

APPARATUS AND METHOD FOR FORMING BARBED SUTURES

TECHNICAL FIELD

[0001] This invention relates to an apparatus and method for forming barbed sutures.

BACKGROUND

[0002] A barbed suture is a suture having protruding barbs along its length. Barbed sutures have been used to close wounds and, more recently, to effect tissue lifts in medical aesthetics procedures that are rapidly gaining in popularity world-wide. Currently, a barbed suture is fabricated by making small cuts into lengths of provided sutures to form the barbs. However, it is difficult to make the small cuts accurately due to the small diameters of the sutures. Furthermore, cutting into the sutures weakens the sutures which can result in suture breakage during use. There is thus a need for a method and apparatus for forming barbed sutures in a cost and time effective way that produces robust sutures having uniformly formed barbs thereon, in order to meet the demand for barbed sutures in the medical aesthetics industry as well as for other medical uses.

SUMMARY

[0003] This application discloses an apparatus and method for forming barbed suture by compression moulding lengths of suture in one or more mould cavities.

[0004] According to a first aspect, there is provided an apparatus for forming barbed sutures, wherein a barbed suture comprises a string-like core and a plurality of barbs disposed at intervals apart along the core, the apparatus comprising: a mould comprising at least one set of mould inserts, wherein some of the mould inserts are provided on a first part of the mould, and others of the mould inserts are provided on a second part of the mould, wherein the second part of the mould is moveable relative to the first part of the mould between an open position and a close position, wherein each mould insert has at least one shaped longitudinal edge that partially defines a profile of the barbed suture such that one shaped longitudinal edge

of each of all the mould inserts in one set of mould inserts together define a mould cavity for forming one barbed suture therein when the mould is in the close position; wherein the mould cavity comprises a core-shaped cavity configured to form the core of the barbed suture therein and a plurality of barb-shaped cavities configured to form the barbs of the barbed suture therein, wherein the core-shaped cavity is defined by all the mould inserts in each set of mould inserts together and wherein each barb-shaped cavity is defined by two adjacent mould inserts in each set of mould inserts when the mould is in the close position; a suture cartridge configured to present at least one length of suture for moulding in the mould cavity to form the barbed suture therefrom; and heating elements provided to heat the mould inserts during compression moulding of the length of suture in the mould cavity.

[0005] Each set of mould inserts may comprise: a first mould insert and a second mould insert provided in contact with each other on a first part of the mould, and a third mould insert and a fourth mould insert provided in contact with each other on a second part of the mould, wherein one shaped longitudinal edge of each of the first, second, third and fourth mould inserts together define a mould cavity for forming one barbed suture when the mould is in the close position.

[0006] The plurality of barb-shaped cavities defined by each set of mould inserts may be defined by at least one pair of adjacent mould inserts when the mould is in the close position, wherein the at least one pair of adjacent mould inserts is selected from the group consisting of: the first and second mould inserts, the third and fourth mould inserts, the first and third mould inserts, and the second and fourth mould inserts; such that the apparatus forms a barbed suture comprising at least one line of barbs disposed at intervals apart along the core.

[0007] The plurality of barb-shaped cavities defined by each set of mould inserts may be defined by four pairs of adjacent mould inserts when the mould is in the close position, the four pairs of mould inserts comprising: the first and second mould inserts, the third and fourth mould inserts, the first and third mould inserts, and the second and fourth mould inserts; such that the apparatus forms a barbed suture comprising four lines of barbs disposed at intervals apart along the core wherein

adjacent lines of barbs are rotationally spaced apart from each other by 90° about a central longitudinal axis of the barbed suture.

[0008] The first part of the mould may be provided with a first row of multiple mould inserts and the second part of the mould may be provided with a second row of multiple mould inserts, wherein the first and second rows of multiple mould inserts together form a plurality of sets of mould inserts for forming a corresponding plurality of barbed sutures, wherein one set of mould inserts comprises a pair of adjacent mould inserts in the first row and a corresponding pair of adjacent mould inserts in the second row.

[0009] Each intermediate mould insert in the first and second rows of mould inserts may have two shaped longitudinal edges.

[0010] The first row may comprise at least five lower mould inserts and the second row may comprise at least five upper mould inserts, wherein the first and fifth lower and upper mould inserts each has only one shaped longitudinal edge, wherein the second, third and fourth lower and upper mould inserts each has two shaped longitudinal edges, wherein the first and second lower and upper mould inserts together form a first set of mould inserts for forming a first barbed suture, wherein the second and third lower and upper mould inserts together form a second set of mould inserts for forming a second barbed suture, wherein the third and fourth lower and upper mould inserts together form a third set of mould inserts for forming a third barbed suture, and wherein the fourth and fifth lower and upper mould inserts together form a fourth set of mould inserts for forming a fourth barbed suture.

[0011] Each mould insert may have a generally rectangular cross-section and the at least one shaped longitudinal edge is provided along one corner of the rectangular cross-section.

[0012] The two shaped longitudinal edges may be provided along adjacent corners of the rectangular cross-section.

[0013] The mould insert may have a cooling channel provided therein for passing a cooling fluid therethrough to cool the mould insert and thereby cool the barbed suture formed in the mould cavity after a moulding operation.

