Description

The present invention relates to hemostatic clips and more particularly to hemostatic clips fabricated from absorbable and non-absorbable polymeric materials.

In many surgical procedures it is often necessary to ligate a plurality of vessels in the surgical site. The vessels may then be severed down-stream of the ligated portion. In some instances the vessel may be ligated at spaced apart areas and the portion of the vessel between the ligations removed. The primary reason for ligating the vessels is to maintain the surgical site free from an excess of blood and to reduce blood loss in the patient. Also, in certain surgical procedures wherein tumors or parts of organs are to be removed, the tumor or organ may have to be separated from certain vessels, and before separating the vessels will have to be ligated.

In the past, the closing of the vessel was usually accomplished using ligatures; that is threads or filaments which the surgeon ties around the vessel desired to be closed, a very time consuming process and one in which positive closure of the vessel is not always accomplished.

In relatively recent years hemostatic clips have replaced the ligatures in many surgical procedures to close blood vessels and other small fluid ducts. These hemostatic clips have been narrow U-shaped or V-shaped strips made from tantalum or stainless steel which are capable of being deformed and possess sufficient strength to retain the deformation when clamped about a blood vessel.

Representative hemostatic clips of the prior art are best illustrated in U.S. Patents Nos. 3,867,944, 3,631,707, 3,439,523, 3,439,522, 3,312,216, and 3,270,745.

Very recently hemostatic clips made from absorbable or non-absorbable polymeric materials have been developed and are being used in various surgical procedures. These polymeric hemostatic clips are more fully described and disclosed in US—A—4 418 694.

The polymeric clips described generally comprise a pair of leg members attached in some manner at their proximal ends. Very often this attachment is in the form of a resilient hinge portion although other means of attachment may be used. The leg members contain smooth inner surfaces disposed towards one another and called the vessel clamping surfaces. It is these surfaces which contact the vessel and close the vessel when the clip is closed. The distal ends of the leg member terminate in an interlocking latch means. The latch means must extend beyond the vessel to be clamped and clear the vessel in order to lock.

Unlike the metal clips which may be deformed about a vessel, the polymeric hemostatic clip as described above latches over the vessel and, hence, surrounds the entire vessel. This means that to use such clips made from absorbable or non-absorbable polymeric materials, the vessel to be ligated must be free or fully dissected from the surrounding tissue so that the clip may entirely encircle the periphery of the vessel. In many surgical procedures there are a number of small vessels and for the surgeon to have to fully dissect these vessels is a very time consuming process. With the metal clip the surgeon does not have to dissect these vessels but can place the clip on the vessel and about surrounding tissue and deform the clip so that it closes the vessel. This is not true with the clips made from polymeric material.

EP—A—0 073 655 (Ethicon) discloses a hemostatic clip, made from a polymeric material, comprising:

first and second leg members connected at their proximal ends, said leg members being adapted to be placed on opposite sides of a vessel to be closed;

an interlocking latch means at the distal ends of said leg members for interlocking to hold said leg members in a closed position; and

means on the first member cooperating with the latch means for penetrating connective tissue adjacent the vessel to be closed to ensure said latch means interlocks when the leg members are closed about the vessel. The penetration means comprises a pointed or sharpened protrusion on one leg member which cooperates with a recess in the other leg member.

An object of the present invention is to produce a clip from absorbable or non-absorbable polymeric materials which may be used to close vessels which have not been fully dissected from the surrounding tissue.

Another object of the present invention is to reduce the time required in a surgical procedure to place hemostatic clips made from polymeric materials.

It is yet another object of the present invention to produce a hemostatic clip from polymeric material wherein the clip has a latch means that can part the tissue and engage and lock the clip about the vessel although there is tissue adjacent the vessel to be closed.

These and other objects of the present invention will be more fully understood from the following description and drawings.

The hemostatic clip of the present invention is characterised in that:

the second leg member has its distal end bevelled to act as a camming surface; and

the penetrating means comprises a sharpened pointed end at the distal end of the first leg member, the sharpened pointed end being arranged to precede the latch means and to scrape against the camming surface as the clip is being closed.

Preferably, the leg members are connected at their proximal ends by a resilient hinge portion.

