(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 3 318 203 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
15.04.2020 Bulletin 2020/16

(51) Int Cl.:
A61B 17/17 *(2006.01)* ***A61B 17/72*** *(2006.01)*

(21) Application number: **17200555.5**

(22) Date of filing: **08.11.2017**

(54) A NON-INVASIVE POSITIONING SYSTEM FOR SCREWING AND FIXING A BONE

NICHTINVASIVES POSITIONIERUNGSSYSTEM ZUM SCHRAUBEN UND FIXIEREN EINES KNOCHENS

SYSTÈME DE POSITIONNEMENT NON INVASIF POUR VISSER ET FIXER UN OS

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **08.11.2016 US 201662419410 P**

(43) Date of publication of application:
09.05.2018 Bulletin 2018/19

(73) Proprietors:
- **Kaohsiung Medical University**
  80708 Kaohsiung City (TW)
- **National Sun Yat-Sen University**
  Gushan District, Kaohsiung City 804 (TW)

(72) Inventors:
- **FU, YIN-CHIH**
  813 Kaohsiung City (TW)
- **WANG, JAU-SHENG**
  204 Keelung City (TW)
- **LEE, TIEN-CHING**
  804 Kaohsiung City (TW)
- **HO, MEI-LING**
  813 Kaohsiung City (TW)
- **CHEN, WEI-CHI**
  428 Taichung City (TW)

(74) Representative: **Lang, Christian**
LangPatent Anwaltskanzlei
Ingolstädter Straße 5
80807 München (DE)

(56) References cited:
EP-A1- 3 155 990 **WO-A2-2012/156915**
US-A- 5 540 691

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 3 318 203 B1

Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a non-invasive positioning system for screwing and fixing a bone, and more particularly to a technique for rapid, safe and accurate in vitro positioning using laser, which penetrates through muscle tissue, bone marrow and output via through-hole from one side of the muscle tissue to determine the precise positioning of screwing and fixing screw to the bone marrow via through-hole.

Description of Prior Art

[0002] Lower extremity fractures are one of the most common fractures in orthopedic clinical practice. The fractures often result in long-term and extensive disability, especially for multiple system injuries after high-intensity trauma. Intramedullary nail and minimally invasive interlocking bone plate are considered to be the primary fixation for treatment of long bone fractures of the lower limbs. In current techniques, although bone nail/bone plate technique of tibia and femur is well developed, distal screw fixing is still a nightmare for many orthopedic surgeons. Free-hand technique of attaining "perfect-circles" with the assistance of fluoroscopy is most common method for the insertion of distal locking screw. Its pitfalls include increased operative time, increased radiation exposure, and the incidence of screw misplacement. Further, many targeting systems and techniques have been developed, such as: drill guide extensions, computer-aided navigation systems, trans-illumination methods, distal targeting guide-lines, and other free-hand techniques, and even "nail-over" procedures by using two intramedullary nails. However, most of them are expensive, difficult-to-operate, or the error is too large to accurately locate the position of through-hole. In addition, the prior art is usually to use in vivo light positioning. Although penetration thickness of the light is thinner, there is a need to consider not only the health problems such as human body compatibility, but also the damage on human body caused by the light source. The prior art is to place light bulb or other lighting device directly into the body. It must take into account the impact of heat radiation produced by the light bulb itself on body tissue when the power of light source is too high; and the risk of damage to the light bulb caused by intramedullary body fluid.

[0003] Document WO 2012/156915 A2 discloses a conventional non - invasive positioning system for screwing and fixing a bone including an intramedullary nail with one through-hole for fixing a screw. The system comprises an in vitro locator having a light source and being rotatable about 180 degrees. The light source is configured to emit a laser beam, wherein a focusing spot of the initial light beam emitted by the light source and a focusing spot of the light penetrated through tissue can be aligned in a line. The through-hole is aligned in the same line, such that alignment of the focusing spots of the initial light beam and the light beam penetrated through the tissue can be used to confirm a position for screwing and fixing the intramedullary nail.

[0004] The present invention is directed to solve the above problems by providing in vitro positioning to find through-hole and screwing and fixing the screw to the intramedullary nail, to reduce the light scattering by optical means, to be suitable for use in a variety of different brands of bone nail/ bone plate, to reduce the time of operation with new positioning method, to reduce misplacement of screw, and to reduce the amount of radiation from fluoroscopy.

SUMMARY OF THE INVENTION

[0005] The present invention provides a non-invasive positioning system for screwing and fixing a bone, where an intramedullary nail is inserted to marrow of the bone, and the intramedullary nail comprises a wall and at least one through-hole running through the wall for screwing and fixing by at least one corresponding set screw, the system also comprises: an in vitro locator having at least one light source, wherein the at least one light source emits a laser with a wavelength to the muscle tissue to form an initial light beam being capable of running through the muscle tissue, the bone and the through hole to form a penetrated light beam, the in vitro locator being movably attached to a slide rail which renders the in vitro locator capable of making a 180 degree rotation with respect to muscle tissue to search for a light spot position corresponding to the initial light beam passing through the through-hole. The brightness of the laser is adjustable. Moreover, an optical holder is provided which includes an optical lens and a positioning ring portion for removably disposing the optical lens, wherein the optical lens and the positioning ring portion can be moved to determine the focusing spot of the initial light beam and focusing spot of the penetrated light, wherein the positioning direction of the optical holder can be aligned with the two focusing spots, wherein, when the focusing spot of the initial light beam and the focusing spot of the penetrated light are aligned in a line the at least one through-hole is aligned on the same line, such that the aligned optical holder can confirm a linear position for screwing and fixing the intramedullary nail.

[0006] Exemplary, when using the non-invasive positioning system of the present invention an intramedullary nail is firstly inserted into marrow of a fractured lower limb bone, the intramedullary nail comprising at least one through-hole for screwing and fixing; then an in vitro locator having at least one light source for emitting a laser with a wavelength to a muscle tissue covering the lower limb bone is provided, the in vitro locator making a 180 degree rotation with respect to the muscle tissue, to search for a position of light penetrating the through-hole, and fine-tuning until the brightest position of the obtained light spot is found, wherein the at least one light source is guided by an optical fiber to emit the laser beam; providing a attenuation sheet such that intensity of the laser coupled to the optical fiber is dimed until easy to observe when penetrating through the muscle tissue; allowing the at least one light source to emit lasers with two wavelengths, the lasers being able to generate a center light spot with two concentric circles, to facilitate positioning of a center point; providing at least one polarizer and adjusting an included angle for passing the two lasers with a fixed direction so that penetrated lasers have a clear light spot; providing an optical holder having a focusing lens fixed to center of the light spot to observe minute light spot directly; fixing one holder of the optical holder on the two light spots of the initial light beam and the penetrated light beam, and to ensure that the two light spots, the through-holes, and a drill aligned in a same line; and cutting skin on a center spot of the penetrated light end until the bone is visible, drilling on the lower limb bone with a drill and screwing a set screw.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007]

Figures 1A and 1B illustrate a schematic diagram of a non-invasive positioning system for screwing and fixing a bone of the present invention. Figure 1A is a schematic diagram of a positioning system of the present invention for searching through-hole (in vitro locator). Figure 1B is a schematic diagram of a positioning system of the present invention for screwing and fixing a screw.

