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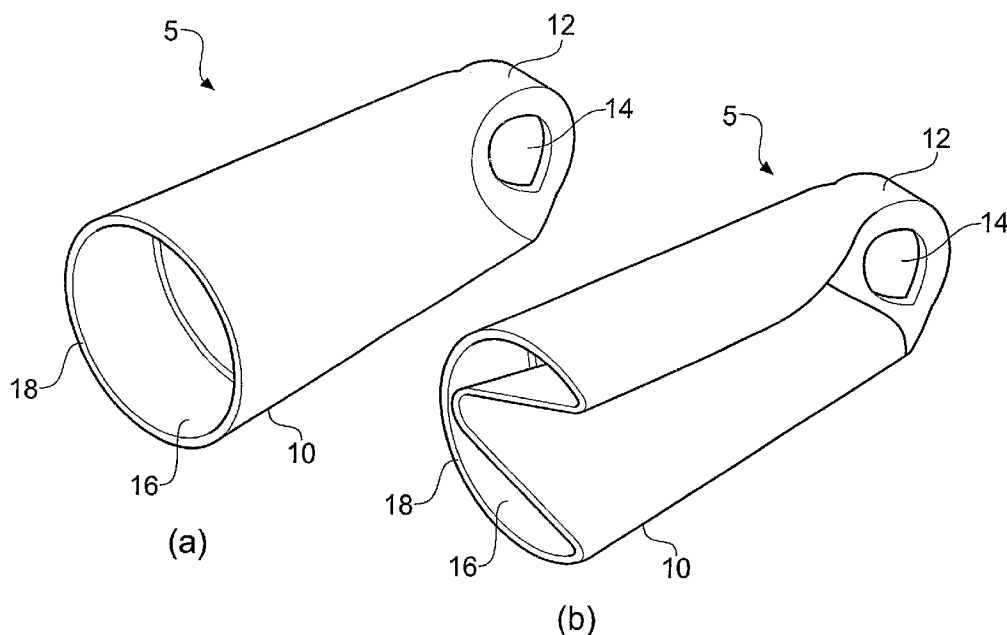
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(54) Title: AGLET FOR ATTACHMENT TO A GRAFT MATERIAL



(57) Abstract: The invention relates to an aglet (5) or surgical anchor for use in the replacement of soft tissues such as ligaments and tendons. The aglet comprises a portion (16) for gripping the tissue and may also comprise a portion (10, 24) for attaching the aglet and retained material to a bone or other structure.

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AGLET FOR ATTACHMENT TO A GRAFT MATERIAL

The invention relates to an aglet for use in surgical procedures, especially procedures in which soft tissues are replaced. It is particularly useful for cruciate ligament surgery.

The knee is a remarkably complex joint with a large range of stable movement. This is made possible by a complicated array of ligaments that run across the joint from the thigh bone (femur) to the shin bone (tibia). The ligaments work in harmony, throughout the range of movement to control and stabilise the joint.

Of all the ligaments, the cruciate ligaments are the most important in controlling forward and backward motion. The cruciate ligaments cross over in the centre of the knee, one from the front (the anterior cruciate ligament (ACL) and one from the back (the posterior cruciate ligament (PCL).

All the knee ligaments can be damaged in an accident, but various patterns of injury are seen most commonly. The rupture of an anterior cruciate ligament is a common, and disabling injury, typically occurring in sports people and often requiring surgical treatment.

Once an ACL has ruptured, the individual is known as ACL deficient (ACLD). ACL deficiency can be diagnosed from patient history, and confirmed by a number of clinical examination techniques, scars shown by magnetic resonance imaging (MRI) and/or keyhole surgery (Arthroscopy).

Curiously some people can tolerate ACL deficiency well, with few symptoms, despite an obvious instability. However, the majority have problems and there are usually noticeable episodes of 'giving way' particularly during twisting, turning and cutting manoeuvres during sports. It is this group of patients that are recommended surgery (Anterior Cruciate Ligament Reconstruction).

It is estimated that in the United States Of America 200,000 ACL ruptures occur annually. Of these 65-75,000 ACL reconstructions are performed every year. As surgery becomes more successful, less invasive, quicker and more available, the numbers will only increase.

Patients are increasingly aware of the technology, are less inclined to modify their lifestyle after injury, and have more time and enthusiasm for a sporting life. ACL ruptures and their reconstruction are here to stay.

Attempts to reconstruct the ACL surgically date back 100 years, but it is only in the last 15-20 years that reliable techniques have emerged. This has been due to a combination of emerging technology such as keyhole surgery (arthroscopy) and the drive from professional sportsmen demanding treatment to overcome what used to be a career-stopping injury.

