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SURGICAL CLIP WITH MEANS FOR RELEASING THE CLAMPING PRESSURE
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11 Claims. (Cl. 128—325)

This application is a continuation-in-part of Serial No. 292,046 filed July 1, 1963, now abandoned, and of Serial No. 382,079, now Patent No. 3,347,239 filed July 13, 1963, both in the name of John W. Codling.

This invention relates to an improved surgical clamp or clip, and more particularly to a device of this nature which may be left in the body to perform its hemostatic or similar function over a predetermined post-operative time period and will automatically relax its clamping pressure so as to avoid pressure necrosis should the clip not be removed sooner. The invention is herein illustratively described in its presently preferred embodiments with its primary application being in connection with arresting post-operative cerebral bleeding, such as when a cerebral aneurysm is a cause of the bleeding. However, it will be recognized that certain modifications and changes therein with respect to details and applications thereof may be made without departing from the essential features involved.

The difficulties with former methods of achieving hemostasis coupled with the need for frequent post-operative inspection of the wound and the tissue adjacent to it, and the need to control bleeding by applying pressure, particularly to materials which are subjected to the effects of body fluids for a long period of time has been a problem. It is an object of this invention to overcome this problem by providing a clip which is capable of exerting a predetermined pressure and which will not erode or dissolve appreciably during the required post-operative period in which the jaws are required to exert pressure on a given area.

A further object hereof is to devise such a clip having predictable and, by design, readily controlled self-release properties. Thus a clip of this invention may be designed to exert substantially constant pressure for a relatively long period of time followed by progressive relaxation of pressure at a predetermined rate, or may be designed to relax the clamping pressure at a predetermined rate commencing almost immediately.

A further and important object of this invention is to provide a means by which to design these controls into a surgical clip regardless of the size, type, shape or function being performed thereby. Broadly speaking the invention in its principal aspect employs a method or means of predetermined or controlling the self-release properties of a surgical clip or the like without unduly restricting the range of choices of the materials which may be used therein, or imposing other design limitations such as shape, initial clamping pressure available, size, etc.

In accordance with this invention in its preferred forms embodying the principal features of novelty, the principle of the galvanic couple effect is employed to achieve the self-release function of a clip. This is accomplished by employing electrochemically dissimilar metals presented to the body fluids in different specific portions of the clip. Thus the jaw surfaces comprise a noble metal or other metallic substance relatively low or inactive in the electrolyte series which, during the clip's functional life within the body, is non-irritating to the tissue and is not dissolved or eroded by the body fluids. Clamping pressure of the jaws is maintained by a connecting means at least a portion of which is of a metal or metal alloy relatively high or active in the electrolyte series. By designing the clip so that the exposed surface area of the relatively active metal is small in comparison with the exposed surface area of the passive metal the galvanic effect which produces accelerated dissolution of the relatively active metal electrolytically is concentrated and the dissolution occurs at a rapid, but predetermined rate. Thus progressive electrolytic dissolution of metal occurs in the connecting structure which is stressed by jaw pressure, and as the critical structural cross-section, diminishes a point is reached at which the pre-existing stress therein produces failure and the jaws are caused to progressively relax their pressure on the tissues. Moreover, by limiting the exposed surface of the relatively active metal to a small area, and preferably by so locating it as to minimize contact with body tissues, relatively active metals may be used which might otherwise be unsuitable due to their irritant effect upon tissues.

The jaws of the clips may be composed entirely of a noble metal or other passive metal which is not susceptible to dissolution, corrosion or erosion upon remotely prolonged contact with body fluids or the jaws may be composed of a metal not as resistant to dissolution, corrosion or erosion by body fluids, the exposed surfaces of which are coated with a noble metal or other passive metal. As a further feature hereof, the clips of the invention may be made at relatively low cost by forming the entire clip of a relatively active metal, such as an aluminum alloy, and coating the entire clip, with the exception of a limited surface areas in a portion interconnecting the two jaw sections, with a noble metal such as silver. In the case of a generally U-shaped clip the area left unplated is usually in the arch of the hinge section. If desired, such entire clip may be coated, such as by electrolysis with passive metal and a hairline scratch made to expose the underlying active metal at the desired point where controlled weakening and failure is to occur by the galvanic
couple effect. As will be evident, a clip of this invention may be pre-bent into its desired operating form or, if desired, it may be produced in a form (flat or otherwise) which is changed or modified prior to application as well as in the act of application when the jaws are being squeezed together against the body tissues.