Figure 2 illustrates a non-invasive positioning system for screwing and fixing a bone of the present invention with polarizers.

Figure 3 illustrates a non-invasive positioning system for screwing and fixing a bone of the present invention with an attenuation sheet.

Figure 4 illustrates a non-invasive positioning system for screwing and fixing a bone of the present invention using two light sources.

Figure 5 illustrates a non-invasive positioning system for screwing and fixing a bone of the present invention using an optical fiber and a plurality of the same light source.

DETAILED DESCRIPTION OF THE INVENTION

[0008] It is an object of the present invention to provide a non-invasive positioning system for screwing and fixing a bone to non invasively emit laser in vitro to precisely and quickly screwing and fixing a screw to intramedullary nail via through-hole.

[0009] Through the non-invasive positioning system of the present invention an in vitro positioning system can be realized in which the optical power is increased so as to be able of penetrating twice the thickness of the bone and soft tissue using the principle of optical fiber coupling.

[0010] A further object of the present invention is to use different wavelengths or polarized light to reduce light scattering as it penetrates the bone and soft tissue.

[0011] The non-invasive positioning system of the present invention is further provided with a circular slide rail that allows fine-tuned positioning to quickly and correctly find the through-hole of intramedullary nail.

[0012] Given that the morphology and anatomical position of fractures in clinical practice may make the position of screw inconsistent: screw misplacement probability for nailing position and angle, a still further object of the present invention is to solve the issue of nailing position using clear light spot to be observed by optical positioning. For nailing angle, the concept of a line from two points is used, that is, the initial light beam and through-hole must be in a line, and the through-hole and the output light must be in a line.

[0013] The present invention discloses a non-invasive positioning system for screwing and fixing a bone, where an intramedullary nail is inserted to marrow of the bone, and the intramedullary nail comprises a wall and at least one through-hole running through the wall for screwing and fixing by at least one corresponding set screw, the system comprises: a slide rail, an in vitro locator attached to the slide rail and having at least one light source, in which the in vitro locator is used to make 180 degree rotation with respect to muscle tissue to search for a position of the through-hole running through the wall by detecting a light beam penetrated therethrough, wherein the at least one light source emits a laser with a wavelength to the muscle tissue to form an initial light beam which is capable of running through the muscle tissue and the bone to form a penetrated light, and brightness of the laser is adjustable; and an optical holder is provided having an optical lens and a positioning ring portion for removably disposing the optical lens, wherein the optical lens and the positioning ring portion are used to determine a focusing spot of the initial light beam and a focusing spot of the penetrated light, wherein, when the focusing spot of the initial light beam and the focusing spot of the penetrated light are aligned in a line, the at least one through-hole is aligned in the same line, wherein the optical holder is fixed on the two light spots to confirm a linear position for screwing and fixing the intramedullary nail.

[0014] In one embodiment, the at least one light source further comprises an optical fiber to guide emission of the laser.

[0015] In one embodiment, the positioning system further comprises a first polarizer disposed between the at least one light source and the muscle tissue, where a polarization angle is adjustable for making the initial light beam emitting along a fixed direction and form a light with a single vibration direction, to penetrate deeply into the muscle tissue.

[0016] In one embodiment, the positioning system further comprises an attenuation sheet disposed at a light penetrated side of the muscle tissue for reducing repetitive scattering light emitted from inner of the muscle tissue to outside of the muscle tissue and allowing straight light to go through.

[0017] In one embodiment, the positioning system further comprises a second polarizer disposed at a light penetrated side of the muscle tissue for passing the penetrated light with the fixed direction, and suppressing scattering light which is passing through the muscle tissue to interfere with external imaging.

[0018] In one embodiment, intensity I of the penetrated light passing the polarizer is calculated by $I=I_0 \cos^2\theta$, where I_0 is intensity of the initial light beam, θ is included angle between a polarization direction and a principal axis of the initial light beam.

[0019] In one embodiment, the at least one light source is able to emit two lasers of different wavelengths for respectively generating a center light spot with two concentric circles to facilitate positioning of a center point.

[0020] In one embodiment, wavelengths of the two lasers are 635 nm and 1064 nm.

[0021] In one embodiment, the positioning system further comprises a fiber coupler (NX1 coupler) for combining at least two light sources which emit laser of the same wavelength to improve luminous power.

[0022] In one embodiment, wavelength of the laser is ranging from 600 nm to 1500 nm.

[0023] The bone to be fixed by the positioning system of the present invention may be a fractured lower limb bone.

[0024] In one embodiment, the positioning system further comprises a charge coupled device (CCD) for receiving the two center light points.

[0025] In one embodiment, the at least one light source is a light source that generates pulsed laser or a light source that controls laser emitted time interval.

[0026] An application example for screwing and fixing a bone by the use of the positioning system of the present invention includes the following steps: inserting an intramedullary nail into marrow of a fractured lower limb bone, the intramedullary nail comprising at least one through-hole for screwing and fixing; providing an in vitro locator having at least one light source for emitting a laser with a wavelength to a muscle tissue covering the lower limb bone, .the in vitro locator making 180 degree rotation with respect to the muscle tissue to search for a position to penetrate the through-hole, and fine-tuning a light spot until the brightest position after the light spot is found, wherein the at least one light source is guided by an optical fiber to emit the laser; providing a attenuation sheet such that intensity of the laser coupled to the optical fiber is dimed until easy to observe when penetrating through the muscle tissue; allowing the at least one light source to emit lasers with two wavelengths, the lasers being able to generate a center light spot with two concentric circles, to facilitate positioning of a center point; providing at least one polarizer and adjusting an included angle for passing the two lasers with a fixed direction so that penetrated lasers have a clear light spot; providing an optical holder having a focusing lens fixed to center of the light spot to observe minute light spot directly; fixing one holder of the optical holder on the two light spots of the initial light beam and the penetrated light, and to ensure that the two light spots, the through-holes, and a drill aligned in a same line; and cutting skin on a center spot of the penetrated light end until the bone is visible, drilling on the lower limb bone with the drill and screwing a set screw.

[0027] In the above example the steps may be further repeated to position two nearer distal through-holes and two nearer proximal through-holes (proximal holes), and screwing a set screw.

[0028] The wavelength of the laser is preferably ranging from 600 nm to 1500 nm.

[0029] The wavelengths of the two lasers are preferably 635 nm and 1064 nm.

EXAMPLES

[0030] The examples below are non-limiting and are merely representative of various aspects and features of the present invention.