[0014] The first and second parts of the mould may each comprise a first heater backing plate and a second heater backing plate respectively, wherein at least one of the heating elements is provided in a channel provided in the first heater backing plate and in contact with the mould inserts provided on the first part of the mould, and wherein at least another one of the heating elements is provided in a channel provided in the second heater backing plate and in contact with the mould inserts provided on the second part of the mould.

[0015] According to a second aspect, there is provided a method of forming barbed sutures, wherein a barbed suture comprises a string-like core and a plurality of barbs disposed at intervals apart along the core, the method comprising the steps of:

- a)** providing a length of suture in alignment with a first partial mould cavity, the first partial mould cavity defined by one shaped longitudinal edge of a first mould insert and one shaped longitudinal edge of a second mould insert, wherein the first and second mould inserts are adjacent on a first part of a mould;
- b)** heating the length of suture;
- c)** moving a second partial mould cavity onto the length of suture, the second partial mould cavity defined by one shaped longitudinal edge of a third mould insert and one shaped longitudinal edge of a fourth mould insert, wherein the third and fourth mould inserts are adjacent on a second part of the mould;
- d)** closing the mould and compression moulding the length of suture in a mould cavity defined by the first partial mould cavity and the second partial mould cavity for a predetermined period of time, thereby filling a plurality of barb-shaped cavities provided in the mould cavity with a material of the length of suture, wherein the first, second, third and fourth mould inserts together form one set of

mould inserts that define the mould cavity, wherein each barbed-shaped cavity is defined by two adjacent mould inserts in the set of mould inserts.

[0016] Heating the length of suture may continue to occur during step c).

[0017] Heating the length of suture may continue to occur during step d).

[0018] Heating the length of suture may comprise heating the four mould inserts using heating elements provided in each of the four mould inserts such that heat from the heated four mould inserts is transferred to the length of suture by at least one of: radiation, convection and conduction.

[0019] The method may further comprise cooling the compression moulded length of suture in the mould cavity to form the barbed suture therein.

[0020] The cooling may comprise passing a cooling fluid through a cooling channel provided in each of the four mould inserts.

[0021] In step a), the length of suture may be not in contact with the first part of the mould cavity.

[0022] The method may be performed using the apparatus of the first aspect.

BRIEF DESCRIPTION OF DRAWINGS

[0023] In order that the invention may be fully understood and readily put into practical effect there shall now be described by way of non-limitative example only exemplary embodiments of the present invention, the description being with reference to the accompanying illustrative drawings, in which:

Fig. 1 is a perspective view of a first exemplary embodiment of an apparatus for forming barbed sutures in a close position.

Fig. 2 is a perspective view of a suture cartridge of the apparatus of Fig. 1.

Fig. 3 is a perspective exploded assembly view of the suture cartridge of Fig. 2.

Fig. 4 is a top plan view of the suture cartridge of Fig. 2 with a suture wound thereon prior to clamping the suture on the suture cartridge.

Fig. 5 is a perspective view of a part of an exemplary barbed suture formed by the apparatus of Fig. 1.

Fig. 6 is a perspective view of an exemplary embodiment of one set of mould inserts for forming one barbed suture.

Fig. 7 is a schematic exaggerated close-up view of the mould inserts of Fig. 6 forming a mould cavity.

Fig. 8a is a perspective view of a shaped longitudinal edge of a first mould insert of the set of mould inserts of Fig. 6.

Fig. 8b is a close-up view of the shaped longitudinal edge of Fig. 8a.

Fig. 9a is a perspective view of two adjacent mould inserts together defining a plurality of barb-shaped cavities.

Fig. 9b is a close-up view of the adjacent mould inserts of Fig. 9a.

Figs. 10a-10d are end views of various embodiments of barbed sutures that can be formed by the apparatus of Fig. 1.

Fig. 11 shows perspective views of various embodiments of barbed sutures each having various lines of barbs disposed at intervals apart along a string-like core of each barbed suture.

Fig. 12 is a perspective view of a mould of the apparatus of Fig. 1 comprising two rows of mould inserts.

Fig. 13 is a schematic illustration of the two rows of mould inserts making up four sets of mould inserts for forming four barbed sutures in one moulding operation.

Fig. 14 is a perspective view of an intermediate mould section having two shaped longitudinal edges.

Fig. 15 is a perspective view of a row of five mould sections partially defining four mould cavities.

Fig. 16 is a perspective exploded assembly view of a row of mould sections.

Fig. 17 is a top view of an intermediate mould section.

Fig. 18 is a longitudinal cross-sectional view of the intermediate mould section of Fig. 17.

Fig. 19 is a perspective exploded assembly view of a mould of the apparatus of Fig. 1.

Fig. 20 is a perspective view of the mould of Fig. 19 in an open position.

Fig. 21 is a perspective view of the apparatus of Fig. 1 in an open position with the suture cartridge positioned on the mould.

Fig. 22 is a flowchart of an exemplary embodiment of a method of forming a barbed suture.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0024] Throughout this document, unless otherwise indicated to the contrary, the terms “comprising”, “consisting of”, “having” and the like, are to be construed as non-exhaustive, or in other words, as meaning “including, but not limited to.”

[0025] Furthermore, throughout the specification, unless the context requires otherwise, the word “include” or variations such as “includes” or “including” will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

[0026] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by a skilled person to which the subject matter herein belongs.