The galvanic or electro-chemical action referred to above is that which is common in metallic couples or galvanic cells used by science and industry in various ways. As is well known, when aluminum, relatively high in the electromotive series, is immersed in an ionic solution such as human body fluids, for example, it tends to dissolve. However, the reaction is very slow in the case of a pure metal or even with an alloy, so that normally a large amount of time would be required in order to dissolve a substantial cross-section of this material. Thus if the cross-section were large, as necessary to carry a substantial clamping force, a clip made entirely of such metal would release its pressure after an unduly long period and the action would be taking place over the entire surface area. However, when such an active metal is immersed in the electrolyte in close proximity to and in electrical contact with a relatively passive metal, low in the electromotive series, the rate of dissolution of the active metal is increased enormously by the so-called galvanic couple effect, and this is the principle applied to advantage by this invention. As will be evident, the rate of dissolution of the active metal is affected by the ratio of the respective exposed surface areas of the active and inactive metals, by their relative proximity and electrical interconnection, by the concentration of the electrolyte solution (natural body fluids, with or without additives), and by temperature. Since temperature and electrolyte properties generally are approximately the same in different human beings there is a high degree of predictability in the performance characteristics of these improved clips. It will of course be evident that thickness of the metal being dissolved at the critical structural section and the initial stress which it carries (determined by jaw pressure) as well as any subsequent increase of stress occasioned by growth of scar tissue also bear directly on the time after installation and the rate at which progressive relaxation of jaw pressure occurs as a result of structural failure of the portion of the clip whose cross-section is being depleted by the galvanic action. These variables are also directly within the control of the designer and/or user.

It is also recognized that certain alloys of metals can be made to precipitate their intermetallic compounds in the grain boundaries by suitable heat treatment. By this controlled heat treatment the area in the vicinity of the grain boundary becomes more active than the grain or matrix material and thus a path exists within the material through which the dissolution can proceed. As this grain boundary area or path is considerably less than the whole grain the active area becomes smaller in relation to the passive area and the rate of corrosion or dissolution will increase substantially. The action is commonly known as intergranular corrosion.

It will be obvious, of course, that metals which are highly active cannot be expected to function satisfactorily as the electrolytically dissoluble connecting portion of the clip because of their potential irritating effect upon body tissues or their inability to retain structural form for a sufficient clamping period in the presence of body fluids. Thus magnesium alloys with an electrode potential in the vicinity of 3 volts (0.1 N CaCl2 in an aqueous solution of 53 g. NaCl and 3 g. H2O2 per liter) are the most active metals considered practical.

These and other features, objects and advantages of the invention will become more fully evident from the following description thereof by reference to the accompanying drawings.

FIGURE 1 is a perspective view of a surgical clip representing one embodiment of the invention.

FIGURE 2 is a fragmentary view of the gullet or hinge portion of the clip shown in FIGURE 1, portions being broken away and shown in cross-section to illustrate details.

FIGURE 3 is a side view of a surgical clip representing a modification of that shown in FIGURE 1, the clip being mounted in a tenaculum preparatory to application.

FIGURE 4 is a side view of another modification.

FIGURE 5 is a perspective view of another modification of the other active metal.

FIGURE 6 is a fragmentary view of the hinge portion of the clip shown in FIGURE 5, illustrating the preferred and presently the most important means for achieving the self-release function of the clip according to this invention.

In the embodiment shown in FIGURES 1 and 2 surgical clip 10 comprises a first jaw 12 having an offset tab 14 and a marginal flange 16 which reinforces the main portion of the jaw member. The forward or mouth end of the jaw 12 is provided with a plurality of teeth 18 designed to engage body tissues in a gripping action. Openings 20 are formed in the face of the jaw member 12 for engagement by prongs or teeth 50 of a tenaculum 14 in a manner more fully described later.

The second jaw 22 is likewise provided with an offset tab 24 and has a marginal flange 26 for reinforcing purposes. Jaw 22 likewise has gripping teeth 28 on its mouth end and a similar pair of openings 30 for engagement by tenaculum prongs 32.

