JOINT DISTRACTION DEVICE FOR ARTHROSCOPIC SURGERY

A joint distraction device for use in an arthroscopic surgery is provided. The device has a joint distraction mechanism, situated in between two bone fixation surfaces, and is capable of changing the relative distance between these two surfaces. The force generated by the mechanism should be sufficient to insert bone spikes affixed to the surfaces into bone, as well as distract the joint to create a sufficient enough gap to allow the intended procedure. With the surfaces and spikes engaged to bone at opposite sites of a joint, an increase in distraction force results in an increase in the relative distance results, hence increasing the space within the joint. Embodiments of this invention, compared to fracture table approaches, effectively eliminate the risk of pudendal nerve injury, allow for longer surgical times, and allow for much more controllable joint distraction.
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG). Published: — with international search report (Art. 21(3))
JOINT DISTRACTION DEVICE FOR ARTHROSCOPIC SURGERY

FIELD OF THE INVENTION

The invention relates to joint distraction devices and surgical procedures.

BACKGROUND OF THE INVENTION

Hip arthroscopy is becoming an increasingly common and effective surgery as it allows for the repair and resurfacing of various parts of the hip with minimal surgical trauma to the patient. However, such a procedure requires distraction of the femoral head from the acetabulum of the pelvis to allow for arthroscopic access to the tissues within the joint.

The hip is a constrained joint, and has an anatomical structure similar to a 'tight' ball and socket joint. Therefore, distraction requires, relatively speaking to other joints, a fairly large amount of traction force to create a space in the joint that is adequate for the surgical procedure.

The current distraction device standard for hip arthroscopy is the fracture table where the femoral head is distracted from the acetabulum by pulling the leg away from the pelvis to create sufficient joint space. Counter-traction is achieved by placing a fixed post placed at the patient's groin. The fracture
Table procedure is a crude and imprecise mechanism that may give risk to postoperative complications such as pudendal nerve injury and other joint (e.g. ankle or knee) damage. Accordingly, there is a need in the art to develop a technology with the goal to reduce such postoperative complications for the patients while maintaining adequate joint space in the hip for arthroscopic surgery. The present invention addresses this need.

**SUMMARY OF THE INVENTION**

The present invention provides a joint distraction device for use in an arthroscopic surgery. The device can be arthroscopically inserted within a body or inserted via an open incision. A joint distraction mechanism is situated in between a proximal and distal bone fixation surface. The proximal end and the distal end of the joint distraction mechanism are affixed respectively to a proximal fixation surface and a distal fixation surface.

The proximal fixation surface has an outer facing surface facing away from the joint distraction device. This outer facing surface has two or more bone spikes for engagement with a proximal bone segment proximally located to a joint. The distal fixation surface has an outer facing surface facing away from the joint distraction device. In one embodiment, this distal fixation surface has one bone spike for engagement with a distal bone segment distally located.
from the joint. In another embodiment, this distal fixation surface could have two or more bone spikes. The bone spikes, screws or other projections to allow fixation (temporary or permanent) are typically connected substantially perpendicular to the respective outer surfaces of the fixation surfaces.

5

The joint distraction mechanism has a force driving mechanism for changing the relative distance between the proximal fixation surface and the distal fixation surface. Examples are provided of a worm gear force driving mechanism or a pneumatic force driving mechanism. This joint distraction mechanism is useful to change the relative distance between the proximal bone segment and the distal bone segment. The force generated should be sufficient to insert the bone spikes (in case they are not screws and do not have to be screwed into the bone), as well as sufficient to distract the joint (i.e. create a sufficient gap to allow the intended surgical procedure). With the surfaces and spikes engaged to bone at opposite sites of a joint, an increase in distraction force results in an increase in the relative distance results, hence increasing the space within the joint. The device is preferably in its shortened position during insertion into and removal from (e.g. arthroscopically) a patient's body.

