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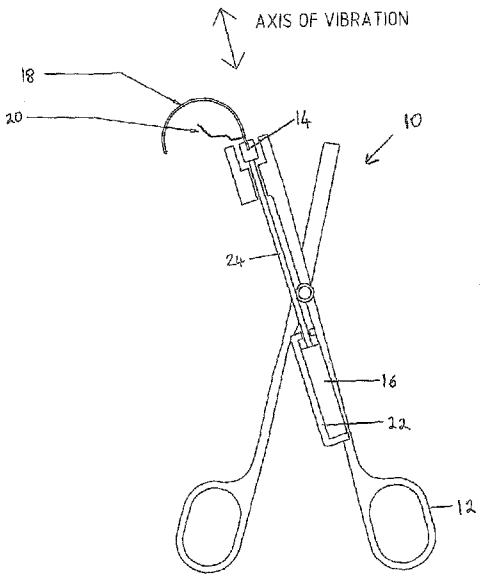
(54) **Title:** DEVICE AND METHOD FOR IMPROVED SURGICAL SUTURING



(57) **Abstract:** The present invention provides a needle holder device for use with a surgical needle which is suitable for use in suturing procedures. The needle holder device comprises handle means to allow manipulation of the needle holder device, means for bringing the surgical needle into engagement with the needle holder device, vibration means for vibrating the needle and means for preventing the vibration of the handle means when the needle is vibrated. The invention further extends to a method of penetrating tissue or blood vessels with a needle during suturing comprising the step of vibrating the needle during the passage of the needle through the tissue or blood vessel. The frequency of vibration of the needle is dependent upon the degree of resistance encountered to the passage of the needle through the blood vessel or tissue.

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DEVICE AND METHOD FOR IMPROVED SURGICAL SUTURING

FIELD OF THE INVENTION

The present invention relates to a device for surgical suturing and to methods for using the same. More specifically, the present invention provides a needle holder device for use with a surgical needle which allows improved suturing during open surgery and minimally invasive surgery, and particularly during cardiac interventions or for vascular indications. The invention further provides a modified suture needle for use with said needle holder device.

BACKGROUND TO THE INVENTION

The problem of penetrating tough tissue with fine surgical suturing needles is often encountered during the suturing of dense scar tissue or calcified vessels. Dense scar tissue is often present during repeat surgery, while calcification generally occurs in coronary arteries, abdominal vessels, femoropopliteal vessels or during other types of valve surgery, aortic surgery and general procedures where vascular access is required. Renal or diabetic patients are particularly prone to calcium metabolic problems.

Surgeons often encounter problems when performing clinical procedures on calcified vessels. For example, it has been identified in one study that 61% of patients with coronary artery disease presented with atherosclerotic plaques. In another study, 30% of asymptomatic patients had fluoroscopically detectable coronary artery calcification. A number of articles in the scientific literature focus on technology for diagnosing the extent of arterial calcification in order to identify the best sites on which to operate. The only means provided in the field to address the problem of arterial calcification involves the use of lasers and/or rotary blades in order to remove excess plaque.

The needles which are presently used when suturing fine vessels such as arteries are so fine that they frequently bend and/or have the tip or needle-point damaged. This makes it difficult to complete the anastomosis. If the calcium deposit present in the vessel is too thick to be penetrated by the needle, then the surgeon has to make a decision about how best to avoid the calcified area. This could compromise the surgery if it results in less than optimal suture placement. In particular, compromised suturing can lead to sub-optimal graft placement resulting from the uneven placement of sutures, which can lead to leakage.

One solution to facilitate needle passage through such calcification is to use a towel clip to force a hole through the vessel such that the needle can then pass through. This is dangerous practice, not only because it could lead to damage of the vessel and compromise repair, particularly in view of the forces which have to be applied in order to penetrate the tissue, but also because sections of the plaque could break away resulting in blockages occurring elsewhere in the vasculature. Such blockages can have potentially fatal consequences.

It would therefore be highly advantageous to provide a modified suturing device which could provide for improved needle penetration through tough, scarred or calcified tissue without excessive or undue force being required to mediate needle penetration and passage through the tissue.

The inventor of the present invention has surprisingly provided an improved device for use in surgical procedures such as suturing, the device having particular utility in facilitating needle penetration of tough tissue, for example tissues which are resistant to needle penetration and passage, such as calcified vessels which may be encountered during the suturing procedure. The present inventor has further provided a method

for suturing using said needle holder device to facilitate needle passage and penetration through tough tissue, such as calcified vessels during the suturing procedure.

The present invention further provides a needle holder device for use in the penetration of a needle through tissue or blood vessels, the needle holder device being conjoined to a needle, and the needle holder device causing controllable vibration of the needle.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a needle holder device for use with a surgical needle which is suitable for use in suturing procedures, said needle holder device comprising:

- handle means to allow manipulation of the needle holder device,
- means for bringing the surgical needle into engagement with the needle holder device,
- vibration means for vibrating said needle, and
- means for suppressing the vibration of the handle means when the needle is vibrated.

The needle is brought into releasable engagement with the needle holder device. This means that the needle may be secured to the needle holder device for a determined period and then released from engagement with the needle holder device.

In certain embodiments, the means for bringing the needle into engagement with the needle holder device is a clamping means which is provided on the needle holder device. Typically, the clamping means comprises a clamping arrangement which comprises at least two opposing faces which can be brought into engagement with each other.

Typically, the clamping means is provided in a jaw-like arrangement wherein two opposing faces are brought together, this bringing together resulting in a needle being grasped by the clamping means. One or more teeth, grooves or serrations may be provided on the faces of the clamping means in order to facilitate improved engagement or gripping of the needle. In certain embodiments, the clamping means is provided with at least one tooth, groove or serration which may facilitate the gripping of the needle. In certain further embodiments, the needle is provided with teeth, grooves or serrations which co-operate with corresponding teeth, grooves or serrations on at least one face of the clamping means in order to facilitate improved gripping of the needle. The bringing together, or closure, of the faces of the clamping means may be performed manually or by electronic means, for example by a motor.

In certain embodiments, the clamping means is provided in a hinged jaw-like arrangement wherein one or both jaws are movable about a pivot in order to bring the opposing faces of the clamping means into engagement with each other, wherein this engagement allows the secure holding or gripping of at least one needle. In alternative embodiments, the clamping means is provided in a sliding jaw-like arrangement wherein one or both jaws are slidable towards each, this allowing the securing or holding of at least one needle.

In certain emodiments, the needle holder device is provided in a scissors-like arrangement comprising two arms. In certain embodiments, the clamping means is provided at a first distal end of each arm, while the handle means is provided at the opposing end of each arm. The arms are movable about a pivot, this allowing the faces of the clamping means to be moved relative to each other and, in particular, to be brought into

engagement with each other, to assume a closed, or gripping configuration.

In order to retain the faces of the clamping means in a closed or gripping position suitable for holding a needle, means for securing the clamping means in a holding position may be provided, for example a ratchet mechanism may be used. The ratchet mechanism serves to retain each arm of the needle holder device in a prescribed position relative to the other. This serves to securely hold the needle within the claming means and, as such, the needle holder device can be used to manipulate the secured needle. The secure grasping or holding of the needle by the clamping means also permits optimal transmission of vibration generated from the vibration means to be communicated to the grasped needle, in order to effect the vibratory movement of the invention.

In certain embodiments, the means for bringing the needle into engagement with the needle holder device comprises control means in the form of, but not limited to, a switch, button, lever or trigger which serves to close and/or secure the needle within the needle holder device. Typically, in an embodiment wherein the means for bringing the needle into engagement with the needle holder device comprises a clamping means, the control means serves to bring the opposing faces of the clamping means into engagement with each other to grasp the needle.

In certain embodiments, the needle may be grasped by a needle holder device, the design and shape of which may be based on a traditional surgical needle holder forceps arrangement (in some instances needle holder forceps are referred to as the needle driver), which allows the needle to be held by the clamping means of the surgical forceps needle

holder. In such an embodiment, the forceps are modified to provide a source of vibration, which, in turn, causes vibration of the needle.

In such an embodiment, the needle may be held by the needle holder device approximately 40% to 85% down the length of the needle as measured from the end of the needle which exhibits the needle point. Typically, the needle will be grasped by jaws of the forceps at a point located on the body of the needle. In a further embodiment, the needle is held by the needle holder device approximately 50% to 75% down the length of the needle body as measured from the end of the needle which exhibits the needle point.

