INTRATHecal Catheter Having A Stylet With A Curved Tip

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Abstract
An apparatus includes a catheter for an intrathecal drug delivery system and a stylet having a curved forward end. Preferably, the curved forward end has a shape in the form of a "J" or a "C." Also preferably, the catheter has a distal end that conforms to the curved forward end of the stylet. Thus, the present invention provides a catheter having a blunt forward end that minimizes the risk of penetrating the substance of the spinal cord. Additionally, the curved forward end of the stylet can be formed of a springy material so that it straightens out during the processes of insertion through a guide needle and retraction from the needle.
INTRATHecal CATHER HAVING A STYLET WITH A CURVED TIP

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 60/690,253, filed Jun. 14, 2005, which is hereby incorporated herein by reference in its entirety for all purposes.

TECHNICAL FIELD

[0002] The present invention relates generally to the field of surgical instruments and methods, and more particularly to an intrathecal catheter having a stylet with a curved forward end.

BACKGROUND OF THE INVENTION

[0003] Human and animal subjects suffering from chronic pain have several options available to help alleviate the pain. One option is intrathecal drug delivery, in which a low dose of a medication, typically a narcotic such as morphine, is delivered to the intrathecal space (i.e., within the spinal canal). A typical system for intrathecal drug delivery includes a drug delivery pump implanted in the patient’s abdomen, which has a reservoir for the medication, and a catheter leading from the pump into the intrathecal space. The pump releases the medication at a set rate, and the medication flows from the pump through the catheter to the site of delivery in the intrathecal space. Intrathecal drug delivery is beneficial because typically smaller doses of the medication can be used to gain relief, as compared to the dosages of those medications taken orally.

[0004] However, implanting the device is not without risk. Inadvertently implanting the catheter into the spinal cord can result in permanent injury to the spinal cord, potentially resulting in irreversible paralysis. For example, there is some risk that the practitioner, when placing the guide needle or the styletted catheter within the spinal canal, might puncture the spinal cord with the sharp tip of the guide needle and/or the styletted catheter and subsequently accidentally thread the styletted catheter into the center of the spinal cord. And since typically, most practitioners choose to perform this operation under general anesthesia in which the patient is completely unaware of the procedure, the patient will not know something is wrong until he or she wakes up, and in a more egregious case, the patient may wake up paralyzed from the waist down.

[0005] Therefore, a need exists for an apparatus and method that allows a catheter for an intrathecal drug delivery system to be guided more safely into proper placement within the intrathecal space.

SUMMARY OF THE INVENTION

[0006] Advantageously, the present invention provides an intrathecal catheter having a curved forward end for placement in the intrathecal space. The intrathecal catheter includes a guide wire or a stylet, within the catheter, that has a curved tip, and the tip of the catheter itself conforms to the shape of the stylet tip. Thus, the catheter provides a blunt forward end, which minimizes the likelihood of puncturing tissue, such as the spinal cord.

[0007] In an example form, the present invention provides an apparatus including a catheter for an intrathecal drug delivery system and a stylet, wherein the stylet has a curved forward end. Thus, the catheter has a tip that can conform to the curved forward end of the stylet. Preferably, the curved forward end of the stylet is in the shape of a “J” or a “C.” Also preferably, the curved forward end of the stylet is formed of a resilient and flexible material.

[0008] In one embodiment, the catheter has a single lumen for housing the stylet and for carrying a fluid from a fluid source to target tissue. Preferably, the catheter has a biocompatible body with at least one opening extending along the body near its distal end for drug delivery to target tissue.

[0009] In another form, the present invention provides a method for introducing a catheter for an intrathecal drug delivery system into the intrathecal space. The method includes the steps of inserting a stylet having a curved forward end into an intrathecal catheter; inserting the intrathecal catheter into an incision in the body; and guiding the intrathecal catheter into the intrathecal space by manipulation of the combination of the stylet and the catheter. The method can further include the steps of removing the stylet from the intrathecal catheter such that the catheter tip straightens out in the intrathecal space; anchoring the intrathecal catheter to adjacent tissue; and connecting the intrathecal catheter to a drug delivery pump.

