

SPECIFICATION

Plastic hemostatic clips

BACKGROUND OF THE INVENTION

The present invention relates to plastic

- 5 hemostatic clips, and, more particularly, to plastic hemostatic clips fabricated from polymeric materials which may be absorbable or nonabsorbable, such clips being capable of being applied to blood vessels and the like.

- 10 Hemostatic clips are utilized in surgical procedures to close severed blood vessels and other small fluid ducts. In the past, hemostatic clips have been narrow U-shaped or V-shaped strips formed of tantalum or stainless steel which are capable of being deformed and possess
- 15 sufficient strength to retain the deformation when clamped about a blood vessel. The clips are generally applied using a forceps-type device having jaws channeled or otherwise adapted to hold the open clip.

- 20 Representative hemostatic clips and appliers of the prior art are best illustrated in U.S. Patents Nos. 3,867,944; 3,631,707; 3,439,523; 3,439,522; 3,363,628; 3,312,216; and
- 25 3,270,745.

- It has been suggested in the prior art, as in U.S. Patent No. 3,439,523, for example, that hemostatic clips might be formed of inexpensive plastics or materials which are slowly absorbable
- 30 in the body. Unfortunately, the very small conventional U- and V-shaped hemostatic clips do not possess the required strength of deformability when constructed of known plastic materials to be successfully clamped about a blood vessel. Thus,
- 35 although the need and desirability of providing inexpensive plastic ligating clips of both absorbable and nonabsorbable materials has been recognized for over ten years, there has been no practical way to satisfy this need.

- 40 U.S. 3,926,195 describes a small, plastic clip designed for the temporary or permanent close of the oviduct and vas deferens in humans. These clips preferably have a clamping surface of from 6 to 10 mm in length and 3 to 6 mm in width. The
- 45 sizes of such clips are accordingly considerably larger than is desirable for hemostatic clips. Additionally, clips of U.S. 3,926,195 require the use of several complex tools to apply the clips which are acceptable for the purposes described
- 50 in the reference but would be unacceptable in a surgically procedure requiring the rapid placement of a large number of hemostatic clips to stem the flow of blood from severed vessels.

- It is accordingly an object of the present
- 55 invention to provide a plastic hemostatic clip effective for clamping off small blood vessels and other fluid ducts in the body. It is a further object of this invention to provide plastic hemostatic clips of both absorbable and nonabsorbable materials.
- 60 It is a yet further object of this invention to provide plastic hemostatic clips which are quickly and easily applied to severed blood vessels and other fluid ducts with a single forceps-type instrument

following the general technique used in applying metallic clips.

65

SUMMARY

The plastic hemostatic clips of the present invention comprises first and second leg members joined at their proximal ends by resilient hinge

70 means and terminating at their distal ends in latch means; each leg member having an outer surface and a vessel clamping inner face, said vessel clamping inner face being in opposition to a vessel clamping inner face of the other leg member;

- 75 said first leg member terminating at the distal end thereof in a portion of the latch means, said portion comprising a deflectable hook member extending from the inner face of said leg member, said hook member having an inner face spaced
- 80 from the inner face of said leg member and substantially parallel thereto, the end face of said hook member being beveled so as to form an acute angle with the inner face of said hook member, the greater portion of the outer surface
- 85 of said leg member extending from said hook member having a substantially constant radius of curvature;

- said second leg member terminating at the distal end thereof in a complementary locking
- 90 portion of the latch means, said portion comprising an end face of said leg member having a bevel complementary to the bevel on the end face of said hook member, said complementary bevel forming an obtuse angle with the inner face
- 95 of said second leg member and adapted to deflect said hook member and enter the space between the inner face of said hook member and the inner face of said first leg member, the greater portion of the outer surface of said second leg member
- 100 being substantially parallel to the inner face of said member;

- whereby when said first and second leg members are pivoted about said hinge means, the distal end of the said second leg member deflects and engages the hook member of the first leg
- 105 member to lock the clip in a closed position.

- The clips may be formed of plastic by injection molding or other suitable technique, and may be composed of a nonabsorbable material such as
- 110 polypropylene or an absorbable material such as a homopolymer or copolymer of lactide and glycolide. The clips are formed in a normally open position and constructed with a small amount of material to minimize tissue reaction. The clips are
- 115 readily applied with a single forceps-type instrument using conventional surgical techniques.