The force with which the needle holder device grasps the needle is determined as the needle holder clamping moment. This is technically defined as a measure of the force exerted by the needle holder jaws on a surgical needle.

In certain further embodiments, the needle may be releasably engageable with the needle holder device by locating one end of the needle, preferably the end of the needle at the opposite end to that which exhibits the point, typically the swage, in a seat, housing or recess which is provided on the needle holder device. The releasable engagement of one end of the needle with the needle holder device allows the vibrational movement which is produced by the needle holder device to be translated to the needle.

In certain further embodiments, the needle may be conjoined to the needle holder device by an appropriate means which allows the needle to be removably engaged with the needle holder device. This may be by way of interlocking the needle to the needle holder device, such as, but not

limited to, a fixed fastening, a quick release fastening or a 'twist and click' style arrangement wherein one end of the needle may be pushed into a needle engaging recess present on the needle holder device in order to allow removable engagement of the needle with the needle holder device.

In certain further embodiments, the needle may be engaged with the needle holder device by arrangements including, but not limited to, the needle being engaged with the needle holder device by means of a screw-type arrangement, a bayonette-type fixing arrangement or the like, or a screw fixing wherein a threaded portion provided upon the needle holder device can be engaged with a receptive fixing provided on the needle holder device.

In certain embodiments, vibration of the needle by the needle holder device may be effected by ultrasonic vibration, said ultrasonic vibration being caused by the vibration means, which, as described above, may be conjoined to or integral with the needle holder device.

It is preferred that the vibration means causes an associated resonance vibration of the conjoined needle, such that the needle vibrates or oscillates in a direction and at a frequency which is suitable to facilitate the penetration and/or passage of the needle through the particular tissue or material through which the needle is to be passed. By the term "facilitate the passage", it is meant that the needle can be passed through the tissue using less force than would be required if the needle was not being vibrated.

A sharpness tester measures the force needed to pass a needle through a membrane that simulates the density of a human tissue. The resistance of a needle to bending is generally measured by determining the force

required to bend the needle by 60° or 90°, this allowing determination of the needle's ultimate bending moment. The needle's yield moment may also be determined, this being the force required to irreversibly deform the needle. Other measurements such as ductility (the resistance of a needle to breaking) may also be made.

The needle holder device of the present invention provides for improved needle performance as the vibration of the needle serves to reduce the force exerted on a needle during penetration and passage of a needle through tissue. The vibration of the needle further results in a substantial associated reduction in the forces encountered by the needle, this resulting in the risk of needle bending or breakage being greatly reduced. This is highly advantageous as reducing the likelihood of needle bending will improve the quality of suturing, which is much less likely to be compromised by a bent or deformed needle. Furthermore, the reduction of the likelihood of needle breakage will not only provide significant benefits in terms of improved suturing but is also significant in terms of improving surgery and reducing needle stick injury to the surgeon.

Accordingly, the vibration of the needle will serve to lower the insertion force which needs to be applied in order to provide for the initial penetration of the needle through the surface of the tissue through which the needle is to be passed. In particular, imparting movement of the needle by means of a vibrational resonance will reduce the penetration resistance of the dermis, where the skin is to sutured. Furthermore, the vibration of the needle will enable or improve suturing of tissue or material that is currently impossible or difficult to suture.

In further certain embodiments, vibration of the needle may be effected by a piezo electric effect. Accordingly, in certain embodiments, a piezo

electric material may be provided at a suitable location within the needle holder device, such that vibrational forces generated by the piezo electric material can be transmitted to the needle which is engaged with the needle holder device.

In certain embodiments, the piezo electric material is located within at least one housing, which is typically positioned within, or conjoined to, the handle means of the needle holder device, such that the piezo electric material can effect vibration of the conjoined needle.

The piezo electric material may be any suitable piezo electric material known to the skilled person in the field, and may, in particular, be selected from the group comprising a polymer, such as PVDF (polyvinylidenedifluoride), a crystal or a ceramic material. The application of electrical power to the piezo electric material results in the vibration of the piezo electric material and, in turn, the vibration of the conjoined needle.

In certain further embodiments, the piezo electric material may further or alternatively act as a sensor to detect the resistance to vibration of the needle. As discussed hereinbefore, the forces encountered by a needle in terms of resistance to penetration and passage of a needle through tissue can result in needle damage and/or breakage. The needle holder device of the present invention facilitates penetration and passage of a needle through a tissue. However, as the present invention has particular utility in the passage of a needle through tough, scarred or calcified tissue, in certain embodiments the piezo electric material can further act to provide an indication of the resistance to vibration, the reduction of the vibration being attributable to dampening encountered during penetration and passage of a needle through a tissue. If a sufficient force of resistance to

needle passage is encountered during needle passage through a tissue, this could result in needle damage or breakage. Accordingly, the utility of the piezo electric material in sensing resistance to vibration and, hence, needle passage will provide an important indicator of the toughness of the tissue and the force required for needle penetration and passage there through.

In further certain embodiments, the vibrational movement of the needle is induced by magnetostriction or by direct magnetic actuation mediated by magnetic shape memory materials. As such, in further certain embodiments, the vibration means is a magnetic shape memory material. In further embodiments, the vibration means causes direct magnetic actuation mediation.

In certain further embodiments, vibration of the needle is effected by a transducer which converts electrical energy into kinetic energy in the form of a resonance vibration at a specific frequency. The transducer may be connected to any suitable electrical energy source. A connecting means conjoins the transducer to the needle allowing the kinetic energy to be transmitted from the transducer to the needle, this resulting in vibration of the needle.

In certain embodiments, the transducer is detachable from the needle holder device. In use, this allows the transducer to be removed prior to sterilisation of the needle holder device. Alternatively, in certain further embodiments, the transducer and the needle holder device form a single unit. Typically, in embodiments where the transducer and the needle holder device form a single unit, the transducer is formed from a material which may be sterilised, or which has a suitable packaging which enables sterilisation without damage to the transducer. Suitable means of

sterilisation of the needle holder device are well known in the art and include, but are not limited to the group consisting of heating, gamma radiation, ethylene oxide and other chemical processes.

Although the needle can be vibrated at any suitable frequency in order to facilitate or effect needle penetration or passage through tissue, in one embodiment the needle holder device, and in particular the vibrating means, causes vibration which results in the needle being vibrated at a resonance frequency of from between about 40 to about 50Hz. Vibration of the needle such that it has a resonance frequency of from between about 40 to about 50Hz is preferred, as such a frequency range is understood by those skilled in the art to cause little or no pain to be felt by the patient from the insertion or passage of the needle through the tissue during the suturing procedure. In a further embodiment, the vibration of the needle occurs at a resonance frequency of between about 20 to about 70Hz. In a further embodiment, the vibration of the needle occurs at a resonance frequency of between about 10 to about 100Hz. In a further embodiment, the vibration of the needle occurs at a resonance frequency of between about 5 to about 150Hz.

In one embodiment, the amplitude of the needle resonance vibration is less than the thickness of a blood vessel wall through which the needle is to be passed.

In a further embodiment, the amplitude of the needle vibration is less than the internal diameter of a vessel, such as a blood vessel, through which the needle is to be passed.

In certain embodiments, the vibration of the needle is effected in such a way that the direction of movement of the needle is the same or

substantially the same as the direction of intended travel or passage of the needle.

In further embodiments, the needle is vibrated such that a tip of the needle moves in a circular or substantially circular plane.

In certain embodiments, the frequency of vibration of the needle is sufficient to facilitate the passage of the needle through blood vessels and/or other tissues.

In a further embodiment, the device comprises means for controlling the vibration imparted by the needle holder device on the needle. In particular, such means may allow for the vibration to be selectively turned on and/or off. Further, the frequency and intensity of the vibration can be controlled, with the ability to control the vibration frequency having a direct correlation in relation to the resonance frequency of the needle which it vibrates.