20
The joint distraction device could further have: (i) an articulating joint or (ii) a fixed joint angle for aligning the relative position of the proximal fixation surface with the proximal bone segment. In other words, this is used for pointing two segments of the device in between the bone surfaces for better alignment. In one example, the articulating joint is a three-dimensional articulating joint. The articulating joint can be locked or fixed in a position useful when the distraction takes place.

Embodiments of the invention pertain to joint distraction devices and the use/application of such devices, which are described herein with distinct advantages when compared to, for example, the use of the fracture table approach. One advantage pertains to the use of the device as it effectively eliminates the risk of pudendal nerve injury common with the fracture table approach. Currently, using the fracture table, surgical time is limited (usually to less than 2 hours) due to the risk of nerve injury from the pressure resulting from the traction-counter traction of the fracture table. With the device of this invention, it is conceivable that the duration of surgery would no longer be limited by fear of complications associated with the fracture table. This would allow for the development and practice of more advanced and complex surgical techniques and procedures. In addition, the device could be placed lateral to the joint and therefore does not obstruct the operating space of the surgeon. Furthermore, in contrast with the fracture table approach, the device
allows for controllable distraction. Yet another advantage in the application to the hip joint is that by applying the distraction force along a line closer to parallel with the femoral neck, the overall force required to distract the hip is reduced.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows according to an exemplary embodiment of the invention a joint distraction device with a worm gear drive mechanism and a three-dimensional articulating joint connecting the worm gear drive mechanism and the proximal fixation surface.

FIG. 2 shows according to an exemplary embodiment of the invention a joint distraction device with a fixed angle in the rod connecting the worm gear drive mechanism and the proximal fixation surface.

FIG. 3 shows according to an exemplary embodiment of the invention a pneumatic cylindrical force driving mechanism.

DETAILED DESCRIPTION

Joint distraction devices according to the invention are intended to arthroscopically distract a joint by applying opposing forces to a proximal and distal bone segment crossing the joint. Specific examples herein relate to the
hip joint, but the invention is not limited as such since these devices can be used for distraction of other joints as well, such the knee joint for meniscus or osteochondral grafting. It could also be used for the elbow joint for osteochondral grafting or soft tissue resurfacing. Further, the ankle joint is a candidate for the use of the device for open ankle surgery.

In the example of the hip joint, the device distracts the hip joint by applying opposing force to non-cartilagenous areas such as the anterior inferior iliac spine (AIIS) and the piriformis fossa. More generally speaking, the forces could be applied to areas on the pelvis and the proximal femur. For example, the device could be applied within the joint capsule or exterior to it. The device is inserted through a cannula under arthroscopic and fluoroscopic visualization starting in the peripheral compartment of the joint space. Fluoroscopic visualization is useful to ensure proper insertion and placement of the device. Fluoroscopy is especially useful for the placement to the piriformis fossa. Arthroscopy could be sufficient for the placement to the AIIS.

The device is inserted in a shortened position and expanded inside the patient. Removal of the device is the reverse order of the insertion procedure meaning that the expansion is reversed and the device is removed from the cannula in the shortened position. During the procedure, the cannula could be free for other instruments needed during surgery.
The expansion and shortening of the joint distraction device could either be done with a helical worm gear drive mechanism, a pneumatic cylindrical mechanism or a combination thereof. Once the device is inside the peripheral compartment (e.g. under muscle and can be in or outside the capsule), a proximal portion of the device goes on to the AIIS and a distal portion of the device goes into the piriformis fossa. Once this happens, distraction occurs as the device continues to be expanded and apply opposing forces to the AIIS and piriformis fossa.

FIG. 1 shows an exemplary joint distraction device 100 with a proximal fixation surface 110 and a distal fixation surface 120, both preventing migration into bone. A joint distraction mechanism 130 is situated in between both fixation surfaces, 110, 120. The proximal end of joint distraction mechanism 130 is affixed to proximal fixation surface 110, and the distal end of joint distraction mechanism 130 is affixed to distal fixation surface 120.

