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(54) Title: HOOK-KNIFE TOOL FOR PERFORMING PALMAR/PLANTAR ANNULAR LIGAMENT (PAL) DESMOTOMY

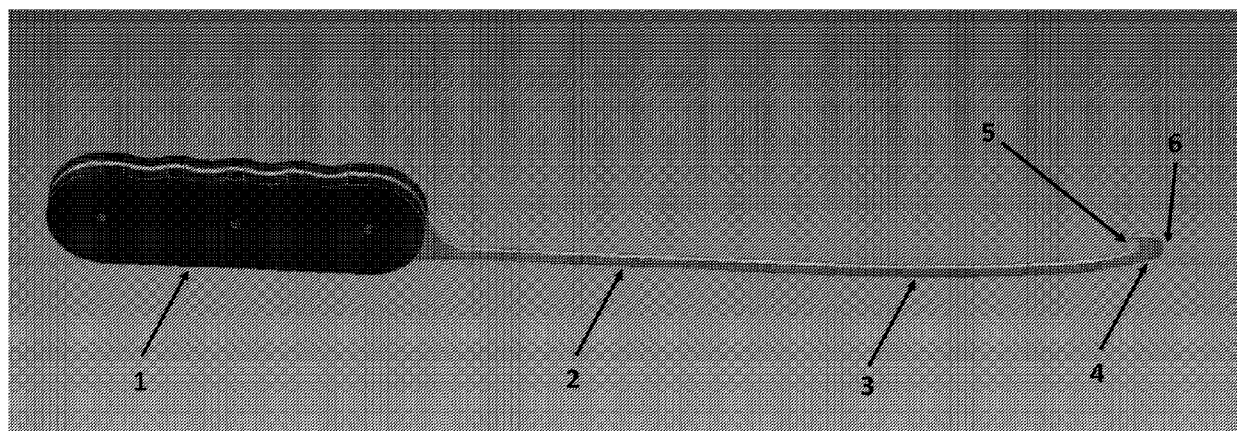


Fig. 5

(57) Abstract: This invention provides a hook-blade surgical instrument useful for transecting an equine palmar/plantar annular ligament (PAL) and/or adhesions within the digital flexor tendon sheath (DFTS).



HOOK-KNIFE TOOL FOR PERFORMING PALMAR/PLANTAR ANNULAR LIGAMENT (PAL) DESMOTOMY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S.
5 Provisional Application No. 62/445,681, filed on January 12, 2017, which is hereby
incorporated herein by reference in its entirety for all purposes.

BACKGROUND

[0002] The digital flexor tendon sheath (DFTS) is an important and complex
synovial structure that envelopes the deep digital flexor tendon (DDFT) and superficial
10 digital flexor tendon (SDFT) from the middle and distal third metacarpus/tarsus proximally
to the proximal aspect of the navicular bursa distally (1-10). The DFTS and its contents
pass over the palmar/plantar aspect of the metacarpo/metatarsophalangeal joint, through the
fetlock canal, which is bordered by the proximal sesamoid bones abaxially,
intersemoidean ligament dorsally, and the palmar/plantar annular ligament (PAL) (8,10-
15 13). The PAL has consistent horizontal fiber orientation and originates/inserts on the
abaxial margins of the proximal sesamoid bones where it blends with the collateral
sesamoidean ligaments (8,14,15).

[0003] PAL desmotomy is a commonly performed procedure in horses with chronic
tenosynovitis to relieve constriction within the DFTS at the level of the fetlock canal (3,11-
20 13). It can also be performed in cases of adhesions between SDFT and the PAL and
enthesopathy of the PAL (16). Constriction syndrome can result from enlargement of the
PAL, hypertrophy of the adjacent fibrous layers of the DFTS, or from digital flexor
tendinitis (11-13). The decision to pursue PAL desmotomy depends on the clinical signs
attributable to fetlock canal constriction, duration of the tenosynovitis, and failure to
25 respond to previous therapies (1). During tenoscopic examination of the DFTS, transection
of the PAL significantly increases the size of the fetlock canal making tenoscopic evaluation
and surgical manipulations within the fetlock canal easier to perform, thus reducing the risk
of iatrogenic damage (3,4,11,17).

[0004] Several techniques for PAL desmotomy have been described which can be
30 performed without the equipment necessary for tenoscopy, including open (18),
extrasynovial (19), and blind approaches using a bistoury knife, scalpel or Mayo scissors

(2,7,20). Disadvantages of these techniques are related to their more invasive approaches as compared to tenoscopic PAL transection, and the potential for iatrogenic damage to intrathecal structures (3,4). Tenoscopic techniques for PAL transection under direct visualization using a slotted cannula and 90 degree blade, curved blades, hook knife, or
 5 electrosurgical devices have also been described (4,6,9-12,21). Tenoscopy offers the additional advantages of complete DFTS exploration and allows for identification and treatment of other commonly encountered intrathecal pathology including DDFT, SDFT and manica flexoria tears, adhesions and proliferative synovial masses (3,11,12). Disadvantages of tenoscopy include the need for general anesthesia and the cost of
 10 specialized equipment (11).

[0005] To date, there have been only sporadic reports describing the use of intraoperative ultrasonography in equine surgery (22-24). Intraoperative ultrasonographic guidance has been reported for desmotomy of the accessory ligament of the deep digital flexor tendon (25), and removal of basilar proximal sesamoid fragments (26,27).

15 Ultrasound has also been reported to be a useful tool for preoperative planning of surgical approaches, identifying relevant anatomical structures and subsequently avoiding iatrogenic damage to these structures (23,24).

SUMMARY

[0006] In one aspect, provided is a hook-blade or hook-knife surgical instrument. In
 20 various embodiments, the instrument comprises:

- (i) a handle or grip (1) that fits in an adult human hand;
 - (ii) a shaft (2) connected to the handle, wherein the cross-section of the shaft is rectangular, optionally with blunt edges; and
 - (iii) a hook (4) comprising an inner arc that comprises a blade (5) capable of
 25 cutting across an equine plantar/palmar annular ligament (PAL), wherein the total length of the hook-blade surgical instrument is in the range of about 20 cm to about 21 cm, 22 cm, 23 cm, 24 cm or 25 cm. In various embodiments, the length of the shaft traces the shape of a fetlock joint of an equine or a bovine. In various embodiments,
- i) the ratio of the width to the length of the handle is in the range of from 1:2 to
 30 1:4, *e.g.*, 1:2, 1:2.5, 1:3, 1:3.5, or 1:4;
 - ii) the ratio of the shaft length relative to the total length of the instrument is from 3:4 to 1:2, *e.g.*, 3:4, 3:4.5, 3:5, 3:5.5, or 3:6;

iii) the ratio of the shaft rectangular cross-sectional width and depth is from 1:1 to 1:4, *e.g.*, 1:1, 1:1.5, 1:2, 1:2.5, 1:3, 1:3.5, or 1:4; and/or

iv) the ratio of the blunt tip (6) with the hook (4) is from 1/7 to 1/29, *e.g.*, 1/7 to 1/8, 1/9, 1/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 1/18, 1/19, 1/20, 1/21, 1/22, 1/23, 1/24, 1/25, 1/26, 1/27, 1/28 or 1/29. In some embodiments, the weight of the instrument is in the range of about 180 grams to about 200 grams. In various embodiments, the instrument is comprised of one or more materials selected from the group consisting of stainless steel, titanium, carbon fiber, carbon fiber composite and a high density polymer (*e.g.*, reinforced with glass or carbon fibers). In various embodiments, the instrument is comprised of a surgical grade stainless steel, *e.g.*, austenitic 316 stainless steel, martensitic 420 stainless steel or martensitic 440 stainless steel. In various embodiments, the instrument is laser cut stainless steel. In various embodiments, the handle is unpadded. In various embodiments, the handle has a length in the range from about 6 cm to about 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 13 cm or 14 cm, a depth in the range from about 0.02 cm to about 0.05 cm, 0.1 cm, 0.2 cm, 0.3 cm, 0.4 cm, or 0.5 cm, and a width in the range from about 1 cm to about 2 cm, 3 cm, 4 cm, 5 cm or 6 cm. In various embodiments, the shaft has a length in the range from about 5 cm to about 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 13 cm, 14 cm, or 15 cm. In various embodiments, the shaft has a cross-sectional width in the range from about 0.5 mm to about 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8 mm, 9 mm or 10 mm and a cross-sectional depth in the range from about 0.5 mm to about 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8 mm, 9 mm or 10 mm. In some embodiments, the shaft comprises an angle, bend or kink (3) at a position about 2/3 distal from the handle and 1/3 proximal to the hook. In some embodiments, the shaft comprises an angle, bend or kink (3) at a position about 9 cm from the handle and 4 cm to the hook. In various embodiments, the angle, bend or kink is in the range of about 60° to about 65°, 70°, 75°, 80° or 85° from the axis of the shaft proximal to the handle from the angle, bend or kink. In some embodiments, inner arc of the hook comprises an arc that is between about 30° to about 180°, *e.g.*, between about 60° to about 120°, *e.g.*, about 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, or 180°. In some embodiments, the blade has a length in the range of about 1 mm to about 2 mm, 3 mm, 4 mm, 5mm or 6 mm. In some embodiments, the hook has an outer width from about 2 mm to about 3mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9mm or 10 mm. In some embodiments, the hook has a length in the range from about 1 mm to about 2 mm, 3 mm, 4 mm or 5 mm. In some embodiments, the tip or blunt end of the hook (4) is blunt such that it does not cut tendinous

or ligamentous adjacent tissue but can be pushed through fascia that surrounds ligament tissue. but can be pushed through fascia that surrounds ligament tissue. In some embodiments, the instrument is sized and proportioned to transect the plantar/palmar annular ligament (PAL) of an adult equine, a juvenile equine, a miniature equine or a pony.

5 **[0007]** In a further aspect, provided is a kit comprising one or more a hook-blade surgical instruments as described above and herein. In some embodiments, the kit comprises two or more a hook-blade surgical instruments as described above and herein, wherein each hook-blade surgical instrument in the kit comprises a hook of a different width and a blade of a different length.

10 **[0008]** In a further aspect, provided is a method of performing desmotomy or transection of an equine plantar/palmar annular ligament. In some embodiments, the methods comprise transecting or cutting the ligament with a hook-blade surgical instrument as described above and herein. In some embodiments, the methods further comprise, prior to the step of transecting or cutting, the steps of:

15 (a) distending with fluid the proximal abaxial recesses (PAR) of the digital flexor tendon sheath (DFTS);

 (b) introducing the hook-blade into the DFTS, directed distally with the blade facing laterally;

 (c) rotating the hook-blade instrument to orient the blade towards the
20 plantar/palmar annular ligament (PAL) and away from the superficial digital flexor tendon (SDFT). In some embodiments, the PAL is transected in a distal to proximal direction. In some embodiments, the methods further comprise the step of transection of adhesions within the digital flexor tendon sheath (DFTS). In some embodiments, the step of adhesion transection is performed while being assisted by or with the assistance of ultrasonographic
25 guidance. In some embodiments, the positioning of the instrument before transecting or cutting, *e.g.*, of a PAL or an adhesion, is assisted by ultrasonography. In some embodiments, the method is performed on a standing sedated equine. In some embodiments, the method is performed on an adult equine, a juvenile equine, a miniature equine, or a pony. In some embodiments, injury to the neurovascular bundles on the lateral
30 and/or medial sides of the limb, and/or iatrogenic injury to the deep digital flexor tendon (DDFT), superficial digital flexor tendon (SDFT) and manica flexoria is reduced or avoided. In some embodiments, the method or procedure can be completed in less than about 30 minutes, *e.g.*, in less than about 25, 20 or 15 minutes.