Typically, the needle holder device is not adversely affected by the vibration of the needle. By adversely affected, it is meant that the handling and operation of the needle holder device is not compromised or restricted due to the vibrational forces which are being generated and/or transmitted to the engaged needle. In order to allow the operator to have full and complete control over the needle, it is preferred that the needle holder device remains static or substantially static in use. By static or substantially static, it is meant that the needle holder device, and in particular the handle means, does not vibrate or is not caused to vibrate as a result of the vibration produced to vibrate the engaged needle. This serves to ensure that the operator's movement or manipulation of the device is not affected by the vibrating needle. As the needle holder device

may be used for procedures which require fine or intricate suturing techniques, it is important that the handling and use of the needle holder device of the invention is not compromised by vibration being transmitted to the handle means of the needle holder device.

Accordingly, the needle holder device has incorporated within it means for suppressing and/or preventing vibration of the handle means when vibration of the needle is effected. Preventing vibration of the handle means ensures that there is no loss of accuracy when using the needle holder device to perform suturing.

In one embodiment, the means for suppressing or preventing the vibration of the handle means is a dampening means, in particular a dampening mechanism. Such a dampening means will be effective in preventing vibration of the handle means when the needle which is conjoined to the needle holder device is being vibrated. Typically, the dampening means will serve to prevent or dampen vibration of the handle means irrespective of the frequency and amplitude at which the needle is being vibrated.

In a further embodiment, vibration of the handle means is prevented or dampened through the use of alternative vibration reducing designs and/or arrangements, for example, strategically placed holes of a certain diameter along the length of the needle holder device which serve to dampen or buffer the transmission of vibration though the needle holder device.

In one embodiment, vibration of the handle means is prevented or dampened through the use of a heavy solid mass, which may be connected to the vibration means in order to prevent or dampen vibration.

The heavy solid mass may be conjoined to, or integral with, the needle holder device.

Alternatively, specific nodal points of high and low energy may be used to effect dampening of the vibration, particularly of the handle means, of the needle holder device The manner of use of such nodal points to minimize vibration would be known to a person skilled in the art.

In a further embodiment, the means for preventing or dampening the vibration of the handle means when the needle is vibrated comprises a flexible element, such as a spring or biasing means, which is shaped to absorb energy, in particular oscillation or vibration, and which therefore functions to prevent or dampen vibration of the handle means when the needle is vibrated. The flexible element may be conjoined to, but is preferably integral with, the handle means.

In certain embodiments, the handle means may be sheathed or provided with a cover which absorbs or dampens the vibration from the needle such that the user does not feel any vibration when the needle is vibrated. Said absorbent cover may be comprised of any suitable synthetic material, for example a rubber, plastics or foam material. In certain embodiments, the material has a high temperature resistance and is approved for autoclave or chemical sterilization, such as VITON™ or silicone.

In certain embodiments, vibration of the handle means is prevented or dampened through the use of a protective coating comprising a synthetic material, such as silicone, which is applied to the handle means. In embodiments of the needle holder device wherein the handle means comprises a forceps arrangement having two loops through which the fingers of an operator may be inserted during use, the protective coating

may be applied to the finger loops of the handle means such that vibration of the handle means is prevented or dampened.

In certain further embodiments, vibration of the handle means is prevented or dampened by means of the selection of suitable materials for the needle holder device. In such embodiments, the handle means comprises a material, such as a plastics or ceramic material, which does not transfer vibrations, thus minimising vibrations in the direction of the operator. Alternatively, the handle means comprises a metal material which is difficult to vibrate. For the conjoining means which conjoins the needle to the device, a material which maximises vibration towards the needle is selected. The use of vibration-maximising materials, which maximise vibration towards the needle, and vibration-minimising materials, which minimise vibration towards the handle means, serves to enhance vibration of the needle while preventing or dampening vibration of the handle means such that the operation of the needle holder device by the operator is not affected by vibration of the needle.

In certain embodiments, vibration of the needle by the needle holder device is selective and controlled by the operator. This selectivity allows the operator to modify and optimise the vibration of the needle to the specific conditions which are required to allow optimum needle passage through the tissue.

In certain further embodiments, vibration of the needle may be variable and may be triggered automatically by a mechanism incorporated into the needle holder device which detects resistance to the passage of the needle through a tissue.

In certain embodiments, such a mechanism may monitor the resistance to the passage of a needle when it is being passed through a specific tissue, with the mechanism triggering vibration of the needle when the resistance encountered by the needle to passage through the tissues reaches a pre-determined threshold.

In further embodiments, the frequency and intensity of vibration of the needle may increase as the passage of the needle through a tissue becomes more difficult, that is, in situations where passage of the needle through tissue requires additional force to be exerted to effect needle passage.

In further certain embodiments, the vibration of the needle may be automatically varied depending upon the resistance encountered by the needle during its passage through a tissue. This may include the absence of vibration if there is no, little or minimal resistance to the passage of the needle through the tissue.

In certain further embodiments, the vibration of the needle may be automatically turned off after a specified time. Typically, the vibration is automatically turned off after about 10 seconds, in particular after about 5 seconds, most specifically after about 2 seconds. The turning off of the vibration reduces vibration time, thus reducing the generation of heat by the needle holder device. Furthermore, the automated turning off of the vibration serves to stop vibration of a vessel when the vessel wall is penetrated. Thus, the needle has ceased vibrating at the time that the operator pulls the needle through to form the suture. Typically, the operator uses a second device to pull the needle through and the cessation of vibration allows the operator to more easily grasp the needle with the second device.

In certain embodiments, the needle holder device comprises a single arm. Alternatively, the needle holder device comprises two arms. In certain embodiments, the needle holder device comprises an integrated handle means and conjoining means comprising two arms which are pivotally mounted upon each other and which, in use, are held by the user, typically by means of the handle means which are provided on the arms or attached thereto. The arms may be connected by means of a pivot or a hinged connection, which may be provided by a pivot point, to allow movement of one arm in relation to the other about the hinge or pivot . At the end of the arms distal to the handle means, grip means are located which have use in gripping the needle. The grip means are provided by portions of the arms which serve to interact with a similar but opposing shaped portion located on the opposing arm. These opposing portions are referred to hereinbefore as faces. The coming together of the grip allows objects to be grasped and secured between the ends of the arms.

In certain embodiments, the transducer is positioned such that the axis of vibration which is effected results in oscillation which is in line with, or in the same place as, at least one arm of the needle holder device.

In use, closure of the arms results in movement of the arms relative to each other and, in turn, engagement of the grip means with the opposing grip means located on the opposing arm. Placement of the needle between the grip allows the needle to be held in a secure engagement by the holder.

Typically, the integrated handle means and conjoining means may be in the form of a pair of pliers or a forceps.

Suitably, the angle at which the needle is connected to the needle holder device may be adjusted as required, for example by adjusting positioning of the needle relative to the grip means or by varying the orientation of the conjoining means such that the needle is at an optimal angle for suturing.

In one embodiment, the needle may be positioned at an angle of between 0° and 180° to the needle holder device or an arm thereof. Alternatively, the needle may be positioned at an angle of between 30°and 150° to the needle holder device or an arm thereof. In one embodiment, the needle is held at an angle of 90° to the needle holder device or an arm thereof.

The selection of a suitable needle for use in a surgical procedure is a task well known to the person skilled in the field. When considering optimum needle selection, a surgeon will typically consider the biomechanical performance of surgical needles, this generally being determined by parameters such as needle sharpness (acuity), needle resistance to bending, needle ductility, resistance to abrasion, smoothness of profile and corrosion resistance.

Typically, the needle which is used with the needle holder device is any needle suitable for suturing or similar surgical procedures. Typically, the needle is a surgical needle.

In certain embodiments, the surgical needle may be selected from the group consisting of, but not limited to, a tapered needle, a round needle, a cutting needle and a reverse cutting needle.

In certain embodiments, the needle is substantially composed of a stainless steel alloy, such material having resistance to corrosion. Stainless steels generally contain a minimum of about 12% chromium

which allows a thin, protective surface layer of chromium oxide to form when the stainless steel is exposed to oxygen.

In further embodiments, the needle may be comprised of high nickel maraging stainless steel. High nickel maraging stainless steel, such as S45500, is generally composed of 7.5% to 9.5% nickel, 0.8%-1.4% titanium and 11-12.5% chromium. Surgical needles composed of high nickel maraging stainless steel have a greater resistance to bending and breaking compared to stainless steel which does not contain nickel.