[0027] Exemplary embodiments of an apparatus 10 and a method (200) for forming barbed sutures 60 will be described below with reference to Fig. 1 to Fig. 22, wherein the same reference numerals are used to refer to the same or similar parts.

[0028] As shown in Fig. 1, in a first exemplary embodiment of the apparatus 10, the apparatus 10 comprises a mould 100 having a core baseplate or first part 16, and a cavity baseplate or second part 11. The second part 11 is moveable relative to the first part 16 to close the mould 100. The mould 100 also comprises at least one set 90 of mould inserts wherein some of the mould inserts 30 are provided on the first part 11 of the mould 100 and others of the mould inserts 20 are provided on the second part 11 of the mould 100. The mould inserts 30, 20 will be described in greater detail below. The apparatus 10 further comprises a removable suture cartridge 40 configured for mounting therein a suture 44 for forming barbed sutures 60 therefrom. To align the suture cartridge 40 on the mould 100, the apparatus 10 may be provided with a plurality of guide pins 15. The guide pins 15 may comprise upright projections provided on the core baseplate or first part 16 of the mould 100 to define a working position of the suture cartridge 40 in the mould 100.

[0029] As shown in Figs. 2-4, in an exemplary embodiment, the suture cartridge 40 comprises two opposing end bars 141, 142 and two opposing side bars 143, 144 that are connected to form a generally rectangular suture frame 45 defining a space therewithin. In an exemplary embodiment, a row of dowel pins 700 are provided on and project perpendicularly from the plane of the frame 45 from each of the end bars 141, 142 respectively. The dowel pins 700 are configured for mounting the suture 44 between and parallel to the two side bars 143, 144, such that by winding a suture 44 in a zig-zag manner from one end bar 141 to the other end bar 142 about the dowel pins 700, as shown in Fig. 3, a plurality of lengths of suture 49 are presented in the space within the suture frame 45. To secure a first end of the suture 44 prior to winding it about the dowel pins 700, a knot 48 may be tied at the first end of the suture 44. In this way, the suture 44 may be passed between two adjacent dowel

pins 701, 702 while the knot 48 is prevented from passing between the two adjacent dowel pins 701, 702, thereby anchoring the first end of the suture 44 at the two adjacent dowel pins 701, 702 as shown in Fig. 4.

[0030] A clamping beam 41, 42 is preferably provided at each of the end bars 141, 142 respectively for securing the mounted suture 44 to the suture frame 45. Each clamping beam 41, 42 is configured to be releasably securable to its corresponding bar 141, 142, by known means, for example using screws. Each clamping beam 41, 42 is preferably provided with a plurality of holes 47 that fit over the dowel pins 700. When the clamping beams 41, 42 have been secured to the end bars 141, 142, end loops of suture 44 around the dowel pins 700 become clamped between the clamping beams 41, 42 and the end bars 141, 142, thereby securing the lengths of suture 49 to the suture cartridge 40, as shown in Fig. 2.

[0031] The apparatus 10 forms a barbed suture 60 from each length of suture 49 in the suture cartridge 40 by compression moulding. An exemplary embodiment of a barbed suture 60 formed by the apparatus 10 is shown in Fig. 5. The barbed suture 60 comprises a string-like core 61 and a plurality of barbs 62 disposed at intervals apart along the core 61 and has a central longitudinal axis L. Preferably, the barbed suture 60 is made of a biodegradable polymeric material that dissolves in human tissue over time.

[0032] To form the barbed suture 60, for each length of suture 49, a mould cavity 69 is comprised in the mould 100 when the mould 100 is in the close position such that one length of suture 49 is compression moulded in one mould cavity 69. Appreciably, the mould 100 may comprise one or more mould cavities 90 to form one or more barbed sutures 60 in each moulding operation.

[0033] Each mould cavity 69 in the mould 100 is defined by one set 90 of mould inserts when the mould 100 is in the close position, wherein some of the mould inserts 30 are provided on the first part 16 of the mould 100 and others of the mould inserts 20 are provided on a second part 11 of the mould 100, as will be described in greater detail below. For example, in a first exemplary embodiment of one set 90 of mould inserts as shown in Figs. 6 and 7, one set 90 of mould inserts may comprise four mould inserts 91-94, i.e., a first mould insert 91, a second mould insert 92, a third

mould insert 93, and a fourth mould insert 94 that together define the mould cavity 69. In the first exemplary embodiment, the first and second mould inserts 91, 92 may be provided on the first part 16 of the mould 100 while the third and fourth mould inserts 93, 94 may be provided on the second part 11 of the mould 100. The first part 16 of the mould 100 may be provided below the second part 11 of the mould 100. In other embodiments (not shown), one set of mould inserts may comprise three mould inserts, or five mould inserts. Each mould insert may be made of steel, for example.

[0034] For all embodiments, each mould insert 91, 92, 93, 94 in one set 90 of mould inserts has at least one shaped longitudinal edge E that partially defines a profile of the barbed suture 60 to be formed. In an exemplary embodiment, each mould insert 91, 92, 93, 94 has a generally rectangular cross-section wherein each shaped longitudinal edge E is along one corner of the rectangular cross-section. For example, Figs. 8a and 8b each depicts the shaped longitudinal edge E of the first mould insert 91 of the exemplary set 90 of mould inserts shown in Fig. 6. Notably, one shaped longitudinal edge of each of all the mould inserts 91E, 92E, 93E, 94E in one set 90 of mould inserts together define the mould cavity 69.