[0009] In another aspect, provided is a method for transection of adhesions, comprising transecting or cutting one or more adhesions within the digital flexor tendon sheath with a hook-blade surgical instrument as described above and herein. In some embodiments, the method of adhesion transection is performed while being assisted by or
5 with the assistance of ultrasonographic guidance.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Figures 1A-E illustrate intraoperative image of a left forelimb of a standing horse. A: the proximal abaxial recess (PAR) is identified by ultrasound after intrathecal
10 distension. B: Manual retraction of the flexor tendons medially to facilitate penetration of the lateral PAR and reduce the risk of inadvertent penetration of the manica flexoria or injury to the flexor tendons. C: The instrument is being guided by ultrasound palmar to the superficial digital flexor tendon. D: Surgical instrument. Dimensions of the hook: length of shaft and handle = 23 cm; length of shaft = 13 cm; outer width of hook = 3.2 mm; inner
15 width of hook = 2.1 mm. E: Appearance of the splint after removing the two straps located in the middle.

[0011] Figures 2A-C: A: Lateral and plantar aspect of the digital flexor tendon sheath (DFTS) after distension. Note the proximal abaxial recess (PAR) (white arrow) protruding proximal to the palmar/plantar annular ligament (PAL). B: Dissection of the
20 DFTS after PAL transection in a cadaveric limb. 1 – PAL; 2 – Superficial digital flexor tendon; 3 – Manica flexoria. The circle represents the location of the PAR. See the fine fold separating the dorsal pouch of the DFTS (white arrow) and the PAR (red arrow). C: Appearance of the PAL completely transected after dissection in an in-vivo limb. Note the separated edges of the PAL (white arrows).

25 [0012] Figures 3A-D: A: Ultrasonographic appearance of the proximal abaxial recess (white arrow) in transverse (A) and (B) longitudinal orientation after DFTS distension. C: Ultrasonographic image of the hook (arrow) at the palmar aspect of the superficial digital flexor tendon. Note how the instrument lifts the palmar/plantar annular ligament (PAL) tensing its longitudinal fibers. D: Appearance of the PAL after transection.
30 Note the separated edges of the PAL (white arrows). Image captured with the limb in a weight bearing position.

[0013] Figure 4: A: Tenoscopic image of the palmar annular ligament after transection using the described technique in one clinical case (Horse 1).

[0014] Figure 5 illustrates a 3-dimensional side view of an embodiment of the hook-knife tool. Images were created using Cinema-4D (Version 11.0). In this embodiment, the shaft has a curvature proximal to the hook that traces or mimics the curvature of an equine fetlock joint. (1) handle; (2) a shaft; (3) an optional angle, bend or kink marking proximal and distal portions of the shaft, *e.g.*, relative to the handle; (4) outer arc of the hook comprising a blunt tip (6); and (5) blade or knife in the inner arc of the hook.

[0015] Figure 6 illustrates a side view of the full length of a stainless steel prototype of the hook-knife tool, including the handle, shaft and hook. In this embodiment, the shaft does not have a curvature that traces or mimics the curvature of an equine fetlock joint. Experimental transection of the PAL in cadaveric limbs allowed us to determine and conclude that a straight distal portion facilitated rotation and maneuverability of the instrument within the digital flexor tendon sheath.

[0016] Figures 7A-B illustrate side views of the hook of the stainless steel prototype of the hook-knife tool.

[0017] Figure 8 illustrates a three-quarter view from the top of the hook of the stainless steel prototype of the hook-knife tool.

[0018] Figure 9 illustrates a top view of the hook of the stainless steel prototype of the hook-knife tool.

[0019] Figure 10 illustrates a side view of the handle and a portion of the shaft distal from the hook from the stainless steel prototype of the hook-knife tool.

DETAILED DESCRIPTION

1. Introduction

[0020] Provided is a hook-knife surgical tool, *e.g.*, for use in an ultrasound guided technique for PAL desmotomy that can be performed in the standing or recumbent horse with high levels of efficacy and reduced incidence of complications associated with the procedure. The herein described technique is easy to perform, well-tolerated in standing horses, and allows for precise transection of the PAL with minimal or no damage to adjacent intrathecal structures.

2. Hook-Knife Tool

[0021] Generally, the hook-knife or hook-blade surgical instrument comprises the structural features of (1) a handle; (2) a shaft connected to the handle, wherein the cross-section of the shaft is rectangular; a hook (4) at the distal end of the shaft, the hook (4) comprising an outer arc and an inner arc, wherein the outer arc of the hook comprises a blunt tip (6); and the inner arc of the hook is formed into a blade or knife (5), as depicted in Figure 6. In embodiments where the shaft has an angle, a bend or a kink (3), *e.g.*, to trace or outline or follow the shape of a fetlock joint of an equine, the proximal and distal portions of the shaft are readily distinguishable. The instrument usually has a length capable of reaching the plantar/palmar annular ligament (PAL) from the entry point into the digital flexor tendon sheath (DFTS) which is located immediately proximal to the proximal margin of the PAL and abaxial to the superficial digital flexor tendon on its lateral aspect. In some embodiments, the instrument has a length, *e.g.*, as measured from the tip of the handle to the end of the blunt tip (6) of the hook, in the range of about 20 cm to about 21 cm, 22 cm, 23 cm, 24 cm or 25 cm. It is generally made of a material that can be readily sterilized, *e.g.*, in an autoclave, and is of a hardness and rigidity sufficient to allow the outer arc of the hook be pushed through fascia and the blade within the inner arc of the hook cut ligament tissue. In various embodiments, the instrument is made of stainless steel or titanium. Other surgical grade alloys may also find use. In certain embodiments, the hook-knife surgical tool is made of a carbon fiber, a carbon fiber composite or a high density polymer, *e.g.*, having sufficiently high tensile strength (*e.g.*, at least about 750 MPa) and sufficiently high Young's modulus (*e.g.*, stiffness or resistance to extension under load, *e.g.*, at least about 150 GPa) to allow the outer arc of the hook be pushed through fascia and the blade within the inner arc of the hook cut ligament tissue. Illustrative high density polymers that can find use include without limitation, *e.g.*, Acetal Copolymer + glass or carbon fiber, Polyamide-Imide, and Polyimide + glass or carbon fiber. Illustrative carbon fiber (composites) having sufficiently high tensile strength and Young's Modulus include without limitation, *e.g.*, TORAYCA T1100G, T1000G, T800S, T700S and T400 (Toray Industries Inc. (Tokyo, Japan)). In various embodiments, the instrument is made of a surgical grade stainless steel, *e.g.*, austenitic 316 stainless steel, martensitic 420 stainless steel or martensitic 440 stainless steel. In various embodiments, the instrument is laser cut stainless steel. Depending of the material of manufacture, in various embodiments, the weight of the instrument is in the range of about 180 grams to about 200 grams, *e.g.*, about 180, 185, 190, 195, 200 grams.

[0022] In various embodiments,

i) the ratio of the width to the length of the handle is in the range of from 1:2 to 1:4, *e.g.*, 1:2, 1:2.5, 1:3, 1:3.5, or 1:4;

ii) the ratio of the shaft length relative to the total length of the instrument is from 3:4 to 1:2, *e.g.*, 3:4, 3:4.5, 3:5, 3:5.5, or 3:6;

iii) the ratio of the shaft rectangular cross-sectional width and depth is from 1:1 to 1:4, *e.g.*, 1:1, 1:1.5, 1:2, 1:2.5, 1:3, 1:3.5, or 1:4; and/or

iv) the ratio of the blunt tip (6) with the hook (4) is from 1/7 to 1/29, *e.g.*, 1/7 to 1/8, 1/9, 1/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 1/18, 1/19, 1/20, 1/21, 1/22, 1/23, 1/24, 1/25, 1/26, 1/27, 1/28 or 1/29.

[0023] As appropriate, the instrument can be sized and proportioned for the transection of the plantar/palmar annular ligament (PAL) of an equine or bovine of any size, *e.g.*, an adult, a juvenile, a miniature species.

a. Handle

[0024] Generally, the handle of the hook-knife or hook-blade surgical instrument is of a shape and size to fit comfortably in a human hand. In various embodiments, the handle is of an oblong or oval shape. In various embodiments, the handle is ergonomically shaped to fit in the palm of an adult human hand. In some embodiments, the ratio of the width to the length of the handle is in the range of from 1:2 to 1:4, *e.g.*, 1:2, 1:2.5, 1:3, 1:3.5, 1:4. In order to facilitate sterilization, in various embodiments, the handle is unpadded. In various embodiments, the handle has a length in the range from about 6 cm to about 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 13 cm or 14 cm, a depth in the range from about 0.02 cm to about 0.05 cm, 0.1 cm, 0.2 cm, 0.3 cm, 0.4 cm, or 0.5 cm, and a width in the range from about 1 cm to about 2 cm, 3 cm, 4 cm, 5 cm or 6 cm. The handle may optionally have ridges to prevent slipping of the hand when pushing the instrument against tissue.

b. Shaft

[0025] Generally, the shaft of the hook-knife or hook-blade surgical instrument is rectangular along its length to allow for lifting of the ligament tissue, *e.g.*, by rotation of the shaft, prior to transection with the blade within the inner arc of the hook. In various embodiments, the rectangular shape along the length of the shaft has rounded or blunted corners. In various embodiments, the ratio of the shaft cross-sectional width to depth of the rectangle is from 1:1 to 1:4, *e.g.*, 1:1, 1:1.5, 1:2, 1:2.5, 1:3, 1:3.5, 1:4. In various

embodiments, the shaft has a cross-sectional width in the range from about 0.5 mm to about 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm or 10 mm and a cross-sectional depth in the range from about 0.5 mm to about 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm or 10 mm.

- 5 **[0026]** In various embodiments, the ratio of the shaft length relative to the total length of the instrument is from 3:4 to 1:2, *e.g.*, 3:4, 3:4.5, 3:5, 3:5.5, 3:6. In various embodiments, the shaft has a length in the range from about 5 cm to about 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 13 cm, 14 cm, or 15 cm.

i. Optional Angle or Bend

- 10 **[0027]** In certain embodiments, the shaft comprises an angle, bend or kink (3) at a position about 2/3 distal from the handle and 1/3 proximal to the hook. In some embodiments, the length of the shaft traces the shape of a fetlock joint of an equine or a bovine. In some embodiments, the shaft comprises the angle, bend or kink (3) at a position or location about 9 cm from the handle and 4 cm to the hook. In various embodiments, the
- 15 angle, bend or kink (3) is in the range of about 60° to about 65°, 70°, 75°, 80° or 85° from the axis of the shaft proximal to the handle from the angle, bend or kink. As used herein, the “proximal portion of the shaft” is the portion of the shaft that is between the handle and the angle, bend or kink. As used herein, the “distal portion of the shaft” is the portion of the shaft that is between the angle, bend or kink and the hook. In various embodiments, the
- 20 shaft comprises an angle, bend or kink, and the distal portion of the shaft is straight or substantially straight.

c. Hook

[0028] Generally, the hook (4) comprises an outer arc that is formed into a blunt tip (6) and an inner arc that is formed into a blade or knife (5).

