METHOD OF FORMING SPINAL NEEDLE

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ABSTRACT

The present application discloses a procedure for forming a beveled tip on a needle assembly including a cannula and an obturator. The assembly is subjected to a swaging or drawing operation for drawing the cannula inner wall into substantial contact with the obturator thereby to frictionally immobilize the latter. In this condition the assembly is provided with a tip. Tipping results in the reduction of gripping friction so that the obturator may be released. The procedure provides an assembly having no appreciable clearance or mismatch between cannula and obturator thereby to substantially reduce incidence of coring of tissue being punctured.

5 Claims, 6 Drawing Figures
METHOD OF FORMING SPINAL NEEDLE

The present invention relates to a process for the formation of a cutting tip on a needle assembly which includes a cannula and an internal obturator. More particularly the process contemplates the formation of a beveled tip on both cannula and obturator during the same operation. Through utilization of the techniques of the present invention the final assembly, firstly, will have no appreciable clearance or mismatch between the cannula and the obturator and, secondly, the tip faces will be flush, parallel and concentric.

Many prior art needles, as for example spinal needles, suffer from a significant problem which arises through usage. This problem is one of mechanical coring of a fragment of skin or tissue which is penetrated. The problem results from a clearance or mismatch between the cannula inner diameter and the obturator surface. In many prior art devices a clearance of up to 0.015 inches has been noted.

The deposition of a skin core in the epidural space accompanying the injection of fluid may result in an abscess, scar formation or an extradural epidermoid cyst. Further, a coring needle may prevent the free flow of fluid to the patient or the aspiration of fluid from the patient. Thus upon this occurrence it may be that while the operator has successfully lodged the needle, fluid flow is impeded requiring removal and aspiration to clear the core. This obviously is an annoying hindrance to the operator and a cause of additional trauma to the patient.

Additionally, a reusable needle which suffers from the problem of coring may be difficult to sterilize. There is reasonable evidence to indicate that in many instances after sterilization bits of tissue have been found lodged between the obturator and the inner cannula surface.

Prior art procedures followed in the fabrication of such a needle assembly fail to provide for the formation of a needle device having features of the type now contemplated. One procedure of the prior art is to introduce the obturator shank within the cannula lumen and mechanically hold the obturator in the desired position relative to the cannula. Even though securely held, the beveling operation causes the obturator shank to "snake" back toward the hub. This is because the obturator shank is of smaller cross-section. After completion of the bevel operation the obturator shank is free again to move forward within the lumen. Forward movement most likely will extend the obturator shank beyond the beveled cannula tip. If, however, the shank does not so extend it may fall short of the beveled cannula tip. In either case the hazard is that in performing a tissue puncture the needle may core the tissue. Further, because of a poor fit, there may be leakage which may cause headache.

The present invention overcomes the above problems and permits the manufacture of a needle assembly in which the clearance between the cannula inner wall and the obturator is at a minimum and the beveled tips of the components lie within a single plane thereby to be flush with one another.

According to one aspect of the present invention, a needle assembly is formed by locating the shank of an obturator in an operative disposition within the lumen of a cannula so that the latter may be either swaged or drawn down substantially on the obturator in at least the vicinity of the cannula end whereupon the components together and under a condition in which the obturator is substantially immobilized both in longitudinal and rotational movement are provided with a beveled tip.

There has thus been outlined rather broadly an important feature of the invention in order that the detailed description thereof that follows may be better understood, and in order that the present contribution to the art may be better appreciated. There are, of course, additional features of the invention that will be described hereinafter and which will form the subject of the claims appended hereto. Those skilled in the art will appreciate that the conception upon which this disclosure is based may readily be utilized as a basis for the designing of other structures for carrying out the several purposes of the invention. It is important, therefore, that the claims be regarded as including such equivalent constructions as do not depart from the spirit and scope of the invention.

