and video feedback. This exemplary endoscope 16 includes one working channel A. To facilitate insertion of additional tools, an overtube 20 can be used, forming a sheath that defines

additional working channels E and F that reach the distal end of endoscope 16. Similarly, Figure 15b shows an endoscope 16' having two working channels A and B. In this case, an overtube 20' only has to provide a passage for one additional working channel F. In this discussion, an "endoscopic device" is used to generally indicate and endoscope and, when required, an overtube defining additional working channels.

In one embodiment, the patient's stomach is insufflated to facilitate the operation. The patient can also be sedated with an intravenous anesthesia injection during the procedure.

Using the present method, the flexible endoscope 16 is first inserted into the patient's mouth, passed through the esophagus 10 and into the stomach, as shown in Figure 1. The inserted endoscope 16 is then used to locate an attachment site 14 at the gastroesophageal junction. The endoscopist, or other practitioner performing the procedure, can locate the site by viewing the GEJ through the endoscope. These methods for endoscopically locating target sites are well known and widely used in the art.

The tissue grasping device 18 can be positioned at the located attachment site 14, and engaged so as to grasp and hold that tissue, as shown in Figure 1. The tissue grasping device 18 passes through a lumen of the endoscope 16 and is operable from the proximal end of the endoscope 16 by the practitioner. Preferably, the practitioner can control the engaging/disengaging of the device 18, as well as the tension which the device 18 applies to the engaged tissue. This tension can be controlled by extending the device 18 past or retracting the device 18 towards the distal end of the endoscope 16. The means with which the tissue grasping device 18 engages, or grasps, and holds the tissue can consist of a hook, clamp, grasper, a combination thereof, or the like, as is known in the art.

After tissue at the GEJ has been grasped, the tissue displacement device 22 is used to displace the gastric fundus 12 so as to effectively create an intussusception 30 of the esophagus 10 into the stomach 32, as shown in Figure

2. The tissue displacement device 22 passes through a lumen of an overtube 20 which surrounds the endoscope 16, and can be pushed or rotated to a position distal to the distal tip of the endoscope 16. The device 22 preferably comprises a spherical tip 23 located at the distal end of a stiff cable or Nitinol band. The practitioner can operate the tissue displacement device 22, for example, by pushing and rotating it into position against the gastric fundus.

Once in position against the gastric fundus 12, the tissue displacement device 22 is further pushed and rotated so as to press against and reposition the gastric fundus 12. Simultaneously, the tissue grasping device 18 holds the tissue at the attachment site 14, applying a force which opposes force supplied by the tissue displacement device 22. The net effect of these counteracting forces is that the gastric fundus 12 is brought in closer proximity to the esophagus, which makes the angle of His, identified at reference numeral 34, more acute. The displacement of the gastric fundus 12 creates a tissue flap 30, which is effectively an intussusception of the esophagus 10 into the stomach 32. In one preferred embodiment, the flaps of tissue can have an approximate length between 1 and 3 cm.

In a preferred embodiment, the steps of pulling the tissue with the tissue grasping device 18 and displacing the fundus with the tissue displacement device 22 are repeated at several positions around the circumference of the intussusception. For example, the procedure can be performed at four to twelve equidistant locations around the circumference of the esophagus.

The reduction in the angle of His 34 and formation of an intussusception 30 reduces the degree to which stomach contents can reflux into the esophagus 10. A valve is essentially built between the stomach and the esophagus. As gases build up in the gastric lumen 32 and, more specifically, in the gastric fundus 12, pressure is brought to bear on the wrapped portion of the esophagus 10, closing it off from the stomach. In addition, stomach contents move around within the gastric lumen 32 due to contraction of the stomach muscles, and body

movement in general. The intussusception 30 alleviates GER by creating a valve like barrier which stomach contents must pass through in order to reach the esophagus 10.

The intussuscepted esophagus 30 is then fastened to the wall of the gastric fundus 12 to fix the arrangement. The fastener delivery device 24 is used to insert fasteners 26 within the intussusception 30 to hold the gastric and esophageal tissue in place. Since a number of nerves and blood vessels typically run through the tissue being manipulated, the practitioner should, before inserting the fasteners 26, locate the nerves and blood vessels, so as not to damage or sever them. In particular, the practitioner should locate the Vagus nerve bundle which runs alongside the esophagus, the aorta, and the various gastric blood vessels. Numerous methods for locating such anatomical features are well known in the art, including use of ultrasound, fluoroscopy and x-ray.