The latch means preferably comprises a return bend deflectable hook portion at the distal end of the first leg member adapted to enclose the opposite end of the second leg member when the clip is in the closed position. Advantageously, the

penetrating means is located on the outer surface of the deflectable bend hook portion.

The clip may be made from an absorbable or non-absorbable polymeric material, and is preferably made from an absorbable polymeric material such as polydioxanone.

The invention will be more fully described in conjunction with the accompanying drawings wherein:

Figure 1 is a perspective view of an improved hemostatic clip of the present invention;

Figure 2 is a front view taken along line 2—2 of Figure 1;

Figure 3 is a front view taken along line 3—3 of Figure 1;

Figure 4 is a perspective view of the clip depicted in Figure 1 in a closed position about a blood vessel;

Figure 4a is a side view of a hemostatic clip of the present invention immediately prior to the clip being closed about a vessel to be ligated;

Figure 4b is a side view of the clip of Figure 4 with the clip in the fully closed position;

Figure 5 is a side view of one type of instrument that may be used in applying the clips of the present invention;

Figure 6 is an enlarged side view of an improved clip of the present invention in an open position and held in the jaws of the clip applying instrument depicted in Figure 5; and

Figure 7 is an enlarged side view of the clip shown in Figure 6 in the closed position in the jaws of the instrument depicted in Figure 5.

Referring to the drawings, there is shown an improved clip 20 of the present invention. As depicted in Figure 1, the clip comprises a pair of leg members 21 and 22 having opposed vessel clamping surfaces 23 and 24. The leg members are connected at their proximal ends by a resilient hinge portion 25. The distal end of one of the leg members terminates in a return bend hook portion 26. The opposite leg member is somewhat shorter and terminates at its distal end in a portion 27 which can be grasped by the hook portion. The end of this leg member is angled at an obtuse angle to the vessel clamping surface. This angle aids in deflecting the hook portion as the two leg members are brought together about the hinge and allows the hook portion to deflect and then accept the leg member in the area between the inner surface 28 of the hook portion and the vessel clamping surface 23 of the opposite leg member. The hook portion includes a sharpened pointed end 29 extending from the hook portion and positioned to lead the hook portion or precede the hook portion as the clip is being closed. As shown in Figure 2, the hook portion has a protrusion 30 dispersed from the central portion of its inner surface 28. This protrusion fits into a recess 31 positioned in the outer surface 32 of the opposite leg member 22. The protrusion and recess interlock when the clip is closed to prevent lateral movement of the leg members. The outside surfaces of the leg members each include a cylindrical boss 33 and 34 for use in holding the clip in a suitable instrument and applying the clip from said instrument as will hereinafter be described.

As may be more clearly seen in Figures 4, 4a, and 4b when the clip 40 is clamped about a vessel 41 to be closed, assuming that the vessel has not been fully dissected from the surrounding connective tissue 42, (such as would be found in the mesentary) the vessel clamping surfaces are placed on opposite sides of the vessel and the leg members urged together about the resilient hinge 43. The penetrating sharpened end 44 of the one leg member 45 will pinch and scrape the connective tissue between itself and the camming surface 48 of the other leg member 46. This scraping action enhances the tissue penetrating ability of the sharpened end. Once the tissue is penetrated the usual sequence of closure takes place. As the leg members are urged closer together the leg member 46 continues to deflect the hook portion 47 and becomes engaged by the leg member 45, thereby locking the clip in place about the vessel without tissue interference with latch security. Though in the embodiment shown the penetrating means is a sharpened beveled end, the penetrating means may have other configurations such as a pointed end tapered at a plurality of sides, a pointed end, a plurality of pointed ends, etc.

In Figure 5 there is shown a simplified drawings of an instrument for applying the clips of the present invention. This instrument 50 comprises a pair of handles 51 and 52 which are connected together at a hinge point 53. The handles are biased with respect to one another by a spring 54. One of handles extends beyond the hinge point in a first jaw member 55 and the opposite handle extends beyond the hinge point in a complementary second jaw member 56. The instrument engaging means comprises cylindrical bosses extending from the back surfaces of the leg members of the clip 57. These bosses fit into recesses in the jaws of the instrument.

The clip is placed in the jaws with the cylindrical bases in the appropriate recesses. The vessel clamping surfaces of the clip are then placed on opposite sides of the vessel to be closed and the instrument handles urged together closing and locking the clip about the vessel and shutting off the vessel.