25 i. Outer Arc Forming Blunt Tip

- [0029]** The outer arc formed into a blunt tip (6) of sufficient hardness and appropriately designed shape, *e.g.*, in the form of a narrow “U,” to allow the outer arc of the hook to be pushed through the lateral incision into the digital flexor tendon sheath and facilitate its entrance. Once into the tendon sheath, the tip or blunt end of the hook (6) is
- 30 blunt such that it does not cut tendinous or ligamentous adjacent tissue causing undesired iatrogenic damage.

[0030] In various embodiments, the hook (4) has an outer, lateral width from about 2 mm to about 3mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9mm or 10 mm. In some embodiments, the hook (4) has a length (*e.g.*, as measured from the end of the blunt tip to the true end of the shaft) in the range from about 1 mm to about 2 mm, 3 mm, 4 mm or 5 mm. As used herein, the “end of the blunt tip” is located at the bottom of the narrow “U” shape.

ii. Inner Arc Formed Into Blade or Knife

[0031] The hook (4) comprises an inner arc that comprises a blade or knife (5) of sufficient hardness and sharpness such that the blade or knife is capable of cutting across and transecting an equine plantar/palmar annular ligament (PAL). In some embodiments, inner arc of the hook comprises an arc that is between about 30° to about 180°, *e.g.*, between about 60° to about 120°, *e.g.*, about 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, or 180°. In some embodiments, the blade (5) has a length in the range of about 1 mm to about 2 mm, 3 mm, 4 mm, 5mm or 6 mm. In various embodiments, the ratio of the blunt tip with the hook is from 1/7 to 1/29, *e.g.*, from 1/7 to 1/8, 1/9, 1/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 1/18, 1/19, 1/20, 1/21, 1/22, 1/23, 1/24, 1/25, 1/26, 1/27, 1/28 or 1/29. In various embodiments, the distance between the blunt tip (6) and the blade/knife (5) is between from about 1mm to 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, or 10mm.

3. Methods of Performing Plantar/Palmar Annular Ligament Desmotomy

[0032] Further provided are of performing desmotomy or transection of an equine or bovine plantar/palmar annular ligament. In various embodiments, the methods comprise transecting or cutting the ligament with a hook-blade surgical instrument as described above and herein. In various embodiments, the methods of performing desmotomy further comprise, prior to the step of transecting or cutting, the steps of:

- (a) distending with fluid the proximal abaxial recesses (PAR) of the digital flexor tendon sheath (DFTS);
- (b) introducing the hook-blade into the DFTS, directed distally with the blade facing laterally;
- (c) rotating the hook-blade instrument to orient the blade towards the plantar/palmar annular ligament (PAL) and away from the superficial digital flexor tendon (SDFT). In some embodiments, the PAL is transected in a distal to proximal direction. To accomplish this, the instrument is pulled in the proximal direction with the blade transecting

or cutting the PAL. In some embodiments, the methods further comprise the step of transection of adhesions within the digital flexor tendon sheath (DFTS). In some embodiments, the step of adhesion transection is performed while being assisted by or with the assistance of ultrasonographic guidance. In some embodiments, the positioning of the instrument before transecting or cutting, *e.g.*, of a PAL or an adhesion, is assisted by ultrasonography.

[0033] In another aspect, provided is a method for transection of adhesions, comprising transecting or cutting one or more adhesions within the digital flexor tendon sheath with a hook-blade surgical instrument as described above and herein. In various embodiments, the method of performing adhesion transection further comprise, prior to the step of transecting or cutting, the steps of:

- (a) distending with fluid the proximal abaxial recesses (PAR) of the digital flexor tendon sheath (DFTS);
- (b) introducing the hook-blade into the DFTS, directed distally with the blade facing laterally;
- (c) rotating the hook-blade instrument to orient the blade towards the adhesion to be transected and away from the superficial digital flexor tendon (SDFT). In some embodiments, the method of adhesion transection is performed while being assisted by or with the assistance of ultrasonographic guidance.

[0034] As appropriate or desired, the methods of PAL or adhesion transection can be performed on a standing sedated equine or bovine. In some embodiments, the method is performed on an adult equine or bovine, a juvenile equine or bovine, a miniature equine or bovine, or a pony. In some embodiments, injury to the neurovascular bundles on the lateral and/or medial sides of the limb, and/or iatrogenic injury to the deep digital flexor tendon (DDFT), superficial digital flexor tendon (SDFT) and manica flexoria is reduced or avoided. In some embodiments, the method or procedure can be completed in less than about 30 minutes, *e.g.*, in less than about 25, 20 or 15 minutes.

4. Kit

[0035] Further provided are kits comprising one or more a hook-blade surgical instruments as described above and herein. In various embodiments, the kit comprises two or more a hook-blade surgical instruments as described above and herein. In various embodiments, each hook-blade surgical instrument in the kit comprises a hook of a different width and a blade of a different length. In various embodiments, the hook (4) has an outer,

lateral width from about 2 mm to about 3mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9mm or 10 mm. In various embodiments, the blade (5) of an instrument in the kit has a length in the range of about 1 mm to about 2 mm, 3 mm, 4 mm, 5mm or 6 mm. In various embodiments, the distance between the blunt tip (6) and the blade/knife (5) is between from about 1mm to 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, or 10mm.

EXAMPLES

[0036] The following examples are offered to illustrate, but not to limit the claimed invention.

Example 1

An Ultrasonographic Assisted Technique For Desmotomy Of The Palmar/Plantar Annular Ligament In Horses.

ABSTRACT

[0037] *Objectives:* To describe an ultrasound assisted technique for desmotomy of the palmar/plantar annular ligament (PAL) and to determine the efficacy and intraoperative complications associated with the procedure.

[0038] *Study Design:* Cadaveric and in-vivo study.

[0039] *Animals:* Cadaveric limbs (n = 12), adult horses (n = 4), and clinical cases (n = 6).

[0040] *Methods:* Ultrasound assisted desmotomy of the palmar/plantar annular ligament (UAD-PAL) was performed in cadaveric limbs and in standing horses with the operated limb placed in a distal limb splint. For the clinical cases, the procedure was performed under general anesthesia and was followed by tenoscopic examination. A custom made hook knife was designed and manufactured for the procedure. Complete transection was assessed by postmortem dissection (10 forelimbs, 10 hindlimbs) and by tenoscopic examination (1 forelimb, 1 hindlimb). Thickness of PAL, surgery time, other intra-operative parameters and complications associated with the procedure were recorded.

[0041] *Results:* Complete PAL transection was accomplished in 20/22 limbs. No iatrogenic damage to adjacent intrathecal structures was identified in any case. Correct positioning of the instrument on the first attempt was achieved in 19/22 cases. The most common intraoperative complication was inadvertent subcutaneous placement of the

instrument (n=2). Significant thickening of the PAL (3mm) was present in 1/2 limbs in which complete transection was not achieved.

[0042] *Conclusions:* UAD-PAL using the hook knife was shown to be an effective method of PAL transection, and was associated with minimal intraoperative complications.

5 The procedure can be performed in the standing sedated horse. In cases of thickened PAL another method should be considered for transection.

[0043] This example is published in Espinosa, *et al.*, *Vet Surg.* (2017) 46(5):611-620, which is hereby incorporated herein by reference in its entirety for all purposes.

MATERIALS AND METHODS

10 [0044] For the in vivo part of the study, the experimental protocol was approved by the Institutional Animal Care and Use Committee of the University of California (Davis).

[0045] *Instrument (hook-knife tool).* A 23 cm long instrument with a sharp hook was designed and custom-made using 440C laser cut stainless steel. Cinema 4D (Version 11.0) was used for the three dimensional design of the instrument. Dimensions are
15 specified in figure 1. Characteristics of the instrument include a rectangular shaft with blunt edges, which can be rotated to elevate the fibers of the PAL away from adjacent intrathecal structures, thereby reducing the risk for iatrogenic injury to the SDFT, DDFT and manica flexoria. Additionally, the thickness and shape of the shaft prevent the instrument from bending at the time of PAL transection.

20 [0046] *Cadaveric Study.* A cadaveric study was initially performed to develop the UAD-PAL technique. Distal forelimbs [(n=6) 3 left, 3 right] and hindlimbs [(n=6) 3 left, 3 right] from 6 horses euthanized for reasons unrelated to lameness or pathology arising from the DFTS, PAL or adjacent structures were collected (Tables 1A-C). For all limbs, ultrasonographic examination of the DFTS was performed by one operator (PE) using a
25 linear array transducer a (5–10 MHz) prior to UAD-PAL to measure the PAL thickness and determine the presence of pre-existing pathology within the DFTS. Forelimbs were sectioned 20 cm proximal to the antebrachiocarpal joint and the hindlimbs 20 cm proximal to the tarsocrural joint. For each limb, the procedure was performed within the first 6 hours following euthanasia.

TABLES 1A-C

Table 1A											
Signalment/ Weight (kg)	Limb	PAL thickness (mm)	Length PAR (mm)	Depth PAR NEUTRAL (mm)	Depth PAR MEDIAL traction (mm)	Depth PAR LATERAL traction (mm)	Saline volume (ml)	Distance portals (cm)	Complete Cut	% Left	Attempts
Cadaveric study											
23/G/Arab/475	RF	1	10	2	4.1	0.9	50	7.2	Yes	-	1
	LH	1.1	9	2	3.2	0.7	55	6.1	Yes	-	1
29/G/Paint/500	LF	3	9	1.2	2	0	55	7.5	No	10% length- ≤25% depth	2
	RH	1.8	10	1	2.2	0	50	6.8	Yes	-	2
16/G/WB/675	RF	1.1	11	1.9	3.2	0.7	60	8.2	Yes	-	1
	LH	1.6	11	1.5	3.9	0.6	65	6.7	Yes	-	1
8/F/QH/450	LF	1	9	0.5	2.7	0	50	6.6	Yes	-	1
	RH	1.1	10	0.3	2.3	0	60	6	Yes	-	2
10/F/Trakehner/500	RF	1.1	11	0.2	1.9	0	60	6.5	Yes	-	1
	LH	1.4	10	1.5	3.2	0	55	5.6	Yes	-	1
15/F/Arab/450	LF	1	9	0.8	2	0	35	6.3	Yes	-	1
	RH	1.1	9	0.7	2.5	0	45	5.7	Yes	-	1