In certain embodiments, the needle may be straight or substantially straight in shape. In further certain embodiments, the needle may be curved, for example it may be substantially or partially semi-circular in shape. The curvature of a needle is described in degrees of subtended arc. The radius of the needle is determined as being the distance from the centre of the needle to the body of the needle if the curvature of the needle was continued to form a full circle.

Generally, the curvature of the needle with one radius of curvature may vary from 90° (1/4), to 135° (3/8), to 180° (1/2), to 225° (5/8). Each of the aforementioned needle shapes lends itself to a specific use in particular surgery. The selection of an appropriate suturing needle is a task which is routinely performed by the person skilled in the art, for example, a needle with a 90° angle of curvature may be used in microsurgery, while a needle with a 180° angle of curvature may be used in deep body cavities.

In addition to its curvature and radius, a surgical needle can be characterised by three other measurements, namely, chord length, needle diameter and needle length. Chord length is the linear distance measured from the central point of the needle swage to the point of the needle. The

needle diameter is the width of the original circular wire used in the manufacturing process for the production of the needle, while needle length is the arc length of the needle as measured at the centre of the wire's cross section.

The cross-sectional area of a needle may be varied. The shape of the cross-sectional area of the needle will influence how securely the needle can be grasped by, or conjoined to, the needle holder device. Typically, the cross-sectional areas of the body of a needle may be selected from the group consisting of, but not limited to, circular, triangular, rectangular and trapezoidal.

Needles having a rectangular cross-section are formed from flattening the top and bottom portions of the needle body. The flattening of the top and bottom portions of the needle body facilitates grasping by the faces of the needle holder jaws, where present on the needle holder device.

A surgical needle is generally comprised of three sections, a swage, a body and a point. The swage provides for attachment of the suture. The swaging process provides a smooth juncture between the needle and the suture. As the needle is typically eyeless, needles produced by the swaging process create smaller holes in tissue than threaded eye needles.

Typically, the needle is attached to the suture by uniformly compressing the walls of the swage against the suture, this creating a strong force which prevents the detachment of the suture from the needle without the exertion of considerable force.

The body portion of the needle is typically the portion which will be grasped, engaged or brought into some form of releasable or fixed engagement with the needle holder device of the invention.

The point of the needle extends from the tip of the needle to the maximum cross-section of the body. Different types of needle point can be provided, with each of these having different features of function. Specifically, each type of needle point is designed to penetrate different types of tissues. For example, a needle point may comprise a cutting edge, a taper point or a combination of both.

Cutting edge needles have at least two opposing edges, which are designed to penetrate tough tissue. In some instances, a cutting edge needle may have three cutting edges. In such cases, the position of the third cutting edge categorises the needle as either a conventional cutting edge needle or a reverse cutting needle. In the case of a conventional cutting edge needle, the third cutting edge is provided on the inside, concave curvature of the needle. In the case of a reverse cutting needle, the third cutting edge is located on the outer convex curvature of the needle.

Where the needle is a taper point needle, the needle tip tapers to a sharp tip. Taper needles are generally used when the surgeon wishes to make the smallest hole possible. Taper needles are generally only used for the penetration of soft tissues, which do not resist needle penetration, for example, vessels, abdominal viscera and fascia. As such, use of a taper point needle with the needle holder device of the present invention is highly advantageous as a taper point needle can be used to penetrate tougher tissues than could be penetrated by the use of the taper point

needle without the use of the needle holder device of the present invention.

In further certain embodiments, the needle may further be provided with means to engage with a suture, wherein said joining means is provided separately to, and duly conjoined with, the needle as appropriate. In further embodiments, the needle comprises at least one eye to facilitate suture engagement or attachment.

The sutures which are used with the needle and needle holder device of the present invention can include any suitable suture known to the person in the art. For example, the suture may be a nonabsorbable suture or an absorbable suture.

Nonabsorbable sutures are typically made from natural fibres such as silk. Such suture types are well know to the person skilled in the field and include sutures commercially available and marketed under the trade mark SOFSILK™, this being a nonabsorbable, sterile, nonmutagenic surgical suture comprised of natural proteinaceous silk fibres called fibroin.

Nonabsorbable sutures further include metallic sutures, which are derived from stainless steel. Further types of nonabsorbable sutures include synthetic sutures made from polymers such as polyamides, polyesters, polyolefins and polytetrafluoroethylene.

Absorbable sutures are typically made from collagen or synthetic polymers. Collagen sutures are generally derived from the submucosal layer of ovine small intestine or the serosal layer of bovine small intestine. Typically, the needle holder device is made from stainless steel. However, any suitable material may be used.

A further aspect of the present invention provides a vibrating needle device for use in surgical suturing procedures, said needle device comprising:

- handle means to allow manual manipulation of said device,
- a needle, protruding from said device and being suitable for the penetration and/or passage though tissue, and
- means for vibrating said needle to the exclusion of the remainder of the device.

In one embodiment, the needle is vibrated by a vibration means. The vibration means may effect vibration of the needle in a number of ways, such as ultrasonic vibration, piezo electric effect, magnetostriction or direct magnetic actuation via magnetic shape memory materials.

In one embodiment, vibration of the needle may be effected by a transducer which serves to convert electrical energy into kinetic energy in the form of a resonance vibration at a specific frequency. A connecting means conjoins the transducer to the needle allowing the kinetic energy to be transmitted from the transducer to the needle, this resulting in vibration of the needle.

In one embodiment, the needle is vibrated at a resonance frequency of between 40 to 50Hz. Vibration at a frequency of between 40 to 50Hz causes little or no pain for the patient during the penetration of the needle through the tissue. In a further embodiment, the vibration of the needle occurs at a resonance frequency of between about 5 to about 150 Hz.

It is further preferred that the vibration of the needle does not result in vibration of the handle means of the device, so as not to compromise the use of the device by the operator.

In one embodiment, the vibration of the needle is effected in such a way that the needle resonates in the direction of intended travel or passage of the needle through the tissue or material through which the needle is to be passed.

In one embodiment, the needle is vibrated such that a tip of the needle moves in a circular plane.

In one embodiment, the needle is held by the needle device approximately 40% to 85% down the length of the needle from the tip. In a further embodiment, the needle is held by the needle device approximately 50% to 75% down the length of the needle from the tip.

The vibration of the needle serves to substantially lower the force required to introduce the needle into, and allow for the passage of the needle through, a tissue or blood vessel in a precise manner that causes no significant damage to the vessel or tissue through which the needle is being passed.

Significant vessel or tissue damage is unnecessary damage which may result from the suturing procedure or the dislodgement of calcification plaques where present.

In one embodiment, the amplitude of the needle vibration is less than the thickness of the blood vessel wall.

In one embodiment, the handle means is sheathed or provided with a cover. This cover serves to absorb and/or dampen the vibration from the needle such that less vibration is transferred to the hand of the user / operator of the device.

In one embodiment, the needle device comprises two arms wherein a needle may be positioned between grip means located at the ends of the arms distal to the handle means. The arms may be connected by means of a hinged connection, or any other suitable pivotable connection, such that when pressure is applied to the handle means, the grip means close to grip the needle.

In one embodiment, the needle is fixed to the needle holder device at a pre-determined angle. Alternatively, the needle holder device may be adjusted to alter the angle of attachment of the needle. This allows the surgeon to accurately position the needle when suturing. In one embodiment, the needle may be positioned at an angle of between 0° and 180° with respect to the needle holder device, or arms thereof. Alternatively, the needle may be positioned at an angle of between 30°and 150° with respect to the needle device, or arms thereof. In one embodiment, the needle is held at an angle of 90° to the needle device or arms thereof.

According to a yet further aspect of the present invention, there is provided the use of a needle, when conjoined to a vibrating needle holder device according to a first aspect of the invention in a surgical procedure, in particular suturing.

The present invention further extends to using the devices of the invention in a method of suturing.

Accordingly a further aspect of the present invention provides a method of penetrating tissue or blood vessels with a needle during suturing, the method comprising the steps of:

- vibrating said needle with a defined amplitude and direction, said vibration serving to facilitate the penetration and passage of the needle through a tissue such as a blood vessel,

wherein the frequency of vibration of the needle is dependent upon the degree of resistance encountered to the passage of the needle through said blood vessel or tissue.

In one embodiment, the needle is any needle suitable for suturing. In one embodiment, the needle is constructed from titanium. In an alternative embodiment the needle is constructed from surgical steel.