[0031] Figures 1A and 1B illustrate a schematic diagram of a non-invasive positioning system for screwing and fixing a bone of the present invention 100. Figure 1A is a schematic diagram of a positioning system of the present invention for searching through-hole (in vitro locator). Figure 1B is a schematic diagram of a positioning system of the present invention for screwing and fixing a screw. Figures 1A and 1B is an example of a non-invasive positioning system for screwing and fixing a bone of the present invention 100, where an intramedullary nail 140 is inserted to marrow of the bone 130, and the intramedullary nail 140 comprises a wall 141 and at least one through-hole 142 running through the wall 141 for screwing and fixing by at least one corresponding set screw (not shown), the system 100 comprises: an in vitro locator 110 having at least one light source 111, in which the in vitro locator 110 is used to make 180 degree rotation with respect to muscle tissue 120 to observe a light spot resulting from the light penetrating through-hole 142 running through the wall 141, wherein the at least one light source 111 emits a laser with a wavelength to the muscle tissue 120 to form an initial light beam and running through the muscle tissue and the bone to form a penetrated light, and brightness of the laser is adjustable; and an optical holder 150 having an optical lens 151 and a positioning ring portion for removably disposing the optical lens, wherein the optical lens and the positioning ring portion 152 are used to determine the positions of the focusing spot of the initial light beam and the focusing spot of the penetrated light in order to fix the optical holder 150 on the two spots, wherein, when the focusing spot of the initial light beam and the focusing spot of the penetrated light are aligned, the at least one through-hole 142 is aligned in the same line, such that the optical holder is able to confirm a linear position for screwing and fixing the intramedullary nail 140.

[0032] Figure 2 illustrates a non-invasive positioning system for screwing and fixing a bone of the present invention 100 with polarizers. As shown in figure 2, the positioning system of the present invention 100 further comprises a first polarizer 160 disposed between the at least one light source 111 and the muscle tissue 120, where a polarization angle is adjustable for making the initial light beam emitting along a fixed direction and form a light with a single vibration direction, to penetrate deeply into the muscle tissue 120. The light running through the bone and soft tissue is scattered seriously and it is more difficult to find center point by in vitro observation. Therefore, the present invention uses the optical characteristics that the imaging is clearer as the initial light beam are increased, improving the contrast of imaging or other support methods to precisely and quickly position the center point. One way to improve is as follows:

[0033] Since the light is an electromagnetic wave, its electric field and magnetic field are interdependent to each other and vibrated perpendicular to each other. During the propagation of the photoelectron wave, the electric field (E), the magnetic field (H) and the propagation direction (K) are vertical to each other. The unpolarized light contains light vibrated in various directions. The polarizer is designed to allow only the light with a certain optical axis to pass through, thus the light passing through the polarizer will become a light with single vibration direction, which is called polarized light.

[0034] Polarized light is generated by the polarizer. As the polarized light is incident to the tissue, the light will penetrate deeply into the deeper tissue According to Malus' law: if the intensity of the initial light beam is I_0, intensity of the penetrated light is I, and included angle between a polarization direction and a principal axis of the initial light beam is θ, the intensity is calculated as $I = I_0 \cos^2\theta$.

[0035] In addition, since the polarizer only allows the light in the fixed direction to passing through, the scattering light which is passing through the muscle tissue to interfere with external imaging is suppressed. The imaging light point for in vitro observation is clearer, as follows:

$$\text{Contrast} = \left| \frac{i_{tar} - i_{bg}}{i_{tar} + i_{bg}} \right| .$$

[0036] Use of polarized light can improve positioning of the center point, so that the error value is reduced. For the existing example, the error can be reduced by about 10%.

[0037] Further the present invention further comprises a second polarizer 160' disposed at a light penetrated side of the muscle tissue 120 for passing the penetrated light with the fixed direction, and suppressing scattering light which is passing through the muscle tissue 120 to interfere with external imaging. The intensity I of the penetrated light passing the polarizer 160 is calculated by $I = I_0 \cos^2\theta$, where I_0 is intensity of the initial light beam, θ is included angle between a polarization direction and a principal axis of the initial light beam.

[0038] As shown in figure 3, the positioning system of the present invention 100 further comprises an attenuation sheet 170 disposed at a light penetrated side of the muscle tissue 120 for reducing repetitive scattering light emitted from inner of the muscle tissue to outside of the muscle tissue and allowing straight light to go through. The most accurate and effective way to observe the center point in vitro is to increase the contrast of the image. And since the intensity of light can be reduced by the attenuation sheet 170 at a constant ratio to obtain appropriate amount of light. The attenuated light does not change the spectral wavelength and the beam size, only the amount of t light is reduced. There is no effect on the color, and only luminous flux is reduced. Therefore, the inventors use the attenuation sheet or other optical component to be coupled to optical fiber, to reduce repetitive scattering light in body emitted from inner to outside. Therefore it is easier to observe the light spot and the error of positioning center point can be reduced.

[0039] Further, there are different transmittances for different attenuation sheets, the suitable attenuation sheet can be selected depending on the requirements.

[0040] As shown in figure 4, in the positioning system of the present invention 100, the at least one light source can be two light sources 1111, 1112 for emitting two lasers of different wavelengths through the optical fiber 113 to an object to be measured, that is, the muscle tissue 120. As described above, there are bone marrow and intramedullary nail in the muscle tissue 120, so that respectively generating a center light spot with two concentric circles on a charge coupled device (CCD) 180 to facilitate positioning of a center point. Two generated lasers of different wavelengths are 635 nm and 1064 nm, respectively.

[0041] Further, according to Rayleigh scattering, intensity of scattering $I(\lambda)$ is inversely proportional to the fourth power of wavelength,

$$I(\lambda)_{scattering} \propto \frac{I(\lambda)_{incident}}{\lambda^4}$$

[0042] Different wavelengths will have different intensities of scattering. If two different wavelengths of light are simultaneously incident, two concentric circles are observed in vitro. It is easier to position the center point.

[0043] As shown in figure 5, the positioning system of the present invention 100 further comprises a fiber coupler (NX1 coupler) for combining at least two light sources which emit laser of the same wavelength to the object to be measured to improve luminous power. In an example of the present invention, wavelength of the laser is ranging from 635 nm.

[0044] In the positioning system of the present invention, wavelength of the laser is ranging from 600 nm to 1500 nm.

[0045] In addition, in the positioning system of the present invention, the bone is a fractured lower limb bone, and also can be applied to the upper limb bone.

[0046] According to an exemplary application case for the above-described positioning system of the present invention, another example is given to explain the procedure for fixing the screw in medullary cavity for lower limb fracture as follow: 1. Preoperative preparation, including anesthesia at the fracture of the patient, cleaning, disinfection, leaving the patient on the surgical position, and manual reduction of the broken bone. 2. Cutting to the appropriate length on the appropriate part of the skin until the bone is visible, and determining the inserted position of nail on the bone. 3. Using a drilling device (reamer) or a drill (awl) to drill holes at the inserted position to open the medullary cavity. 4. Pushing the nail forward slowly to running through the fracture portion. Note that the nail should be kept in the center of the medullary cavity. 5. Using a tubular drilling device or a thinner nail to expand the medullary cavity for subsequent insertion of a fixing nail as needed.