Although there are still some variations in practice, the vast majority of surgeons perform an autograft technique. This is a way of harvesting part of the patients own knee and refashioning it into a new ACL and fixing this into the exact position of the original ruptured ligament. The two popular techniques involve either using the middle third of the knee-cap tendon (mid 1/3 bone tendon bone (BTB)) or hamstring tendons. ACL reconstruction is reliable and is now very regularly used; however, there remains controversy over graft choice: BTB vs. hamstrings.

In BTB, a 10 mm strip of tendon about 5 cm long with an attached piece of bone at either end is harvested from the knee cap tendon. This is inserted with the help of a keyhole camera (arthroscopically assisted) and fixed in place with interference screws to form a new strong single strand of ACL.

In hamstring autograft, 2 strips of hamstring tendon are harvested from a small incision over the upper inner side of the shin just below the knee. The tendons are from the semitendinosus gracilis muscle. The tendons are longer and thinner than BTB and have no bone attached. They range in diameter from 3 to 5 mm and are about 15 -20 cm long. To make them strong, they are doubled over to make a 4 strand graft. When compressed they form as four strands onto an overall diameter of 8 - 11 mm.

The debate continues, but the pendulum of opinion and now the majority of practice has swung towards the hamstring technique, because the hamstring is a less invasive procedure with fewer side effects e.g. pain at the harvest/donor site, and is quicker to recover from, and some patients are able to have the surgery carried out without needing to stay in hospital

overnight, making it cheaper than BTB for which an overnight stay is required. However, BTB is easier to tension being a single strand and easier to fix with its bone end.

Accordingly, it would be advantageous to be able to improve the tensioning and fixation in the hamstring technique.

When using hamstring grafts there still remains a wide choice of fixation techniques and devices. The double-strand of the hamstring can be fixed in the bone by looping it over a device (suspensory fixation) within the bone tunnel or it can be jammed in the tunnel with a screw running past it (interference fit). It can also be pulled onto the surface and screwed (with a claw) or stapled onto the bone.

However, regardless of which device is used, the tendons are all prepared with a whipstitch to enable them to be passed and pulled into position. To facilitate pulling the tendon into the right place, tensioning it and extending it, the current practice is to apply a whipstitch to each of the four ends of the hamstring graft. This is done with a suture and needle sewn into a 'saxon stocking' effect into the last two centimetres of ligament. The job can be aided by an assistant and/or a special preparation board. There is significant potential for needle-stick injuries nevertheless. In smaller strands of ligament it can be a little unreliable. Since the whipstitch is done manually, it is time-consuming, potentially dangerous, due to needle-stick injuries, and fiddly. It would be useful to eliminate the need for the whipstitch.

US5,108,431 discloses a ligament anchor having two parts, a clamp sleeve that is placed onto the ligament graft and an anchor that is inserted into a bone. When the clamp sleeve is placed into the anchor portion, the clamp sleeve is deformed about the ligament. The disadvantage of this device are that two components are required, and the clamp sleeve cannot be fixed on to the ligament until inserted into the anchor. Also, the ligament can only be mounted by drilling into and inserting the anchor sleeve into a bone.

The inventor has created a device that can be used to replace the whipstitch and that is simpler in construction and easier to use than the device in US5,108,431. Accordingly, there is provided a surgical aglet for attachment to a graft material comprising a retaining portion for attachment to the material, the retaining portion having a textured inner surface, wherein, in use, the retaining portion is compressed or crimped such that it is attached to the material.

The retaining portion is preferably permanently deformable, from a position in which the graft material may be inserted, into a gripping position.

An aglet is a tag or sheath covering the end of a cord. Aglets are typically seen on the ends of shoe laces. Herein, the term aglet refers to a sheath or cladding for use on material to be used in surgery, especially for use on soft tissue, such as ligaments or tendons. Specifically, the aglet may be used to grip and anchor such tissues.. The retaining portion of the aglet may be placed on or around the material or soft tissue. The retaining portion of the aglet may then be crimped or crushed in order to grip the material. The textured surface of the retaining portion aids the gripping of the material. The aglet then allows the material to be manoeuvred because the aglet can be held easily.

The aglet provides significant advantages over the device described in US5,108,431. In particular, a second anchor portion is not required. The aglet may be crimped into the graft material prior to attachment to bone and can be used to help manoeuvre the graft into position.

The term "graft material" refers to any material for use in surgery to replace or repair damaged tissue. In particular it refers to soft tissue such as a ligament or a tendon. It may also refer to an artificial replacement therefore.