Table 1B										
<i>In-vivo study</i>										
Signalment/ Weight (kg)	Limb	PAL thickness (mm)	Length PAR (mm)	Depth PAR NEUTRAL (mm)	Depth PAR MEDIAL traction (mm)	Depth PAR LATERAL traction (mm)	Saline volume (ml)	Distance portals (cm)	Complete Cut	% Left Attempts
26/G/TB/535	LF	1	9	1.2	3	-	35	7	Yes	- 1
	RH	1	11	1.1	3.4	-	35	6.4	Yes	- 1
25/G/QH/555	RF	1	10	1.9	3.5	-	40	7.1	Yes	- 1
	LH	1.1	9.5	1.8	3.1	-	45	6.2	Yes	- 1
23/G/QH/515	LF	1.7	11	1.5	2.7	-	40	7.1	Yes	- 1
	RH	1	9	1	1.8	-	40	6.2	Yes	- 1
25/F/STB/530	RF*	1.4	10	2.5	4.2	-	60	7.3	No	20% length- ≤25% depth 1
	LH**	1.1	10	3.1	4.9	-	50	6.4	Yes	- 1

Table 1C										
<i>Clinical cases</i>										
Signalment/ Weight (kg)	Limb	PAL thickness (mm)	Length PAR (mm)	Depth PAR NEUTRAL (mm)	Depth PAR MEDIAL traction (mm)	Depth PAR LATERAL traction (mm)	Saline volume (ml)	Distance portals (cm)	Complete Cut	% Left Attempts
11/F/Arab-X/525	RF	1.2	11	1	3.8	-	55	7	Yes	- 1
14/F/WB/590	RH	1.1	10	1.1	3.2	-	50	6.1	Yes	- 1
10/G/PRE/515	RF	1.3	10	1.2	3.4	-	50	6.4	Yes	- 1
10/G/QH/488	RH	1.1	9	1	3.1	-	50	6.3	Yes	- 1
17/F/QH/566	RF	1.2	10	1.3	3	-	55	7	Yes	- 1
12/F/Arab/505	RF	1.1	11	1	3.7	-	50	7	Yes	- 1

[0047] *Limb preparation.* For the cadaveric and the in-vivo part of the study the limbs were clipped from carpus/tarsus distally to the coronary band. In order to achieve partial flexion of the fetlock joint and to facilitate passage of the instrument through the fetlock canal, the cadaveric limbs were placed in a commercial aluminum dorsal splint b
5 and secured with straps in a standing position. The limbs were secured in the splint using only the proximal nylon strap at the level of the proximal metacarpus/metatarsus and the distal nylon strap at the level of the heels. The two middle nylon straps of the splint were removed to allow access to the DFTS (Figure 1E). When operating on forelimbs, the contralateral limb was placed in a support-boot c in order to balance both limbs.

10 **[0048]** *Surgical technique.* A 1.5 inch (38.1mm) long 19 gauge needle was introduced into the DFTS using an axial sesamoidean approach (28). Successful entry into the DFTS was confirmed by observation of synovial fluid in the hub of the needle. Following accurate needle placement, a prefilled 33 inch (83.8 cm) extension set with sterile saline 0.9% was attached to the needle. A 3 way stopcock was then placed on the distal end
15 of the extension set, and a 35 mL syringe containing sterile saline 0.9% was used to distend the DFTS until the proximal abaxial recesses (PAR) of the DFTS were visually and palpably distended. Following distention, the 3-way stopcock was closed, and the syringe removed. The needle was left in place until PAL transection was accomplished. The PAR is located on both sides of the SDFT proximal to the proximal edge of the PAL (Figure 2).
20 PAR was distended in order to create a maximal operating space. Distension was considered adequate when the distended lateral PAR of the DFTS was visible ultrasonographically with minimal manual pressure placed on the transducer (Figure 3). If deemed necessary, additional small volumes of saline were infused into the DFTS through the previously placed needle, extension set and stopcock to achieve this goal. The total
25 volume of saline injected was then recorded. Ultrasound was then used to measure the dimensions of the lateral PAR of the DFTS. The longitudinal distance was measured from the most proximal aspect of the DFTS distally, to the proximal aspect of the PAL (Figure 3). The transverse distance was measured at the widest point of the recess, from the lateral aspect of the DFTS axially, to the lateral border of the digital flexor tendons. These
30 measurements were obtained under three different conditions as follows: without manipulation of the flexor tendons within the sheath; with pressure applied on the flexor tendons at the level of mid metacarpus/tarsus displacing them medially; with pressure applied at the same level but displacing the flexor tendons laterally. The pressure to

displace the tendons was applied by two different methods, manually or using the proximal nylon strap of the splint. In the in-vivo part of the study, the strap of the splint was used pushing tendons only towards medial. When the procedure was performed on the clinical case under general anesthesia only manual pressure was used.

5 **[0049]** For PAL transection, ultrasound was used to determine the exact location within the lateral PAR where the distance between the lateral aspect of the DFTS and the lateral border of the SDFT was greatest (Figure 3). A #15 scalpel blade was used to create a 5-mm incision through the skin and subcutaneous tissue at this location for subsequent introduction of the instrument into the DFTS. A second skin incision was made distal to the
10 distal border of the PAL and between the ergot and the neurovascular bundle. The location of the second incision was located at the level of the standard tenoscopic portal used for comprehensive exploration of the DFTS (11). The purpose of this distal incision was used to better describe the exact location of the PAR relative to this landmark. Following completion of the procedure, the location of and the distance between both incisions were
15 recorded. Following creation of both skin incisions, a stab incision into the DFTS was made through the proximal skin incision and the custom made hook knife was immediately introduced into the DFTS (Figure 1) and directed distally with the blade facing laterally. Ultrasonographic guidance was used to safely pass the blade between the PAL and the palmar/plantar aspect of the SDFT (Figure 3). Once the instrument was placed
20 palmar/plantar to the SDFT, it was rotated 45 to 90 degrees in a palmar/plantar direction. This rotation and the rectangular shape of the shaft of the instrument resulted in deflection of the transverse fibers of the PAL away from the SDFT, better delineating these adjacent structures as the hook was advanced distally to lie just distal to the distal border of the PAL. The tip of the instrument was palpable distal to the PAL, and the handle rotated to orient the
25 blade towards the PAL and away from the SDFT. Care should be taken to avoid iatrogenic injury to the axial mesotenon of the SDFT. Finally, the distal border of the PAL was engaged with the hook blade, and transected in a distal to proximal direction, by placing traction on the instrument. The neurovascular bundle is located dorsal to the operated region, and care was taken to avoid damage to this structure at the time of PAL transection.

30 **[0050]** Inadvertent incorrect positioning the hook, and the number of attempts necessary to position it in the correct location prior to PAL transection were recorded. For the in-vivo portion of the study and the two clinical cases in which the technique was employed the surgery time was recorded from DFTS distention to PAL transection. Once

the procedure was completed, iatrogenic damage to adjacent intrathecal structures (manica flexoria, SDFT, DDFT and proximal digital annular ligament) was assessed by DFTS dissection. The PAL was assessed grossly for completeness of transection. The depth and length of PAL transection was recorded. When the transection was incomplete the remaining depth was measured using a caliper and then classified as complete, <25% remaining, 26-50% or >50% remaining. Also, the length of the remaining ligament was measured with a ruler and documented in percentage of total length transected.

[0051] *In-vivo study.* Following the cadaveric study, the technique was performed in 4 adult horses that were subsequently euthanized. Four adult horses (3 geldings, 1 mare; 2 mixed breed, 1 Thoroughbred, aged 4–7 years, weighing 400–450 kg) were used for the study (Tables 1A-C). For all horses, physical and lameness examination, palpation and ultrasonographic examination of the DFTS were within normal limits. For each horse, one forelimb and one hindlimb were selected for UAD-PAL, and included equal numbers of left and right fore and hindlimbs. The DFTS was scanned prior to UAD-PAL to determine the presence of pre-existing pathology and PAL thickness. Horses were sedated with detomidine hydrochloride (0.01 mg/kg [0.005 mg/lb] IV) and butorphanol tartrate (0.01 mg/kg [0.005 mg/lb] IV). A ring block was performed at the level of the proximal third of the third metacarpus/tarsus on the operated limb using a total volume of 20mL 2% lidocaine hydrochloride. The operated limb was then placed in the splint as described for the cadaveric study. Based on the results of the cadaveric study, the proximal nylon strap was always placed to secure the splint by wrapping it around the proximal metacarpus/tarsus in a palmaro/plantarolateral to palmaro/plantaromedial direction. In this manner, the proximal nylon strap of the splint would displace and maintain the flexor tendons medially, allowing greater access to the lateral PAR of the DFTS. UAD-PAL was performed as previously described for the cadaveric study, but with one exception. In one horse, the front foot would not fit into the splint, so a 5cm tall wood wedge was taped to the heel of the operated limb in order to simulate the heel elevation produced by the splint. Only measurements of the lateral PAR of the DFTS were obtained with the flexor tendons maintained in a medially displaced position by the proximal nylon strap of the splint, as this was the planned site of surgical entry into the DFTS. Immediately following surgery and removal of the splint, the PAL was reevaluated ultrasonographically with the horse weight bearing, to assess separation of the transected margins of the PAL (Figure 3D). All horses were humanely euthanized immediately following the procedure using sodium pentobarbital (86 mg/kg

[39mg/lb] IV). The DFTS was then dissected to evaluate the desmotomy as described for the cadaveric study.

[0052] *Clinical cases.* After the cadaveric and in-vivo studies were completed, the technique was performed in six clinical cases. In two cases (11-year-old Arabian/Fresian mare and 14-year-old Warmblood mare) the procedure was followed by tenoscopy of the DFTS, on the other 4 cases PAL desmotomy alone using the described technique and instrument was successfully performed. An 11-year-old Arabian/Fresian mare (Horse 1) used for endurance was evaluated for lameness on the right forelimb of 9 months duration. Clinical examination revealed a grade 3/5 right forelimb lameness as graded on a 5 point scale (29). Horse 2, a 14-year-old Warmblood mare used for show jumping was presented with a history of right hind lameness of 5 months duration. Lameness was graded as 2/5 and significantly worsened after distal limb flexion. In both of these cases, moderate to severe DFTS effusion, with characteristic notching at the level of the proximal border of the PAL was observed, and the lameness was localized to the distal metacarpo metatarso-phalangeal region using perineural anesthesia (medial and lateral palmar/plantar nerves and palmar/plantar metacarpal-metatarsal nerves). For Horse 1, ultrasonographic examination of the DFTS revealed mild to moderate multifocal deep digital flexor tendonitis with associated tenosynovitis. Ultrasonographic examination of the DFTS in Horse 2 revealed enlargement of the DDFT in both the pastern and distal metatarsal regions. In both cases the dimensions of the PAL were within normal limits (30). Prior to presentation, both horses had failed to respond to conservative management consisting of rest, systemic anti-inflammatories and intrathecal hyaluronic acid administration.