[0047] The detailed steps of positioning of the through-hole on the nail is described below: (1) Using in vitro locator making 180 degree rotation with respect to the tissue to search for a position of the through-hole. (2) Fine-tuning a light spot until the brightest position after the light spot is found. (3) Using an attenuation sheet or other optical element such that intensity of the laser coupled to the optical fiber is dimed until easy to observe. (4) And then using the lights of different wavelengths of light to reduce light scattering in the body. (5) Adjusting an included angle of the polarizer to show linear polarized light or circular polarized light until the light spot is the clearest. The purpose of this step is to make two light spots outside the body more clear and easy to determine the position of center point. (6) Using optical lens fixed in the center of the light spot, so that doctors can observe minute light spot directly. (7) Fixing one designed holder on the two light spots, and to ensure that the two light spots, the through-holes, and a drill aligned in a same line to avoid nail misplacement. (8) Cutting skin on a center spot of the penetrated light end until the bone is visible, drilling on the lower limb bone with the drill and screwing a set screw. (9) Repeating the steps of (1) to (8) to position two nearer distal through-holes and two nearer proximal through-holes (proximal holes) and screwing a set screw.

[0048] In the positioning system of the present invention wavelength of the laser is ranging from 600 nm to 1500 nm.

[0049] In addition, wavelengths of the two lasers are 635 nm and 1064 nm.

[0050] Further, according to the present invention, the at least one light source is a light source that generates pulsed laser or a light source that controls laser emitted time interval to avoid continuous exposure to the light in the same area for a long time, and to use the time resolution to achieve increased accuracy of positioning.

References numerals:

[0051]

100	non-invasive positioning method for screwing and fixing a bone
100a	a schematic diagram of a positioning system for searching through-hole
100b	a schematic diagram of a positioning system for screwing and fixing a screw
110	in vitro locator
111,1111,1112	at least on light source
112	slide trail
113	optical fiber
120	muscle tissue
130	bone marrow
140	intramedullary nail
141	wall
142	through-hole
150	optical holder
151	optical lens
152	positioning ring portion
160	first polarizer
160’	second polarizer
170	attenuation sheet
180	charge coupled device (CCD)
190	optical fiber coupler

Claims

1. A non-invasive positioning system (100, 100a, 100b) for screwing and fixing a bone, the system (100, 100a, 100b) including an intramedullary nail (140) for being inserted to marrow of the bone (130), wherein the intramedullary nail (140) comprises a wall (141) and at least one through-hole (142) running through the wall (141) for screwing and fixing by at least one corresponding set screw, the system (100, 100a, 100b) further comprising:

an in vitro locator (110) having at least one light source (111, 1111, 1112), wherein the at least one light source (111, 1111, 1112) is configured to emit a laser beam with a specific wavelength to the muscle tissue (120) surrounding a bone to be fixed to form an initial light beam which is capable of penetrating the muscle tissue

(120),the bone to be fixed and the at least one through-hole (142) thereby defining a penetrated light beam, wherein the system (100, 100a, 100b) is further configured to sense a light spot of the penetrated light beam,

characterized in that

brightness of the laser is adjustable; and

the system (100, 100a, 100b) further comprises a slide rail (112) for placing the at least one light source (111, 1111, 1112) for rotation, wherein the in vitro locator (110) is movably attached to the slide rail (112) to render the in vitro locator (110) rotatable about 180 degrees with respect to the muscle tissue (120) surrounding a bone to be fixed to search for a position in which the initial light beam is capable of passing through through-hole (142) and search for the brightest position after a light spot of the penetrated light beam is found,

an optical holder (150) including an optical lens (151) and a positioning ring portion (152) for removably disposing the optical lens (151), wherein the optical lens (151) removably attached to the positioning ring portion (152) serves to determine a focusing spot of the initial light beam and a focusing spot of the penetrated light beam in order to position the optical holder (150) on the two spots of the initial light beam and the penetrated light beam, wherein, when the focusing spot of the initial light beam and the focusing spot of the penetrated light beam are aligned in a line, the at least one through-hole (142) is aligned in the same line to confirm a linear position for screwing and fixing the intramedullary nail (140).

2. The positioning system (100, 100a, 100b) of claim 1, **characterized in that** the at least one light source (111, 1111, 1112) further comprises an optical fiber to guide emission of the laser.

3. The positioning system (100, 100a, 100b) of claim 1, **characterized by** further comprising a first polarizer (160) configured to be disposed between the at least one light source (111, 1111, 1112) and the muscle tissue (120) surrounding a bone to be fixed, where a polarization angle is adjustable for making the initial light beam being emitted along a fixed direction and form a light with a single vibration direction, wherein the initial light beam is configured to penetrate deeply into the muscle tissue (120) surrounding a bone to be fixed.

4. The positioning system (100, 100a, 100b) of claim 1, **characterized by** further comprising an attenuation sheet (170) configured to be disposed at a light penetrated side of the muscle tissue (120) surrounding a bone to be fixed for reducing repetitive scattering light emitted from the inner side of the muscle tissue (120) to the outside of the muscle tissue (120) and allowing straight light to go through.

5. The positioning system (100, 100a, 100b) of claim 3, **characterized by** further comprising a second polarizer (160') configured to be disposed at a light penetrated side of the muscle tissue (120) surrounding a bone to be fixed for passing the penetrated light with the fixed direction, and capable of suppressing scattering light which is passing through the muscle tissue (120) to interfere with external imaging.

6. The positioning system (100, 100a, 100b) of claim 5, **characterized in that** intensity I of the penetrated light passing the polarizer is calculated by $I=I_0 \cos^2\theta$, where I_0 is intensity of the initial light beam, θ is included angle between a polarization direction and a principal axis of the initial light beam.

7. The positioning system (100, 100a, 100b) of claim 1, **characterized in that** the at least one light source (111, 1111, 1112) is able to emit two laser beams of different wavelengths for respectively generating a center light spot with two concentric circles to facilitate positioning of a center point.

8. The positioning system (100, 100a, 100b) of claim 7, **characterized in that** wavelengths of the two lasers are 635 nm and 1064 run.

9. The positioning system (100, 100a, 100b) of claim 1, which further comprises a fiber coupler (NX1 coupler) (190) for combining at least two light sources (1111, 1112) which emit laser of the same wavelength to improve luminous power.

10. The positioning system (100, 100a, 100b) of claim 1, **characterized in that** the wavelength of the laser is ranging from 600 nm to 1500 nm.

11. The positioning system (100, 100a, 100b) of claim 1, **characterized in that** the positioning system (100, 100a, 100b) is adapted to be used with the bone being a fractured lower limb bone.

12. The positioning system (100, 100a, 100b) of claim 7, which further comprises a charge coupled device (CCD) (190) for receiving the two center light points.

13. The positioning system (100, 100a, 100b) of claim 1, **characterized in that** the at least one light source (100, 100a, 100b) is a light source that generates pulsed laser or a light source that controls laser emitted time interval.