Specific embodiments of the invention have been chosen for purposes of illustration and description and are shown in the accompanying drawings forming a part of the specification wherein:

FIG. 1a is a side view of the needle assembly;

FIG. 1b is a view of the assembly tip rotated, with respect to FIG. 1a, through 90°;

FIG. 2 is an enlarged view in partial section of the assembly tip;

FIG. 3 is a view similar to FIG. 2 with, however, the cannula swaged or drawn down on the obturator therein;

FIG. 4 is a view similar to FIG. 2 illustrating the beveled tip; and

FIG. 5 is an end view of the beveled tip of FIG. 4.

The invention may be seen to best advantage in FIGS. 2-5 illustrating the several steps in the process of forming the beveled cutting tip of noncoring needle 10. The needle as seen in FIG. 1 includes a hub 12 and an elongated needle cannula 14 secured at one end to the hub. The hub may be formed of molded plastic or, if desired, of metal. However, if the assembly is to be of the disposable type preferably it will be of molded plastic. The cannula is secured to the hub in any conventional manner. Staking or use of an adhesive epoxy system, for example, may be employed for securing. An obturator including a hub portion 16 and a shank portion 18 is supported by cannula hub 12 so that the shank passes within the lumen.

The shank length of the obturator will be substantially equal to the shank length of the cannula. Therefore, upon mating receipt and support of the obturator hub 16 within the needle hub 12 the shank will extend at least to the end of the cannula. Care should be taken that this disposition pertains.

The invention as has been briefly discussed contemplates the formation of a cutting tip on a needle assembly which by the elimination of appreciable clearance and mismatch between the cannula and obturator points and wall surfaces substantially eliminates the problem of tissue coring. Following the procedure assembly components are received and positively oriented one within the other, i.e., the obturator is received by the cannula throughout the length of the latter. Structure for assuring proper relationship of assembled components and for preventing rotational displacement of components during use of the needle may
be as desired. In the present invention, however, the needle hub includes a slot. A projection on the obturator hub is received by the slot in the operative position. This is generally illustrated at 20 in FIG. 1.

The process to be described hereinafter relates to the formation of a bevel tip on a needle, such as a spinal needle, and a contained obturator such that the surface formed will be perfectly flush in all planes. The invention may be carried out upon assemblies including a needle and obturator of any particular extending length. Further, the principles of the invention may be practiced upon needles of any suitable gauge.

By way of example and not for the purpose of limitation, a needle of 22-gauge has been successfully utilized in the process. In this connection there was no appreciable clearance and mismatch between the cannula and the obturator points and wall surfaces in the final assembled product. Thus as illustrated in FIGS. 1 and 4, the length of the cannula and obturator are equal so that the beveled cutting surfaces lie in the same plane.

The cannula may be, for example, 1/4, 2 and 3 1/2 inches (all ± 1/8 inch) in length as measured from the hub 12. While these dimensions are considered of standard length for medical needles, it should be apparent that the length of the needle shank may vary from the aforementioned, as desired. The length is denoted by the indicia A in FIG. 1.

Both the needle 14 and the obturator 18 are subjected to the foregoing operations (see FIG. 3). As described above, care must first be taken with regard to the positioning of the obturator. Thus, the obturator must be disposed in the position of FIG. 1 at the commencement of either the swaging or drawing operation. There also must be care taken in assuring proper length of obturator shank. The obturator shank should be at least equal in length to the length of the cannula which may further lengthen by a small increment when swaged or drawn.

The operations are conventional. Generally, however, swaging may be accomplished by means of dies of proper shape which are caused to rotate about the piece to be swaged and which are caused to strike blows at suitable intervals as the needle assembly is inserted or pushed into the swager with a slow and even pressure. The assembly preferably is disposed in a centering fixture for this operation. The dies are thrown clear of the piece by centrifugal force. Each blow of the die produces a flow of metal which is greatest in the direction opposite to that of the feed direction. The piece is retained against movement at the speed of the die spindle so that the blows will overlap each other to produce a smooth surface. Removal of the assembly from the swager must also be with a slow even movement.