[0053] A 10-year-old Andalusian (PRE) gelding used for dressage presented with a history of right front lameness associated to chronic tenosynovitis and thickening of the PAL. The horse was induced under general anesthesia and PAL transection was performed using the described technique and instrument. Three months after the surgery significant improvement of the lameness was appreciated by the owner and trainer. PAL desmotomy with the described instrument was also performed in a 10-year-old QH gelding with right hind lameness associated to the DFTS. The horse positively responded to transection of the PAL and returned to function 4 months after the surgery. A 17-year-old QH mare admitted for chronic RF lameness associated to the DFTS underwent PAL transection with the described instrument under general anesthesia. The procedure was performed successfully and the degree of lameness improved three months after the surgery. A 12-year-old Arabian

mare presenting with RF lameness of 4-month duration and obvious distension of the DFTS was operated under general anesthesia and the PAL was transected using the described instrument. No complications were recorded during or after the surgery and the mare returned to exercise three months after the procedure.

5 [0054] The horses were anesthetized and placed in left lateral recumbency. The affected limb was clipped and aseptically prepared for surgery.

[0055] In both cases the DFTS was distended with 2% mepivacaine hydrochloride, the ultrasound probe was placed in a sterile rectal sleeve, and ultrasonographic assisted PAL desmotomy performed under general anesthesia as previously described. Immediately
10 following PAL desmotomy, the arthroscope was introduced into the DFTS using the standard approach (11). Transection of the PAL, without iatrogenic injury to adjacent structures was confirmed, followed by comprehensive examination of the sheath contents. In Horse 1, tenoscopic examination revealed fibrillation and longitudinal tearing of the lateral margin of the DDFT through the fetlock canal, extending 2 cm proximal to the
15 proximal edge of the PAL. In Horse 2 tenoscopic examination revealed fibrillation and tearing on the dorsolateral margin of the DDFT proximal to the manica flexoria. The tear and the fibrillated regions were debrided using a radiofrequency probed. No incisional complications were observed postoperatively. At the completion of surgery, the portals were closed with simple interrupted non-absorbable sutures (2-0 polypropylene), and a
20 distal limb bandage placed. Both horses recovered uneventfully from anesthesia.

RESULTS

[0056] The volume of fluid used to adequately distend the DFTS, depth and length of the PAR, distance between portals and number of attempts necessary for correct positioning of the hook knife are available in Tables 1A-C. PAL thickness measured 1.1
25 mm (median) and ranged from 1-3 mm. The volume of intrathecal fluid required for appropriate distension of the proximal abaxial recess was 50 mL (median, range 35-65 mL). No difficulties were encountered in any case during DFTS distension. Longitudinal and transverse measurements of the distended PAR were obtained ultrasonographically (Tables 1A-C). Longitudinal measurements were 10 mm (median, range 9-11 mm). Transverse
30 measurements were obtained at the widest point of the PAR. Highest measurements were obtained when tendons were displaced towards medial (3.1 mm median, range 1.8-4.9 mm) (Tables 1A-C). The distance between the portal created for UAD-PAL and the standard tenoscopic portal 11 was 7.1 mm (median, range 6.3 - 8.2 mm) in the forelimbs,

and 6.2 mm (median, range 5.6 - 6.8 mm) in hindlimbs. Following completion of the procedure, gross dissection was performed for the cadaveric and in-vivo portions of the study (20 limbs). No iatrogenic injury to the flexor tendons or manica flexoria was identified in any limb (Figure 2).

5 **[0057]** *Cadaveric study.* Complete transection of the PAL was accomplished in 11/12 of the cadaveric limbs. In one case in which PAL measured 3 mm the transection was uncomplete. For this case, 10% of the total length of the PAL had not been completely transected. The remaining fibers of the PAL were <25% of the original thickness, and they were located midway between the proximal and distal borders of the ligament. In 3/12
10 cadaveric limbs, more than one attempt was required for accurate placement of the hook knife (Tables 1A-C). In one case the instrument was initially placed between the SDFT and DDFT. In the other two, the instrument was initially placed subcutaneously, plantar to the PAL. For these 3 cases, ultrasonographic guidance resulted in visualization of incorrect placement of the instrument and subsequent repositioning in the desired location. In each
15 case, only one additional attempt was necessary for proper placement.

[0058] *In-vivo study.* Complete transection of the PAL was accomplished in 7/8 of the operated limbs. In one case a partial transection was obtained and 20% of the total length remained uncut. The remaining fibers of the PAL were <25% of the original thickness, and they were also located midway between the proximal and distal borders of
20 the ligament. For this case, the thickness of the PAL measured 1.4 mm. This same horse was uncooperative when hindlimb UAD-PAL was attempted, therefore the procedure was successfully performed immediately following euthanasia with the horse positioned in lateral recumbency with the operated limb uppermost. Only one attempt was necessary for proper placement of the instrument in all of the operated limbs of the in-vivo study.

25 Ultrasound was used to evaluate PAL transection with the horses bearing full weight on the operated limb without the splint. Identification of the separated edges of the transected PAL was possible in 6/8 of the operated limbs. In one case, the edges were not completely separated due to incomplete transection of the PAL which was confirmed on postmortem exam. On the same horse, the procedure was done in lateral recumbency for safety reasons
30 and the ultrasound was performed non-weight bearing.

[0059] *Clinical cases.* For the clinical cases, only one attempt was required to place the instrument in the desired location, and tenoscopic examination revealed complete transection of the PAL on both cases (Figure 4). For Horse 1, at 6 months recheck lameness

examination, the DFTS distention had significantly decreased and the patient was sound at the trot. Horse 2 was reassessed six weeks after surgery; the distension of the DFTS had significantly improved. No lameness re-evaluation was performed at recheck considering that surgery was recently performed. For the in-vivo portion of the study and the two
5 clinical cases in which the technique was employed the procedure was completed in 11 minutes (median, range 8-15 minutes).

DISCUSSION

[0060] This report describes a new technique for safe and precise PAL transection that can be performed in standing horses or under general anesthesia using real-time
10 ultrasonographic imaging to assist with instrument positioning. This technique allows identification and transection of the PAL through a minimally invasive approach. The goal of the current study is not to underscore the importance of diagnostic or surgical tenoscopy, but only to report an efficient technique for standing transection of the PAL when clinically indicated.

[0061] The technique for PAL transection reported here is quick, safe and can be performed in the standing horse. Several recent reports emphasize the importance of tenoscopic examination in cases of chronic tenosynovitis (1,9). This is due to the fact that identification of intrathecal injury to the DDFT, SDFT and manica flexoria, are often under-
15 diagnosed by other imaging modalities including ultrasound (1,9,11). Clinical cases that would benefit from the described technique are those that failed to respond to tenoscopic treatment in which PAL desmotomy was not performed at the time of surgery. In these cases with persistent signs of tenosynovitis with lameness localized to the DFTS, UAD-
20 PAL transection could be considered as an adjunctive treatment option. Additionally, UAD-PAL could be used in cases in which PAL desmotomy is elected as an initial treatment when tenoscopy is not an option due to either a lack of specialized equipment
25 necessary to explore the DFTS or client financial constraints (3,17).

[0062] The current technique was not compared to previously reported blind techniques described for PAL transection. However, the authors believe the technique described here is preferable to blind techniques, as ultrasonographic identification of the
30 instrument within the DFTS palmar/plantar to the SDFT and out of the manica flexoria allows the surgeon to perform PAL transection with more confidence and lower risk of inadvertent iatrogenic injury to adjacent intrathecal structures. We demonstrated gross

evidence of complete annular ligament transection without damaging adjacent structures, however to our knowledge this has not been reported for blind techniques.

[0063] In one limb included in the cadaveric portion of the study, the PAL was not fully transected, and in this case thickness of the ligament was 3 mm. For PAL measuring > 3mm, a larger hook may be required to achieve complete transection. With this in mind, in cases of primary PAL desmitis with significant thickening of the PAL as previously described (7,17), UAD-PAL may not be suitable for PAL transection. UAD-PAL would need to be performed in a larger number of cases in which the PAL measures >3mm to determine the efficacy of the reported technique for this subset of horses.

[0064] In 7/8 limbs of the in-vivo study UAD-PAL was performed successfully standing with sedation and local desensitization of the area. One of our horses was not a good candidate for standing PAL transection due to fractious behavior. Following administration of additional detomidine hydrochloride, butorphanol tartrate, and proximal metatarsal ring block the horse was reactive and tried to kick several times. Therefore, we elected to perform the procedure in lateral recumbency in the recovery stall immediately following euthanasia. Performing the procedure in the standing sedated animal has the advantages of short surgery time, reduce cost and avoidance of the potential complications related to general anesthesia especially in large warmbloods and draft horses (31). In the authors' opinion, horses operated standing tolerated the splint better on the hindlimb compared to the frontlimb. In consequence less movement and weight shifting was seen during the surgery making the procedure relatively easier on the hindlimb.

[0065] On the fractious horse, a 5 cm tall wood wedge was taped to the heel of the operated fore limb in order to simulate the heel elevation produced by the splint as the foot would not fit into the splint. During the procedure the horse kept shifting weight and could not balance well himself. In addition, in order to slide the instrument palmar to the flexor tendons the limb had to be partially elevated by an assistant. At the time of transection, the horse was still bearing weight, making the procedure more difficult.

[0066] Intrathecal distention of the DFTS resulted in subsequent distension of the PAR of the sheath allowing for safe entry into and surgical manipulations within the sheath. Additionally, medial displacement of the flexor tendons by either digital manipulation or by of the strap of the splint seemed to increase the transverse depth of the PAR further, consequently reducing the risk of iatrogenic damage to the SDFT and avoiding entrance into

manica flexoria. However, no statistical analysis was performed to compare the size of the PAR in transverse section among the 3 types of manipulation.

[0067] For surgeons experienced in the use of ultrasound to guide instruments intraoperatively, the current technique offers a rapid and accurate method for PAL

5 transection. We reported a surgery duration between 8 and 15 minutes. Using tenoscopic guidance, surgery time of 15–37 minutes for sharp and 51 minutes for radiofrequency PAL transection have been previously reported (6,21). It appears that UAD-PAL is faster and as safe as the techniques using tenoscopic guidance.

[0068] In three cases the hook was initially positioned incorrectly. In all of these
10 cases ultrasound allowed for visualization of the incorrect positioning of the instrument and was further utilized during repositioning to ensure correct placement palmar/plantar to the SDFT out of the manica flexoria. Real-time accurate positioning of the instrument is one of the main advantages of the ultrasound in the current technique.

[0069] Proficiency with musculoskeletal ultrasound is required to perform the
15 procedure and the surgeon must have a good understanding of the ultrasonographic appearance and anatomy of the DFTS, before performing UAD-PAL. Practice in cadaveric limbs following the description reported in the current study is advisable before performing the procedure.

[0070] Limitations of the current study include the low number of clinical cases and
20 the use of the technique in horses with normal thickness of the PAL. Future studies evaluating this method of PAL transection are necessary to fully determine the safety and efficacy in clinical cases. Moreover, for cases of thickened PAL, further evaluations of variations in the size of the hook blade on the designed instrument are necessary.

Additionally, refinement and modification of the reported technique may also be utilized for
25 transection of adhesions between the SDFT and the PAL, a condition reportedly identified during dynamic ultrasonographic examination of the fetlock canal during flexion of the fetlock joint (32).