Patentansprüche

1. Nichtinvasives Positionierungssystem (100, 100a, 100b) zum Schrauben und Fixieren eines Knochens, wobei das System (100, 100a, 100b) einen intramedullären Nagel (140) zum Einführen in das Mark des Knochens (130) umfasst, wobei der intramedulläre Nagel (140) eine Wand (141) und zumindest ein Durchgangsloch (142) umfasst, das zum Schrauben und Fixieren durch zumindest eine entsprechende Feststellschraube durch die Wand (141) geht, wobei das System (100, 100a, 100b) ferner umfasst: einen in-vitro Lokator (110), der zumindest eine Lichtquelle (111, 1111, 1112) aufweist, wobei die zumindest eine Lichtquelle (111, 1111, 1112) darauf ausgelegt ist, einen Laserstrahl mit einer spezifischen Wellenlänge auf das Muskelgewebe (120) zu emittieren, das den zu fixierenden Knochen umgibt, um einen initialen Lichtstrahl auszubilden, der dazu in der Lage ist, in das Muskelgewebe (120), den zu fixierenden Knochen und das zumindest eine Durchgangsloch (142) einzudringen, wodurch ein eingedrungener Lichtstrahl ausgebildet wird, wobei das System (100, 100a, 100b) ferner darauf ausgelegt ist, einen Lichtpunkt des eingedrungenen Lichtstrahls zu erfassen,
dadurch gekennzeichnet, dass
die Helligkeit das Lasers einstellbar ist und
das System (100, 100a, 100b) ferner umfasst:

    eine Gleitschiene (112) zum Platzieren der zumindest einen Lichtquelle (111, 1111, 1112) zum Drehen, wobei der in-vitro Lokator (110) beweglich an der Gleitschiene (112) angeordnet ist, um den in-vitro Locator (110) um 180 Grad in Bezug auf das Muskelgewebe (120), das einen zu fixierenden Knochen umgibt, drehbar zu machen, um eine Position zu suchen, in der der initiale Lichtstrahl in der Lage ist, durch das Durchgangsloch (142) zu laufen und nach der hellsten Position zu suchen, nachdem ein Lichtpunkt des eingedrungenen Lichtstrahls gefunden wurde,
    einen optischer Halter (150), der eine optische Linse (151) umfasst und einen Positionierungsringabschnitt (152) zum lösbaren Anordnen der optischen Linse (151), wobei die optische Linse (151), die beweglich an dem Positionierungsringabschnitt (152) angeordnet ist, dazu dient, einen Fokussierungspunkt des initialen Lichtstrahls zu bestimmen und einen Fokussierungspunkt des eingedrungenen Lichtstrahls, um den optischen Halter (150) an den zwei Punkten des initialen Lichtstrahls und des eingedrungenen Lichtstrahls zu positionieren, wobei, wenn der Fokussierungspunkt des initialen Lichtstrahls und der Fokussierungspunkt des eingedrungenen Lichtstrahls in einer Linie ausgerichtet sind, das zumindest eine Durchgangsloch (142) in derselben Linie ausgerichtet ist, um eine lineare Position zum Schrauben und Fixieren des intramedullären Nagels (140) zu bestätigen.

2. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die zumindest eine Lichtquelle (111, 1111, 1112) ferner eine optische Faser umfasst, um die Emission des Lasers zu führen.

3. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** es einen ersten Polarisator (160) umfasst, der darauf ausgelegt ist, zwischen der zumindest einen Lichtquelle (111, 1111, 1112) und dem Muskelgewebe (120), das den zu fixierenden Knochen umgibt, angeordnet zu werden, wobei ein Polarisierungswinkel einstellbar ist, um zu bewirken, dass der initiale Lichtstrahl entlang einer fixen Richtung emittiert wird und ein Licht mit einer einzelnen Schwingungssrichtung auszubilden, wobei der initiale Lichtstrahl darauf ausgelegt ist, tief in das Muskelgewebe (120) einzudringen, das den zu fixierenden Knochen umgibt.

4. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** es ferner ein abdämpfendes Blatt (170) umfasst, das darauf ausgelegt ist, an einer vom Licht durchdrungenen Seite des Muskelgewebes (120) angeordnet zu werden, das einen Knochen umgibt, der fixiert werden soll, um repetitives Streulicht zu reduzieren, das von der Innenseite des Muskelgewebes (120) zu der Außenseite des Muskelgewebes (120) emittiert wird und es dem direkten Licht zu erlauben, durchzugehen.

5. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 3, **dadurch gekennzeichnet, dass** es ferner einen zweiten Polarisator (160') umfasst, der darauf ausgelegt ist, an einer lichtdurchdrungenen Seite des Muskelgewebes (120), das eine zu fixierenden Knochen umgibt, angeordnet zu werden, um das eingedrungene Licht mit der fixen Richtung durchzulassen und dazu in der Lage ist, Streulicht zu unterdrücken, das durch das Muskelgewebe (120) geht und die externe Bildgebung stört.

6. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 5, **dadurch gekennzeichnet, dass** die Intensität I des eingedrungenen Lichts, das den Polarisator passiert, durch $I = I_0 \cos^2 \theta$ berechnet wird, wobei I_0 die Intensität des initialen Lichtstrahls ist und θ der zwischen einer Polarisierungsrichtung und einer Hauptachse des initialen Lichtstrahls eingeschlossene Winkel ist.

7. Positionierungssystem (100, 100a, 100b) gemäß

Anspruch 1, **dadurch gekennzeichnet, dass** die zumindest eine Lichtquelle (111, 1111, 1112) in der Lage ist, zwei Laserstahlen von verschiedenen Wellenlängen zu emittieren, um jeweils einen zentralen Lichtpunkt mit zwei konzentrischen Kreisen zu erzeugen, um die Positionierung eines zentralen Punktes zu erleichtern.

8. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 7, **dadurch gekennzeichnet, dass** Wellenlängen der zwei Laser 635 nm und 1064 nm sind.

9. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, das ferner einen Faserkoppler (NX1 coupler) (190) umfasst, um zumindest zwei Lichtquellen (1111, 1112) zu kombinieren, die Laserlicht derselben Wellenlänge emittieren, um die Lichtleistung zu verbessern.

10. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die Wellenlänge des Lasers im Bereich von 600 nm bis 1500 nm liegt.

11. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** das Positionierungssystem (100, 100a, 100b) darauf ausgelegt ist, bei einem Knochen angewandt zu werden, der ein gebrochener Knochen einer unteren Gliedmaße ist.

12. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 7, das ferner eine ladungsgekoppelte Vorrichtung (CCD) (190) umfasst, um die zwei zentralen Lichtpunkte zu empfangen.

13. Positionierungssystem (100, 100a, 100b) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die zumindest eine Lichtquelle (100, 100a, 100b) eine Lichtquelle ist, die ein gepulstes Laserlicht erzeugt oder eine Lichtquelle, die das Zeitintervall der Laseremission steuert.