[0010] In yet another example form, the present invention includes a kit for intrathecal drug delivery. The kit can include one or more of the following items packaged in a single kit: an intrathecal catheter, a stylet having a curved forward end, a drug delivery pump, a guide needle, an insertion device, a tunneling tool, and suturing supplies.

[0011] These and other aspects, features and advantages of the invention will be understood with reference to the drawings and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 depicts a perspective view of a catheter having a stylet with a curved forward tip according to an example embodiment of the present invention.

[0013] FIG. 2 depicts a longitudinal cross-sectional view of an end portion of the catheter of FIG. 1.

[0014] FIG. 3 depicts a pictorial representation of advancing the catheter of FIG. 1 through the intrathecal space.

[0015] FIG. 4 depicts a pictorial representation of the catheter of FIG. 1 implanted in the intrathecal space.

DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS

[0016] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to
be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a,""an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[0017] Referring to FIGS. 1-4 a catheter 10 having an associated flexible stylet 12 extending therethrough for an intrathecal drug delivery system is shown by way of an example embodiment. Intrathecal drug delivery systems, commonly referred to as morphine pumps, and methods of implanting such pumps are generally well known. Intrathecal drug delivery systems typically include a catheter 10 and a drug delivery pump 13, as shown in FIGS. 3 and 4. Referring back to FIGS. 1 and 2, the catheter 10 has a biocompatible body 14 constructed of a biocompatible and flexible material. Preferably, the body 14 has a single lumen or canal 16 extending therethrough for carrying a medication from the pump 13 to the intrathecal space and for housing the stylet 12. Alternatively, the catheter 10 can include dual lumens, one for carrying a medication and one for housing the stylet 12.

[0018] In an example embodiment, the catheter 10 has a length of about 60 to about 90 cm, an internal diameter in the range of about 0.4 to about 0.6 mm and more preferably in the range of about 0.5 mm to about 0.6 mm. In an example embodiment, the catheter 10 has an internal diameter of about 0.53 mm. The external diameter can be about 1.0 to about 3.0 mm, and more preferably from about 1.4 mm to about 2.0 mm, though those skilled in the art will understand that the dimensions can be larger or smaller. Preferably, the catheter 10 has a closed distal end 17. The distal end 17 also preferably includes at least one and preferably a plurality of lateral openings, slots, or holes 18 in the body 14 of catheter 10 through which the medication can be pumped. As shown in the figures, the catheter 10 has three such openings 18, though those skilled in the art will understand that the catheter can have more or fewer openings. Those skilled in the art will also understand how to determine the placement of the openings and the spacing between the openings 18.

[0019] Also, a fitting 19, such as a conventional fitting as shown in FIG. 4, can be attached to the proximal end of the catheter 10 to connect to the drug delivery pump 13 implanted in the patient's abdomen once the stylet 12 has been removed.

[0020] The stylet 12 has a tip 20 at its distal end and a handle 21 at its proximal end for manipulating the stylet. Those skilled in the art will understand that the handle 21 shown in FIG. 1 is exemplary and that the handle can have a variety of shapes and sizes. Preferably, the tip 20 of the stylet 12 has the shape of a "J", a "C", or is otherwise curved so as to provide a blunt, forward end that will not puncture tissue as the stylet and associated intrathecal catheter 10 are guided through the intrathecal space. Thus, the distal end 17 of the catheter 10 conforms to the shape of the tip 20 of the stylet 12. Preferably, the tip 20 of the stylet 12 is stiffer or less flexible than the distal end 17 of the catheter 10. By providing a blunt end, the risk of puncturing tissue that otherwise should not be punctured is greatly minimized, as compared to using a sharp tip.

[0021] Preferably, the stylet 12 is constructed of a resilient and flexible material that allows the tip 20 to adjust from a curved position in its neutral state to a straight position when being inserted through a guide needle or when being retracted from the catheter 10. Thus, at least the tip 20 of the stylet 12 is springy or flexible in the sense that when the stylet is retracted from the catheter 10, the tip of the stylet straightens itself out, and in so doing straightens out the distal end 17 of the catheter 10, so that removal from the catheter is made easier and minimizes the chances of tearing the catheter. The tip 20 of the stylet 12 can be constructed of a spring or coil material. Additionally, the entire stylet 12 can be a unitary piece that is constructed of a resilient, flexible, and biocompatible material, such as a plastic or a metal.