[0035] The mould cavity 69 comprises a core-shaped cavity 691 (as can be seen in Fig. 7) configured to form the core 61 of the barbed suture 60 therein and a plurality of barb-shaped cavities 692 configured to form the barbs 62 of the barbed suture 60 therein. In particular, for all embodiments, the core-shaped cavity 691 is defined by all the mould inserts 91, 92, 93, 94 together in each set 90 of mould inserts when the mould 100 is in the close position. Each barb-shaped cavity 692 is defined by a pair of adjacent mould inserts in each set 90 of mould inserts when the mould 100 is in the close position. For example, Figs. 9a and 9b each depict the adjacent first and second mould inserts 91, 92 together defining a plurality of barbed-shaped cavities 692, and partially defining the core-shaped cavity 691. In this way, where one set 90 of mould inserts comprises four mould inserts, each pair of adjacent mould inserts defines half the profile of the barbed suture 60 to be formed, and one longitudinal edge E of each mould insert defines a quarter of the profile of the barbed suture 60 to be formed.

[0036] Notably, in the first exemplary embodiment where one set 90 of mould inserts comprises four mould inserts 91, 92, 93, 94, the pair of adjacent mould inserts in each set 90 of mould inserts that define barb-shaped cavities 692 when the mould 100 is in the close position may be at least one pair of adjacent mould inserts selected from the group consisting of: the first and second mould inserts 91, 92; the third and fourth mould inserts 93, 94; the first and third mould inserts 91, 93; and the second and fourth mould inserts 92, 94. Depending on which of the above mentioned pairs of adjacent mould inserts are configured to define barb-shaped cavities 692, the resulting barbed suture 60 formed by the set 90 of mould inserts may have one to four lines of barbs 62 disposed at intervals along the core 61 of the barbed suture 60, as will be described below with reference to Figs. 10a to 10d.

[0037] Fig. 10a shows an end view of a barbed suture 60 that is formed when only the third and fourth mould inserts 93, 94 define the plurality of barbed cavities 692. The barbed suture 60 in Fig. 10a thus has only one line of barbs 62 disposed at intervals apart along the core 61.

[0038] Fig. 10b shows an end view of a barbed suture 60 that is formed when the first and third mould inserts 91, 93 define a first plurality of barbed cavities 692; and the second and fourth mould inserts 92, 94 define a second plurality of barbed cavities 692. The barbed suture 60 in Fig. 10b thus has two lines of barbs 62 disposed at intervals apart along the core 61. In this exemplary embodiment, the two lines of barbs 62 are rotationally spaced apart from each other by 180° about the central longitudinal axis L of the barbed suture 60. In other embodiments, the two lines of barbs 62 may be rotationally spaced apart from each other by 90° about the central longitudinal axis L of the barbed suture 60 by configuring the third and fourth mould inserts 93, 94 to define the second plurality of barbed cavities 692 instead.

[0039] Fig. 10c shows an end view of a barbed suture 60 that is formed when the first and third mould inserts 91, 93 define a first plurality of barbed cavities 692, the second and fourth mould inserts 92, 94 define a second plurality of barbed cavities 692, and the third and fourth mould inserts 93, 94 define a third plurality of barbed cavities 692. The barbed suture 60 in Fig. 10a thus has three lines of barbs 62 disposed at intervals apart along the core 61.

[0040] Fig. 10d shows an end view of a barbed suture 60 that is formed when the first and third mould inserts 91, 93 define a first plurality of barbed cavities 692, the second and fourth mould inserts 92, 94 define a second plurality of barbed cavities 692, the third and fourth mould inserts 93, 94 define a third plurality of barbed cavities 692, and the second and fourth mould inserts 92, 94 define a fourth plurality of barbed cavities 692. The barbed suture 60 shown in Fig. 10d thus has four lines of barbs 62 disposed at intervals apart along the core 61, where adjacent lines of barbs 62 may be rotationally spaced apart from each other by 90° about the central longitudinal axis L of the barbed suture 60. Various embodiments of the barbed suture 60 that may be formed using the presently disclosed apparatus 10 are shown in Fig. 11, wherein each barbed suture 60 may have two, three or four lines of barbs disposed along the core 61 in various configurations of interval spacings between adjacent barbs 62 along a line of barbs 62, depending on the configuration of the shaped longitudinal edges E of the mould inserts 91-94 used to form them.

[0041] In an exemplary embodiment, the apparatus 10 may be configured to form multiple barbed sutures 60 in each moulding operation. Accordingly, the apparatus 10 may comprise multiple sets 90 of mould inserts wherein one barbed suture 60 is compression moulded by one set 90 of mould inserts. The multiple sets 90 of mould inserts may be provided as a first row 30 of mould inserts on the first part 16 of the mould 100 and a second row 20 of mould inserts on the second part 11 of the mould 100, as can be seen in Figs. 1 and 12. In this configuration, one set 90 of mould inserts would comprise a pair of adjacent mould inserts provided in the first row 30 and a corresponding pair of adjacent mould inserts provided in the second row 20. This will be explained in greater detail below with reference to Figs. 12 and 13.