Once the aforementioned features are located, the practitioner loads a fastener 26 into the fastener delivery device 24 and inserts the device 24 through a second sheath channel 25 until the operating end of the delivery device 24 is positioned at a desired fastener insertion site. The device 24 is then used to place a fastener at a desired site, as shown in Figure 3. Fasteners 26 are preferably inserted through the intussusception at 1cm and 2.5 cm above the tip 14 of the newly-formed tissue flap 30, which extends into the gastric lumen 32. The fasteners 26 can be inserted also at other locations along the length of the tissue flap, which in the preferred case has a length of between about 1 and 3 cm.

The fastener delivery device 24 can be rotated within the esophagus and gastric lumen so as to insert fasteners around the entire circumference of the esophagus. Preferably, fasteners are inserted at locations approximately 30° apart. For example, from an initial insertion site, the device 24 may be rotated in one direction, inserting fasteners at 30°, 60°, 120°, and 180° from the initial site. The device 24 is then returned to the initial insertion site and rotated in the

opposite direction, again inserting fasteners at, for example, 30° intervals, until the entire circumference of the intussusception has been fastened.

Preferably, the intussusception should extend a full 360 degrees, i.e., the entire circumference of the esophagus. The valve formed by the intussusception is similar to the "gerd standard" open or laparosopic procedure, a Nissen Fundoplication. However, a full 360 degrees may not be achievable with an endoluminal approach. In that case, a Toupet fundoplication, spanning approximately 270 degrees of the circumference around the esophagus can be performed. The endoluminal procedure thus cannot generally be performed on an arc of approximately 60 degrees, on the back side of the esophagus. In the remaining portion of the esophagus circumference, fasteners can be attached, for example, at 30 degrees intervals.

Figure 5 shows a hypotube 40 with a beveled edge which has been inserted through the fastener delivery device 24 and further advanced so as to penetrate tissue of both the esophageal and gastric walls, 44 and 46 respectively. Hypotube 40 can be, for example, an hypodermic needle cannula, or another type of thin tubing, preferably of stainless steel.

A T-fastener 42 of the type known in the art can be inserted through the hypotube 40 until the distal end of the fastener 42 is deployed on the stomach side of the intussusception. The hypotube 40 is then retracted towards the sheath 24 so that the deployed distal end of the T-fastener engages the gastric wall 46 as the hypotube 40 is retracted, as shown in Figure 6. As shown in Figure 7, the hypotube 40 is further retracted into the sheath 24 until the proximal end of the T-fastener is pulled out of the hypotube 40 by the tension exerted from the distal end of the T-fastener 42. The proximal end of the T-fastener 42 then seats against the inner wall of the esophagus, thereby holding the gastric wall and the esophagus together. The length of the longitudinal center portion of the T-fastener determines the maximum distance between the inner wall of the esophagus and the inner wall of the fundus.

Figures 9-11 illustrate various configurations of T-fasteners which may be used to secure the esophageal and gastric walls. The traditional T-fastener 48 has a simple T-bar at each end. With this fastener, the forces of securing the gastric and esophageal tissue in the post-deformation position are borne by the T-bars at each end of the fastener, which have a small area over which to distribute the forces. This type of T-bar may pull through either the gastric or esophageal wall. Thus, it may be desirable to utilize T-fasteners in conjunction with the present invention which have T-bar configurations with increased area over which the forces of securing the tissue will be distributed. Figure 9 shows a T-fastener with two T-bar bolster at each end. In addition, the area over which the forces of securing tissue are distributed can be increased by, for example, utilizing a T-fastener with three prongs, four prongs, or six prongs. (Shown in Figures 10, 9, and 11 respectively.)

Figure 12 shows an alternative fastener 56 which can be used to secure gastric and esophageal tissue according to the present invention. The fastener 56 has a longitudinal center portion with inflatable balloons 58 at each end. This fastener 56 may be inserted through the gastric and esophageal tissue in the same manner as that described above with respect to T-fastener insertion. Once the fastener 56 is in place, air, water or other material may be introduced into the inflatable ends 58, thereby inflating the ends 58 and securing the gastric and esophageal tissue. The inflatable ends may be spherical or disk-shaped.

In one exemplary embodiment, the balloon can be formed on the distal end of fastener 42, as shown in Figure 12, and can be stored in hypotube 40 during insertion through walls 44, 46. As hypotube 40 is retracted, the balloon can be inflated with a fluid passing through an inflation tube formed within hypotube 40. A similar process can take place to inflate a balloon at the proximal end of fastener 42, before separation from hypotube 40. Seals of known design can be used to maintain both balloons inflated.