[0071] In conclusion, we demonstrated that UAD-PAL is a safe, rapid and feasible
30 procedure that can be performed in standing sedated or anesthetized horses. In cases of lameness associated with constriction syndrome, financial constraints, or lack of availability of tenoscopic equipment precluding exploration of the DFTS, UAD-PAL could be considered as an initial treatment option. Also, in a clinical situation where tenoscopy has

been performed and tenosynovitis and lameness remains, UAD-PAL could be considered as an adjunctive procedure to alleviate persistent signs of lameness.

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[0072] It is understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims. All publications, patents, and patent applications cited herein are hereby incorporated by reference in their entirety for all purposes.

CLAIMS

What is claimed is:

1. A hook-blade or hook-knife surgical instrument, comprising:
 - (i) a handle or grip (1) that fits in an adult human hand;
 - 5 (ii) a shaft (2) connected to the handle, wherein the cross-section of the shaft is rectangular; and
 - (iii) a hook (4) comprising an inner arc that comprises a blade (5) capable of cutting across an equine plantar/palmar annular ligament (PAL), wherein the total length of the hook-blade surgical instrument is in the range of about 20 cm to about 25 cm.
- 10 2. The hook-blade surgical instrument of claim 1, wherein:
 - i) the ratio of the width to the length of the handle is in the range of from 1:2 to 1:4;
 - ii) the ratio of the shaft length relative to the total length of the instrument is from 3:4 to 1:2;
 - 15 iii) the ratio of the shaft rectangular cross-sectional width to depth is from 1:1 to 1:4 and/or
 - iii) the ratio of the blunt tip with the hook is from 1/7 to 1/29.
3. The hook-blade surgical instrument of any one of claims 1 to 2, wherein the length of the shaft traces the shape of a fetlock joint of an equine or a bovine
- 20 4. The hook-blade surgical instrument of any one of claims 1 to 3, wherein the weight of the instrument is in the range of about 180 grams to about 200 grams.
5. The hook-blade surgical instrument of any one of claims 1 to 4, wherein the instrument is comprised of one or more materials selected from the group consisting of stainless steel, titanium, carbon fiber, carbon fiber composite and a high
25 density polymer.
6. The hook-blade surgical instrument of any one of claims 1 to 5, wherein the instrument is comprised of a surgical grade stainless steel selected from the group consisting of austenitic 316 stainless steel, martensitic 420 stainless steel or martensitic 440 stainless steel.

7. The hook-blade surgical instrument of claim 6, wherein the instrument is laser cut stainless steel.

8. The hook-blade surgical instrument of any one of claims 1 to 7, wherein the handle (1) is unpadded.

5 9. The hook-blade surgical instrument of any one of claims 1 to 5, wherein the handle (1) has a length in the range from about 6 cm to about 14 cm, a depth in the range from about 0.02 cm to about 0.5 cm, and a width in the range from about 1 cm to about 6 cm.

10 10. The hook-blade surgical instrument of any one of claims 1 to 9, wherein the shaft (2) has a length in the range from about 5 cm to about 15 cm.

11. The hook-blade surgical instrument of any one of claims 1 to 10, wherein the shaft (2) has a cross-sectional width in the range from about 0.5 mm to about 10 mm and a cross-sectional depth in the range from about 0.5 mm to about 10 mm.

15 12. The hook-blade surgical instrument of any one of claims 1 to 11, wherein the shaft (2) comprises an angle, bend or kink (3) at a position about 2/3 distal from the handle and 1/3 proximal to the hook.

13. The hook-blade surgical instrument of any one of claims 1 to 11, wherein the shaft (2) comprises an angle, bend or kink (3) at a position about 9 cm from the handle and 4 cm to the hook.

20 14. The hook-blade surgical instrument of any one of claims 12 to 13, wherein the angle (3) is in the range of about 60° to about 85° from the axis of the shaft proximal to the handle.

15. The hook-blade surgical instrument of any one of claims 1 to 14, wherein the inner arc of the hook comprises an arc that is between 30° to 180°.

25 16. The hook-blade surgical instrument of any one of claims 1 to 15, wherein the blade (5) has a length in the range of about 1 mm to about 6 mm.

17. The hook-blade surgical instrument of any one of claims 1 to 16, wherein the hook (4) has an outer width from about 2 mm to about 10 mm.

18. The hook-blade surgical instrument of any one of claims 1 to 17, wherein the hook has a length in the range from about 1 mm to about 5 mm.

19. The hook-blade surgical instrument of any one of claims 1 to 18, wherein the distance between the blunt tip (6) and the blade/knife (5) is between 1 and 10
5 mm.

20. The hook-blade surgical instrument of any one of claims 1 to 19, wherein the tip of the hook (6) is blunt and does not cut tendinous or ligamentous adjacent tissue but can be pushed through fascia that surrounds ligament tissue.

21. The hook-blade surgical instrument of any one of claims 1 to 20,
10 wherein the instrument is sized and proportioned to transect the plantar/palmar annular ligament (PAL) of an adult equine, a juvenile equine, a miniature equine or a pony.

22. A kit comprising one or more a hook-blade surgical instruments of any one of claims 1 to 21.

23. The kit of claim 22, comprising two or more a hook-blade surgical
15 instruments of any one of claims 1 to 21, wherein each hook-blade surgical instrument in the kit comprises a hook of a different width and a blade of a different length.

24. A method of performing desmotomy or transection of an equine plantar/palmar annular ligament, comprising transecting or cutting the ligament with a hook-blade surgical instrument of any one of claims 1 to 21.

20 25. The method of claim 24, further comprising, prior to the step of transecting or cutting, the steps of:

(a) distending with fluid the proximal abaxial recesses (PAR) of the digital flexor tendon sheath (DFTS);

(b) introducing the hook-blade into the DFTS, directed distally with the
25 blade facing laterally;

(c) rotating the hook-blade instrument to orient the blade towards the plantar/palmar annular ligament (PAL) and away from the superficial digital flexor tendon (SDFT).

26. The method of any one of claims 24 to 25, wherein the PAL is transected in a distal to proximal direction.

27. The method of any one of claims 24 to 26, further comprising the step of transection of adhesions within the digital flexor tendon sheath.

5 28. The method of claim 27, wherein the method is performed assisted by ultrasonographic guidance.

29. The method of any one of claims 24 to 28, wherein the positioning of the instrument before transecting or cutting is assisted by ultrasonography.

10 30. The method of any one of claims 24 to 29, wherein the method is performed on a standing sedated equine.

31. The method of any one of claims 24 to 30, wherein the method is performed on an adult equine, a juvenile equine, a miniature equine, or a pony.

15 32. The method of any one of claims 24 to 31, wherein injury to the neurovascular bundles on the lateral and/or medial sides of the limb, and/or iatrogenic injury to the deep digital flexor tendon (DDFT), superficial digital flexor tendon (SDFT) and manica flexoria is reduced or avoided.

33. The method of any one of claims 24 to 32, wherein the method or procedure can be completed in less than 30 minutes.

20 34. A method of transection of adhesions, comprising transecting or cutting one or more adhesions within the digital flexor tendon sheath with a hook-blade surgical instrument of any one of claims 1 to 21.

35. The method of claim 34, wherein the method is performed assisted by ultrasonographic guidance.

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*Fig. 1A-E*

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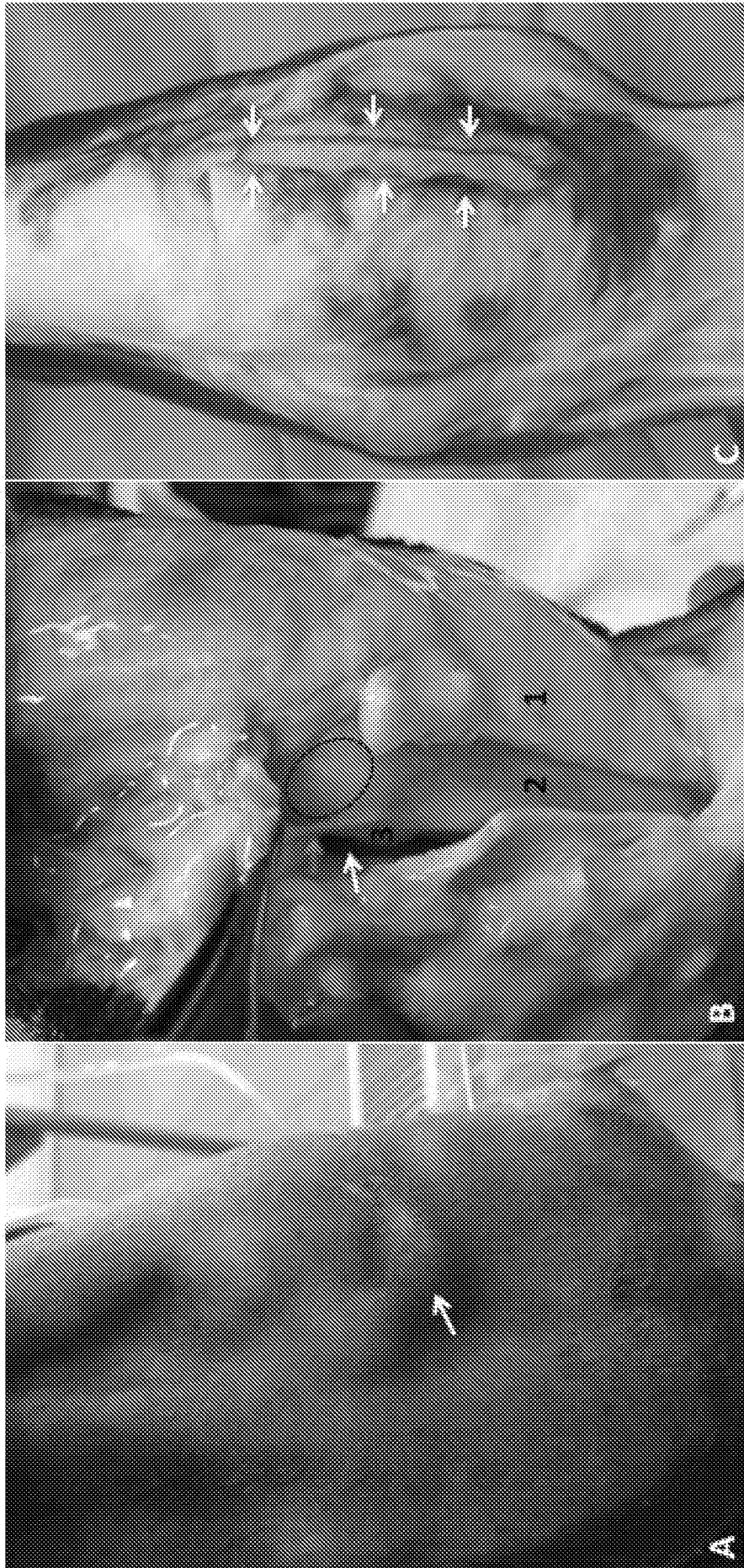