As mentioned previously, in surgery like ACL reconstruction, a number of strands of tissue may be used together to replace, for example, a ligament. In such a case, an aglet may be applied to one or both ends of each strand of tissue, or a number of strands may be put together and one aglet applied to a number of ends. When one aglet is applied to a number of strands, it is particularly useful that the aglet may be applied and fixed in position prior to attachment to the bone, as this is much easier to carry out and ensure all strands are gripped proper.

The retaining portion of the aglet may be any appropriate shape to receive the material. For example, it may be tubular, allowing it to be placed on to the material to be gripped. Alternatively, it may be flat, but, in use, bent or shaped around the tissue.

The retaining portion is preferably substantially tubular in shape, and is hollow, defining a cavity. The retaining portion preferably has two ends, at least one of which is open to allow access of the material to the cavity. The other end of the aglet may be open or closed. It is preferably open, to aid entry of the material into the cavity. The shape of the retaining portion may be selected to be appropriate for the surgery for which it is to be used. For example, the retaining portion may be tapered from one end to the other. In particular, the retaining portion may be substantially cylindrical or frusto-conical in shape.

It is particularly advantageous for the retaining portion to be tubular, especially cylindrical or frusto-conical in shape, because such shapes allow the retaining portion to be crimped or crushed very easily so that it retains the material. The aglet may be used on material that has been harvested from the body. It may be applied to the material during surgery. It is important that any tools used to crimp or crush the aglet are sterilisable. Accordingly, it is helpful if as few tools as possible are required. A tubular aglet can be crimped into a retaining position very easily, using one crimping action and one crimping tool that can be sterilised. The inner surface of the retaining portion is the surface that contacts the graft material.

The texture on the inner surface of the body may be made in any manner. For example, there may be protrusions such as teeth, or, preferably, one or more ridges on the inner surface. Such ridges may run in any direction, but are preferably substantially perpendicular to the axis of insertion of the material into the retaining portion.

The aglet preferably also comprises a manipulation portion. The manipulation portion allows the aglet to be even more easily manoeuvred. The manipulation portion may be any appropriate shape, but is preferably an elongate arm extending from one end of the retaining portion. The manipulation portion may include or form a tensioning means, such as a hook, loop or aperture, which may be used to aid manipulation of the device, for example by passing an instrument or suture through the hook or hole and pulling the aglet into a particular position using the instrument or suture. Such a means may also be used to tension the material held by the aglet, again by pulling using an instrument or suture. The manipulation portion is preferably positioned at the opposite end of the retaining portion to the opening for receiving the material.

The aglet may comprise a fixing means, to allow the aglet to be fixed to, for example, a bone or other body part. The fixing means may be any appropriate means, including, for example, an aperture through which a screw, staple or stitch may be passed. The fixing means is preferably found on or in or as part of the manipulation portion.

The aglet may be used in one of two ways. It may simply be used to position and/or tension material or it may be additionally used to fix the material in place. For example, when replacing a ligament, the aglet is attached to the replacement material and used to hold and position it. The material may then be screwed or stapled to the bone to which it should be attached and the aglet cut away. Alternatively, the aglet may be used to fix the material in place, the aglet being screwed or stapled to the bone, via the fixing means.

The aglet preferably has a smooth outer surface. In particular, the outer surface of the retaining portion is preferably smooth. The retaining portion preferably does not comprise ridges or shoulders on its outer surface. This is to allow a smooth and easy passage of the aglet through the body, particularly through narrow areas such as bone tunnels. The manipulation portion is preferably smaller in diameter than the retaining portion.

In order to aid gripping of the material, the aglet is preferably suitable for crimping or crushing. The aglet may preferably be crimped or crushed substantially in line with the axis of insertion of the material. In other words, the aglet is preferably crimped or crushed along the axis of elongation of the retaining portion. The aglet may be provided with a weakened portion, to encourage crimping or crushing at a particular point or along a particular line.

The aglet may be made from any material that is suitable for use in surgery and that may be crimped or crushed. The material is malleable; it can be crimped or crushed and retains its crimped or crushed shape. In particular the aglet may be made from surgical steel, but other materials such as plastics and titanium are also envisaged.

The aglet may be partially or completely coated with a growth promoting substance. This is to encourage regeneration of the tissues surrounding the site of surgery.