Figures 13-14 show yet another alternative fastener 60 which may be used

to secure gastric and esophageal tissue according to the present invention. The fastener 60 is a longitudinal member with deformable portions 62, 64 near the proximal and distal ends, and may preferably be made of polypropylene or other biocompatible durable material.

The deformable portions 62, 64 preferably have a mesh-like structure which may be expanded radially by, for example, buckling when the ends of the fastener 60 are compressed toward on another. The fastener 60 is inserted into the gastric and esophageal tissue in the same manner as described above with respect to T-fastener insertion, as shown in Figures 5-7. When the proximal and distal ends are in desired positions within the esophagus and the stomach respectively, the ends are expanded.

In one exemplary embodiment, the fastener 60 may be formed such that it is normally biased toward the deformed position, as shown in Figure 13b. A fastener 60 of this type can be maintained in the reduced diameter configuration while contained within in the hypotube 40, and would expand due to its natural bias upon release therefrom. The deformable portions 62 and 64 are compressed so as to allow insertion of the fastener through the delivery device 24 and through both gastric and esophageal tissue. The fastener 60 can then be advanced through the hypotube 40 until the distal deformable portion 64 exits the distal end of the hypotube 40, and regains its normally radially expanded position. The hypotube 40 can then be retracted, allowing the proximal deformable portion 62 to expand to its normally radially expanded position. The deformed portions 62 and 64 then act as bolsters which secure the gastric and esophageal tissue in place.

Alternatively, a fastener 60 with deformable portions 60 may be formed such that it is normally in the un-deformed position, as shown in Figure 13a. The normally un-deformed fastener would be inserted through the gastric and esophageal tissue in the same manner as described above with respect to the normally deformed embodiment. The normally un-deformed fastener must then

be manipulated into the deformed position shown in Figure 13b after being placed in the desired position spanning the esophageal and stomach tissue. A crimping device, inserted through the lumen of the endoscope, can be used to perform such manipulation. This device may resemble a known mechanism used for inserting rivets. As would be understood by those skilled in the art, any device which may be inserted through the lumen of an endoscope and which can compress the ends of the fastener 60 so as to buckle the deformable portions may be used as the crimping device.

The fastener 60 may also be formed with a needle-like point at its distal end to aid insertion. Such a distal end would enable insertion of the fastener 60 directly through the gastric and esophageal tissue, eliminating the need for the hypotube 40.

As shown in Figure 16, the hypotube 40 previously described with reference to Figures 5-7 can be replaced with an insertion device 100 that deploys a fastener 102. When insertion device 100 is in position across the esophageal and gastric walls 44, 46, as shown in Figure 16a, an actuating wire 104 that extends the length of endoscope 16 is pulled, so that a distal stent 106 is deployed, as seen in Figure 16b. As the insertion device 100 is withdrawn, actuating wire 104 is pulled again as shown in Figure 16c, so that proximal stent 108 is deployed, and the walls 44, 46 are sandwiched between stents 106, 108, as shown in Figure 16d.

In a different embodiment according to the invention, a two-piece fastener comprising a barbed tack 70 and a mating washer 74, as shown in Figure 14, may be employed. The barbed tack 70 consists of a disk portion 71 with a barbed connector 72. The barbed connector 72 can be inserted through the mating washer 74 such that the connector 72 is engaged by the washer 74. Both components 70 and 74 can preferentially be made of a resilient polymeric material.

In one alternative exemplary embodiment of a device according to the

invention, the barbed tack 70 and mating washer 74 may be inserted using a fundoplication device 120, that is described in Figures 17a to 17e. Figure 17a shows a device 120 at the end of a flexible tube 121, that is inserted through esophagus 10 into the patient's stomach 32. An endoscope 16 can also be introduced, to visually monitor the procedure. Once in position, device 120 deploys a pivotable tissue displacing portion 124, shown in Figure 17b, that is moved in position towards the gastric fundus 12.

A gripping portion 128 of device 120 is used to grasp an attachment site 14 at the gastroesophageal junction, as shown in Figure 17c, so that downward movement of device 120 pulls that region of the esophagus 10 into stomach 32. A spike 130 can also be used to facilitate this procedure. Once the esophagus opening is in the proper position, tissue displacement portion 124 is pivoted towards an anvil portion 126 of the device 120, so that fundus 12 is pushed towards the esophagus, forming an intussusception.

When tissue displacement portion 124 reaches anvil portion 126, as shown in Figure 17d, the barbed portion 70 of the fastener, mounted on tissue displacement portion 124, pierces the gastric wall 46 and esophageal wall 44, and is secured to mating washer 74, mounted on anvil portion 126. This procedure results in formation of a flap of tissue 132. As previously discussed for other embodiments according to the invention, this procedure can be repeated at different circumferential locations around the esophagus, to form a valve of desired shape separating stomach 32 from esophagus 10, as shown in Figure 17e.