[0042] As shown in Figs. 12 and 13, in a first exemplary embodiment, the apparatus 10 comprises four sets 90-1 to 90-4 of mould inserts. The four sets 90-1 to 90-4 of mould inserts are made up of a first row 30 of five lower mould inserts 31, 32, 33, 34, 35 provided on the first part 16 of the mould, and a second row 20 of five upper mould inserts 21, 22, 23, 24, 25 provided on the second part 11 of the mould 100.

[0043] As mentioned above, one set 90 of mould inserts comprises a pair of adjacent mould inserts provided in the first row of mould inserts 30 and a corresponding pair of adjacent mould inserts provided in the second row of mould inserts 20. Thus, as illustrated in Fig. 13, the pair of adjacent first and second lower mould inserts 31, 32 in the first row 30 and the corresponding pair of adjacent first and second lower mould inserts 21, 22 in the second row together form a first set 90-1 of mould inserts. The pair of adjacent second and third lower mould inserts 32, 33 in the first row 30 and the corresponding pair of second and third adjacent upper mould inserts 22, 23 in the second row together form a second set 90-2 of mould inserts. The pair of adjacent third and fourth lower mould inserts 33, 34 in the first row 30 and the corresponding pair of adjacent third and fourth upper mould inserts 23, 24 in the second row together form a third set 90-3 of mould inserts. The pair of adjacent fourth and fifth lower mould inserts 34, 35 in the first row 30 and the corresponding pair of adjacent fourth and fifth upper mould inserts 24, 25 in the second row together form a fourth set 90-4 of mould inserts. In this way, five mould inserts 31-35, 21-25 in each row 30, 20 of mould inserts together make up four sets 90-1 to 90-4 of mould inserts.

[0044] Relating the two rows of mould inserts 20, 30 shown in Fig. 13 with the set 90 of mould inserts shown in Figs. 6 and 7, it can be appreciated that the first and second lower mould inserts 31, 32 of the first row of mould inserts 30 and the first and second upper mould inserts 21, 24 of the second row of mould inserts 20 respectively form the first, second, third and fourth mould inserts 91, 92, 93, 94 of the first set 90-1 of mould inserts. Similarly, the second and third lower mould inserts 32, 33 of the first row of mould inserts 30 and the second and third upper mould inserts 22, 23 of the second row of mould inserts respectively form the first, second, third and fourth mould inserts 91, 92, 93, 94 of the second set 90-2 of mould inserts, and so on for the third 90-3 and fourth 90-3 sets of mould inserts.

[0045] In order for the two rows of mould inserts 20, 30 to make up multiple sets 90 of mould inserts for forming multiple barbed sutures 60, each intermediate mould insert 32-34, 22-24 in each row 30, 20 of mould inserts is provided with two shaped longitudinal edges E1, E2 as can be seen in Fig. 14. An intermediate mould insert 32-34, 22-24 is any mould insert that is located between two other mould inserts in a

same row of mould inserts. In embodiments where each mould insert has a generally rectangular cross-section, the two shaped longitudinal edges E1, E2 of each intermediate mould insert 32-34, 22-24 are provided along adjacent corners of the rectangular cross-section as shown in Fig. 14.

[0046] In Fig. 15 that shows the first row of mould inserts 30, it can be seen that one row 30 of five mould inserts 31-35 partially defines four mould cavities 90. It can also be said that one row 30 of five mould inserts 31-35 defines four partial mould cavities 95, wherein each partial mould cavity 95 is defined by a pair of adjacent mould inserts. Although not depicted, the second row of mould inserts 20 may be similarly configured. Fig. 16 that shows an exploded assembly view of the second row of mould inserts 20 depicts how multiple mould inserts 21-25 may be assembled together to form one row of mould inserts 20. In the exemplary embodiment, the multiple mould inserts 21-25 may be aligned by means of one or more guide pins 27 that pass through alignment holes 28 provided in each of the mould inserts 21-25, and secured by one or more screws 26 that pass through all the mould inserts 21-25 in the row of mould inserts 20. Although not depicted, the first row of mould inserts 30 may be configured to be similarly assembled.

[0047] Fig. 18 shows a longitudinal cross-section of an intermediate mould section 22-24, 32-24 as taken along the plane A-A shown in Fig. 17. As can be seen, each intermediate mould section 22-24, 32-24 comprises alignment holes 28 and screw holes 29 for aligning and securing the mould sections together to form a row of mould sections 20. Although not depicted, end mould sections 21, 25, 31, 35 may be similarly provided with alignment holes 28 and screw holes 29.

[0048] Appreciably, the apparatus 10 is not confined to comprising only five mould inserts 21-25, 31-35 in each row 20, 30 of mould inserts. The apparatus 10 may minimally comprise two mould inserts in each row of mould inserts, or any desired number of multiple mould inserts in each row of mould inserts, e.g. six or more mould inserts per row. In exemplary embodiments where each mould insert has a generally rectangular cross-section, the number of mould inserts in each row of mould inserts is one more than the number of barbed sutures 60 that are simultaneously formed in one moulding operation.