Figures 6 and 7 show an enlarged view of the jaws and the recesses in the jaws for holding the clip. In Figure 6 the clip 60 is in the open position in the jaws 61 and 62; whereas, in Figure 7 the clip 60 has been closed by the jaws of the instrument. The clip comprises a pair of leg members 63 and 64 connected at their proximal ends by a resilient hinge 65. One of the leg members terminates in a return bend portion 66 which is deflectable. The other leg member terminates in an obtuse angle at its end surface 67. On the outer surface of each leg member is a cylindrical boss 68 and 69. The bosses are engaged by complementary recesses 70 and 71 in the jaws of the instrument. As may be seen, the ends of the jaws have been sloped away

from the general surfaces of the jaws. The reasons for this are more clearly seen in Figure 7. As may be seen in Figure 7, as the leg members are urged towards one another, the deflectable hook portion is deflected and engages the end of the second leg member. The deflectable hook portion includes a penetrating point or blade 72 which is a sharpened point. As the clip is closed, the penetrating point will separate and penetrate through the tissue still attached to the vessel to be closed. The cut-away portions of the jaws of the instrument allow the deflectable portion and the sharpened point free movement about the other leg member so that the clip may be closed as is seen in Figure 7. In the clip of the present invention, as the clip is closed the point or blade scrapes along the end surface 67 of the opposite leg member. This scraping action enhances the penetration of the tissue by the penetrating point or blade.

It should be pointed out that although there are shown resilient hinges connecting the leg members, other types of connecting means such as non-resilient hinges or interlocking means may be used to connect the proximal ends of the leg members. Also, as may be appreciated, the distal ends of the leg members may have other interlocking means. What is important is that the distal end of at least one of the leg members includes or carries a penetrating means to allow that distal end to penetrate connective tissue and allow the clip to be closed and locked about the vessel thus providing hemostasis.

The clips of the present invention may be made from various polymeric materials, either absorbable or non-absorbable. Suitable absorbable polymer materials are the polymers and copolymers of glycolides, lactides, polydioxanones, and the like. Suitable non-absorbable polymeric materials are nylon, polypropylene, polyesters, etc. The clips of the present invention may be provided in a sterile state ready for medical and surgical uses. Depending on the polymeric material used, the clips may be sterilized either by heat, radiation, ethylene oxide treatment or other well known sterilization methods.

Claims

1. A hemostatic clip, made from a polymeric material, comprising:

first and second leg members (21, 22) connected at their proximal ends (25), said leg members (21, 22) being adapted to be placed on opposite sides of a vessel to be closed;

an interlocking latch means (28, 30, 31, 32) at the distal ends of said leg members (21, 22) for interlocking to hold said leg members (21, 22) in a closed position; and

means (29) on the first leg member (21) cooperating with the latch means (28, 30, 31, 32) for penetrating connective tissue adjacent the vessel to be closed to ensure said latch means (28, 30, 31, 32) interlocks when the leg members (21, 22) are closed about the vessel,

characterised in that:

the second leg member (22) has its distal end bevelled to act as a camming surface (48, Figure 4A); and

the penetrating means comprises a sharpened pointed end at the distal end of the first leg member (21), the sharpened pointed end (29) being arranged to precede the latch means (28, 30) and to scrape against the camming surface (48) as the clip is being closed.

2. The clip of claim 1, wherein the penetrating means (29) comprises a sharpened blade (44, Figure 4A) extending orthogonally to the general axis of the first leg member (21).

3. The clip of claim 1 or claim 2, wherein the leg members (21, 22) are connected at their proximal ends by a resilient hinge portion (25).

4. The clip of any one of claims 1 to 3, wherein the latch means comprises a return bend deflectable hook portion (26) at the distal end of the first leg member (21) adapted to enclose the opposite end (27) of the second leg member (22) when the clip is in the closed position.

5. The clip of claim 4, wherein the penetrating means (29) is located on the outer surface of the deflectable bend hook portion (26).