Proximal fixation surface 110 has an outer facing surface facing away from joint distraction device 100. Outer facing surface of proximal fixation surface 110 has two or more bone spikes for engagement with a proximal bone segment (e.g. AIIS) proximally located to a joint.
Distal fixation surface 120 has an outer facing surface facing away from joint
distraction device 100. Outer facing surface of distal fixation surface 120 has
one or more bone spikes for engagement with a distal bone segment (e.g.
piriformis) distally located from the joint.

Joint distraction mechanism 130 has a force driving mechanism for changing
the relative distance between proximal fixation surface 110 and distal fixation
surface 120, and therewith the relative distance of proximal bone segment and
distal bone segment, thus changing the space within the joint (e.g. hip). It is
noted that joint distraction mechanism 130 is also used for changing the length
of device 100 for insertion into and retraction from the patient's body.

In one example, joint distraction mechanism 130 has a worm gear drive
mechanism. Worm gear 132 is a special type of helical gear whose helix
angle is close to perpendicular with the axis of the gear's drive shaft.
Resembling a corkscrew, worm gears 132 are usually produced by wrapping a
single tooth around the gear's central axis at a given helix angle.

As worm gear 132 is turned, the tooth is advanced in a direction parallel to the
gear's central axis. Worm gears could be meshed with either spur gears or
helical gears with a complimentary helix angle to create a drive mechanism.
Using this arrangement of gears, rotation about a horizontal axis is translated
into rotation about a vertical axis, while using minimal space.
In one example, in place of an ordinary helical gear to mesh with the worm gear, gear teeth with a complimentary helix angle could be formed onto about a 72 mm (about 3 inch) long cylinder 134. A tap hole could be drilled through the length of cylinder 134 and threaded to allow distal fixation surface (or stud) 120 and a threaded rod 136 to be screwed into its opposing ends. The exposed end of threaded rod 136 could then be fixed to an articulating joint or head 140 used to attach to the AIIS. This allows cylinder 134 to unscrew from threaded rod 136 when articulating joint 140 is held fixed. When worm gear 132 is turned along a horizontal axis, it meshes with cylinder 134 and causes it to rotate about its vertical axis.

With articulating joint 140 at one end of device 100 held in a fixed position (i.e. simulating attachment to the AIIS), rotation causes cylinder 134 to unscrew from threaded rod 136. As cylinder 134 is unscrewed, the displacement that this creates presses against a distal fixation surface 120 and creates a force in the vertical direction. When this force is applied across the AIIS and the piriformis, distraction will be produced at the hip joint. Since cylinder 134 can be driven by worm gear 132, but not vice-versa, the worm gear drive mechanism in device 100 is self-locking and will hold the generated distraction until worm gear 132 is turned in reverse to release distraction.
It is noted that worm gear 132 could be driven by something outside the patient's body and stays fairly fixed in space other than rotating to generate the force and therefore separation between proximal and distal points.

The mechanism of attachment to the proximal bone segment (e.g. AIIS) has two features. The first feature is proximal fixation plate 110 with two or more bone spikes 112, similar to bones screws or nails, on the outer facing surface that will engage the proximal bone segment. The second feature is the articulating head 140.

When device 100 is inserted through the cannula and proximal fixation plate 110 is pressed against the AIIS, spikes 112 on the plate's surface will insert a short distance into the AIIS and fix it to the bone. As long as two or more spikes are used on the fixation plate surface, a rigid attachment to the surface of the bone is provided which will help stabilize device 100 during joint distraction. Once proximal fixation plate 110 has been fixed to the AIIS, articulating joint 140 can be maneuvered to direct device 100 toward the piriformis fossa and then locked in a fixed position for hip distraction by a friction or set screw mechanism. Articulating joint 140 can also be loosened and adjusted during distraction to change the orientation of the patient's leg and give the surgeon access to different surfaces within the hip during the procedure.
It is noted that articulating joint 140 is shown with an exemplary two ball mechanisms that can be clamped together with e.g. a screw or similar fastening mechanism. As a person skilled in the art would appreciate articulating joint 140 could be established with various (joint) mechanisms like a single ball mechanism and is not limited to these examples. In general, the intent of using articulating joint 140 is to align proximal fixation surface 110 against the proximal bone segment (e.g. AIIS) and/or to allow maneuvering of device 100 to point to the opposing bone surfaces. Articulating joint 140 is preferably a three-dimensional articulating joint. However, articulating joint 140 could also have fewer degrees of rotation freedom or even have just a fixed angle (142 in FIG. 2) for aligning the relative position of proximal fixation surface 110 with a proximal bone segment, depending on the type of surgical procedure and/or joint to be distracted.