In one embodiment, the needle is vibrated by a needle holder device reversibly conjoined to the needle. As such, the method further includes the step of releasably engaging the needle with a needle holder device according to the first aspect of the invention.

In one embodiment, the step of vibrating the needle is performed using ultrasonic vibration. In further embodiments, the vibration of the needle is effected through the use of the piezo electric effect, magnetostriction or direct magnetic actuation via magnetic shape memory materials. In one embodiment, vibration of the needle may be effected by a transducer which serves to convert electrical energy into kinetic energy in the form of a resonance vibration at a specific frequency. In one embodiment the needle is vibrated at a resonance frequency of from between about 40 to about 50Hz. Vibration at a frequency of from between about 40 to about 50Hz causes little or no pain for the patient during the penetration of the needle through the tissue.

In one embodiment, the amplitude of the vibration (the resonance frequency) results in the vibrational movement of the needle being less than the thickness (width) of a blood vessel wall through which the needle is to be passed. In particular, it is preferred that the amplitude of the vibration of the needle is less than the internal diameter of the vessel.

In one embodiment, the vibration of the needle is effected in such a way that the needle resonates in the direction of intended travel or passage of the needle through the tissue or material through which the needle is to be passed.

In one embodiment, the needle is vibrated such that a tip of the needle moves in a circular plane.

The vibration of the needle serves to substantially lower the force required to introduce the needle into, and allow for the passage of the needle through, a tissue or blood vessel in a precise manner that causes no significant damage to the vessel or tissue through which the needle is being passed.

Significant vessel or tissue damage is unnecessary damage which may result from the suturing procedure or the dislodgement of calcification plaques where present.

The present invention further extends to a needle for use in suturing and/or other surgical procedures which may be used with the vibrating needle holder device according to the invention.

Accordingly, a yet further aspect of the present invention provides for a suturing needle for use with the needle holder device, said needle

comprising a needle point and a body, wherein the body is adapted to enhance engagement with the needle holder device of the present invention.

By the term "enhance engagement", it is meant that the needle can be grasped by the needle holder device with an increased clamping moment.

The needle may be removably conjoined to, or engaged with, the vibrating needle holder.

In one embodiment, the needle is comprised or substantially comprised of titanium. In a further embodiment, the needle is composed of surgical steel. In certain further embodiments, the needle is composed of any material as described hereinbefore.

In certain embodiments, the needle is provided with teeth, grooves or serrations which co-operate with corresponding teeth, grooves or serrations on at least one face of the clamping means of the needle holder device in order to facilitate improved gripping of the needle.

Unless otherwise defined, all technical and scientific terms used herein have the meaning commonly understood by a person who is skilled in the art in the field of the present invention.

Throughout the specification, unless the context demands otherwise, the terms 'comprise' or 'include', or variations such as 'comprises' or 'comprising', '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.

The present invention will now be described with reference to the following examples, which are provided for the purpose of illustration and are not intended to be construed as being limiting on the present invention and, further, with reference to the figures.

Brief description of the figures

Figure 1(a) shows a top view of a needle holder device according to a first aspect of the present invention having a needle for suturing attached thereto;

Figure 1(b) shows a front view of the needle holder device of Figure 1(a);

Figure 1(c) shows the needle holder device of Figure 1(b) following removal of the needle;

Figure 2(a) shows a needle holder device as shown in Figure 1(b) wherein the handle means is in a closed position;

Figure 2(b) shows the needle holder device of Figure 2(a) wherein the handle means is in an open position;

Figure 3(a) shows a top view of an alternative embodiment of a needle holder device according to the present invention having a needle for suturing attached thereto; and

Figure 3(b) shows a front view of the needle holder device of Figure 3(a).

EXAMPLES

It is preferred that the needle holder device will be light in weight and of such a shape that it will be easy to handle and, in particular, easily manoeuvrable when handled by the operator. In particular, the design of the device will be easily controllable and, as such, will respond to small movements made by the operator. Further, it is preferred that there will be no unnecessary wires or cables connected to or emanating from the device which could cause complications during surgical procedures.

The power required by the device can be supplied by an internal battery to avoid the requirement for a power supply lead which connects to an external power supply. The internal battery may be replaceable or may be rechargeable.

Further, the device will preferably comprise means which allow the vibration imparted on the conjoined needle to be controlled, be capable of switching vibration on at variable speeds and will also be able to give control over precise penetration versus tactile feedback as required.

This vibration of the needle preferably results in movement of the needle in the direction of tissue passage or in the direction which the needle is travelling or is intended to travel during the suturing procedure. Alternatively, general vibration may be provided to the needle by the needle holder device which is sufficient to result in easier penetration of the needle through tissue. As discussed above, such an embodiment should be light and easily moveable through fine movements. In one embodiment, the needle is vibrated such that a tip of the needle moves in a circular plane.

In one embodiment, there will be a range of suture needles for use with the device which are similar to those currently available, except in that

they have an adapted holding point so that they can be conjoined to the needle holder device.

One method of vibrating the needle is through the use of ultrasound. It would be more difficult to effectively vibrate a needle that was manually grasped by the surgeon. In addition, in order to vibrate effectively with needle technology, every needle would have to be grasped in exactly the same spot and the needle length and shape would need to be designed so that the needle vibrates at the correct frequency. In view of this, the design of the device should permit the connection between the needle holder device and the needle to allow the transmission of vibration from the needle holder device to the needle. It is further preferable that there is no vibration of the needle holder device.

Further, the needle must be able to vibrate efficiently and, preferably, should be made of a suitable material, such as titanium or steel. Although upon vibration the needle may heat slightly, it would be undesirable for the needle when incorporated into the needle holder device to become too hot. Vibration of the needle ultrasonically serves to minimise the heat in the needle. Alternatively or additionally, the duration of the vibration of the needle is limited in order to prevent or reduce heating of the needle, and/or the frequency of the vibration is selected in minimise the heating of the needle.

In certain further embodiments of the present invention, the device includes means to provide the operator with the ability to have the needle vibrate only when resistance is met during the suturing or needle passage procedure. This selective vibration may either be controlled by the operator or alternatively may be triggered automatically by a mechanism incorporated into the needle holder device which detects a resistant force

on the needle during needle passage or suturing and triggers vibration when this resistant force reaches a pre-determined threshold.

The ability to selectively control the vibration of the needle will result in increased control and sensitivity for the operator and will additionally allow the operator to feel the needle penetrating the vessel or tissue through which needle passage is desired.

When the device of the present invention is used in suturing at the skin surface, the needle will be designed to vibrate at a frequency that does not activate human pain receptors. Pacini receptors are activated at frequencies of between 50 Hz and 300 Hz, whereas free nerve endings react at frequencies of between 0.5 Hz and 40 Hz. The device will preferably operate at a frequency which does not damage adjacent tissue, i.e. between 40-50 Hz, to prevent feeling of pain.

Because there are no pain receptors present in heart tissue or blood vessel walls, the frequency of needle vibration does not necessarily have to be within this range when the device is being used on these tissues.

Detailed Description of the Invention

With reference to the Figures, a needle holder device (10) comprises handle means (12), a needle engaging recess (14) and a transducer (16). The transducer (16) serves to convert electrical energy into kinetic energy in the form of a resonance vibration at a specific frequency.

The handle means (12) comprises a scissor-like arrangement, or forceps, comprised substantially of first and second arms (12a and 12b), which are joined together at a suitably positioned pivot point such that each arm can be moved relative to the other. At one end of the handle means (12),

there is provided a handle in the form of loops for a user's fingers, which facilitates the holding of the needle holder device (10). Specifically, the handle means (12) is adapted to allow manual manipulation of the needle holder device (10).

The needle engaging recess (14) is arranged for receipt of an end of needle (18) as shown in Figure 1(b). The engagement of the needle (18) within the recess (14) serves to secure the needle (18) to the needle holder device (10). The needle (18) is adapted for insertion of sutures (20), as shown in Figures 1(a) and (b).

The transducer (16) connects to the needle (18) and to an energy source (not shown) allowing kinetic energy to be transmitted to the needle (18), this resulting in resonance vibration of the needle (18) in a specified direction. Specifically, the vibration is directed in the direction of intended travel or passage of the needle (18), as shown by the arrows in Figure 1(b) and in Figures 2(a) and (b).