Also provided are tools to be used with the aglet of the invention. In particular there is provided a pair of crimping bits or jaws. The pair of bits or jaws preferably comprises a

female bit or jaw having at least one recessed portion shaped to receive the aglet, and a male bit or jaw having a protrusion shaped to crimp the aglet when the bits are forced together. When the aglet is cylindrical, the female bit or jaw preferably comprises at least one recessed portion shaped to receive a cylindrical aglet, that is, the cross section of the recess portion is substantially semi-circular. When the aglet is frusto-conical, the female bit or jaw preferably comprises at least one recessed portion shaped to receive a frusto-conical aglet, that is, the cross section of the recess portion is substantially semi-circular and tapers from one end to the other. The protrusion on the male jaw or bit is preferably V-shaped, so that the protrusion is wider at the point at which it leaves the surface of the jaw and tapers to a narrow point.

Also provided is a crimping tool comprising a pair of jaws or bits according to the invention. The crimping jaws and crimping tool are preferably made from sterilisable material.

Further provided is a method of preparing a tissue graft for surgery comprising inserting the tissue into the body of an aglet according to the invention and crimping the aglet so that it grips the tissue. The tissue is preferably isolated from the patient.

Also provided is a tissue graft comprising an isolated piece of tissue having an aglet according to the invention attached thereto.

The invention will now be described in detail, by way of example only, with reference to the drawings, in which:

figure 1 shows an aglet according to the invention in uncrimped (A) and crimped (B) forms; figure 2 shows a second according to the invention in uncrimped (A) and crimped (B) forms; figure 3 shows views of the aglet from one end (a), and the other end (b) and a cross section of the aglet (c); figure 4 shows male and female crimping bits for crimping the aglet; and figure 5 shows the results of a stress test applied to the aglet when attached to a ligament graft.

In a first embodiment, the aglet 5 comprises a body or retaining portion 10 and a manipulation portion 12. The manipulation portion includes an aperture 14 which can be used to tension the material to be gripped by the aglet.

The body may be any shape. In the embodiment shown, the body is frusto-conical.

The body defines a cavity 16, into which material to be gripped by the aglet may be inserted. The material is inserted into the cavity via the open first end 18 of the body. The second end 20 of the body may also be open to aid insertion of the material. The material can be pulled into the body using an instrument or suture inserted through the open second end. The inner surface of the body, surrounding the cavity, is textured. As shown in the figures, the texture may be made up of one or more ridges 22. The ridges may run in any direction. In the embodiments shown, the ridges run around the circumference of the cavity, rather than from end to end of the body.

As indicated previously, the manipulation portion may include a tensioning means 14. As shown in figure 2, it can also include a fixing means 24 to allow the aglet to be fixed to, for example, a bone.

In use, the aglet is used for gripping material to be used in surgery, especially soft tissue such as ligaments or tendons. The material is inserted into the body via the open first end. The aglet is then crimped, preferably along its length, to form an aglet as shown in figures 1B or 2B. Crimping the aglet grips the material in the cavity. The material is held in place by the textured inner surface. This is particularly useful when a number of strands of material are being used. The aglet is crimped using a crimping tool. Any appropriate tool may be used, but the jaws or bits must be appropriately shaped to receive the aglet and crimp it. As shown in figure 4, one jaw 26 is female and has at least one recessed portion 28. The other jaw 30 is male and has at least one protrusion 32.

Once crimped, the aglet can also be used to manoeuvre the material, for example it can be gripped using an instrument, or a suture can be passed through the tensioning means and used to pull the aglet. The tensioning means can also be used to place the gripped material under tension. When the aglet comprises a fixing means it may be used to fix the material in place. For example, a suture, staple or screw may be passed through the fixing means.

Although the use of the aglet in anterior cruciate ligament reconstructive surgery is described herein, the aglet could also be used for any surgery in which it is necessary to replace strands of soft tissue. The size and shape of the aglet may be modified accordingly.

In order to test the ability of the aglet to withstand the forces that could be placed upon it during use, an aglet was attached to a tendon and the tendon placed under tension, by pulling the aglet. The force at which the aglet came off the tendon was recorded. The aglet was able to withstand a force of up to 160 Newtons before it was separated from the tendon. The results of this test are shown in figure 5. The aglet was able to withstand forces considerably higher than those likely to be placed upon it during normal use.

Claims

1. A surgical aglet for attachment to a graft material comprising a retaining portion for attachment to the material, the retaining portion having a texture on its inner surface, wherein, in use, the retaining portion is compressed about a portion of the material, such that it grips the material.
2. A surgical aglet according to claim 1, in which the retaining portion of the aglet is substantially cylindrical or frusto-conical in shape.
3. A surgical aglet according to claim 1 or claim 2, in which the texture on the inner surface is formed by one or more ridges.
4. A surgical aglet according to any preceding claim, further comprising a manipulation portion.
5. A surgical aglet according to any preceding claim, further comprising a tensioning means.
6. A surgical aglet according to claim 5, wherein the tensioning means is an aperture or a hook.
7. A surgical aglet according to any preceding claim, further comprising a fixing means.
8. A surgical aglet according to claim 7, wherein the fixing means is an aperture.
9. A surgical aglet according to any preceding claim, wherein the outer surface of the aglet is substantially smooth.
10. A surgical aglet according to any preceding claim, wherein the aglet is made from surgical steel.

