"Needle Driving Apparatus and Methods of Suturing Tissue"; U.S. Pat. No. 5,665,109 entitled "Methods and Apparatus for Suturing Tissue"; U.S. Pat. No. 5,759,188 entitled "Suturing Instrument with Rotatably Mounted Needle Driver and Catcher"; U.S. Pat. No. 5,860,992 entitled "Endoscopic Suturing Devices and Methods"; U.S. Pat. No. 5,954,733 entitled "Suturing Instrument with Rotatably Mounted Needle Driver and Catcher"; U.S. Pat. No. 6,719,763 entitled "Endoscopic Suturing Device"; and U.S. Pat. No. 6,755,843 entitled "Endoscopic Suturing Device", all of which are incorporated by reference in their entireties for the teachings therein.

[0009] Assignees' U.S. Pat. No. 5,437,681, U.S. Pat. No. 5,540,705 and U.S. Pat. No. 6,923,819 disclose a suturing device with thread management comprising a protective cartridge, suturing needle and needle rotation drive, the disclosures of which are hereby incorporated by reference. The devices described in the above-mentioned patents and patent application comprise a mechanism for driving a protected needle however, the needle is rotated about an axis that is parallel to the axis of the device. In addition, the orientation and size of the suturing device makes it difficult to visualize and cumbersome to use for MIS.

[00010] Therefore, there remains a need in the art for a minimally invasive suturing device that is easily manipulated within the small diameter of the cannula; functions in an environment characterized by limited space, limited visualization, and limited mobility; mimics the preferred method of suturing used by surgeons; permits the surgeon to secure and tie knots quickly and with controlled tension; places continuous stitches; and protects user's from accidental needle sticks during needle handling, as well as internal organs and vessels, from inadvertent needle-pricks.

SUMMARY

[00011] Devices and methods for minimally invasive suturing of tissue internal to a body are disclosed herein.

[0011a] According to an aspect of the present invention, there is provided a suturing device comprising a suturing head, the suturing head comprising:

a) a needle track housing portion including a needle disposed in a needle track, the needle track being adapted and configured to guide the needle along a curved path about an axis of rotation substantially perpendicular to a longitudinal axis of the suturing head;

b) a drive housing portion containing a drive, wherein the drive includes an elongate flexible member, at least a portion of the elongate flexible member being adapted and configured to reciprocate along a direction substantially parallel to the longitudinal axis, characterized by the needle having:

i) a curved body, the curved body covering an arc greater than about 180°; and

ii) an engagement surface for driving the needle, the engagement surface including a notch; and

the elongate flexible member being further adapted and configured to engage the notch of the needle and advance the needle through a circular arc as the elongate flexible member is pulled in a rotation cycle along the longitudinal axis in a proximal direction,

whereby the needle moves through a first and then a second 180° revolution during the rotation cycle.

[0012] According to ~~aspects illustrated~~the disclosure herein, there is provided a medical device for closing openings internal to a patient's body, which closely emulates or replicates the manual suturing actions carried out by a surgeon. The device may offers several advantages over conventional methods used by surgeons for suturing tissue during minimally invasive surgery

in that the device provides a hand-held suturing instrument of relatively simple mechanical construction that requires no external motive source. The presently disclosed embodiments provide relative ease of operation for the surgeon with only one hand.

[0013] According to ~~aspect illustrated~~the disclosure herein, a suture head assembly may be removably attached to an actuator mechanism of the suturing device. The diameter of the device is small enough to fit into a typical cannula, thus making the device extremely easy to maneuver, as well as suture, during endoscopic or other MIS procedures. Also, the suture head assembly of the device can be laterally articulated to the left of center, to the right of center, up and down, once inside the cannula, which ~~is~~may be ideal for use in the course of endoscopic surgery, including laparoscopy, thoracoscopy and arthroscopy, as well as other less-invasive surgical procedures.

[0014] The device of the present disclosed embodiments may closely ~~emulates~~ or replicates the manual suturing actions carried out by a surgeon. For example, during manual suturing by hand, the needle is held in forceps and travels in a circular arc with no obstructions anywhere in the interior of the arc. The design of the suturing device of the present disclosed embodiments allows for a lack of obstruction in the center of the arc of the needle during suturing. In other words, there is no hub at the center of the circular arc of the suturing needle. The entire area within the circular arc of the needle is unobstructed. This allows for the user to have better visualization during operation, unlike the present mechanical suturing methods, while maintaining control over needle movement.