Fig. 2A-C

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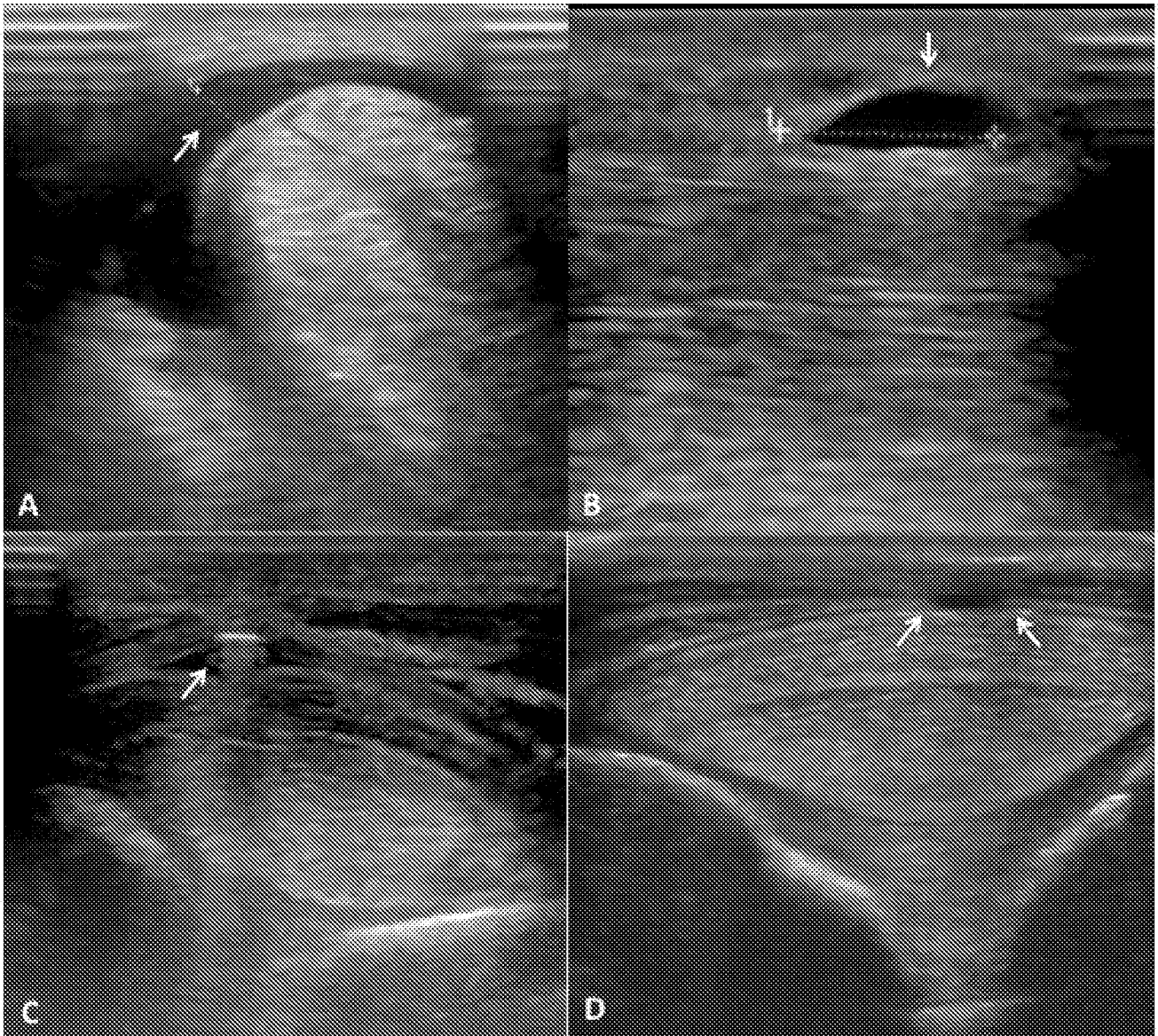


Fig. 3A-D

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Fig. 4

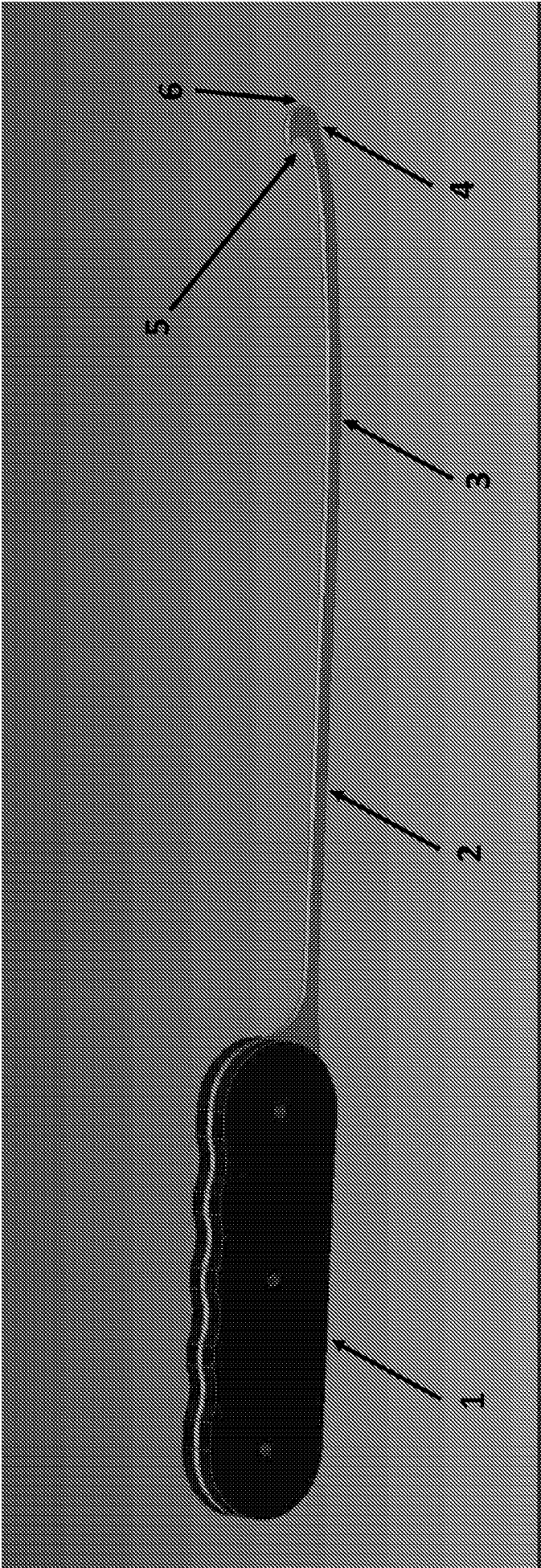


Fig. 5

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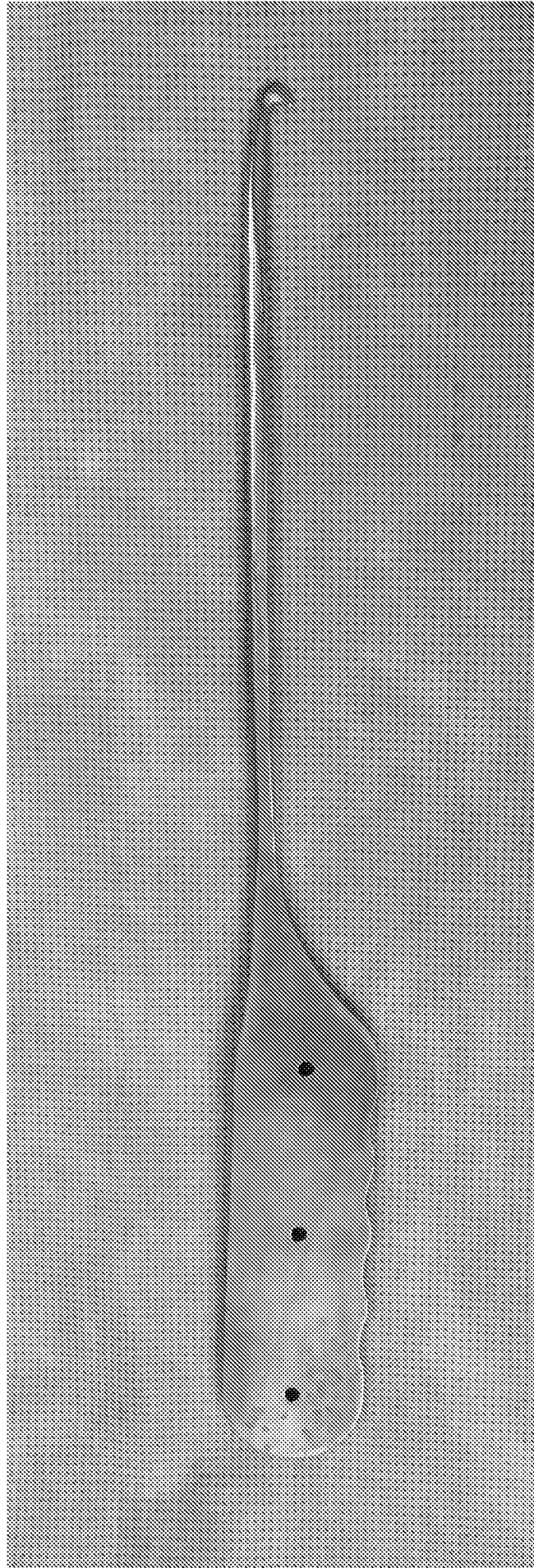
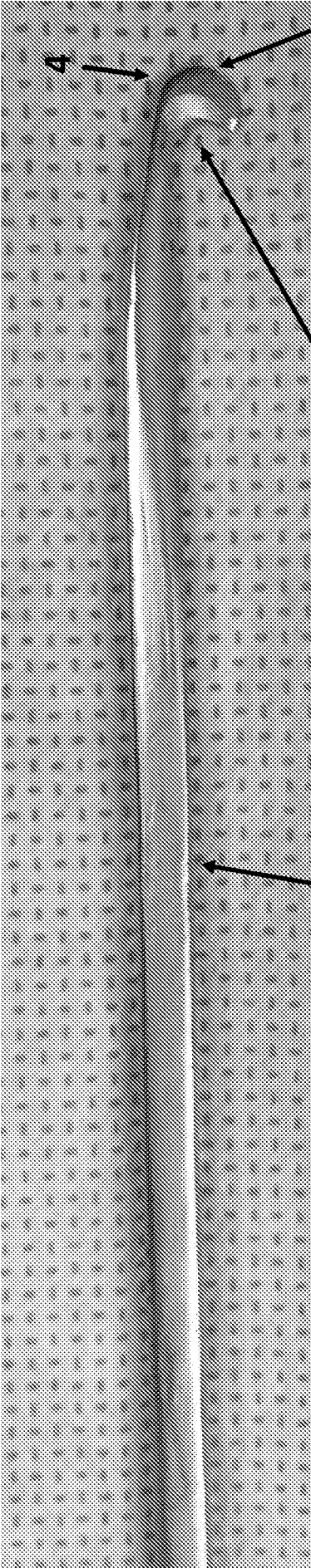