11. A surgical aglet according to any preceding claim, wherein the aglet is partially or completely coated with a growth promoting substance.
12. A pair of jaws for a crimping tool for crimping an aglet according to any preceding claim, the pair of jaws comprising a female jaw comprising at least one recessed portion for receiving the aglet, and a male jaw comprising at least one protrusion for crimping the aglet.
13. An aglet or pair of jaws substantially as described herein, or as shown in the drawings.
14. A crimping tool comprising a pair of jaws according to claim 12 or claim 13.
15. A method of preparing a tissue graft for surgery comprising inserting a piece of an isolated tissue into the retaining portion of an aglet according to any of claims 1 to 11 and crimping the aglet so that it grips the tissue.
16. A tissue graft comprising an isolated piece of tissue having an aglet according to any of claims 1 to 11 attached thereto.

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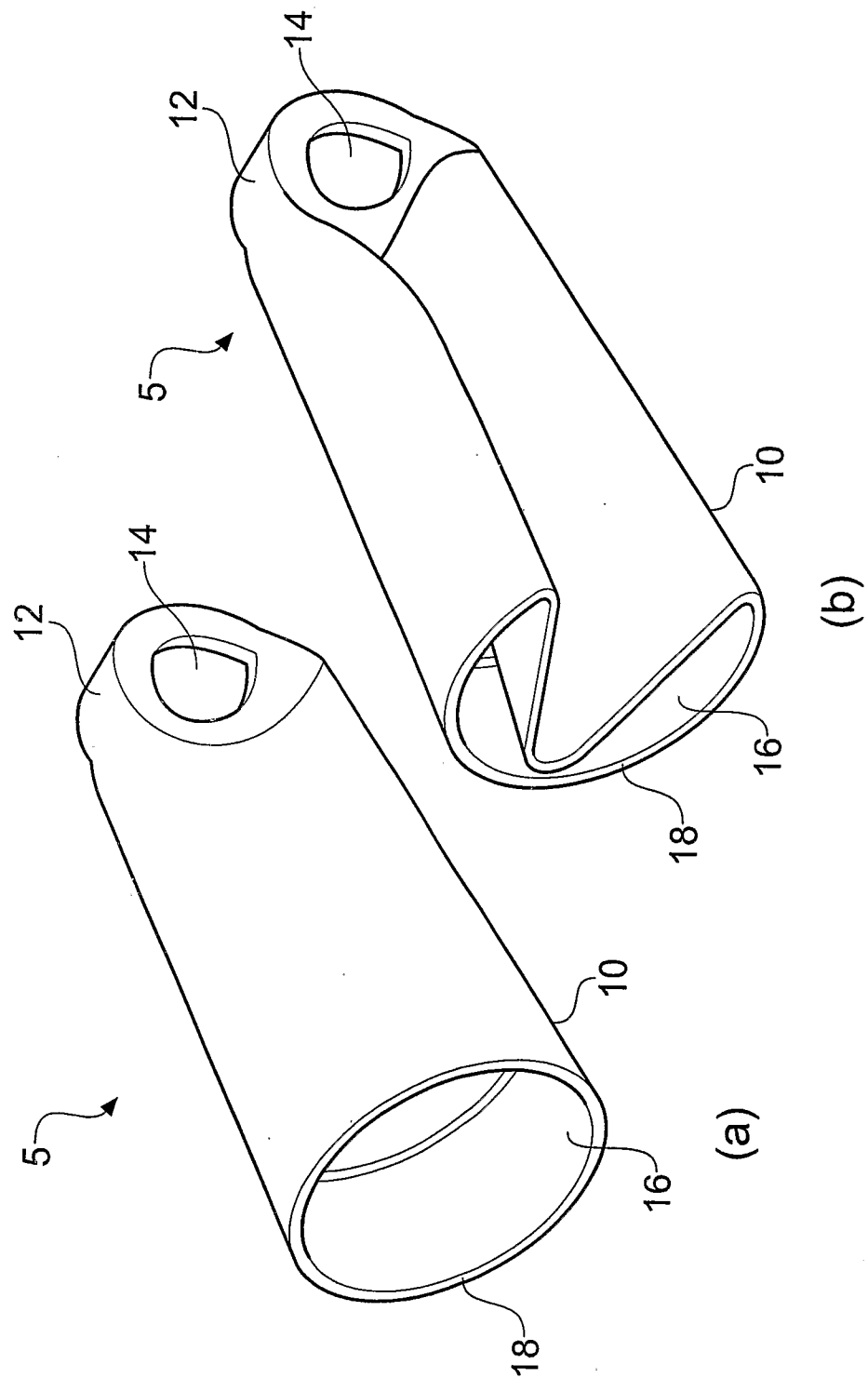