Finally, a bonding agent can be injected into the tissue of the intussusception, as shown in Figure 4, causing a fibrotic reaction which secures the gastric and esophageal tissue of the fundoplication. Sodium morrhuate, for example, is a known agent that may be injected into the tissue fold formed between the gastric and esophageal tissue, so as to create a fibrotic reaction that adheres the gastric fundus to the esophagus permanently.

Several compounds can be used as bonding agents. For example, among the adhesive compounds, cyanoacrylate can be used, as well as fibrin sealant, muscle adhesive protein, Transforming Growth Factor Beta, Prolamine gel, Gelatin-Resorcinol-Formol glue and Hystoacryl. Among the sclerosant compounds, Morrhuate Sodium, Sodium Tetradecyl Sulfate, Ethanolamine Oleate, aerosol-tale and sterile Bleomycin Sulfate can be used.

When such a bonding agent is used, the fastener need only secure the tissue until the reaction caused by the agent has sufficiently secured the tissue in place. The fastener used may then be made of a biodegradable or bioabsorbable material, or can be removed.

What is claimed is:

1. A method for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising:

forming an intussusception of the esophagus into the stomach by pulling a selected portion of the esophagus into the stomach, and by displacing a fundus portion of the stomach towards the esophagus;

placing a fastener across the intussusception, said fastener maintaining an esophageal wall and a gastric wall forming the intussusception adjacent to one another; and

injecting a bonding agent between the esophageal wall and a gastric wall to bond the intussusception.

2. The method according to claim 1, further comprising removing the fastener after bonding the intussusception.

3. The method according to claim 1, further comprising the preliminary steps of:

introducing through the esophagus and positioning an endoscope device adjacent a gastroesophageal junction;

extending from the endoscope device a grasping device adapted to grasp and pull the opening portion of the esophagus; and

extending from the endoscope device a tissue displacement device adapted to displace the fundus portion of the stomach.

4. The method according to claim 1, further comprising:

introducing through the esophagus and positioning a fastener delivery device adjacent to the intussusception at a desired fastening location;

delivering the fastener from the delivery device to attach the esophageal wall to the gastric wall.

5. The method according to claim 4, further comprising;

extending a hypotube from the fastener delivery device through the esophageal wall and the gastric wall forming the intussusception;

deploying a distal end of the fastener to prevent withdrawal of the fastener;

withdrawing the hypotube from the intussusception; and

deploying a proximate end of the fastener to maintain the esophageal wall adjacent to the gastric wall.

6. The method according to claim 4, further comprising repeating the positioning and delivering steps a selected number of times.

7. The method according to claim 6, further comprising successively positioning the delivery device and delivering the fastener at selected positions around a circumference of the intussusception.

8. The method according to claim 5, wherein the deploying steps further comprise inflating bladders disposed at the distal and at the proximate end of the fastener.

9. The method according to claim 5, wherein the deploying steps further comprise extending deformable portions disposed at the distal and proximate ends of the fastener.

10. The method according to claim 1, wherein the injecting step further comprises injecting at least one of an adhesive and a sclerosant agent.

11. The method according to claim 1, wherein the forming an intussusception and the placing a fastener steps further comprise:

introducing through the esophagus and placing adjacent a

gastroesophageal junction a fastening device having a gripping portion and a tissue displacing portion;

gripping an opening portion of the esophagus with the gripping portion, and pulling the opening portion into the stomach;

moving a fundus portion of the stomach towards the esophagus by pivoting the tissue displacing portion towards an anvil portion of the fastening device, such that the gastric wall and the esophageal wall are between the anvil portion and the pivoted tissue displacing portion;

driving a barbed portion of a fastener disposed on the tissue displacing portion through the gastric wall and the esophageal wall; and

securing the barbed portion of the fastener to a mating washer portion of the fastener disposed on the anvil portion.

12. A method for performing endoluminal fundoplication comprising the steps of:

inserting an endoscope through a patient's esophagus into the patient's stomach;

inserting a grasping device through the esophagus to a position adjacent the gastroesophageal junction;

inserting a tissue displacement device through the esophagus to the position adjacent the gastroesophageal junction;

grasping and moving into the stomach a selected portion of the esophagus with the grasping device, to form an esophageal wall;

displacing a fundus portion of the stomach towards the esophageal wall with the tissue displacement device, to form a gastric wall;

inserting a fastening device through the esophagus to a position adjacent the gastroesophageal junction; and

deploying a fastener from the fastening device, to attach the esophageal wall to the gastric wall.