A connecting means (24) serves to conjoin the transducer (16) to the recess (14) in which the base of the needle (18) is located. Accordingly, a first end of the connecting means (24) is conjoined to, or forms, the recess (14) in which the needle (18) is seated, while the opposing end is disposed to the transducer (16). The connecting means (24) functions to communicate the vibrational kinetic energy produced by the transducer (16) and relays this to the recess (14) in which the needle (18) is seated such that the needle (18) is vibrated.

The handle means (12) is movable between a first closed position (Figure 2(a)) and a second open position (Figure 2(b)).

Figure 3(a) and (b) show an alternative embodiment in which the needle (18) has a substantially semi-circular shape and is grasped between grip means (26) provided at the ends of arms (12a and 12b) distal to the handle means (12) provided at the opposing ends of the arms (12a and 12b). The needle (18) is held by releasable engagement of the grip means (26) provided on the opposing arms (12a and 12b), with the needle being grasped at a position approximately 75% of the way down the length of the needle as measured from the tip of the needle (18), which is used for introducing and leading the needle through the material to be sutured.

Alternatively, the transducer (16) is positioned directly in line with one of the needle holder arms (12a or 12b). In such an embodiment (not shown), one finger loop of the handle means (12) at an end of one of the arms (12a or12b) is replaced by a housing for the transducer (16) such that the axis of vibration is directly in line with the selected needle holder arm (12a or 12b). A replacement finger loop may be attached or moulded to the outside of the transducer housing, forming an alternative handle means (12), to allow the needle holder device to be easily gripped and manipulated by an operator.

In use, a needle (18) of a size appropriate for the procedure being carried out is selected. In general, the suturing of larger vessels such as the aorta requires larger sized needles (18) than the suturing of smaller vessels such as cardiac arteries. Following the selection of an appropriately-sized needle (18), a suitably sized needle holder device (10) is then selected. Although a needle holder device (10) can accommodate a range of needle (18) sizes, it may be desirable to select a smaller and lighter needle holder device (10) when using smaller needles (18) and/or when suturing smaller and more delicate vessels. The size of the needle holder device (10) may thus vary depending on both the selected needle (18) size and the

procedure being carried out. The selected needle (18) is inserted into the needle engaging recess (14) at the distal end of the selected needle holder device (10) and secured. Alternatively, in the embodiment shown in Figure 3, the needle is placed between releasably engageable grip means (26) provided at the distal ends of the arms (12a and 12b) of the handle means (12). Pressure is applied to the handle means (12) to close the distal ends of the arms (12a and 12b) and grasp the needle (18) as the grip means (26) are brought into engagement.

Upon activation of the ultrasonic power supply, the transducer (16) converts electrical energy into kinetic energy in the form of vibrational movement. This vibration is relayed to the needle by means of the connecting means (24) which joins the transducer with the needle, this causing the needle (18) to vibrate in a specified direction which is preferably the direction of intended passage of the needle (18), as indicated by the arrows in Figure 1(b) and Figures 2(a) and (b). The transducer (16) is programmed to cause vibration at a maximum amplitude which is less then the thickness of the vessel wall on which the procedure is being performed. The frequency of the vibration of the needle (18) can be changed within certain limits, however the frequency reverts to the optimal frequency unless programmed otherwise.

In use, the surgeon positions the needle (18) at the correct position on the tissue to be sutured and at the correct angle and pushes the needle (18) through the tissue. The vibration of the needle (18) enables the needle (18) to penetrate the tissue wall even in the advent of the tissue being hardened, for example, by deposition and accumulation of calcium crystals.

The dampening means of the needle holder device (10) prevents the needle holder device (10) from vibrating and allows the surgeon to perform the delicate procedure smoothly. Once the needle (18) has penetrated the tissue, the needle (18) is then disengaged from the needle holder device (10) and pulled through the tissue. This passage of the needle through the tissue may be performed by hand or through the use of an instrument such as appropriately sized surgical forceps. The needle (18) is then re-inserted into the needle holder device (10) as described above and the sequence of events repeated until the suturing procedure has been completed.

In another embodiment, the needle (18) is not energized unless the needle (18) meets a certain resistance, for example, when the surgeon meets hardened tissue. Upon reaching the resistance, the transducer (16) is automatically activated and transmits the energy to the needle (18), thus causing the needle (18) to vibrate in the direction indicated by the arrows (Figure 1(b) and Figures 2(a) and (b)). The needle (18) can thus pass easily through the hardened tissue.

In a further embodiment, the needle (18) is only energised in order to allow the initial penetration of the tissue, the energised, vibrating needle (18) causing a reduction in the insertion force which needs to be applied to allow the insertion of the needle (18) into the tissue.

In a yet further embodiment (not shown), the device comprises handle means which comprises only a single arm. Said handle means may have mounted thereon a recess for engagement with a needle. The handle means would further co-operate with a transducer or other means for generating vibration. Said transducer may be provided within a housing which is conjoined to the handle means.

Vibration of the suture needle (18) allows the needle (18) to pass through areas of tough tissue through the application of reduced force, while inducing a minimum amount of local trauma and, in particular, resulting in no, or a minimal amount of, disruption to calcified plaques or areas of calcium build up which may be present on and/or in the wall of a vessel.

The vibrating needle holder device (10) of the present invention would provide particular improvements in relation to the use of needles and suturing in the following areas: (i) the penetration of tough tissue such as calcified vessels; (ii) the use of needles in cases where tissue is very friable and easily damaged, such as the liver; and (iii) the use of a needle in cases where tissue could be accidentally damaged by the needle, such as endoscopic, minimally invasive, keyhole surgery.

A further area where the present invention would have particular utility would be laparoscopic surgery where the needle could be relatively blunt until it is vibrated. Despite being blunt, vibration of the needle would allow it to more effectively penetrate tissue and, accordingly, the vibrating needle would be suitable for suturing. This would further reduce the risk of accidental needlestick injury to surgeons or other users of the device.

The device would have particular benefits if adopted in the following medical fields:

(i) the cardiac field, where such a device would be of particular benefit in view of the occurrence of calcification of the aorta and vessels encountered in coronary artery bypass patients. The use of the present device would allow surgeons to place stitches where they want to, rather than where they have to. This is particularly important for cardiac surgeons, as they are often limited in the selection of vessels presented to

them. In addition, the risk of distal emboli is present. It would therefore be useful to have a product which would allow surgeons to penetrate even the most calcified of vessels;

(ii) the vascular field - like cardiac surgeons, vascular surgeons are frequently faced with hardened vessels, resulting in the same problems as faced by their colleagues in the cardiac field. Further, vascular surgeons face the additional problem of trying to suture graft materials. Grafts can bend needles, and thus the application of vibration to the needle would also provide an improvement in this field. Ideally this would be done using a very fine needle and suture material. Fine needles have a tendency to bend very easily with this bending resulting in damage, particularly to the tip of the needle. In order to avoid such bending, a larger needle is selected but not by preference as this would lead to larger holes resulting from the suturing procedure. If the needle is damaged to the extent that the repair cannot continue, then the suture often needs to be removed leaving holes in the graft which will leak. Such problems are particularly seen in patients who are diabetic, as they frequently have calcified vessels;

(iii) the field of plastic surgery. Plastic surgeons could see some benefit when suturing very fine vessels such as arterial injuries to the hand, where it can be difficult to gain counterpressure to allow passage of the needle; and

(iv) general surgery. General surgeons could see benefit for laparoscopic surgery, where there is a slight risk of accidental needlestick injury. However, relatively little laparoscopic suturing is carried out.

Although the above describes the main uses as being for vascular and cardiac surgery, there are also niche possibilities, for example, during general surgery or more specific uses during laparoscopic suturing or ophthalmic surgery. The main procedures would include, but are not limited to: (i) coronary artery bypass, (ii) valve surgery, (iii) aortic surgery, (iv) femoropopliteal surgery, and (v) vascular access for renal or diabetic patients.

From a review of the literature in the associated fields, it is indicated that around 50 percent of the time, surgeons will come across calcified vessels which can lead to complications such as (i) compromised suturing (because of suboptimal positioning of sutures), (ii) suboptimal graft placement (if sutures are not evenly spaced, then graft is sometimes loose), which could lead to leakage, (iii) damaged needles (bent needles, bent points), in some cases leading to the need to re-suture or resulting in traumatised tissue, and (iv) risk of breaking off sections of plaque which could lead to potentially fatal embolism.