The mechanism of attachment to the distal bone segment (e.g. piriformis fossa) features a distal fixation plate 120 with one or more bone spikes 122, similar to bones screws or nails, on the outer facing surface that will engage the distal bone segment (i.e. piriformis fossa).

As cylinder 134 unscrews from threaded rod 136 to create distraction, bone spike 122 is pressed into the distal bone segment and holds device 100 in
Since the attachment mechanism at the distal end of device 100 is made up of a single point 122, device 100 will be free to rotate with respect to the distal bone segment after bone spike 122 has been pressed into the bone. This will allow device 100 to continue producing a distraction force after both proximal and distal ends have been fixed securely to the bone. Since a larger surface of the distal fixation surface/stud will press against the piriformis fossa once the bone spike has been inserted, the force required to produce distraction will be spread over a larger area and decrease the contact pressure at the proximal femur or piriformis fossa.

In another embodiment, joint distraction mechanism 130 could have a pneumatic cylindrical force driving mechanism shown in FIG. 3. Pneumatic cylinder 300 is powered through a connection to a pressurized air tank or line. The two air inlets 310, 312 are connected to two isolated chambers within the cylinder. When pressurized air is channeled to air inlet 310 via an external switch valve, a piston 320 is extended. When air is channeled to inlet 312, the piston is retracted. This extension of the piston by pressurized air is the mechanism that generates the force applied across the piriformis fossa and the AIIS to generate distraction at the hip.
The mechanism to attach pneumatic cylinder driving mechanism 300 to the AIIS is the same as the one described above in the worm gear device description. Here, the articulating head is instead bonded to the back of the pneumatic cylinder and can be maneuvered to point the piston in the direction of the piriformis fossa. The mechanism to attach pneumatic cylinder 300 mechanism to the piriformis fossa is also similar to the one detailed in the worm gear device description. Here, a bone spike similar to a bone screw or nail is attached to the piston of the pneumatic cylinder. As air pressure pushes the piston toward the piriformis fossa, this spike will embed in the piriformis fossa and fix that end of the device to the bone during distraction.

**Exemplary Details**

Devices according to the invention could display various physical measurements depending on the type of surgical procedure, patient size, morphology of the patient's hip (e.g., gender variations), joint or even species. The following is merely an example of measurements for use of the device in hip arthroscopy procedures. It is noted that the invention should not be limited to these exemplary details.

- The cannula for insertion and removal of the device could be about 8.25 mm (about .32 inches).
The size of the device in shortened position is about 70 mm (about 2.75 inches) and extended position about 102 mm (about 4 inches). These sizes could vary about 20% and are based on anatomical differences and device design.

- The device attaches to bone using small bone spikes on each end. The force generated through the joint distraction mechanism is sufficient to insert these spikes into bone, which for an exemplary and common cross-section area of screw/pin is about or less than 267 N (60 lbs).

- The one (or more) bone spikes or pins for the piriformis fossa could be about 2-4 mm long and about 1-2 mm in diameter.

- The two or more bone spikes or pins on the AIIS side could be about 1 mm long and about 1 mm in diameter.

- The proximal and distal joint facing fixation surfaces for the AIIS and proximal femur could each be about 50 mm².

- In one variation, the number of bone spikes at the proximal fixation surface could be one or more provided sufficient fixation (where the articulating mechanism could play a role) to hold the proximal end of the device in place during expansion/distraction.