Fig. 6

A



B

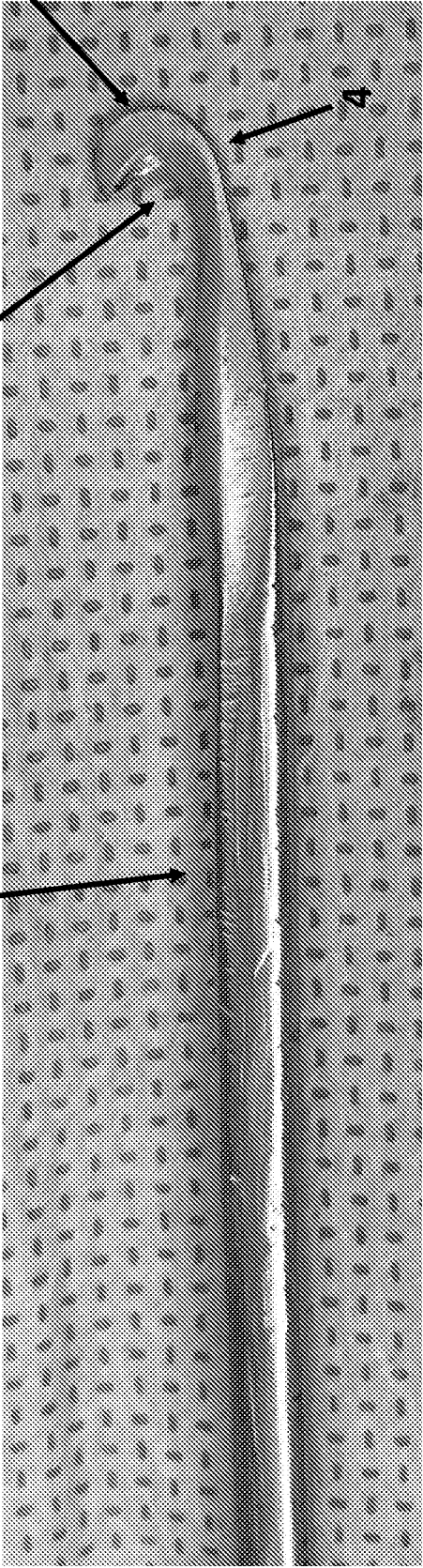


Fig. 7A-B

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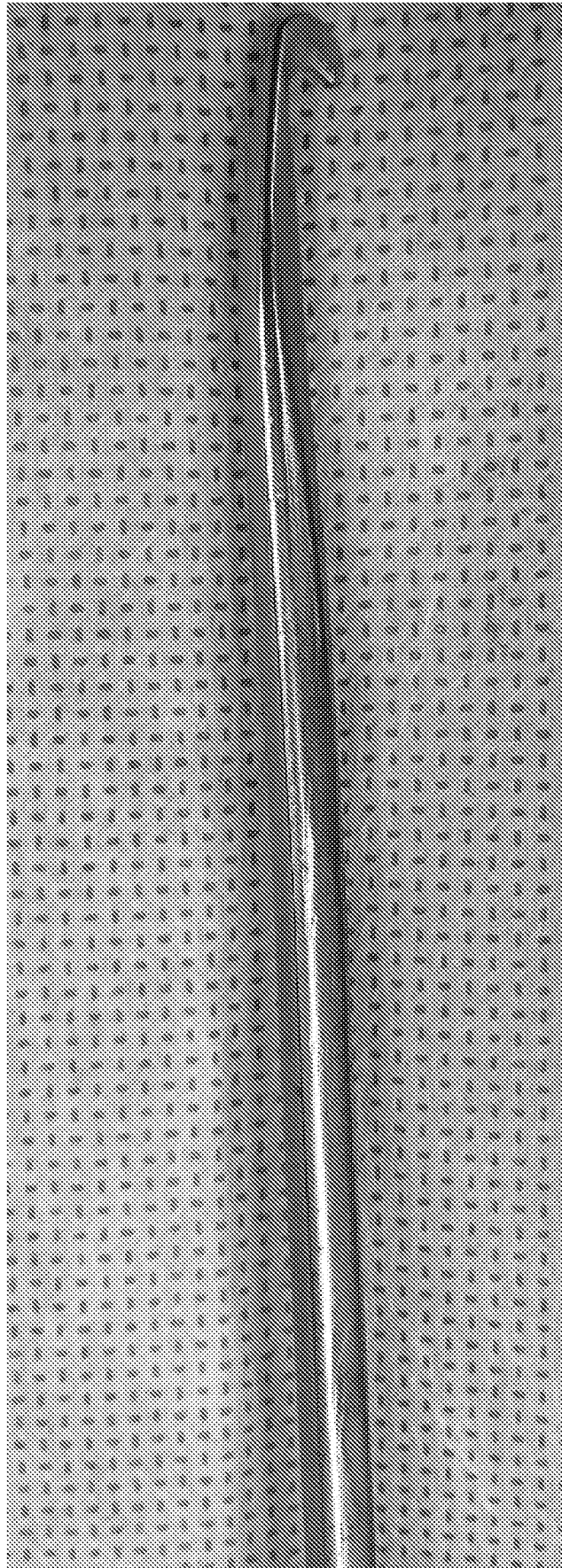


Fig. 8

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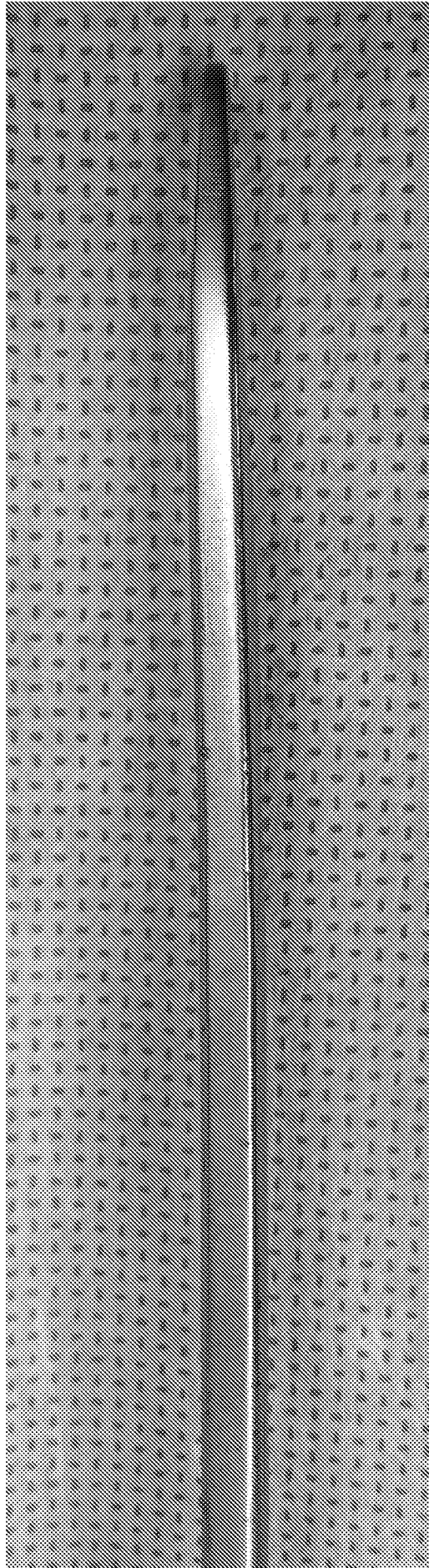


Fig. 9

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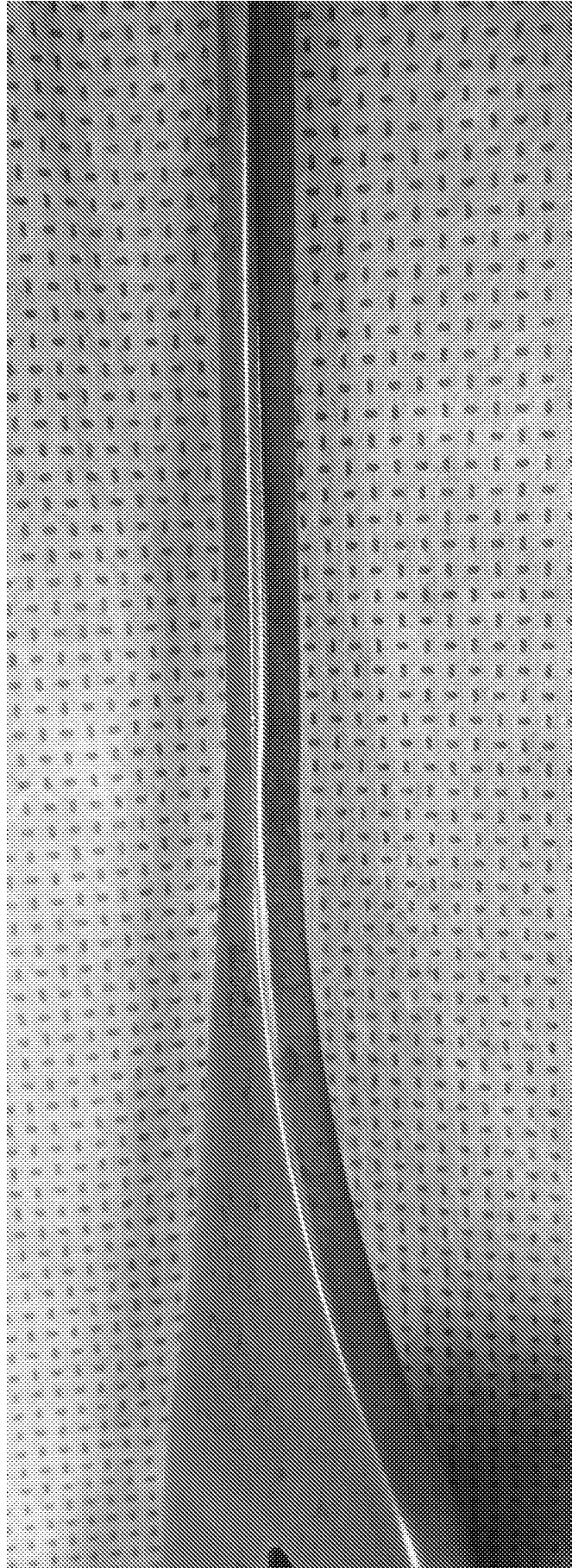


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/012400

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A22B 5/16; A22C 25/00; A61B 17/32; A61B 17/3211; B26B 3/00; B26B 9/00; B26B 9/02 (2018.04)

CPC - B26B 9/02; A22B 5/168; A61B 17/320036; B26B 3/00; B26B 9/00; B26B 11/006; B26B 27/00 (2018.02)

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)

See Search History document

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

USPC - 30/142; 30/155; 30/294; 30/314; 30/317; 30/353; 168/48.1; 606/170 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0208910 A1 (DUDLEY JR et al) 13 November 2003 (13.11.2003) entire document	1-3
A	US 5,359,778 A (SEBER et al) 01 November 1994 (01.11.1994) entire document	1-3
A	US 2008/0178474 A1 (SPENCER et al) 31 July 2008 (31.07.2008) entire document	1-3



Further documents are listed in the continuation of Box C.



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 application or patent 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

11 February 2018

Date of mailing of the international search report

23 FEB 2018

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/012400

Box No. 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
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.: 4-35
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. 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 additional fees, this Authority did not invite payment of additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.