DESCRIPTION OF DRAWINGS

- 120 FIGURE 1 is a greatly enlarged view in perspective of a surgical clip according to the present invention.

FIGURE 2 illustrates the clip of FIGURE 1 clamped about a blood vessel.

- 125 FIGURE 3 illustrates a forceps-type applier useful with the clips of the present invention.

FIGURE 4 illustrates the clip of FIGURE 1

retained in the jaws of a forceps-type clip applier.

FIGURE 5 illustrates a modification of the clip of FIGURE 1.

FIGURE 6 illustrates the clip of FIGURE 5

retained in the jaws of a clip applier.

FIGURE 7 illustrates a modification of the clip of FIGURE 1.

FIGURE 8 illustrates the clip of FIGURE 7 retained in the jaws of a clip applier.

10 DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to FIGURE 1, there is illustrated hemostatic clip 10 constructed of two leg segments 11 and 12 connected at the proximal ends thereof by hinge section 13. Leg 11

terminates at the distal end thereof in hook member 14. Inner face 15 of hook member 14 is substantially parallel to inner face 16 of leg 11. Surface 25 of extension 17 of hook member 14 forms an obtuse angle α with inner face 16 of jaw 11, and acute angle β with inner face 15 of hook 14.

Leg segment 12 has inner face 18 terminating in end surface 19 forming obtuse angle α' with face 18 and acute angle β' with the outer surface 20. Surface 20 is substantially parallel to face 18 at the distal end of leg 12, but approaches face 18 at the proximal end inasmuch as it exhibits the curvature indicated at 21.

The outer surface at the distal end of leg 11 defines a curve of substantially constant radius extending from extension 17 into the body of leg 11. The effect of this curvature is to permit the clip to slide forward and rotate in the jaw of the applier during closure as hereafter described. The curvature also reduces the thickness of the leg at the distal end thereof to increase the flexibility of hook member 14 while maintaining strength and rigidity towards the center of the leg. The deflectability of hook 14 may be further increased by diminishing the thickness of extension 17 as illustrated in FIGURE 1 where outer surface 24 is made parallel to inner surface 25. Leg 11 also decreases in thickness along plane 23 extending over the proximal one-third of the leg and has a minimum thickness at the junction with leg 12 to form a hinge along line 13.

The length and width of faces 16 and 18 are substantially equal as are angles α and α' , and β and β' . Face 15 of hook 14 is spaced from face 16 of leg 11 by a distance corresponding to the thickness of leg 12 between face 18 and surface 20. When legs 11 and 12 are pivoted about hinge 13 to bring faces 18 and 16 into opposition, hook 14 is deflected by surface 19 of leg 12 until the distal end of leg 12 snaps under hook 14 and is thereby locked in place. Front surface 26 of hook 14 is preferably rounded and angled as illustrated to facilitate the passage of leg 12 during clip closure.

When the clip is closed over a tubular vessel as illustrated in FIGURE 2, surfaces 16 and 18 engage and compress vessel 27 to close the lumen. Surfaces 16 and 18 may be smooth as illustrated in FIGURE 1, or may be provided with

ridges or grooves to increase vessel holding power. The distal end of surface 18 of leg 12 is preferably beveled as illustrated by broken line *a* in FIGURE 1 to reduce the thickness at the tip of the leg, thereby compensating for inward deflection of hook 14 during closure which reduces the clearance between surfaces 15 and 16 and may otherwise interfere with the latching of the clip.

The significance of the clip configuration as illustrated in FIGURE 1 and described above will be appreciated in connection with the instrument used to apply and close the clip as illustrated in FIGURE 3 and FIGURE 4.

FIGURE 3 illustrates a forceps-type ligating clip applier 30 comprising two handle members 31 and 32 crossing at hinge point 33 and maintained in a normally open position by spring 38. Handle 31 extends beyond hinge 33 forming jaw member 34 while the extension of handle 32 forms jaw member 35.

FIGURE 4 illustrates the detail of the construction of jaw 34 and 35 and the interaction of the jaws with the clip of FIGURE 1. Jaw 35 contains dished channel 39 on the inner jaw surface extending back from the tip of the jaw. Jaw 34 is provided with dished channel 40 connecting with straight channel 41 at point 42. Channel 41 terminates in a blind end near the tip of jaw 34 forming ledge 43 which restrains leg 12 against forward movement when in position between the jaws. The widths of channels 39, 40 and 41 correspond to the width of clip 10 to prevent twisting or lateral movement of the clip when held in the jaws of the applier.