13. The method according to claim 12, further comprising injecting one of an adhesive and a sclerosant agent between the gastric wall and the esophageal wall.

14. The method according to claim 12, further comprising inserting an overtube over the endoscope, defining a channel for insertion of at least one of the grasping device, tissue displacement device, and fastening device.

15. The method according to claim 12, further comprising rotating the fastening device by a selected rotation, and repeating the deploying step.

16. The method according to claim 15, wherein the rotating step comprises rotating the fastening device by about 30 degrees.

17. The method according to claim 12, further comprising removing the fastener after bonding of the gastric wall to the esophageal wall.

18. A device for performing endoluminal fundoplication of a patient's esophagus and stomach, comprising:

a flexible tube having a distal end adapted for insertion in the stomach through the esophagus;

a tissue grasping device disposed at the distal end of the flexible tube, adapted to grasp a selected portion of the esophagus;

a tissue displacement device disposed adjacent the tissue grasping device, adapted to move a fundus portion of the stomach towards the esophagus; and

an anvil portion, pivotable relative the tissue displacement portion, wherein the tissue displacement device and the anvil portion releasably carry complementary portions of a fastener, such that said complementary portions are joined when the fundus portion is moved towards the esophagus.

19. The device according to claim 18, further comprising a barbed portion of the flexible tube adapted to move a selected portion of the esophagus.

20. The device according to claim 18, wherein the tissue grasping device comprises a pair of jaws operable independently of the tissue displacement device.

21. The device according to claim 18, wherein the fastener comprises a barbed portion and a mating washer portion.

22. The device according to claim 18, wherein pivoting motion of the tissue displacement device and the anvil portion places the selected portion of the esophagus and the moved fundus portion of the stomach between the tissue placement device and the anvil portion.