In drawing, the assembly is placed in a clamping fixture. A drawing die with required diameter, radius and angle is forced onto the tip of the assembly and moved through a distance of approximately 1/8 and 3/16 inches. A successful drawing operation requires rigidity and high polish on the drawing surface of the die.

During the aforementioned process the outer diameter B of the needle will have been reduced from approximately 0.0280 to 0.0285 inches to approximately 0.0260 to 0.0270 inches. As indicated, the operation in addition to reducing both the internal and outside diameter of the needle may also serve to cause the material of the needle to flow in the feed direction and thereby increase the length by a small increment.

It is contemplated that the swaging or drawing operation will force the needle wall throughout substantially the swaged or drawn length thereof into substantial contact with the obturator shank. More particularly, it is contemplated that the internal diameter of the swaged or drawn needle will be in excess of the outer diameter of the obturator by approximately 0.000050/0.000300 inches. The diameter C of the obturator shank may be from approximately 0.0140 to 0.0145 inches while the swaged or drawn internal diameter of the needle E will be in excess thereof by the above factor. At this point the obturator is for all intents and purposes immobilized within the cannula by surface friction. In the example disclosed the needle will have been drawn or swaged to an outer diameter D of from approximately 0.0260 to 0.0270 inches through a length F of from approximately 0.187 to 0.062 inches. As illustrated in FIG. 3, the swaging or drawing of the needle wall becomes more pronounced toward the tip. The spacing between the internal needle wall and the obturator surface becomes progressively less approaching the tip wherein the spacing will be substantially nonexistent.

FIG. 4 illustrates the assembly after having provided the needle 14 to obturator 18 with a beveled tip. Through the swaging or drawing of the needle, as above, the obturator will be prevented in any appreciable movement and the tipping operation by which the faces are formed to be flush, parallel and concentric may be carried out on the two components at the same time. To this end the assembly is positioned in a split die which is then closed by means of a mechanical clamp. Each die will necessarily be of correct gauge and have the desired angle. A cutting punch is cycled to shear the point to the desired bevel. During this operation the needle assembly is held rigidly both on the diameter of the cannula and the swaged portion of the cannula. A bevel length G from approximately 0.061 to 0.072 inches and at a bevel angle of from approximately 20° 30' to 23° 30' may be provided. A second point length H of from approximately 0.021 to 0.031 may also be provided. The second point is shown at 22 in FIG. 5. A grinding operation may also be employed in tip formation. The spacing between the needle wall and the obturator becomes increasingly less toward the tip end (see FIG. 3). Therefore, away from this end the spacing is greater. The tipping operation, utilizing a die or grinding techniques, results in a shortening of the cannula length within the area of greatest frictional gripping. Through this operation the frictional gripping capability will be reduced and the obturator will be adapted for free sliding movement within the cannula lumen.

By the foregoing a needle assembly including a cannula and an internal obturator is provided with a smooth or flush surface across the beveled tip. Further, by practicing the process as described an assembly is formed which has no appreciable clearance between the needle internal wall and the obturator so that the problem of tissue coring is substantially obviated.

Having described the invention, I claim:

1. A method for forming a beveled tip on a needle assembly including at least a needle cannula and an obturator capable of receipt and positioning within as well as removal from the lumen of the cannula which com-
comprises the steps of introducing and moving said obturator within said cannula to an operative position, drawing down, for a portion of the length of a tip end, the cannula wall into substantial contact with said obturator to thereby immobilize said obturator in said cannula, and then, while said obturator is immobilized in said cannula, forming a beveled tip on said cannula and said obturator simultaneously whereby after said forming operation both tips lie within a plane.

2. The method of claim 1 wherein said beveled tip is formed by grinding.

3. The method of claim 1 wherein said cannula and obturator are passed within a die and said beveled tip is formed by shearing.

4. The method of claim 1 including the step of forming a second point throughout a portion of said tip.

5. The method of claim 1 wherein said portion of the length of said tip end is 3/16 inch or less.

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