Pin 36 is mounted in jaw 34 behind and aligned with channel 40. Opening 37 centered in jaw 35 above pin 36 is of a sufficiently larger diameter as illustrated in FIGURE 4 to allow the free ingress and egress of pin 36 during opening and closing of the jaws.

Clip 10 is initially loaded in applier 30 in the normally open position as illustrated in FIGURE 4. After moving the jaws of the applier and the clip into position over the vessel to be ligated, the jaws of the applier are closed and the clip is locked in position over the vessel as illustrated in FIGURE 2. As the jaws of the applier are closed, leg 11 of clip 10 moves forward with curved surface 22 sliding and rotating in channel 39. Simultaneously, the clip moves backward until surface 23 abuts pin 36. As the clip continues to close, leg 12 pivots on fulcrum 42 with the proximal end of leg 12 dropping into channel 40 and the distal end rising from channel 41 to be engaged by hook 14. Once the clip is fully closed and locked onto the vessel, the jaws of the applier are allowed to open and the applier is withdrawn from the site to be reloaded with another clip.

Referring now to FIGURE 5, there is illustrated a variation of the clip of FIGURE 1 wherein leg 12 has been modified by the addition of indent 42 across the outer surface near the distal end thereof. The clip applier is similarly modified to accept the clip as illustrated in FIGURE 6 by providing lower jaw 34 with step 44 sized to fit

within indent 42. As illustrated, the distal tip of jaw 34 forward of step 44 is slotted to provide clearance for the distal tip of leg 12 and for the passage of hook 14 as the clip is closed. The clip is also illustrated with the inside face of leg 12 beveled at 46 to assure ready closure of the clip as hereinbefore described.

During closure of the clip of FIGURE 5, the distal end of leg 11 moves forward with radial surface 22 of leg 11 rotating and sliding in dished channel 39 of leg 35. Leg 12 pivots on step 44 of jaw 34 and the proximal end lowers into channel 45 which conforms to the general shape of the clip. During the final stage of closure, leg 12 lies substantially stationary on jaw 34 and leg 11 pivots at the hinge point until hook 14 engages the distal end of leg 11 thereby locking the clip in a closed configuration. In this embodiment, pin 36 in the applier is generally not contacted by the clip unless the clip is dislodged from step 44 during the closure.

Referring now to FIGURE 7, there is illustrated another embodiment of the ligating clip of FIGURE 1 wherein leg 12 is provided with lug 47, and jaw 34 of the applier is provided with channel 49 including slot 48 conforming to the outer shape of leg 12. In this embodiment, leg 12 is stationary and securely set in jaw 34 of the applier and pin 36 as illustrated in FIGURE 3 is unnecessary. During closure, leg 11 of clip 10 moves forward with radial surface 22 rotating and sliding in dished channel 39 of leg 35 until the distal end of leg 12 is engaged by hook 14, thereby locking the clip in position. As illustrated in FIGURE 8, the distal tip of jaw 34 is slotted below the tip of leg 12 to allow hook 14 to bypass and lock with leg 11.

As further illustrated in FIGURE 7 and FIGURE 8, lug 47 is set back from the distal end of leg 12 by a distance corresponding to the length of inner face 15 of hook 14 to permit maximum closure of the hook when engaging leg 12. Since jaw 34 of the applier occupies a portion of the space between lug 47 and the distal end of leg 12 when the clip is in the applier, hook 14 engages the available portion of leg 12 with the tip of hook 14 abutting the end of jaw 34 as the clip is closed. As the jaws of the applier are opened after setting the clip and the clip is released therefrom, hook 13 moves to fully engage leg 12 up to lug 47.

The clips of the present invention are characterized by the structure which permits the legs of the clip to pivot about a hinge point with one leg sliding forward within the jaws of the holder during closure while the other is restrained against forward movement. This unique action of the clip is accomplished by providing one jaw of the applier with a dished channel which guides the clip without restraining its forward movement. The clip is curved on the outer surface at the distal end of the moving leg to permit its forward movement and rotation in the dished channel. The other jaw of the applier is provided with means interacting with the second leg of the clip to hold the clip in the applier during positioning and closure. The

second leg of the clip may be held stationary on the jaw of the applier or may pivot to a limited degree during closure.