Revendications

1. Système de positionnement non invasif (100, 100a, 100b) pour visser et fixer un os, le système (100, 100a, 100b) incluant un clou intramédullaire (140) destiné à être inséré dans la moelle de l'os (130), dans lequel le clou intramédullaire (140) comprend une paroi (141) et au moins un trou traversant (142) courant à travers la paroi (141) pour visser et fixer par au moins une vis de réglage correspondante, le système (100, 100a, 100b) comprenant en outre:

un positionneur in vitro (110) présentant au moins une source de lumière (111, 1111, 1112), dans lequel la au moins une source de lumière (111, 1111, 1112) est configurée pour émettre un faisceau laser de longueur d'onde spécifique vers le tissu musculaire (120) entourant un os à fixer pour former un faisceau lumineux initial qui est capable de pénétrer dans le tissu musculaire (120), l'os à fixer et le au moins un trou traversant (142) définissant ainsi un faisceau lumineux pénétré, dans lequel le système (100, 100a, 100b) est en outre configuré pour détecter un point lumineux du faisceau lumineux pénétré,
caractérisé en ce que:

la brillance du laser est ajustable; et
le système (100, 100a, 100b) comprend en outre:

un rail de glissière (112) pour placer la au moins une source de lumière (111, 1111, 1112) pour une rotation, dans lequel le positionneur in vitro (110) est fixé de manière mobile au rail de glissière (112) pour rendre le positionneur in vitro (110) rotatif d'environ 180 degrés par rapport au tissu musculaire (120) entourant un os à fixer pour rechercher une position dans laquelle le faisceau lumineux initial est capable de passer dans le trou traversant (142) et rechercher la position la plus brillante une fois qu'un point lumineux du faisceau lumineux pénétré est trouvé,
un support optique (150) incluant une lentille optique (151) et une partie annulaire de positionnement (152) pour disposer de manière amovible la lentille optique (151), dans lequel la lentille optique (151) fixée de manière amovible à la partie annulaire de positionnement (152) sert à déterminer un point de focalisation du faisceau lumineux initial et un point de focalisation du faisceau lumineux pénétré en sorte de positionner le support optique (150) sur les deux points du faisceau lumineux initial et du faisceau lumineux pénétré, dans lequel, lorsque le point de focalisation du faisceau lumineux initial et le point de focalisation du faisceau de lumière pénétré sont alignés sur une ligne, le au moins un trou traversant (142) est aligné sur la même line pour confirmer une position linéaire pour visser et fixer le clou intramédullaire (140).

2. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce que** la au moins une source de lumière (111, 1111, 1112) comprend en outre une fibre optique pour guider l'émission du laser.

3. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce qu'**il comprend en outre un premier polariseur (160) configuré pour être disposé entre la au moins une source de lumière (111, 1111, 1112) et le tissu musculaire (120) entourant un os à fixer, , où un angle de polarisation est ajustable pour faire en sorte que le faisceau lumineux initial soit émis le long d'une direction fixe et forme une lumière avec une seule direction de vibration, dans lequel le faisceau lumineux initial est configuré pour pénétrer profondément dans le tissu musculaire (120) entourant un os à fixer.

4. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce qu'**il comprend en outre une feuille d'atténuation (170) configurée pour être disposée d'un côté pénétré par la lumière du tissu musculaire (120) entourant un os à fixer pour réduire la lumière de dispersion répétitive émise du côté interne du tissu musculaire (120) vers l'extérieur du tissu musculaire (102) et permettre à de la lumière droite de passer.

5. Système de positionnement (100, 100a, 100b) selon la revendication 3, **caractérisé en ce qu'**il comprend en outre un second polariseur (160') configuré pour être disposé sur un côté pénétré par la lumière du tissu musculaire (120) entourant un os à fixer pour faire passer la lumière pénétrée de direction fixe et capable de supprimer la lumière de dispersion qui passe à travers le tissu musculaire (120) pour interférer avec l'imagerie externe.

6. Système de positionnement (100, 100a, 100b) selon la revendication 5, **caractérisé en ce que** l'intensité I de la lumière pénétrée passant par le polariseur est calculée par $I=I_0\cos^2\theta$, où I_0 est l'intensité du faisceau lumineux initial, θ étant l'angle inclus entre une direction de polarisation et un axe principal du faisceau lumineux initial.

7. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce que** la au moins une source de lumière (111, 1111, 1112) est à même d'émettre deux faisceaux laser de différentes longueurs d'onde pour générer respectivement un point lumineux central avec deux cercles concentriques pour faciliter le positionnement d'un point central.

8. Système de positionnement (100, 100a, 100b) selon la revendication 7, **caractérisé en ce que** les longueurs d'onde des deux lasers sont de 635 nm et de 1064 nm.

9. Système de positionnement (100, 100a, 100b) selon la revendication 1, qui comprend en outre un coupleur de fibres (coupleur NX1) (190) pour combiner au moins deux sources de lumière (1111, 1112) qui émettent un laser de la même longueur d'onde pour améliorer le pouvoir lumineux.

10. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce que** la longueur d'onde du laser se situe dans une plage de 600 nm à 1500 nm.

11. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce que** le système de positionnement (100, 100a, 100b) est à même d'être utilisé avec l'os qui est un os de membre inférieur fracturé.

12. Système de positionnement (100, 100a, 100b) selon la revendication 7, qui comprend en outre un dispositif à couplage de charge (CCD) (190) pour recevoir les deux points lumineux centraux.

13. Système de positionnement (100, 100a, 100b) selon la revendication 1, **caractérisé en ce que** la au moins une source de lumière (100, 100a, 100b) est une source de lumière qui génère un laser pulsé ou une source de lumière qui commande un intervalle de temps d'émission de laser.