[0049] To facilitate the compression moulding of each length of suture 49 in a mould cavity 69, the apparatus 10 is configured to heat the length of suture 49 during each moulding operation. To that end, the apparatus 10 is provided with heating elements 13 to heat the mould inserts 30, 20 during the moulding operation. In the exemplary embodiment shown in Fig. 19, the heating elements 13 may each comprise a flexible tubular heater that comprises wiring covered with a Teflon® shrink tube, a layer of fiberglass insulation tubing and Teflon® coated wiring with pure nickel lugs (not shown). The first 16 and second 11 parts of the mould 100 may each be provided with a first and a second heater backing plate 12-1, 12-2 respectively. The first heater backing plate 12-1 is provided between the first part 16 of the mould 100 and the mould inserts 30 on the first part 16 of the mould 100. The second heater backing plate 12-2 is provided between the second part 11 of the mould 100 and the mould inserts 20 on the second part 11 of the mould 100. The heater backing plates 12-1, 12-2 may each be provided with a channel 17 in which a heating element 13 is located such that the heating element 13 is in contact with the mould inserts 30, 20 when the mould insert 30, 20 are assembled with their respective heater backing plates 12-1, 12-2. In this way, the heating elements 13 can heat the mould inserts 30, 20 and consequently heat the lengths of suture 49 during the moulding operation. For each part 16, 11 of the mould 100, the mould inserts 30, 20 and the heater backing plate 12-1, 12-2 (with heater elements 13 provided therebetween) may be attached to the respective part 16, 11 of the mould 100 by means of screws (not shown) that pass through the mould inserts 30, 20 and the heater backing plate 12-1, 12-2 into the respective part 16, 11 of the mould 100. In the apparatus 10, the first part 16 of the mould 100 with the first row of mould inserts 30 and first heater backing plate 12-1 and heater element 13 assembled thereon may be considered a core sub-assembly or first mould assembly 110, while the second part 11 of the mould 100 with the second row of mould inserts 20 and second heater backing plate 12-2 and heater element 13 assembled thereon may be considered a cavity sub-assembly or second mould assembly 120, as shown in Figs. 19 and 20.

[0050] To complete the moulding operation, barbed sutures 60 that have been compression moulded in the apparatus 10 are preferably cooled before being released from the mould 100. To that end, each mould insert may be provided with a cooling channel 70 as shown in Fig. 18 in which a cooling fluid (such as an air jet)

may be passed therethrough in order to cool the mould insert so that the moulded barbed suture 60 is also cooled to retain its compression moulded shape that comprises barbs 62 on the core 61 of the suture 60.

[0051] To properly align the mould inserts 30, 20 that are separately provided on the two parts 16, 11 of the mould 100 in order to form the requisite mould cavities 69 when the mould 100 is in the close position, in an exemplary embodiment, main guide pins 14 may be provided that pass through corresponding end mould inserts 31, 35, 21, 35 of the respective rows of mould inserts 30, 20 when the mould 100 is closed, as can be seen in Fig.19.

[0052] In use, the first and second mould assemblies 110, 120 may be provided on a pneumatic press (not shown) that allows the mould assemblies 110, 120 to be moved relative to each other to open and close the mould 100 over the lengths of suture 49 on the suture cartridge 40, in order to form the barbed sutures 60 by compression moulding of the lengths of suture 49 in the mould 100.

[0053] In an exemplary embodiment of a method (200) of forming a barbed suture 60, referring to Figs. 21 and 22, the method 200 begins with providing the length of suture 49 in alignment with a first partial mould cavity 95 that is defined by a pair of adjacent mould inserts on the first part 16 of the mould 100 (210). Using the exemplary embodiment of the apparatus 10 described above with reference to Figs. 1-21, this comprises placing the suture cartridge 40 on the first part 16 of the mould 100 as shown in Fig. 22. On the suture cartridge 40, a suture 44 has been wound to present a plurality of lengths 49 of suture for compressing moulding by the mould inserts 30, 20. The suture cartridge 40 is aligned on the first part 16 of the mould 100 by the guide pins 15 such that each length of suture 49 is suspended above a partial mould cavity 95 formed by a pair of adjacent mould inserts in the first row of mould inserts 30.

[0054] The lengths of suture 49 on the suture cartridge 40 are then heated (220). Heating the lengths of suture 49 increases their malleability for better shape conformance during subsequent compression moulding or thermoforming. This may be achieved by heating the mould inserts 30 via the heating elements 13 provided in the first heater backing plate 12-1 to a temperature of 92°C, for example, so that the

lengths of suture 49 are heated by heat emanating from the first row of mould inserts 30 without the lengths of suture 49 being in contact with the first row of mould inserts 30. The lengths of suture 49 may additionally be heated by heat emanating from the second row of mould inserts 20 as the second mould assembly 120 is moved towards the first mould assembly 110 while the heater element 13 in the second heater backing plate 12-2 heats the second row of mould inserts 20, also without the lengths of suture 49 being in contact with the second row of mould inserts 20. At this point, the lengths of suture 49 may be about 150 microns away from each of the two rows of heated mould inserts 30, 20, for example, although other distances may be envisaged depending on the heating temperature and specific material of the lengths of suture 49.

[0055] After heating the length of suture 49, the next step (230) comprises moving a second partial mould cavity 95 onto the length of suture 49. The second partial mould cavity 95 is defined by a corresponding pair of adjacent mould inserts on the second part 11 of the mould 100, and is a partial mould cavity 95 formed by the corresponding pair of adjacent mould inserts in the second row of mould inserts 20. Using the exemplary embodiment of the apparatus 10 described above with reference to Figs. 1-21, this step (230) comprises moving the second mould assembly 120 towards the first mould assembly 110 until the second row of mould inserts 20 comes into contact with the lengths of suture 49 on the suture cartridge 40.