FIG. 1

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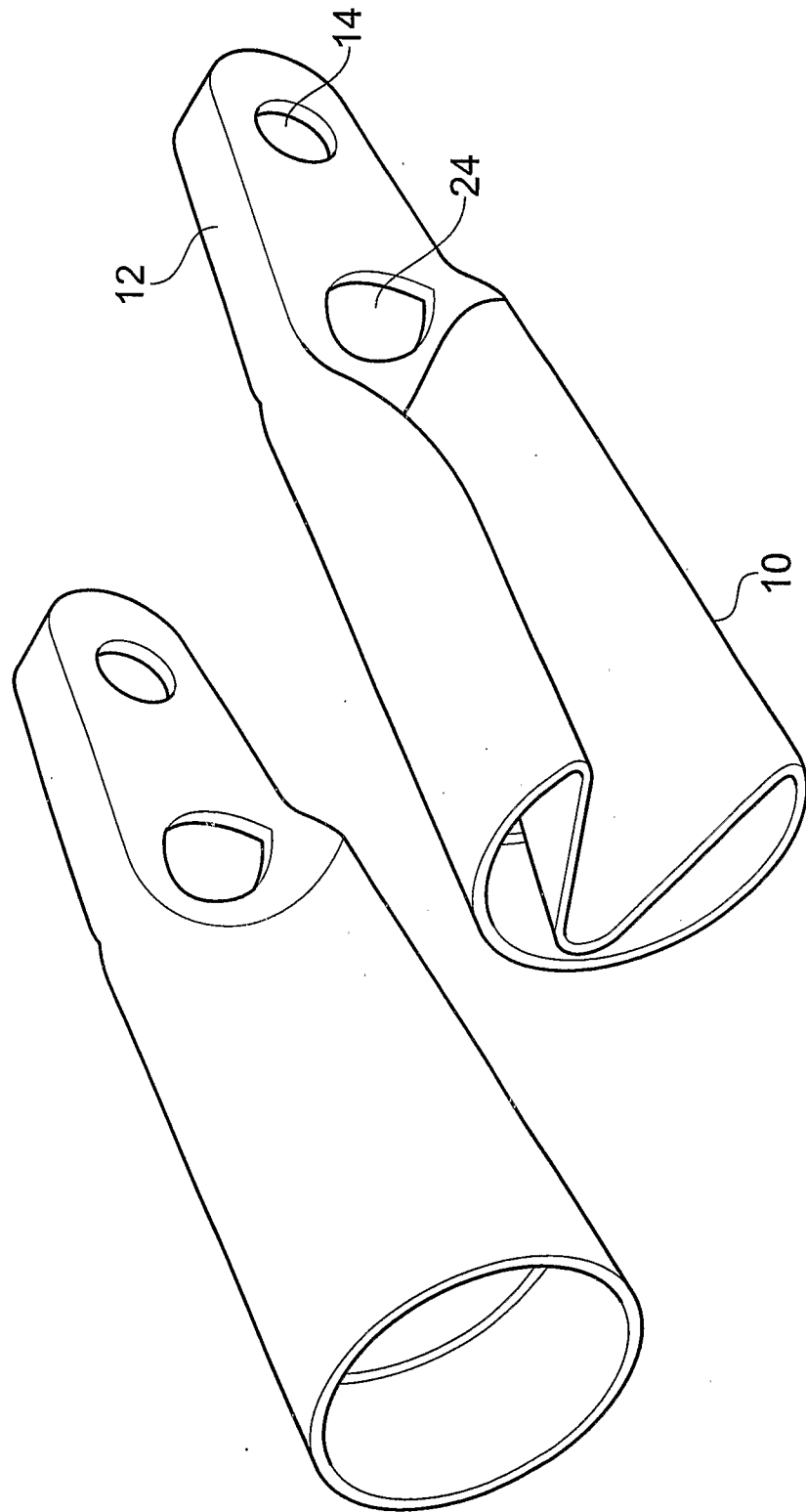