The clips of the present invention may be constructed in various sizes according to their intended function. Hemostatic clips are typically less than 6 mm in length, about 1.5 mm in width, and have a vessel clamping surface about 3 mm in length. The dimensions of the clip may be reduced by about 50 percent for certain applications in microsurgery. Larger clips for special hemostatic applications and other functions such as closure of oviducts or vas deferens may have dimensions of about double those of a typical hemostatic clip. The various sizes of clips are preferably matched with individual appliers having jaws tailored to the size of the clip for best performance.

The clips of the present invention are most conveniently molded of biologically acceptable plastic materials which may be absorbable or nonabsorbable. Preferred absorbable polymers include homopolymers and copolymers of glycolide and lactide, and poly(*p*-dioxanone). Preferred nonabsorbable polymers include nylon and polypropylene. All these materials have been demonstrated to be biologically acceptable when used as sutures or other implantable medical devices. The clips may also be cast or machined from solid polymeric materials or from metals such as aluminium, magnesium, stainless steel, tantalum, and various alloys of these, some of which may also be absorbable in biological tissue. Many variations in the clip other than the embodiments disclosed herein will be apparent to those skilled in the art and are contemplated within the scope of the present invention.

CLAIMS

1. A plastic hemostatic clip comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means; each leg member having an outer surface and a vessel clamping inner face, said vessel clamping inner face being in opposition to a vessel clamping inner face of the other leg member;
 - said first leg member terminating at the distal end thereof in a portion of the latch means, said portion comprising a deflectable hook member extending from the inner face of said leg member, said hook member having an inner face spaced from the inner face of said leg member and substantially parallel thereto, the end face of said hook member being beveled so as to form an acute angle with the inner face of said hook member, the greater portion of the outer surface of said leg member extending from said hook member having a substantially constant radius of curvature;
 - said second leg member terminating at the distal end thereof in a complementary locking portion of the latch means, said portion comprising an end face of said leg member having a bevel complementary to the bevel on the end face of said hook member, said complementary



24

within indent 42. As illustrated, the distal tip of jaw 34 forward of step 44 is slotted to provide clearance for the distal tip of leg 12 and for the passage of hook 14 as the clip is closed. The clip is also illustrated with the inside face of leg 12 beveled at 46 to assure ready closure of the clip as hereinbefore described.

During closure of the clip of FIGURE 5, the distal end of leg 11 moves forward with radial surface 22 of leg 11 rotating and sliding in dished channel 39 of leg 35. Leg 12 pivots on step 44 of jaw 34 and the proximal end lowers into channel 45 which conforms to the general shape of the clip. During the final stage of closure, leg 12 lies substantially stationary on jaw 34 and leg 11 pivots at the hinge point until hook 14 engages the distal end of leg 11 thereby locking the clip in a closed configuration. In this embodiment, pin 36 in the applier is generally not contacted by the clip unless the clip is dislodged from step 44 during the closure.

Referring now to FIGURE 7, there is illustrated another embodiment of the ligating clip of FIGURE 1 wherein leg 12 is provided with lug 47, and jaw 34 of the applier is provided with channel 49 including slot 48 conforming to the outer shape of leg 12. In this embodiment, leg 12 is stationary and securely set in jaw 34 of the applier and pin 36 as illustrated in FIGURE 3 is unnecessary. During closure, leg 11 of clip 10 moves forward with radial surface 22 rotating and sliding in dished channel 39 of leg 35 until the distal end of leg 12 is engaged by hook 14, thereby locking the clip in position. As illustrated in FIGURE 8, the distal tip of jaw 34 is slotted below the tip of leg 12 to allow hook 14 to bypass and lock with leg 11.

As further illustrated in FIGURE 7 and FIGURE 8, lug 47 is set back from the distal end of leg 12 by a distance corresponding to the length of inner face 15 of hook 14 to permit maximum closure of the hook when engaging leg 12. Since jaw 34 of the applier occupies a portion of the space between lug 47 and the distal end of leg 12 when the clip is in the applier, hook 14 engages the available portion of leg 12 with the tip of hook 14 abutting the end of jaw 34 as the clip is closed. As the jaws of the applier are opened after setting the clip and the clip is released therefrom, hook 13 moves to fully engage leg 12 up to lug 47.