[0056] The subsequent step (240) comprises closing the mould 100 and compression moulding the length of suture 49 in the mould cavity 69 defined by the first and second partial mould cavities 95 for a predetermined period of time (e.g. 15 seconds). This may be achieved by keeping the pair of adjacent mould inserts on the first row of mould inserts 30 in contact with the corresponding pair of adjacent mould inserts on the second row of mould inserts 20 for the predetermined period of time. In this step (240), the plurality of barbed shaped cavities 692 in the mould cavity 69 are filled with a material of the length of suture 49. As described above, the pair of adjacent mould inserts on the first row of mould inserts 30 and the corresponding pair of adjacent mould inserts on the second row of mould inserts 20 together form a set 90 of mould inserts that define the mould cavity 69. Each barbed-shaped 692

cavity is defined by two adjacent mould inserts in the set 90 of mould inserts. During the compression moulding (240), the mould inserts may optionally continue to be heated.

[0057] Using the exemplary embodiment of the apparatus 10 described above with reference to Figs. 1-21, the compression moulding step (240) forms four barbed sutures 60 as the four lengths of sutures 49 are enclosed in the four mould cavities 69 formed by the four sets 90 of mould inserts that are made up of the first and second rows 30, 20 of five mould inserts each, as described above.

[0058] Subsequently, the compression moulded length of suture 49 in the mould cavity may be cooled. Using the exemplary embodiment of the apparatus 10 described above with reference to Figs. 1-21, this may be achieved by jetting air into the cooling channels 70 of the mould inserts to harden the moulded barbed sutures 60 in the mould cavities 69. In an exemplary embodiment, passing air into the cooling channels 70 may lower the temperature of the mould inserts 20, 30 by about 10°C.

[0059] Thereafter, the first and second mould assemblies 110, 120 may be separated to open the mould 100. This exposes the compression moulded and barbed sutures 60 on the suture cartridge 40. The suture cartridge 40 supporting the moulded barbed sutures 60 thereon can be removed from the mould 100 and replaced by another suture cartridge 40 on which new lengths of suture 49 are presented to repeat the moulding process in order to form another lot of barbed sutures 60.

[0060] The presently disclosed apparatus 10 and method 200 thus allow barbed sutures 60 to be compression moulded by providing at least one set 90 of mould inserts that define a mould cavity 69 for compression moulding one barbed suture 60 therein. In the exemplary embodiment of the apparatus 10, four barbed sutures 60 can be simultaneously formed in one moulding operation. By compressing moulding the barbed suture 60 from a length of suture 49, no cuts need to be made on the suture, thereby avoiding weakening the suture 49. Furthermore, using the presently disclosed apparatus 10 and method 200, multiple barbed sutures 60 can be formed significantly more quickly compared to making individual cuts on a length of suture to individually form barbs on the suture. In addition, as each of the barb-shaped

cavities 69 in the present invention is defined by two shaped longitudinal edges E, fabricating the mould inserts to comprise the shaped longitudinal edges E is made feasible, whereas it would otherwise be much more difficult and costly to fabricate mould inserts where each barb-shaped cavity is defined by only one mould insert. The presently disclosed apparatus and method thus allow robust barbed sutures to be formed in a cost and time-effective manner.

[0061] While there has been described in the foregoing description exemplary embodiments of the present invention, it will be understood by those skilled in the technology concerned that many variations in details of design, construction and/or operation may be made without departing from the present invention.

CLAIMS

1. An apparatus for forming barbed sutures, wherein a barbed suture comprises a string-like core and a plurality of barbs disposed at intervals apart along the core, the apparatus comprising:
 - a mould comprising at least one set of mould inserts, wherein some of the mould inserts are provided on a first part of the mould, and others of the mould inserts are provided on a second part of the mould,
 - wherein the second part of the mould is moveable relative to the first part of the mould between an open position and a close position,
 - wherein each mould insert has at least one shaped longitudinal edge that partially defines a profile of the barbed suture such that one shaped longitudinal edge of each of all the mould inserts in one set of mould inserts together define a mould cavity for forming one barbed suture therein when the mould is in the close position;
 - wherein the mould cavity comprises a core-shaped cavity configured to form the core of the barbed suture therein and a plurality of barb-shaped cavities configured to form the barbs of the barbed suture therein, wherein the core-shaped cavity is defined by all the mould inserts in each set of mould inserts together and wherein each barb-shaped cavity is defined by two adjacent mould inserts in each set of mould inserts when the mould is in the close position;
 - a suture cartridge configured to present at least one length of suture for moulding in the mould cavity to form the barbed suture therefrom; and
 - heating elements provided to heat the mould inserts during compression moulding of the length of suture in the mould cavity.
2. The apparatus of claim 1, wherein each set of mould inserts comprises: a first mould insert and a second mould insert provided in contact with each other on a first part of the mould, and a third mould insert and a fourth mould insert provided in contact with each other on a second part of the mould, wherein one shaped longitudinal edge of each of the first, second, third and fourth mould inserts together define a mould cavity for forming one barbed suture when the mould is in the close position.