The benefits of a device according to the present invention are thus inherently evident to cardiac and vascular surgeons who are familiar with the problems with the prior art.

The device of the invention would save time and reduce high-risk activities (having to force a hole through heavily plaqued wall; having to compromise when suturing graft or anastomosis; having to remove suture and reanastomose). Further, a potential reduction in adverse events (e.g. Emboli, graft/anastomosis leakage) could also be achieved.

All documents referred to in this specification are herein incorporated by reference. Various modifications and variations to the described

embodiments of the inventions will be apparent to those skilled in the art without departing from the scope of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes of carrying out the invention which are obvious to those skilled in the art are intended to be covered by the present invention.

Claims

1. A needle holder device for use with a surgical needle which is suitable for use in suturing procedures, said needle holder device comprising:

- handle means to allow manipulation of the needle holder device,
- means for bringing the surgical needle into engagement with the needle holder device,
- vibration means for vibrating said needle, and
- means for suppressing the vibration of the handle means when the needle is vibrated.

2 A needle holder device as claimed in claim 1 wherein vibration of the needle by the needle holder device is effected by ultrasonic vibration.

3. A needle holder device as claimed in claim 1 wherein vibration of the needle is induced by piezo electric effect.

4. A needle holder device as claimed in claim 1 wherein the vibrational movement of the needle is induced by magnetostriction.

5. A needle holder device as claimed in claim 1 wherein the vibrational movement of the needle is induced by direct magnetic actuation via magnetic shape memory materials.

6. A needle holder device as claimed in claim 1 wherein the vibration means comprises a transducer.

7. A needle holder device as claimed in claim 6 wherein the transducer is located in a housing conjoined to the handle means.

8. A needle holder device as claimed in claim 6 or 7 wherein the transducer is connected to the means for bringing the surgical needle into engagement with the needle holder device by a connecting means.

9. A needle holder device as claimed in any of the preceding claims wherein the handle means comprises first and second arms connected at a pivot point to form a scissors-like arrangement.

10. A needle holder device as claimed in any of the preceding claims wherein the means for bringing the surgical needle into engagement with the needle holder device comprises a recess provided on the handle means, the recess being adapted to allow engagement with the base of the needle.

11. A needle holder device as claimed in any of the preceding claims wherein the needle holder device causes vibration of the needle at a frequency of between 40 to 50Hz.

12. A needle holder device as claimed in any of the preceding claims wherein the means for preventing the vibration of said handle means when said needle is vibrated comprises a dampening mechanism.

13. A needle holder device as claimed in any of the preceding claims wherein vibration of the needle by the needle holder device is selective and controlled by the operator.

14. A needle holder device as claimed in claim 13 wherein vibration of the needle by the needle holder device is variable and is triggered automatically by a mechanism incorporated into the needle holder device which detects resistance to the passage of the needle through a tissue.

15. A needle holder device as claimed in any preceding claim wherein the means for bringing the surgical needle into engagement with the needle holder device comprises a fixed fastening, a quick release fastening or a 'twist and click' style arrangement where one end of the needle is pushed into a receiving recess present on the needle holder device in order to allow removable engagement of the needle and needle holder device.

16. A vibrating needle device for use in surgical suturing procedures, said needle device comprising:

- handle means to allow manual manipulation of said device,
- a needle, protruding from said device and being suitable for passage though tissue, and
- means for vibrating said needle to the exclusion of the remainder of the device.

17. Use of a needle when conjoined to a vibrating needle holder device according to any one of claims 1 to 15 in a surgical procedure.

18. Use of a vibrating needle device according to claim 16 in a surgical procedure.

19. Use as claimed in claim 17 or 18 wherein the surgical procedure is suturing.

20. A method of penetrating tissue or blood vessels with a needle during suturing, the method comprising the step of:

- vibrating said needle during the passage of the needle through the tissue or blood vessel,

wherein the frequency of vibration of the needle is dependent upon the degree of resistance encountered to the passage of the needle through said blood vessel or tissue.

21. A method as claimed in claim 20 wherein the vibration of the needle is effected through the use of a piezo electric effect, magnetostriction, direct magnetic actuation via magnetic shape memory materials or a transducer.

22. A method as claimed in claim 20 or 21 wherein the needle is vibrated at a resonance frequency of between 40 to 50Hz.

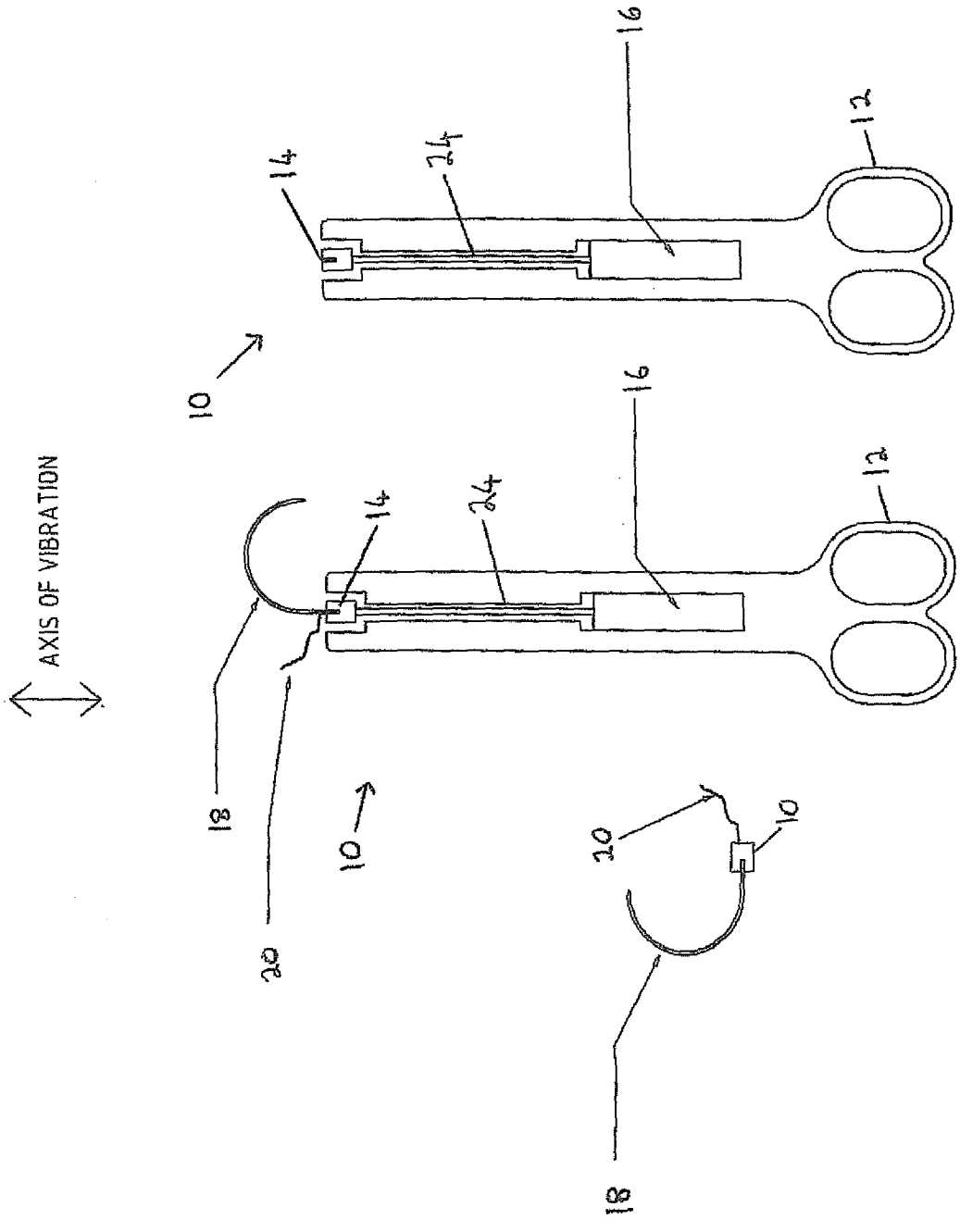

Figure 1(a)