6. The clip of any one of claims 1 to 5, wherein the polymeric material is an absorbable polymer.

7. The clip of claim 6, wherein the polymeric material is polydioxanone.

Patentansprüche

1. Blutgefäßklemme aus einem polymeren Material mit einem ersten und einem zweiten Schenkel (21, 22), die an ihren benachbarten Enden (25) miteinander verbunden sind und an einander gegenüberliegenden Seiten eines zu verschließenden Blutgefäßes plaziert werden sollen,

einer Verriegelungseinrichtung (28, 30, 31, 32) an den freien Enden der Schenkel (21, 22), um die Schenkel (21, 22) in einer geschlossenen Position verriegelt zu halten, und

einer Einrichtung (29) an dem ersten Schenkel (21), die mit der Verriegelungseinrichtung (28, 30, 31, 32) so zusammenwirkt, daß sie in das dem zu verschließenden Gefäß benachbarte, verbindende Gewebe eindringt, um sicher zu stellen, daß die Verriegelungseinrichtung (28, 30, 31, 32) einrastet, wenn die Schenkel (21, 22) um das Gefäß geschlossen sind,

dadurch gekennzeichnet, daß

der zweite Schenkel (22) an seinem freien Ende abgekantet ist, und als Nockenfläche (48, Figur 4A) wirkt, und daß die Eindringeinrichtung ein geschärftes, spitzes Ende am freien Ende des ersten Schenkels (21) aufweist, wobei das geschärfte, spitze Ende (29) der Verriegelungseinrichtung (28, 30) vorangeht und gegen die Nockenfläche (48) bei sich verschließender Klammer schabt.

2. Klemme nach Anspruch 1, dadurch gekennzeichnet, daß die Eindringeinrichtung (29) eine geschärfte Schneide (44, Figur 4A) aufweist, die

from the general surfaces of the jaws. The reasons for this are more clearly seen in Figure 7. As may be seen in Figure 7, as the leg members are urged towards one another, the deflectable hook portion is deflected and engages the end of the second leg member. The deflectable hook portion includes a penetrating point or blade 72 which is a sharpened point. As the clip is closed, the penetrating point will separate and penetrate through the tissue still attached to the vessel to be closed. The cut-away portions of the jaws of the instrument allow the deflectable portion and the sharpened point free movement about the other leg member so that the clip may be closed as is seen in Figure 7. In the clip of the present invention, as the clip is closed the point or blade scrapes along the end surface 67 of the opposite leg member. This scraping action enhances the penetration of the tissue by the penetrating point or blade.

It should be pointed out that although there are shown resilient hinges connecting the leg members, other types of connecting means such as non-resilient hinges or interlocking means may be used to connect the proximal ends of the leg members. Also, as may be appreciated, the distal ends of the leg members may have other interlocking means. What is important is that the distal end of at least one of the leg members includes or carries a penetrating means to allow that distal end to penetrate connective tissue and allow the clip to be closed and locked about the vessel thus providing hemostasis.

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characterised in that:

the second leg member (22) has its distal end bevelled to act as a camming surface (48, Figure 4A); and

the penetrating means comprises a sharpened pointed end at the distal end of the first leg member (21), the sharpened pointed end (29) being arranged to precede the latch means (28, 30) and to scrape against the camming surface (48) as the clip is being closed.

2. The clip of claim 1, wherein the penetrating means (29) comprises a sharpened blade (44, Figure 4A) extending orthogonally to the general axis of the first leg member (21).

3. The clip of claim 1 or claim 2, wherein the leg members (21, 22) are connected at their proximal ends by a resilient hinge portion (25).

4. The clip of any one of claims 1 to 3, wherein the latch means comprises a return bend deflectable hook portion (26) at the distal end of the first leg member (21) adapted to enclose the opposite end (27) of the second leg member (22) when the clip is in the closed position.

5. The clip of claim 4, wherein the penetrating means (29) is located on the outer surface of the deflectable bend hook portion (26).

6. The clip of any one of claims 1 to 5, wherein the polymeric material is an absorbable polymer.

7. The clip of claim 6, wherein the polymeric material is polydioxanone.

Patentansprüche

1. Blutgefäßklemme aus einem polymeren Material mit einem ersten und einem zweiten Schenkel (21, 22), die an ihren benachbarten Enden (25) miteinander verbunden sind und an einander gegenüberliegenden Seiten eines zu verschließenden Blutgefäßes plaziert werden sollen,