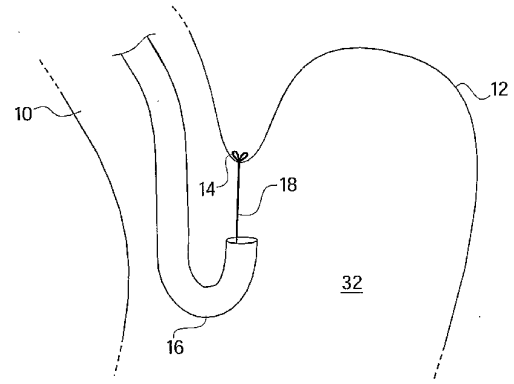


FIG. 1

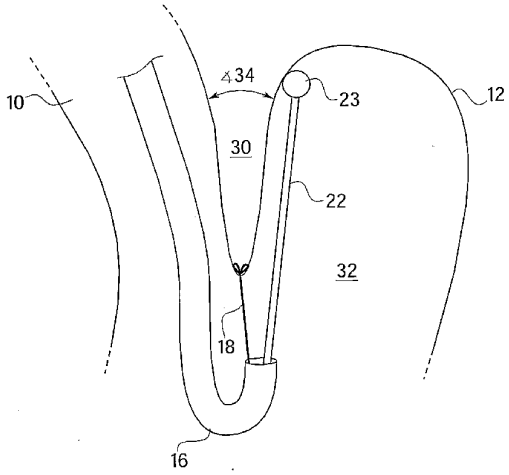


FIG. 2

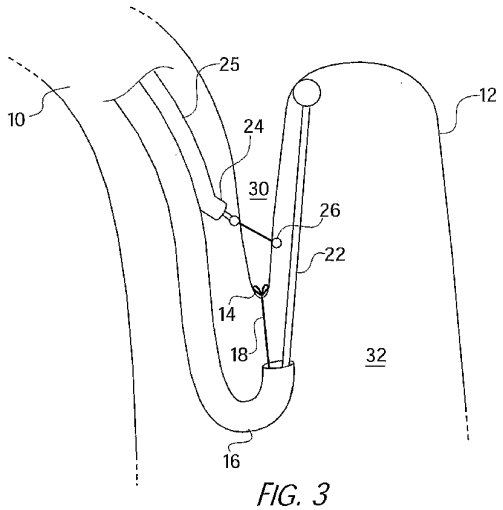


FIG. 3

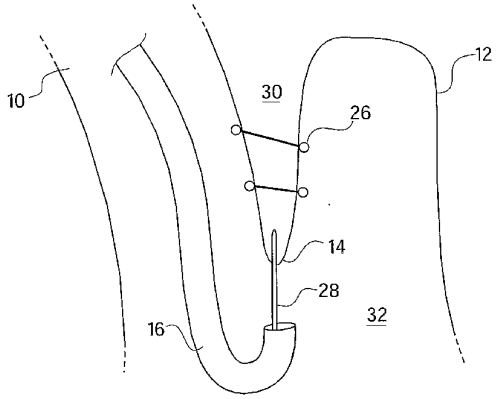


FIG. 4

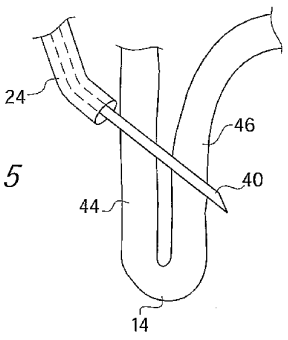


FIG. 5

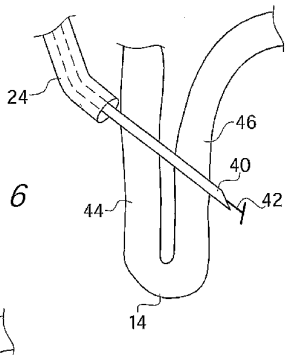


FIG. 6

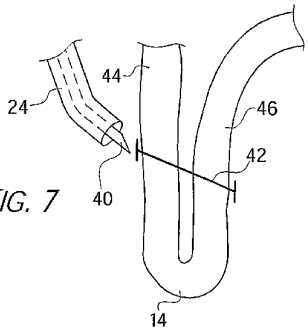


FIG. 7

FIG. 8

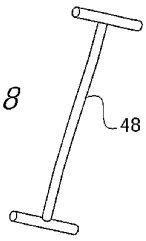


FIG. 9

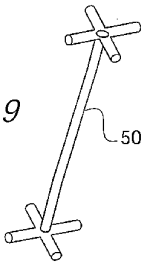


FIG. 10

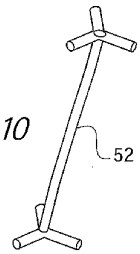


FIG. 11

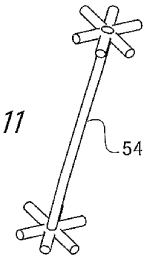
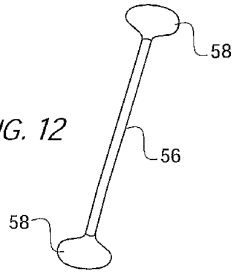