3. The apparatus of claim 2, wherein the plurality of barb-shaped cavities defined by each set of mould inserts are defined by at least one pair of adjacent mould inserts when the mould is in the close position, wherein the at least one pair of mould inserts is selected from the group consisting of:
 - the first and second mould inserts,
 - the third and fourth mould inserts,
 - the first and third mould inserts, and
 - the second and fourth mould inserts;such that the apparatus forms a barbed suture comprising at least one line of barbs disposed at intervals apart along the core.
4. The apparatus of claim 3 wherein the plurality of barb-shaped cavities defined by each set of mould inserts are defined by four pairs of adjacent mould inserts when the mould is in the close position, the four pairs of mould inserts comprising:
 - the first and second mould inserts,
 - the third and fourth mould inserts,
 - the first and third mould inserts, and
 - the second and fourth mould inserts;such that the apparatus forms a barbed suture comprising four lines of barbs disposed at intervals apart along the core wherein adjacent lines of barbs are rotationally spaced apart from each other by 90° about a central longitudinal axis of the barbed suture.
5. The apparatus of any one of the preceding claims, wherein the first part of the mould is provided with a first row of multiple mould inserts and wherein the second part of the mould is provided with a second row of multiple mould inserts, wherein the first and second rows of multiple mould inserts together form a plurality of sets of mould inserts for forming a corresponding plurality of barbed sutures, wherein one set of mould inserts comprises a pair of adjacent mould inserts in the first row and a corresponding pair of adjacent mould inserts in the second row.
6. The apparatus of claim 5, wherein each intermediate mould insert in the first and second rows of mould inserts has two shaped longitudinal edges.

7. The apparatus of claim 5 or claim 6, wherein the first row comprises at least five lower mould inserts and the second row comprises at least five upper mould inserts,
 - wherein the first and fifth lower and upper mould inserts each has only one shaped longitudinal edge,
 - wherein the second, third and fourth lower and upper mould inserts each has two shaped longitudinal edges,
 - wherein the first and second lower and upper mould inserts together form a first set of mould inserts for forming a first barbed suture,
 - wherein the second and third lower and upper mould inserts together form a second set of mould inserts for forming a second barbed suture,
 - wherein the third and fourth lower and upper mould inserts together form a third set of mould inserts for forming a third barbed suture, and
 - wherein the fourth and fifth lower and upper mould inserts together form a fourth set of mould inserts for forming a fourth barbed suture.
8. The apparatus of any one of the preceding claims, wherein each mould insert has a generally rectangular cross-section and the at least one shaped longitudinal edge is provided along one corner of the rectangular cross-section.
9. The apparatus of claim 8 when dependent on claim 6, wherein the two shaped longitudinal edges are provided along adjacent corners of the rectangular cross-section.
10. The apparatus of any one of the preceding claims, wherein each mould insert has a cooling channel provided therein for passing a cooling fluid therethrough to cool the mould insert and thereby cool the barbed suture formed in the mould cavity after a moulding operation.
11. The apparatus of any one of the preceding claims, wherein the first and second parts of the mould each comprise a first heater backing plate and a second heater backing plate respectively, wherein at least one of the heating elements is provided in a channel provided in the first heater backing plate and in contact with

the mould inserts provided on the first part of the mould, and wherein at least another one of the heating elements is provided in a channel provided in the second heater backing plate and in contact with the mould inserts provided on the second part of the mould.

12. A method of forming barbed sutures, wherein a barbed suture comprises a string-like core and a plurality of barbs disposed at intervals apart along the core, the method comprising the steps of:

- a) providing a length of suture in alignment with a first partial mould cavity, the first partial mould cavity defined by one shaped longitudinal edge of a first mould insert and one shaped longitudinal edge of a second mould insert, wherein the first and second mould inserts are adjacent on a first part of a mould;
- b) heating the length of suture;
- c) moving a second partial mould cavity onto the length of suture, the second partial mould cavity defined by one shaped longitudinal edge of a third mould insert and one shaped longitudinal edge of a fourth mould insert, wherein the third and fourth mould inserts are adjacent on a second part of the mould;
- d) closing the mould and compression moulding the length of suture in a mould cavity defined by the first partial mould cavity and the second partial mould cavity for a predetermined period of time, thereby filling a plurality of barb-shaped cavities provided in the mould cavity with a material of the length of suture, wherein the first, second, third and fourth mould inserts together form one set of mould inserts that define the mould cavity, wherein each barbed-shaped cavity is defined by two adjacent mould inserts in the set of mould inserts.

13. The method of claim 12, wherein heating the length of suture continues to occur during step c).

14. The method of claim 12 or claim 13, where heating the length of suture continues to occur during step d).

15. The method of any one of claims 12 to 14, wherein heating the length of suture comprises heating the four mould inserts using heating elements provided in each of the four mould inserts such that heat from the heated four mould inserts is transferred to the length of suture by at least one of: radiation, convection and conduction.
16. The method of any one of claims 12 to 15, further comprising cooling the compression moulded length of suture in the mould cavity to form the barbed suture therein.
17. The method of claim 16, wherein the cooling comprises passing a cooling fluid through a cooling channel provided in each of the four mould inserts.
18. The method of any one of claims 12 to 17, wherein in step a), the length of suture is not in contact with the first part of the mould cavity.
19. The method of any one of claims 12 to 18, wherein the method is performed using the apparatus of any one of claims 1 to 11.