[00015] A benefit provided by the suturing device of the presently disclosed embodiments is that the device may ~~enables~~ maneuvering a suturing material through a tissue incision in a manner substantially similar to the way a surgeon would do so by hand. In particular, the suturing device first pushes a suturing needle from the tail of the needle and drives the point of the needle through the tissue. The device then picks up the point of the needle that passed through the tissue, and pulls the remainder of the suturing needle and the suture attached to the suturing needle through the tissue. The suturing needle thus consistently follows the arc of the needle's own curve, which is the preferred method of suturing, in the most atraumatic way of passing a needle through tissue. A benefit provided by the suturing device of the presently disclosed embodiments is the ability of the suturing needle to pull the suturing thread entirely through the tissue segments being closed, following

each stitch. When using the suturing device of the presently disclosed embodiments, no ancillary instruments or tools such as needle holders, pick-up forceps or the like ~~are~~may be needed to complete the stitch. A forceps can be used to tighten the knots.

[0016] According to ~~aspects illustrated~~the disclosure herein, there is provided a suturing device that includes a suturing needle that is protected by a housing, the suturing needle is not exposed to or handled directly by the user, thereby preventing inadvertent needle sticks. The configuration of the suturing device of the presently disclosed embodiments can also protects against inadvertent penetration of internal organs or vessels by the needle, since the housing acts as a shield between the organs and the needle.

[0017] According to ~~aspects illustrated~~the disclosure herein, there is provided a method for suturing tissue during minimally invasive surgery that includes: (a) engaging a suturing needle with a pointed end and a second end to a suture head assembly at a distal end of a suturing device, the suture head assembly includes a curved track, whereby the suturing needle follows a curved path along the track during rotation of the suturing needle, and a latch that provides a protective housing for the suturing needle; (b) introducing the distal end of the suturing device into a body cavity; (c) positioning an opening in the needle holder assembly to span a plurality of separated tissue segments or a single tissue segment; (d) activating an actuator coupled to a drive mechanism that engages the suturing needle to cause rotational movement of the suturing needle about an axis approximately perpendicular to a longitudinal axis of the suturing device and advance the suturing needle through the plurality of separated tissue segments or the single tissue segment; (e) pulling a suturing material attached to the suturing needle through the plurality of separated tissue segments or a single tissue segment forming a stitch; and repeating steps (c) through (e) to cause a plurality of stitches to be placed through the separated tissue segments or a single tissue segment.

[0018] According to ~~aspects illustrated~~the disclosure herein, there is provided a method for suturing tissue during minimally invasive surgery that includes inserting a distal end of a suturing device having a suturing needle with a pointed end into a body; positioning the suturing needle to span a plurality of separated tissue segments; activating an actuator a first time causing the pointed end of the suturing needle to extend beyond a protective housing of a cartridge to engage the plurality of separated tissue segments; and activating the actuator a second time to cause the suturing needle to complete a revolution and pull a suture extending

from the suturing needle through the plurality of separated tissue segments to form a stitch.

[00019] In addition to the advantages discussed above, the suturing device of the presently disclosed embodiments ~~is~~may be relatively simple and cost efficient to manufacture. Therefore, the suturing device ~~should~~may find widespread suturing applications that include single stitches or continuous stitches, e.g. spiral, mattress, purse string, etc., that are required to close tissue incisions, attach grafts, or the like.

[00020] These and other advantages of the presently disclosed embodiments are illustrated through the embodiments described hereinafter. The presently disclosed embodiments accordingly comprise the features of construction, combination of elements and arrangement of parts that will be exemplified in the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[00024] The presently disclosed embodiments will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the presently disclosed embodiments.

[00025] **FIGS. 1-11** describe an embodiment of a device made in accordance with the invention.

[00026] **FIGS 12-25** describe still a further embodiment of a device made in accordance with the invention.

[00027] While the above-identified drawings set forth presently disclosed embodiments, other embodiments are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the presently disclosed embodiments.