The offset tabs 14 and 24 of jaws 12 and 22 are held together structurally by a rivet 34 having heads 36 at each end. The rivet 32 may be provided with an axial bore 38 from end to end so as to increase its rate of structural failure. It is of a metal, such as an aluminum alloy (e.g. No. 6061, 2017, or other) more highly active in the electromotive series than the metal comprising or forming the surface of the jaws 12 and 22. The bore through the rivet as well as the residual thickness of rivet metal, its relationship in the electromotive series to the material of the jaw members and its surface area in relation to the exposed surface area of the jaw members bear directly on the amount of time required for the rivet to fail as a structural connection under stress between the jaw members.

Referring specifically to FIGURE 3, it will be noted that the tenaculum 14 comprises a pair of jaws 42, 44 pivoted together in opposition to each other and having handles 48 for manual manipulation of the instrument. Each jaw 42 and 44 has prongs 50 which pass through either the openings 20 or 30 of the jaws 12 and 22 respectively or similar opening in clip 70 of the alternative form shown in FIGURE 3.

In use, the clips are positioned between the jaws 42 and 44 of the tenaculum and prongs 50 pass through the jaw openings of the clip. At this time the jaws of the clip have been spread apart sufficiently to receive the body tissues which are to be gripped. In the case of post-operative hemostasis of a conized cervix, one jaw of the clip will be inserted in the entrance of the cervix and the other jaw will overlap the surrounding cervix tissue, whereupon the wall of the cervix will be clamped as the tenaculum jaws are forced together and the relatively plastic material comprising the clip proper will be set or formed and will retain its set in order to maintain clamping pressure on the cervix tissues. The jaw teeth 18 and 28 press into the tissues so as to hold the clip in place. The tenaculum teeth 50 also pass into the tissue as aid in establishing the clip in the proper initial position. Thereupon the tenaculum jaws are spread and the tenaculum withdrawn in order to receive another clip for insertion in and application to the conized cervix, the process being repeated along the periphery of the conized cervix until, with clips in successive adjacent positions, substantially the entire operated area is clamped as desired in order to effect hemostasis.
Clip 70 of FIGURE 2 has arms 72 and 74 provided with teeth 76 and openings (not shown) through which the tungsten teeth 59 may pass as already described. The ends 73 and 75 of arms 72 and 74 are overlapped in this case in a plane generally perpendicular to the longitudinal mid-plane which bisects the angle between the divergent jaw members. In the previous embodiment the offset portions of the jaw members were formed parallel to the bisecting plane. In FIGURE 3 the connecting rivet 76 performs essentially the same function as the rivet 52 in the preceding embodiment although in this instance the loading of the rivet heads is related differently to jaw pressure than in the first embodiment.

In either case the jaw members or the surface thereof presented to the electrolyte substance in the human body when the clip is left in situ post-operatively are formed of or comprise a relatively passive metal, of which the noble metals are relatively ideal examples. Silver is perhaps the least expensive of the true noble metals and the most suitable for economic use in this category. However, other metals and alloys may also be used as the passive metal. For example "nickel silver" is a very suitable alloy useful as the passive metal of the clip and if necessary it may be made more passive by plating with a noble metal such as silver.

Clips 10 and 70, for example, may be formed of silver-plated nickel-silver jaws through which is passed a 3/6" rivet 76 (or 52), with the rivet being formed of 2017 aluminum alloy suitably heat treated so as to disintegrate intergranularly. In a test case heads .015" thick were formed on the rivet and the rivet was bored axially with a 0.039" diameter hole from end to end. Previous to insertion such rivets were solution heat treated, quenched in boiling water and baked or aged at 350°F. for varying periods of time. In the case of aluminum alloy rivets of the nature described above it was determined that the deterioration was intergranular and more rapid in rivets which had been subjected to a shorter aging period (2.5 hours) than when exposed for a longer time to the elevated temperature, which is in conformance with known technology. Rivets which were aged for longer periods of time (4 hours) corroded by pitting and took considerably longer to fail. This is also the way in which non-aged rivets fail. It will be recognized, however, that the choice and preparation of materials, their shape and thickness and other variables are matters largely of choice in design, however much any one factor may bear on ultimate properties of a manufactured clip.