The clips of the present invention are characterized by the structure which permits the legs of the clip to pivot about a hinge point with one leg sliding forward within the jaws of the holder during closure while the other is restrained against forward movement. This unique action of the clip is accomplished by providing one jaw of the applier with a dished channel which guides the clip without restraining its forward movement. The clip is curved on the outer surface at the distal end of the moving leg to permit its forward movement and rotation in the dished channel. The other jaw of the applier is provided with means interacting with the second leg of the clip to hold the clip in the applier during positioning and closure. The

second leg of the clip may be held stationary on the jaw of the applier or may pivot to a limited degree during closure.

The clips of the present invention may be constructed in various sizes according to their intended function. Hemostatic clips are typically less than 6 mm in length, about 1.5 mm in width, and have a vessel clamping surface about 3 mm in length. The dimensions of the clip may be reduced by about 50 percent for certain applications in microsurgery. Larger clips for special hemostatic applications and other functions such as closure of oviducts or vas deferens may have dimensions of about double those of a typical hemostatic clip. The various sizes of clips are preferably matched with individual appliers having jaws tailored to the size of the clip for best performance.

The clips of the present invention are most conveniently molded of biologically acceptable plastic materials which may be absorbable or nonabsorbable. Preferred absorbable polymers include homopolymers and copolymers of glycolide and lactide, and poly(*p*-dioxanone). Preferred nonabsorbable polymers include nylon and polypropylene. All these materials have been demonstrated to be biologically acceptable when used as sutures or other implantable medical devices. The clips may also be cast or machined from solid polymeric materials or from metals such as aluminium, magnesium, stainless steel, tantalum, and various alloys of these, some of which may also be absorbable in biological tissue.

Many variations in the clip other than the embodiments disclosed herein will be apparent to those skilled in the art and are contemplated within the scope of the present invention.

CLAIMS

1. A plastic hemostatic clip comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means; each leg member having an outer surface and a vessel clamping inner face, said vessel clamping inner face being in opposition to a vessel clamping inner face of the other leg member;

said first leg member terminating at the distal end thereof in a portion of the latch means, said portion comprising a deflectable hook member extending from the inner face of said leg member, said hook member having an inner face spaced from the inner face of said leg member and substantially parallel thereto, the end face of said hook member being beveled so as to form an acute angle with the inner face of said hook member, the greater portion of the outer surface of said leg member extending from said hook member having a substantially constant radius of curvature;

said second leg member terminating at the distal end thereof in a complementary locking portion of the latch means, said portion comprising an end face of said leg member having a bevel complementary to the bevel on the end face of said hook member, said complementary



bevel forming an obtuse angle with the inner face of said second leg member and adapted to deflect said hook member and enter the space between the inner face of said hook member and the inner face of said first leg member, the greater portion of the outer surface of said second leg member being substantially parallel to the inner face of said member;

10 whereby when said first and second leg members are pivoted about said hinge means, the distal end of the said second leg member deflects and engages the hook member of the first leg member to lock the clip in a closed position.

15 2. The hemostatic clip of Claim 1 wherein a portion of the outer surface of the first leg member having a substantially constant radius of curvature is flattened so as to improve the deflectability of said hook member.

20 3. The hemostatic clip of Claim 2 wherein the flattened portion is immediately adjacent the hook member.

25 4. The hemostatic clip of Claim 1 or 3 wherein said resilient hinge means is defined by a line of minimum clip thickness at the juncture of the first and second leg members.

5. The hemostatic clip of Claim 1 or 3 wherein

said hook member is spaced from said inner face of said first leg member by a distance at least equal to the thickness of the distal end of the said second leg member.

30 6. The hemostatic clip of Claim 1 or 3 wherein said second leg member includes a channel across the width of the outer surface of said second leg member near the distal end thereof.

35 7. The hemostatic clip of Claim 6 wherein said channel is spaced from the tip of said distal end by a distance corresponding to the length of the inner face of said hook member.

40 8. The hemostatic clip of Claim 1 or 3 wherein said second leg member includes a lug across the width of the outer surface of said second leg member near the distal end thereof.

45 9. The hemostatic clip of Claim 1 or 3 wherein said lug is spaced from the lip of said distal end by a distance corresponding to the length of the inner face of said hook member.

10. The hemostatic clip of Claim 8 wherein said lug is angled toward the distal end of said second leg member.

50 11. A hemostatic clip as claimed in claim 1, substantially as described with reference to the accompanying drawings.