Figure 1A

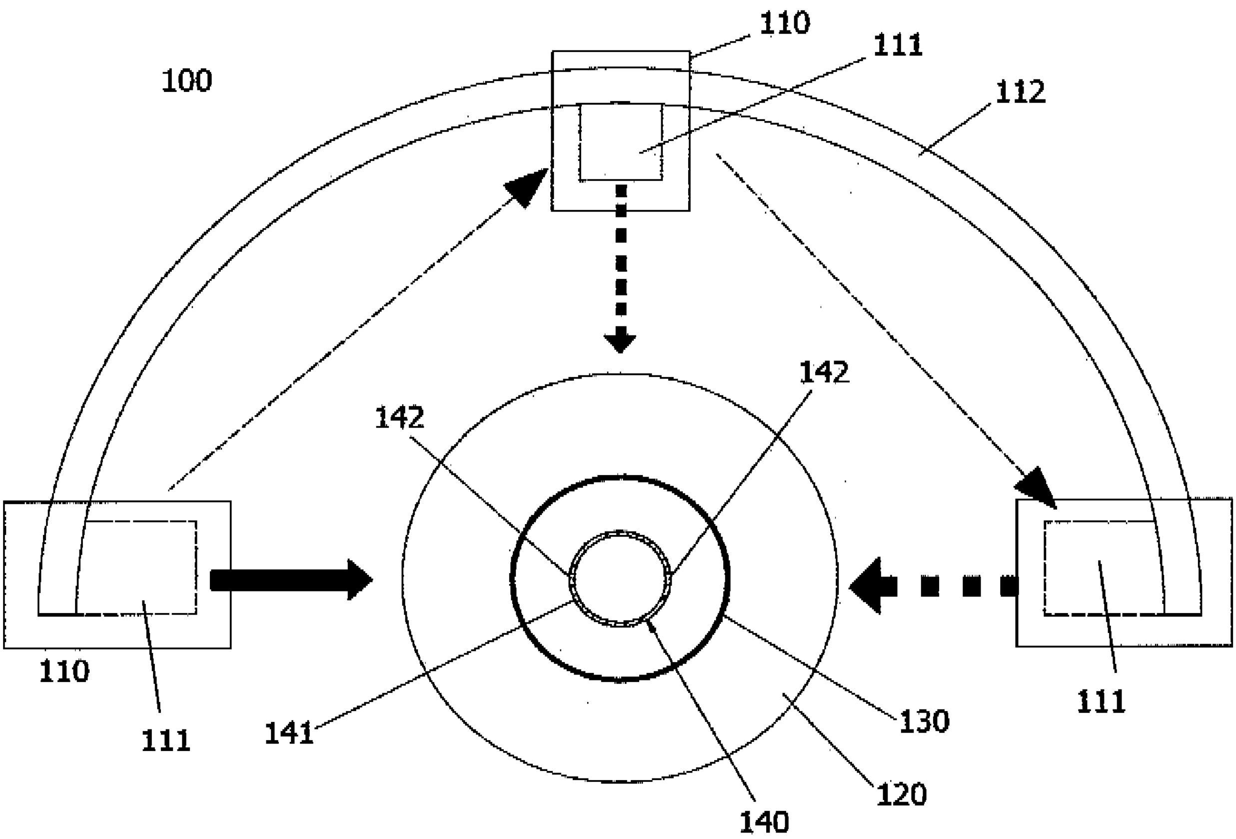


Figure 1B

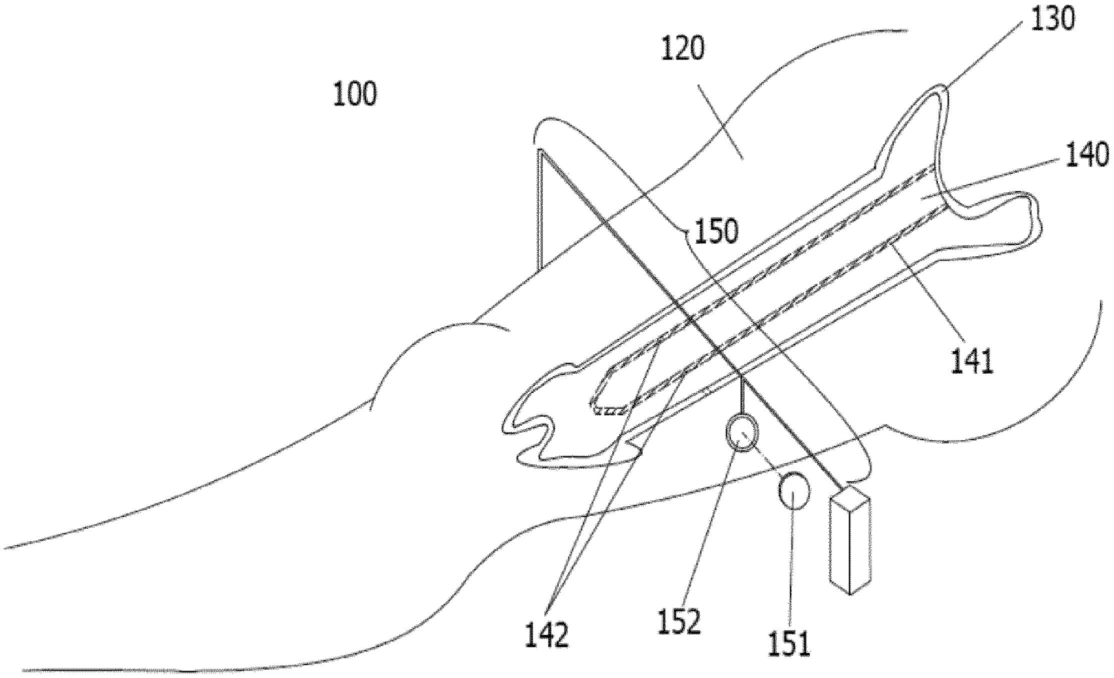


Figure 2

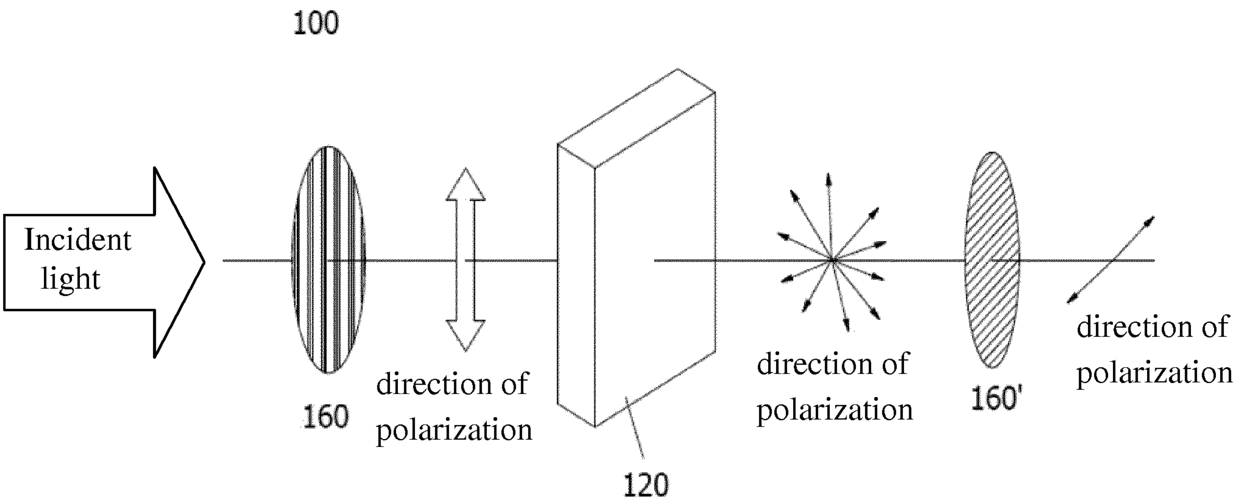

100
Incident light
160
direction of polarization
120
direction of polarization
160'
direction of polarization

Figure 3

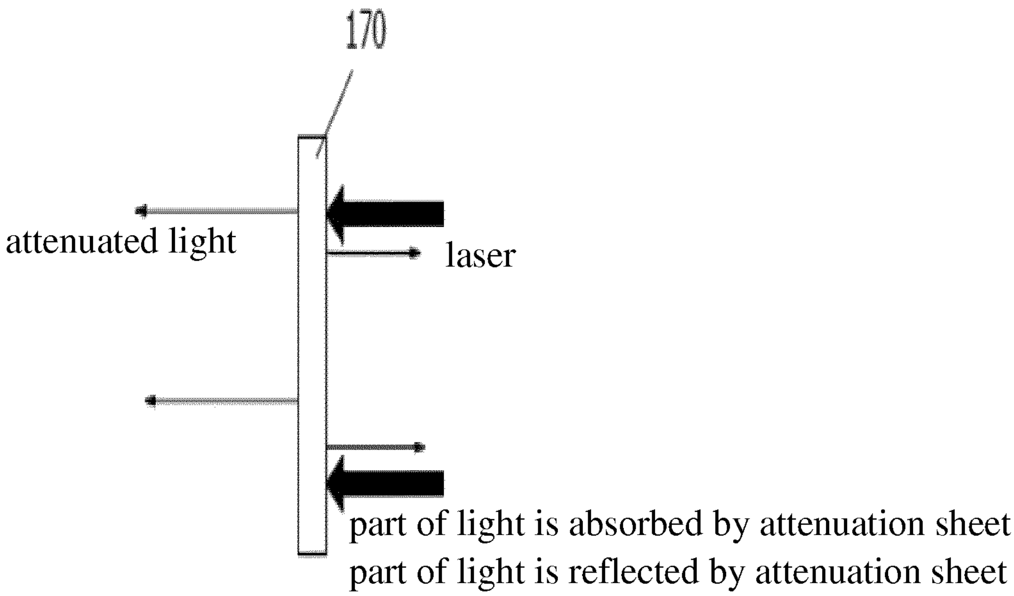

170
attenuated light
laser
part of light is absorbed by attenuation sheet