In case the jaw members are formed of a metal which is relatively active in the electromotive series, the jaw member surfaces may be electro-plated with silver or other relatively noble metal so as to provide a higher degree of protection against the possibility of tissue irritation and also to prevent corrosion and disintegration of the jaw members during the desired post-operative clamping period. Moreover such plating of the jaw members with a relatively noble metal such as silver establishes the galvanic couple effect producing dissolution of the rivet to the point of structural failure under stress from jaw pressure and thereby relaxation of jaw pressure.

In FIGURE 4 jaws 62 and 64 of clip 60 are provided with teeth 66 on each side and are joined at the hinge or gullet portion by a thin connecting web 68 of a metallic substance more active in the electromotive series than the metallic substance forming the surface of the jaw 62 and 64, which is reflector coating in this case was joined to the jaws by welding techniques, although because welding of such dissimilar metals is difficult to achieve by present technology this particular type of construction is presently considered to be less desirable than the others described.

In the embodiment of FIGURES 5 and 6, the clamp comprises a tapered first jaw 100 and a flared or spatulate second jaw 120 integrally joined thereto by a hinge or bend portion 140 in an integral one-piece clip construction. Jaw 100 generally tapers from the bend 140 to a narrow end having a single tooth or prong 160. Conversely jaw 120 flares from bend 140 and is provided with a pair of spaced-apart teeth or prongs, 150. As shown, teeth 150 straddle tooth 160. The edges of jaw 190 are provided with flanges 110 which serve to stiffen the jaw. A concavo-convex dimple or depression 150 in either or both jaws provides for engagement of the jaw 100 by means of a speculum of conventional design. Likewise jaw 120 has flanges 130 for the same purpose. It is desirable that the opposed or tissue-contacting faces of jaws 100 and 120 be smooth and substantially planar with the respective flanges curved smoothly therefrom. As shown in FIGURE 6 the bend of gullet 140 desirably has a uniform cross section which is unflanged and is readily bent from whatever may be its initial form in order to close the jaws together in a gripping action.

Following the stapping and shaping of the clips of FIGURES 5 and 6 from a relatively non-elastic aluminum alloy or other metal alloy comprised of metals relatively active in the electromotive series, the one-piece clips are subjected to an electro-plating operation in which they are fully coated with a metal which is relatively low in the electromotive series, preferably one of the noble metals, silver or platinum. Subsequently the plating is interrupted as at point 200 and/or 210 at some point along the portion of the clip interconnecting or transmitting force between the jaws when the clamp is engaged. This interruption in the electro-plating exposes the underlying base metal to electro-chemical attack by the ionizable body fluids according to the galvanic couple principle previously described. Such an interruption of the coating may be accomplished by any of different techniques such as grinding, filing, scratching or by applying, before plating, a mask over the surface area to remain uncoated and removing the mask after the electro-plating operation. Alternatively, perforations may be made through the coating to expose the base metal on either or both surfaces of bend 140. To further control the ratio of active to passive area a hole of selected diameter can be drilled at the center of bend 140 before plating. Depending on the diameter of the hole the active or anodic area can be varied considerably as well as the total cross-section to be corroded to the point of structural failure.

Various materials may be used for the clip body (or for the rivet or other connection in the alternative embodiments). However, as previously stated, aluminum alloys which have been specially heat treated to promote intergranular corrosion are of particular value for the purpose because of their initial strength coupled with their rapid corrosion rate in a galvanic couple. Examples of suitable aluminum alloys for this purpose are the following:

<table>
<thead>
<tr>
<th>Commercial Designation</th>
<th>Composition (Alloying Ingredients)</th>
<th>Intermetallic Compound</th>
</tr>
</thead>
<tbody>
<tr>
<td>2094</td>
<td>4.5 Cu, 1.3 Mg, 0.6 Mn, 0.1 Cr</td>
<td>Al-Cu-Mg</td>
</tr>
<tr>
<td>2190</td>
<td>0.6 Cu, 0.3 Mn, 0.1 Cr, 0.15 Y</td>
<td>Al-Cu-Mn</td>
</tr>
<tr>
<td>3005</td>
<td>0.6 Mg, 0.1 Mn, 0.1 Cr, 0.15 Y</td>
<td>Al-Mg</td>
</tr>
<tr>
<td>6000</td>
<td>1.0 Fe, 0.6 Si, 0.25 Cu, 0.25 Cr</td>
<td>Mg-Si</td>
</tr>
<tr>
<td>7005</td>
<td>0.5 Cu, 2.5 Mn, 1.5 Cr, 0.5 Cr</td>
<td>Mg-Zn</td>
</tr>
</tbody>
</table>