Figure 1(b)

Figure 1(c)

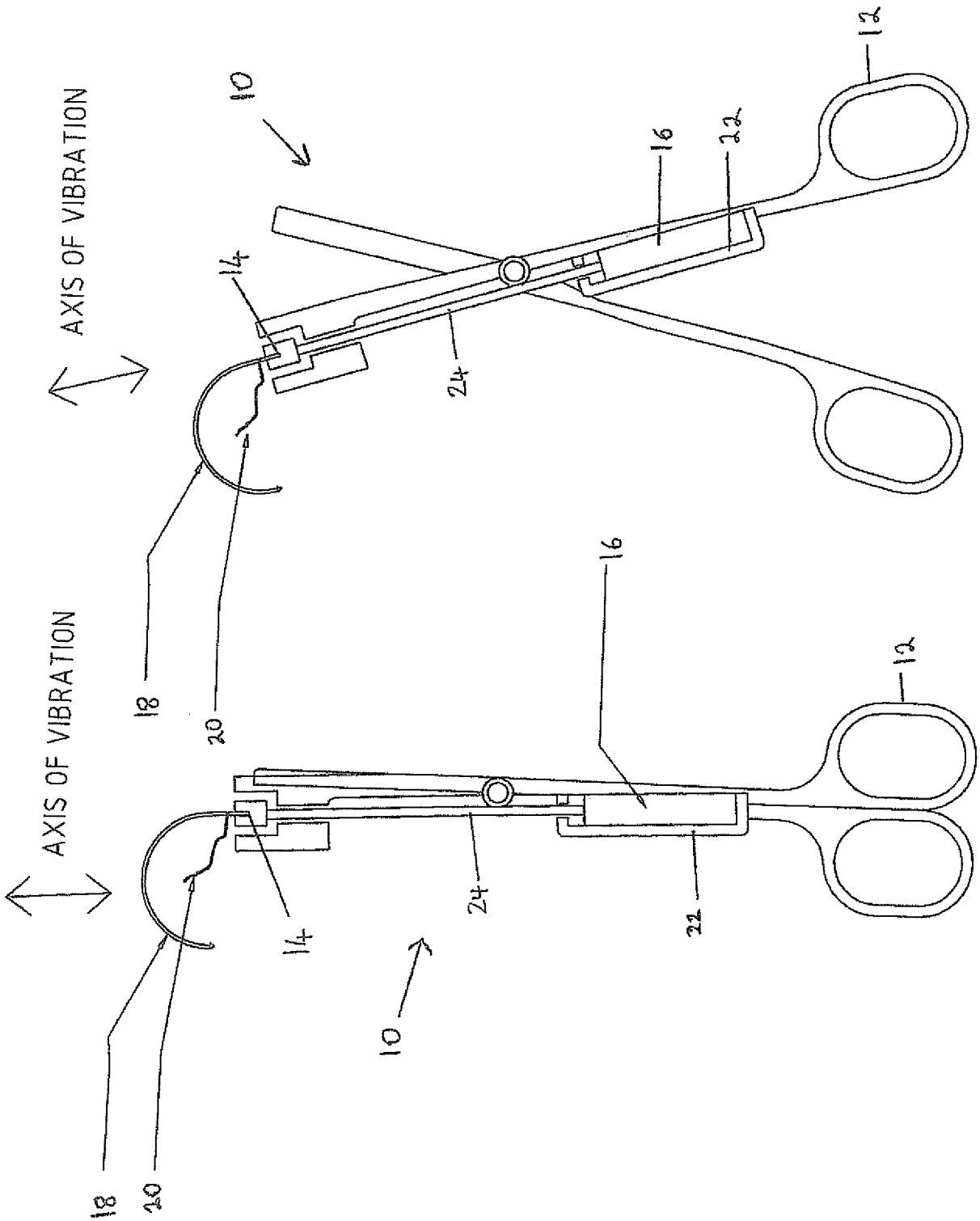

Figure 2(b)

Figure 2(a)

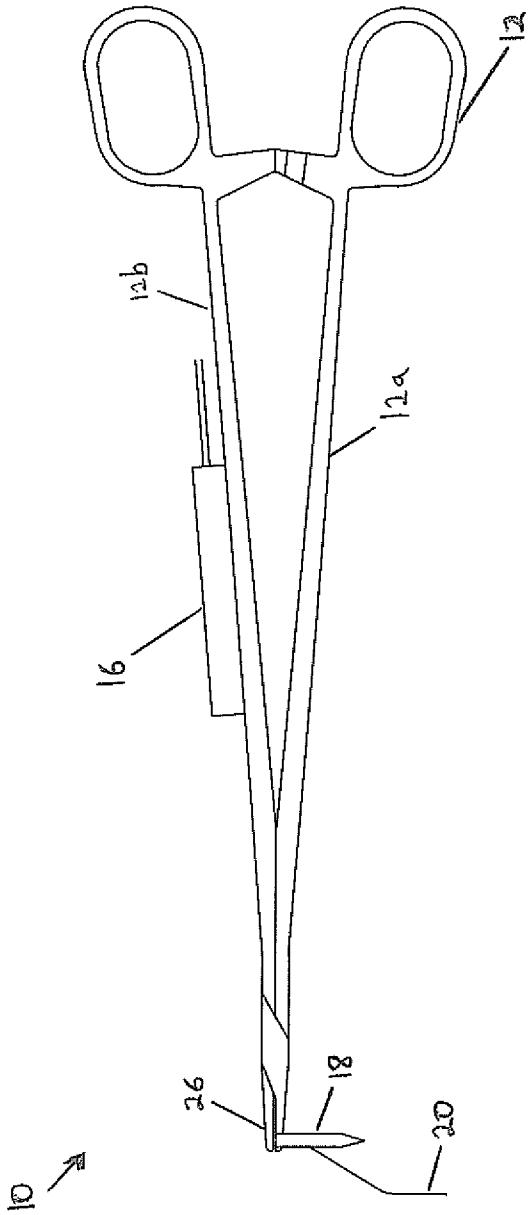

Figure 3(b)

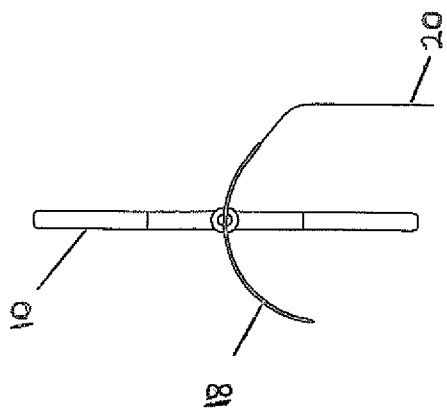

Figure 3(a)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/050242

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61C

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 245 091 B1 (BUNCKE HARRY J [US]) 12 June 2001 (2001-06-12) abstract; figures 1,3	1,10,11, 13,15,16
Y	US 6 238 384 B1 (PEER FERDINAND [DE]) 29 May 2001 (2001-05-29) columns 3,4; figure 1	1-13,15
Y	CA 1 098 003 A1 (ROMERO SIERRA CESAR A; CANADA MAJESTY IN RIGHT OF) 24 March 1981 (1981-03-24) pages 1,2; figure 1	1,10,11, 13,15,16
Y	WO 01/28452 A (TRISA HOLDING AG [CH]; HAEFLIGER PETER [CH]; FISCHER FRANZ [CH]; ELSTE) 26 April 2001 (2001-04-26) abstract	1-13,15, 16

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2007	29/08/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Assion, Jean-Charles

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 624 346 A2 (ETHICON INC [US]) 17 November 1994 (1994-11-17) column 5, line 52 - column 6, line 10; figures 7,8	1-8,10, 12-16
X	US 5 938 633 A (BEAUPRE JEAN [US]) 17 August 1999 (1999-08-17) columns 3,9; figures 1,7	1-9,12, 13,15,16
X	US 6 328 703 B1 (MURAKAMI EIJI [JP]) 11 December 2001 (2001-12-11) columns 5,6; figures 4,5,7	1-10,12, 13
X	EP 0 908 154 A1 (ETHICON ENDO SURGERY INC [US]) 14 April 1999 (1999-04-14) paragraph [0025]; figures 1-3	1-10,12, 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/050242

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-22
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2007/050242

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