part of light is reflected by attenuation sheet

Figure 4

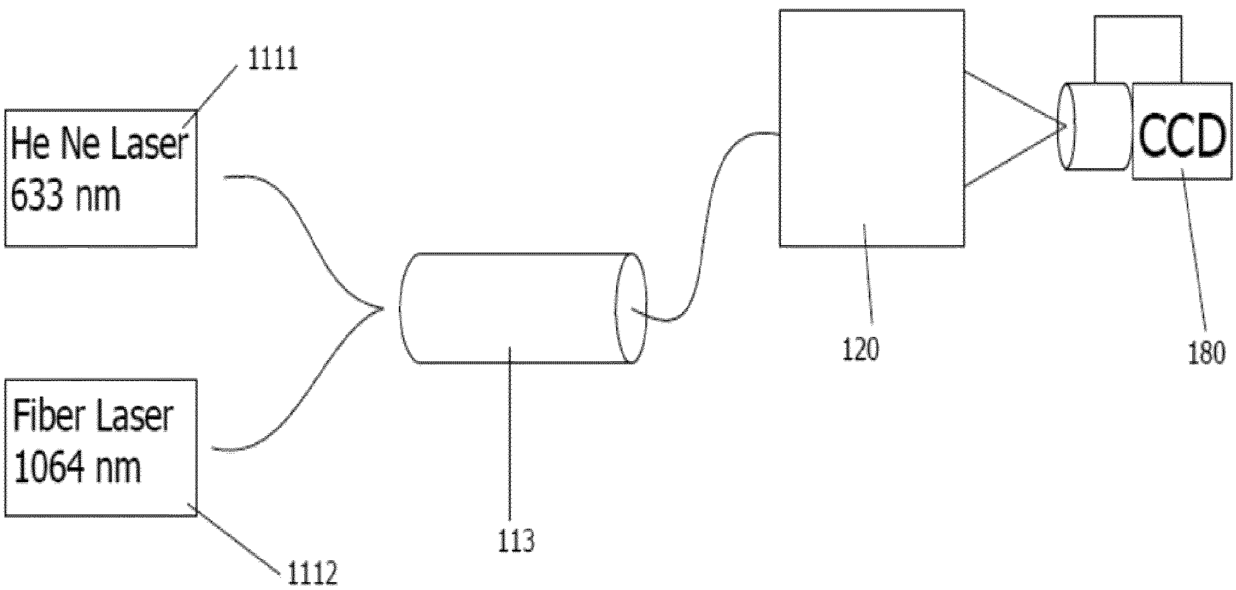
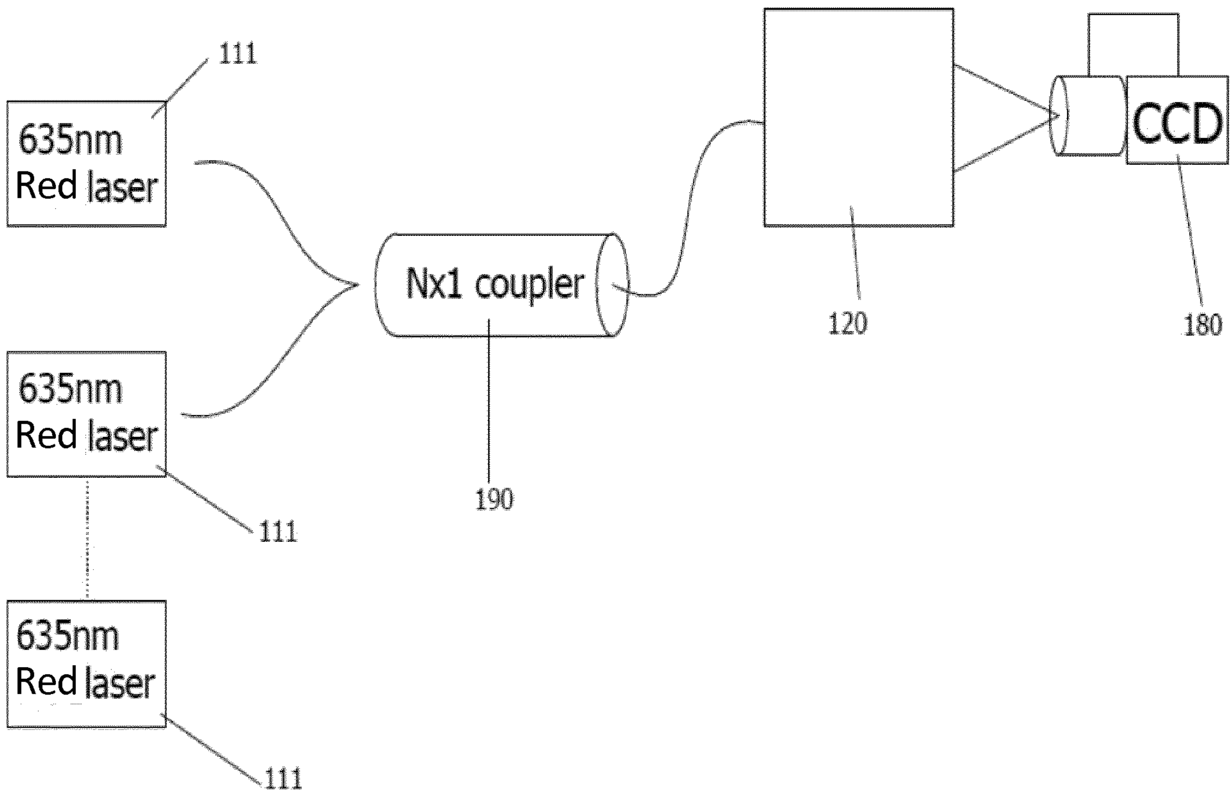

1111
He Ne Laser
633 nm
Fiber Laser
1064 nm
1112
113
120
CCD
180

Figure 5


111
635nm
Red laser
635nm
Red laser
111
635nm
Red laser
111
Nx1 coupler
190
120
CCD
180

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 2012156915 A2 **[0003]**