[0022] The size of the stylet 12 can vary, but in an example embodiment, the diameter of the stylet is smaller than the internal diameter of the catheter 10 and is about 0.46 mm. Those skilled in the art will understand that the stylet 12 can have a larger or smaller diameter, such as in the range of about 0.2 mm to about 0.52 mm and more preferably in the range of about 0.4 mm to about 0.5 mm. The length of the stylet 12 is preferably similar to the length of the catheter 10, and can be about 38 cm to about 89 cm, though those skilled in the art will understand that the dimensions can be larger or smaller.

[0023] The practitioner inserts the catheter 10 with the stylet 12 through a guide needle previously inserted through an incision in the patient's back and into the intrathecal space. Those skilled in the art will understand where and how to insert the guide needle. To facilitate threading the stylet 12 into the needle, an insertion device 22, as depicted in FIG. 1, can be used. The insertion device 22 is funnel-shaped, and has a larger distal end 24 through which the catheter 10 and stylet 12 are inserted, and a narrower forward end 26 which has an opening that can mate with the opening of the needle. Thus, the insertion device 22 facilitates threading the stylet 12 through the needle by allowing the practitioner to insert the distal end 17 of the catheter along with the tip 20 of the stylet into the insertion device. Alternatively, the stylet 12 can be inserted through a guide needle having a flared proximal end. Also alternatively, the stylletted catheter can be inserted through a stiff or rigid sheath. Additionally, the insertion device 22 or another generally funnel-shaped piece can be used to facilitate the threading of the stylet 12 into the catheter 10.

[0024] The guide needle or sheath generally deflects the curved tip 20 of the stylet 12 to at least a somewhat straight position so that the catheter and stylet can be threaded through the needle or sheath. Thus, while the stylletted catheter 10 is threaded through the needle, the tip 20 of the
stylet 12, and hence the distal end 17 of the catheter 10, temporarily straighten out. Once the styletted catheter 10 is threaded through the needle, the tip 20 of the stylet 12 springs back into its curved shape (i.e., back to its neutral position), which causes the distal end 17 of the catheter 10 to curve in shape. Alternatively, the curved tip of the catheter 10 can be threaded through a needle or sheath of a diameter sufficient to accommodate the diameter of the catheter in its curved tip position. Thus, the catheter 10 has a blunt forward end that can be manipulated through the intrathecal space.

3. The apparatus of claim 1, wherein the catheter has a tip that conforms to the curved forward end of the stylet.

4. The apparatus of claim 1, wherein the curved forward end of the stylet has a shape generally in the form of a “J.”

5. The apparatus of claim 1, wherein the curved forward end of the stylet has a shape generally in the form of a “C.”

6. The apparatus of claim 1, wherein the curved forward end comprises a resilient and flexible material.

7. The apparatus of claim 1, wherein the catheter has a biocompatible body with at least one opening extending along the body near its distal end for drug delivery to target tissue.

8. The apparatus of claim 7, wherein the intrathecal catheter has a closed distal end.

9. A method for introducing a catheter for an intrathecal drug delivery system into the intrathecal space, comprising:

- inserting a stylet having a curved forward end into an intrathecal catheter;
- inserting the intrathecal catheter having a forward tip into an incision in the body; and
- guiding the intrathecal catheter into the intrathecal space by manipulation of the stylet.

10. The method of claim 9, further comprising removing the stylet from the intrathecal catheter such that the curved forward end of the stylet straightens out during removal from the catheter.

11. The method of claim 10, wherein removing the stylet further comprises causing the tip of the catheter to straighten out in the intrathecal space.

12. The method of claim 9, wherein inserting the catheter into the body further comprises inserting the catheter through a guide needle positioned in the intrathecal space.

13. The method of claim 9, further comprising anchoring the intrathecal catheter to adjacent tissue.

14. The method of claim 13, further comprising connecting the intrathecal catheter to a drug delivery pump.

15. A kit for intrathecal drug delivery, comprising:

- an intrathecal catheter;
- a stylet having a curved forward end; and
- a drug delivery pump, wherein all of the above are packaged in a single kit.

16. The kit of claim 15 further comprising a guide needle and an insertion device.

17. The kit of claim 15 further comprising suturing supplies.

18. The kit of claim 15 further comprising a tunneling tool.