FIG. 12



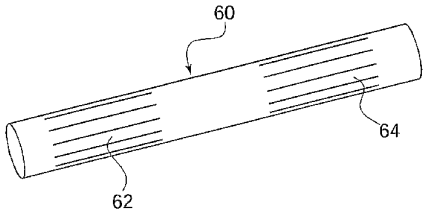


FIG. 13a

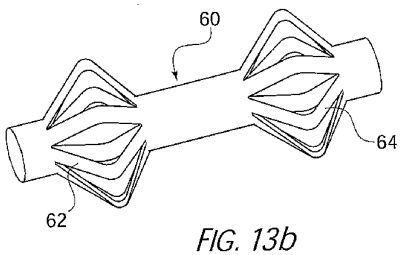


FIG. 13b

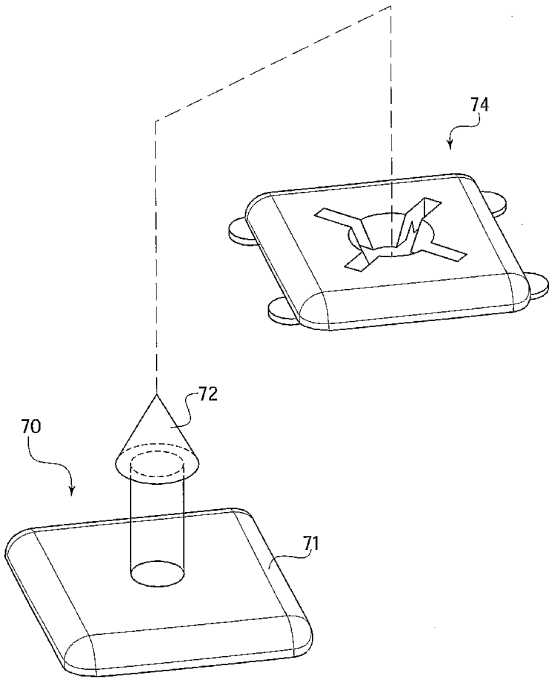


FIG. 14

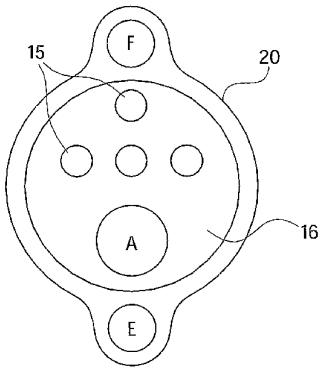


FIG. 15a

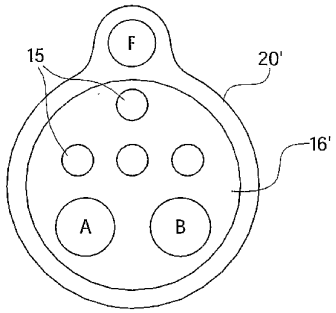


FIG. 15b

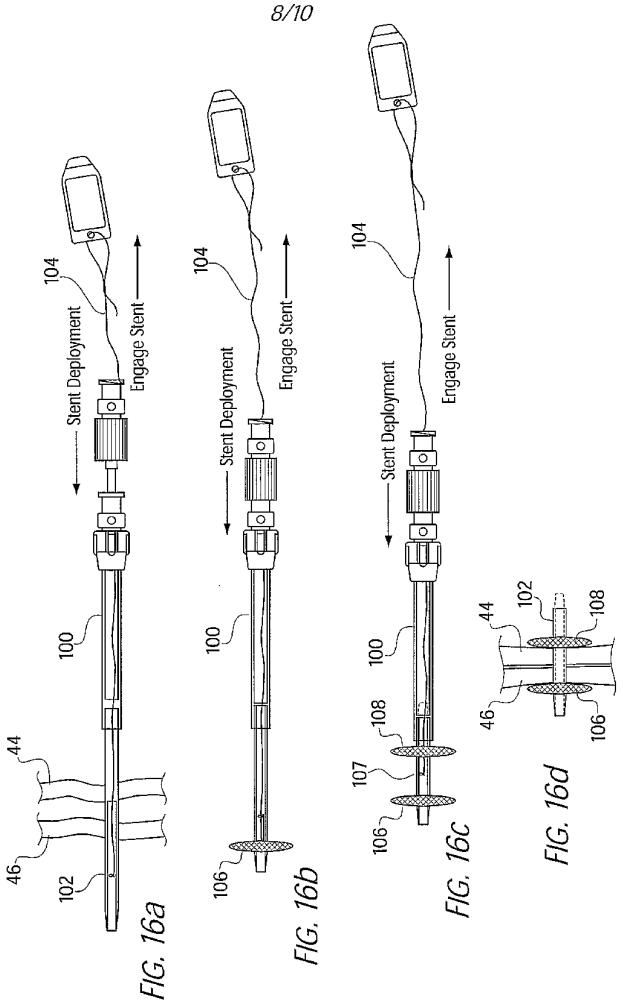


FIG. 16a FIG. 16b FIG. 16c FIG. 16d

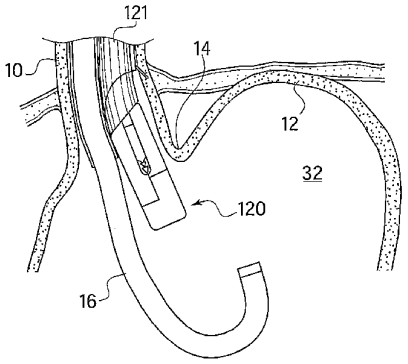


FIG. 17a

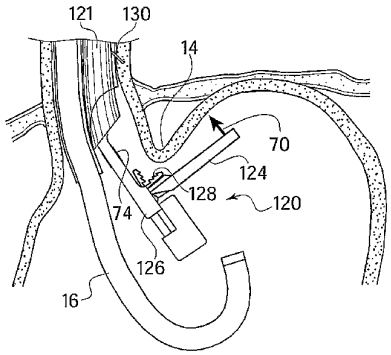


FIG. 17b

FIG. 17c

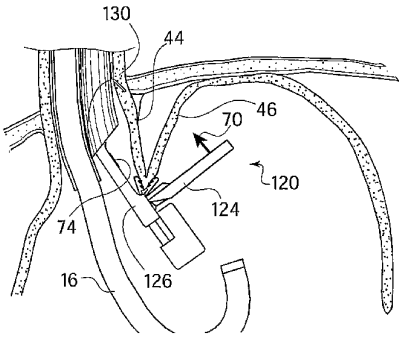


FIG. 17d

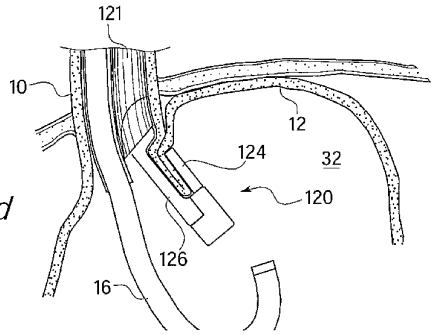
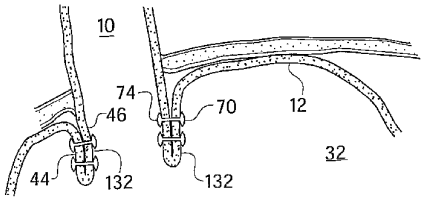


FIG. 17e



【国際調査報告】

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 01/29593

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/072 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 676 674 A (BLEWETT JEFFREY J ET AL) 14 October 1997 (1997-10-14) column 2, line 9 - line 10 column 5, line 6 - line 19 column 8, line 21 -column 9, line 61; figures 19-28 ---	18,20,22
Y	US 5 382 231 A (SHLAIN LEONARD M) 17 January 1995 (1995-01-17) column 5, line 1 - line 12; figures 1,2 column 6, line 45 -column 7, line 3; figures 7-10 ---	18,20,22
A	WO 00 53102 A (GAZAYERLI MOHAMED MOUNIR EL) 14 September 2000 (2000-09-14) abstract; figures 1,2A-2D --- -/--	18,22

[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
5 February 2002	13/02/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Ducreau, F

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Inte nal Application No
PCT/US 01/29593

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 086 600 A (KORTENBACH JUERGEN ANDREW) 11 July 2000 (2000-07-11) column 2, line 64 -column 3, line 17; figures 11-15	18,21,22
A	US 5 787 897 A (KIETURAKIS MACIEJ J) 4 August 1998 (1998-08-04) abstract; figures 1,2	18