- The force distraction vector generated by the device onto the bone surfaces is preferably as close as possible and as close to be parallel to the joint axis that is being distracted. This would reduce the amount of force required to distract the hip as well as further improve safe distraction.
CLAIMS

What is claimed is:

1. A joint distraction device for use in an arthroscopic surgery, comprising:

   (a) a proximal fixation surface;

   (b) a distal fixation surface; and

   (c) a joint distraction mechanism, situated in between said proximal and distal surfaces, having a proximal end affixed to said proximal fixation surface and having a distal end affixed to said distal fixation surface,

   wherein said proximal fixation surface has an outer facing surface facing away from said joint distraction device, and wherein said outer facing surface of said proximal fixation surface has two or more bone spikes for engagement with a proximal bone segment proximally located to a joint,

   wherein said distal fixation surface has an outer facing surface facing away from said joint distraction device, wherein said outer facing surface of said distal fixation surface has one or more bone spikes for engagement with a distal bone segment distally located from said joint, and
wherein said joint distraction mechanism comprises a force driving
mechanism for changing the relative distance between said
proximal fixation surface and said distal fixation surface, and
wherein the force generated by said force driving mechanism
should be sufficient to insert said bone spikes into said respective
bone segments, as well as distract said joint to create a sufficient
enough joint gap to allow an intended procedure.

2. The joint distraction device as set forth in claim 1, wherein said
joint distraction mechanism comprises (i) an articulating joint or
(ii) a fixed joint angle for aligning the relative position of said
proximal fixation surface with said proximal bone segment.

3. The joint distraction device as set forth in claim 2, wherein
said articulating joint is a three-dimensional articulating joint.

4. The joint distraction device as set forth in claim 1, wherein
said articulating joint can be locked or fixed in a position.
5. The joint distraction device as set forth in claim 1, wherein said joint distraction device can be arthroscopically inserted within a body or inserted via an open incision.

6. The joint distraction device as set forth in claim 1, wherein said spikes are connected substantially perpendicular to said respective outer surfaces of said fixation surfaces.

7. The joint distraction device as set forth in claim 1, wherein said force driving mechanism comprises a worm gear force driving mechanism or a pneumatic force driving mechanism.

8. The joint distraction device as set forth in claim 1, wherein said joint is a hip joint, said proximal bone segment is an area on a pelvis and said distal bone segment is an area on a femur.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2013/039117

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/02 (2006.01)
A61B 17/56 (2006.01)
A61B 1/317 (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 1/3 17, 17/02, 17/56

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

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

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>US 6102928 A1 (GENERAL SURGICAL INNOVATIONS, INC.) 15.08.2000, col. 9, line 42-col. 10, line 12, fig. 11, 12</td>
<td>1-8</td>
</tr>
<tr>
<td>A</td>
<td>RU 9278 1 U1 (GOSUDARSTVENNOE OBRAZOVATELNOE UCHREZHDENIE VYSHEGO PROFESSIONALNOGO OBRAZOVANIYA MOSKOVSKAYA MEDITSINSKAYA AKADEMIYA IM. L.M.SECHENOVA FEDERALNOGO AGENCYKA PO ZDRAVOKHONENIYU I SOTSIALNOMY RAZVITYU) 10.04.2010</td>
<td>1-8</td>
</tr>
<tr>
<td>A</td>
<td>US 6616673 B1 (BIOMET, INC.) 09.09.2003</td>
<td>1-8</td>
</tr>
<tr>
<td>A</td>
<td>US 7828727 B2 (EBI, LLC) 09.11.2010</td>
<td>1-8</td>
</tr>
<tr>
<td>A</td>
<td>US 7766918 B2 (WARSAW ORTHOPEDIC, INC.) 03.08.2010</td>
<td>1-8</td>
</tr>
</tbody>
</table>

☐ 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 document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 June 2013 (20.06.2013)

Date of mailing of the international search report

22 August 2013 (22.08.2013)

Name and mailing address of the ISA/ FIPS

Russia, 123995, Moscow, G-59, GSP-5, Berezukovskaya nab., 30-1

Facsimile No. +7 (499) 243-33-37

Authorized officer

R. Fedorova

Telephone No. 8(495)53 1-64-8 1

Form PCT/ISA/210 (second sheet) (July 2009)