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einer Einrichtung (29) an dem ersten Schenkel (21), die mit der Verriegelungseinrichtung (28, 30, 31, 32) so zusammenwirkt, daß sie in das dem zu verschließenden Gefäß benachbarte, verbindende Gewebe eindringt, um sicher zu stellen, daß die Verriegelungseinrichtung (28, 30, 31, 32) einrastet, wenn die Schenkel (21, 22) um das Gefäß geschlossen sind,

dadurch gekennzeichnet, daß

der zweite Schenkel (22) an seinem freien Ende abgekantet ist, und als Nockenfläche (48, Figur 4A) wirkt, und daß die Eindringeinrichtung ein geschärftes, spitzes Ende am freien Ende des ersten Schenkels (21) aufweist, wobei das geschärfte, spitze Ende (29) der Verriegelungseinrichtung (28, 30) vorangeht und gegen die Nockenfläche (48) bei sich verschließender Klammer schabt.

2. Klemme nach Anspruch 1, dadurch gekennzeichnet, daß die Eindringeinrichtung (29) eine geschärfte Schneide (44, Figur 4A) aufweist, die

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sich senkrecht zur Hauptachse des ersten Schenkels (21) erstreckt.

3. Klemme nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Schenkel (21, 22) an ihren benachbarten Enden mittels eines elastischen Gelenks (25) miteinander verbunden sind.

4. Klemme nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Verriegelungseinrichtung am freien Ende des ersten Schenkels (21) einen nach rückwärts biegbaren Hakenabschnitt (26) aufweist, der das gegenüberliegende Ende (27) des zweiten Schenkels (22) bei geschlossener Klemme umschließt.

5. Klemme nach Anspruch 4, dadurch gekennzeichnet, daß die Eindringeinrichtung (29) an der Außenfläche des biegbaren Hakenabschnitts (26) liegt.

6. Klemme nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß als polymeres Material ein resorbierbares Polymer verwendet wird.

7. Klemme nach Anspruch 6, dadurch gekennzeichnet, daß das polymere Material Polydioxanon ist.

Revendications

1. Pince hémostatique faite d'une matière polymère comprenant:

une première et une deuxième branches (21, 22) réunies à leurs extrémités proximales (25), lesdites branches (21, 22) étant adaptées pour être mises en place sur les côtés opposés d'un vaisseau à obturer;

des moyens de blocage à verrouillage (28, 30, 31, 32) prévus aux extrémités distales desdites branches (21, 22) pour se verrouiller de façon à maintenir lesdites branches (21, 22) dans une position fermée; et

des moyens (29) prévus sur la première branche (21) et qui coopèrent avec ces moyens de blocage (28, 30, 31, 32) pour pénètrer dans le tissu conjonctif adjacent au vaisseau à obturer pour faire en sorte que lesdits moyens de blocage (28, 30, 31, 32) se verrouillent lorsqu'on referne les branches (21, 22) autour du vaisseau,

caractérisée en ce que la deuxième branche (22) possède une extrémité distale chanfreinée de façon à jouer le rôle d'une surface de came (48, 4A); et

les moyens pénétrants comprennent une extrémité pointue tranchante prévue à l'extrémité distale de la première branche (21), l'extrémité pointue tranchante (29) étant agencée pour précéder les moyens de blocage (28, 30) et pour racler contre la surface de came (48) pendant que l'on ferme la pince.

2. Pince selon la revendication 1, dans laquelle les moyens pénétrants (29) comprennent une lame tranchante (44, figure 4A) qui s'étend perpendiculairement à l'axe général de la première branche (21).

3. Pince selon la revendication 1 ou la revendication 2, dans laquelle les branches (21, 22) sont réunies à leurs extrémités proximales par une partie charnière élastique (25).

4. Pince selon l'une quelconque des revendications 1 à 3, dans laquelle les moyens de blocage comprennent une partie crochet flexible formant un coude en retour (26), prévue à l'extrémité distale de la première branche (21) et adaptée pour entourer l'extrémité opposée (27) de la deuxième branche (22) lorsque la pince est en position fermée.

5. Pince selon la revendication 4, dans laquelle les moyens pénétrants (29) sont placés sur la surface extérieure de la partie crochet formant coude flexible (26).

6. Pince selon l'une quelconque des revendications 1 à 5, dans laquelle la matière polymère est un polymère résorbable.

7. Pince selon la revendication 6, dans laquelle matière polymère est un polydioxanone.

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