A	US 5 403 326 A (FLAKE ALAN W ET AL) 4 April 1995 (1995-04-04) the whole document	18,20,22

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

formation on patent family members

Int[illegible]onal Application No
PCT/US 01/29593

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5676674	A	14-10-1997	US 5571116 A		05-11-1996
			US 5897562 A		27-04-1999
US 5382231	A	17-01-1995	NONE		
WO 0053102	A	14-09-2000	US 6159146 A		12-12-2000
			AU 3623300 A		28-09-2000
			WO 0053102 A1		14-09-2000
US 6086600	A	11-07-2000	AU 1295499 A		24-05-1999
			EP 0969770 A2		12-01-2000
			JP 2001507615 T		12-06-2001
			WO 9922649 A2		14-05-1999
			US 6312437 B1		06-11-2001
			US 2001049469 A1		06-12-2001
US 5787897	A	04-08-1998	US 5558665 A		24-09-1996
			US 6067990 A		30-05-2000
			WO 9600030 A1		04-01-1996
US 5403326	A	04-04-1995	NONE		

Form PCT/ISA/210 (patent family annex) (July 1992)

フロントページの続き

(81)指定国 AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

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Ｆターム(参考) 4C060 CC02 CC32

专利名称(译)	使用该方法执行用于Lumbal绝缘和装置的腔壁的方法		
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申请(专利权)人(译)	波士顿科学Rimitido		
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发明人	アダムス,ロナルド ディー. パグスリー,チャールズ エイチ.ジュニア		
IPC分类号	A61B17/11 A61B17/00 A61B17/064 A61B17/128 A61B17/28		
CPC分类号	A61B17/068 A61B17/00234 A61B17/0643 A61B17/10 A61B17/1285 A61B2017/003 A61B2017/00353 A61B2017/0417 A61B2017/0419 A61B2017/0647 A61B2017/2905		
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代理人(译)	石田 敬 西山雅也		
优先权	09/675601 2000-09-29 US		
其他公开文献	JP2004528857A5 JP4805527B2		
外部链接	Espacenet		

摘要(译)

用于执行腔内地板墙创建的方法和设备技术领域本发明涉及用于执行腔内地板墙创建的方法和设备。单元用于在胃肠把持胃肠食管结合部的一部分绘制，并且包括一个单元，其用于朝向一个部分移动到所述底部的食道的装置通过食管进入患者的GI插入附连到的点。装置还可以用于保持胃肠壁和食道壁一起，以放置紧固件茹茹以形成食道和胃肠之间的阀。粘合剂化合物可用于稳定两个壁的缝合。