To achieve the objectives aluminum alloy clip bodies should be made from annealed material. To meet the requirements of electrolytic disintegration in a relatively short period of time at the bend site, within the material through which the disintegration can proceed. After forming, the annealed 2024, 2219, 6061 or 7075 alloys can be heat treated and cooled in such a manner as to have their respective intermetallic compounds precipitated at the grain boundaries. The 5056 alloy in the annealed condition has no intermetallic compounds in solid solution; however, it can be caused to precipitate at the grain boundaries if strain hardened to a degree and artificially aged.
2. The surgical clip defined in claim 1, wherein the tissue-contacting jaws have a surface exposable to body fluids composed of a metallic substance which is relatively low in the electromotive series and wherein the connecting portion is made of a material which is relatively low in the electromotive series and cooperates with such jaw substance in a galvanic couple accelerating dissolution of said connecting means metal.

3. The surgical clip defined in claim 2, wherein the jaws and the connecting portion are made of an integral one-piece construction of the aforesaid connecting means metal and wherein the jaws are protectively coated with the metal which is relatively low in the electromotive series.

4. A self-releasing surgical clip retainable in the body post-operatively comprising tissue-engaging elements of predetermined form and having tissue-contacting surfaces thereof of a material which is relatively passive in body fluids, said elements being structurally interconnected by means adapted to maintain the force applied to the jaws for compressing body tissue between them, said interconnecting means including a metallic material adapted for transmitting such force and adapted when applied in the body for electro-chemical dissolution in body fluids over a period of time, said clip also comprising a metal surface area of metal lower in the electromotive series than said interconnecting means metal and reactive with the latter in body fluids by the galvanic couple effect.

5. A self-releasing surgical wound clip adapted to be left in situ within the body and adapted for applying pressure to body tissues comprising physically compatible and electrically interconnected clip portions respectively comprising galvanically dissimilar metals exposable to body fluids upon installation of the clip, one such portion comprising the most active metal being adapted after predetermined dissolution and weakening thereof in body fluids to diminish the clip pressure.

6. A self-releasing surgical pressure applicator adapted for retention within the body post-operatively and operable under the attack of body fluids to release such pressure after a predetermined time, said applicator comprising tissue-contacting portions having surface areas comprising a metal relatively low in the electromotive series, and a means interconnecting said portions for transmitting force therebetween and including therein a region exposable to body fluids upon installation of the clip, comprising a metal relatively high in the electromotive series and erosion of which occurs by the galvanic couple effect to diminish the structural cross-section thereof.

7. A hemostatic clip comprising a U-shaped metallic body providing an integral pair of opposed toothed jaws adapted to engage and grip tissues, said body being formed of a metal which is relatively high in the electromotive series and being coated with a metal which is relatively low in the electromotive series, except for a restricted area of said body adjacent the bend of the U thereof which is uncoated so as to expose the underlying body material to body fluids with the clip installed.

8. The hemostatic clip defined in claim 7 in which the U-shaped metallic body is formed of a metal selected from the group consisting of aluminum alloys heat treated to induce intergranular corrosion and wherein the coating metal is selected from the group consisting of the noble metals.

9. A surgical clip comprising a pair of tissue-engaging closeable jaw members having means joining said jaw members formed of a substance exposable to body fluids by installation of the clip and subject to structural deterioration when subjected to such body fluids, at least certain surface areas of said tissue-engaging jaw members being formed of a substance which is relatively inert to such fluids.
10. The clip defined in claim 9 wherein the means joining the jaw member comprises a separate element physically interconnecting the same and subjected to stress by and during pressure of the jaw members against body tissues.

11. A surgical clip comprising a pair of tissue-engaging closeable jaw members formed of a noble metal, and means joining said jaw members formed of a metallic substance less noble than said noble metal and cooperating therewith when exposed to body fluids to form a galvanic couple producing electro-chemical depletion of said joining means.