FIG. 2

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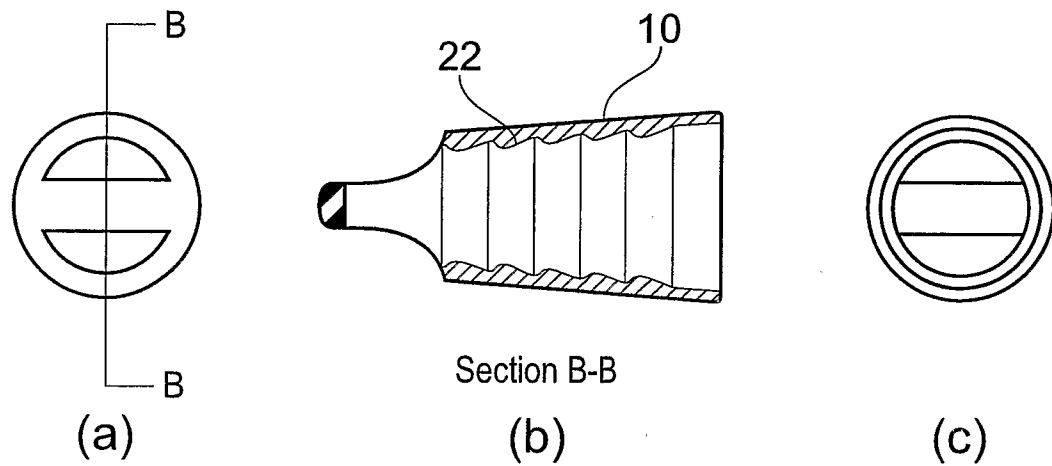


FIG. 3

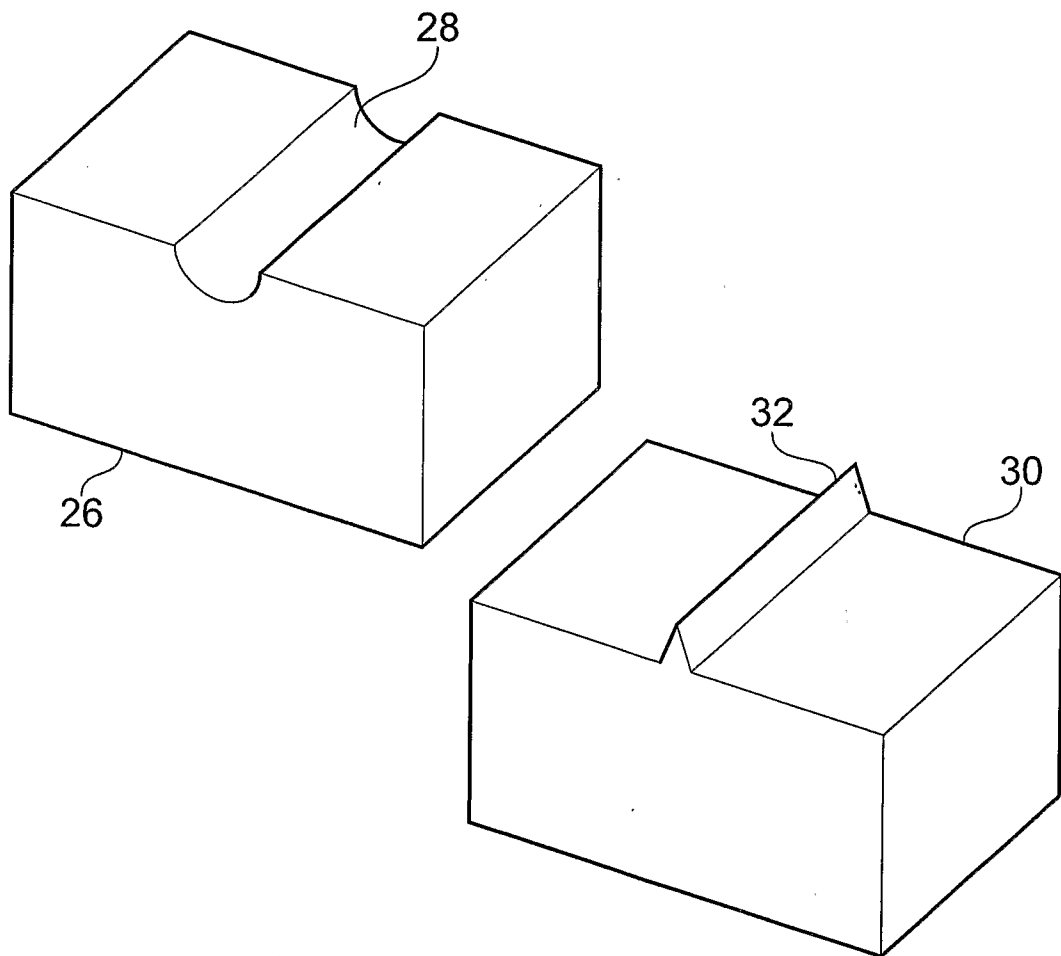


FIG. 4

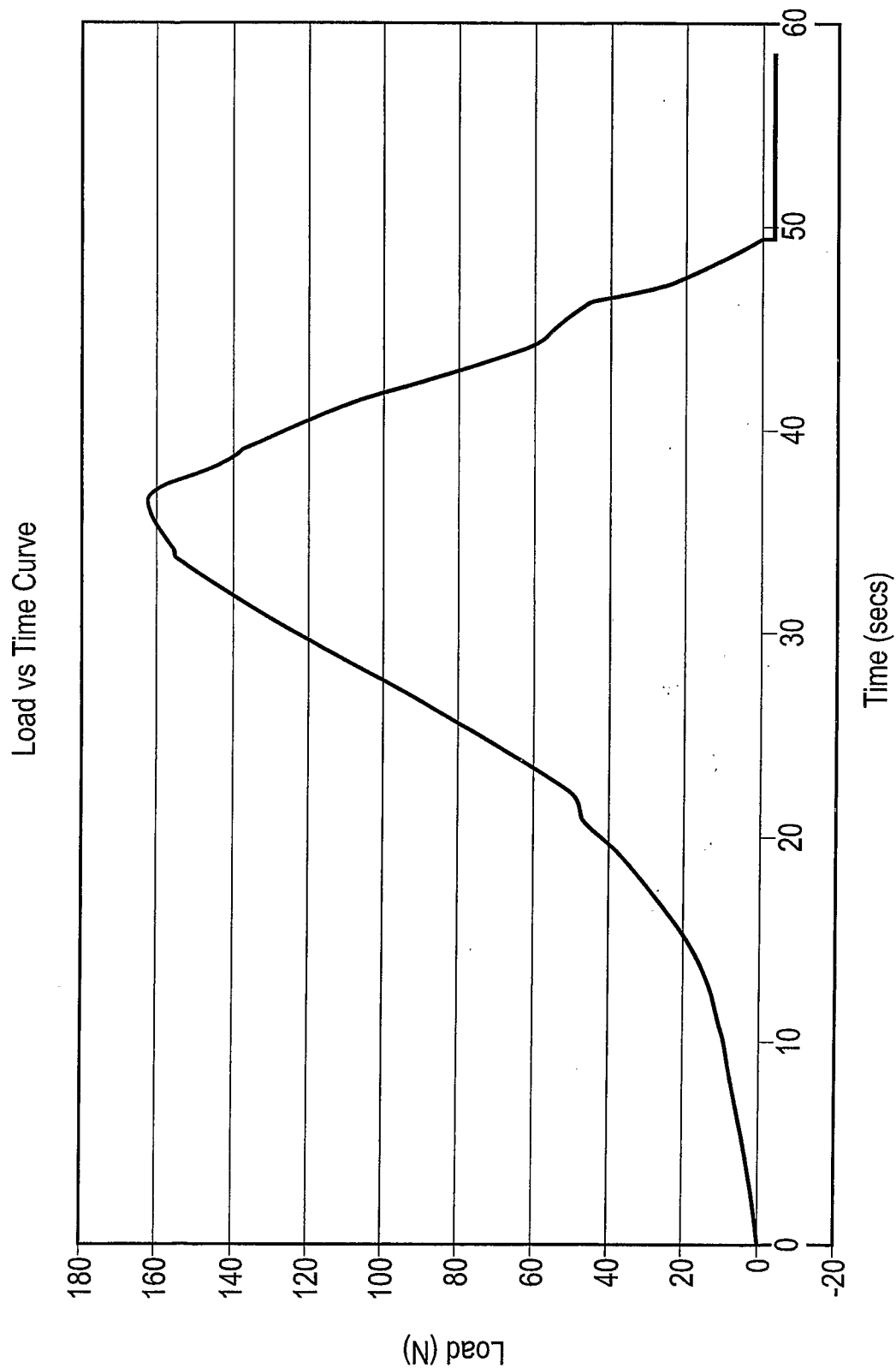


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/08

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)

A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C.



See patent family annex.

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INTERNATIONAL SEARCH REPORT

International application No

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