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B. E. BALDWIN ETAL

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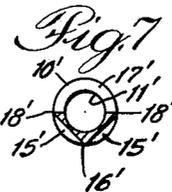
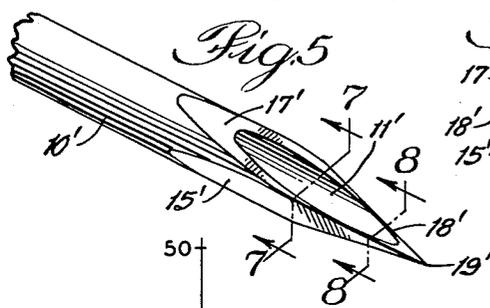
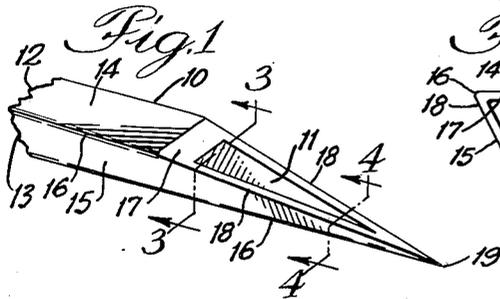


Fig. 9

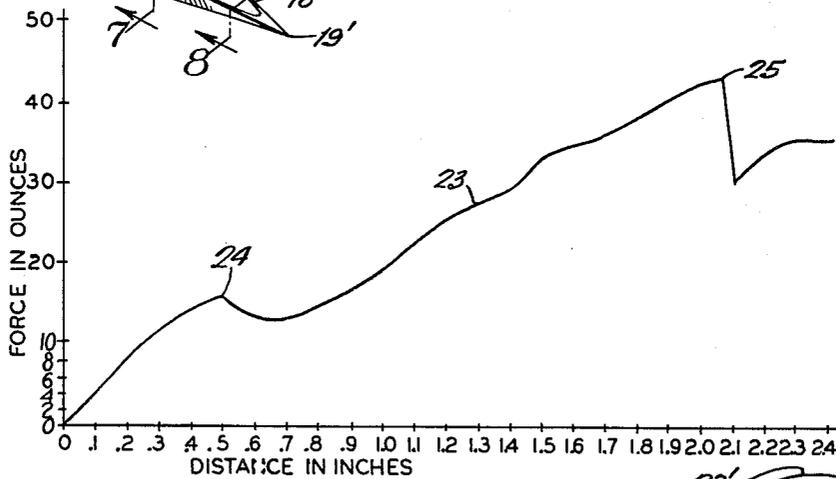


Fig. 10

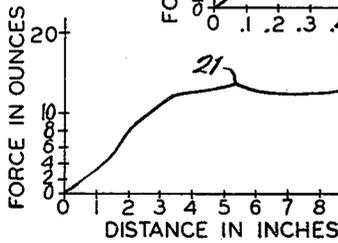
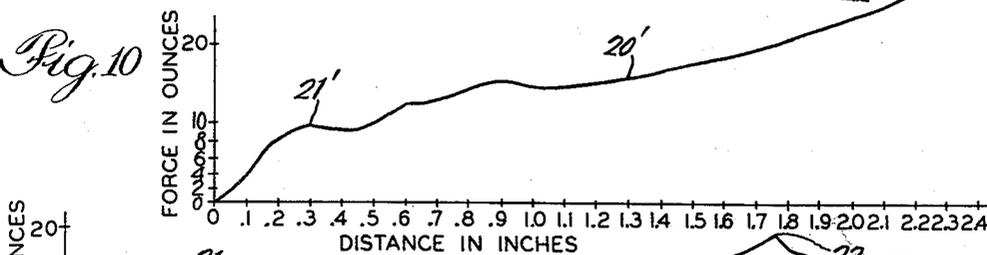


Fig. 11

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This invention relates to an improved hollow needle particularly suitable for hypodermic use.

While hypodermic needles of different point geometry are known in the art, the most common shape is the lancet, so designated because of its double side bevels. Such a needle is formed by first grinding a tube so that its front face extends along a plane angling through the tube's longitudinal axis. Following this operation, the tube has an elliptical front face and lacks a sharply pointed tip. To sharpen the tip, the partially finished needle is rotated and re-ground to form secondary side faces extending at obtuse angles with reference to the original front face, the remainder of which then constitutes the "heel" of the needle, or at least a substantial portion thereof.

Although the provision of the usual side bevels, as described above, may result in a sharply-pointed needle, the pointed tip is obtained only at the expense of reducing the sharpness of the needle's cutting edges. The surfaces which converge to define these cutting edges form acute angles (when the needle is viewed in transverse section) only adjacent the extreme tip of the needle. A substantial proportion of each side cutting edge is formed by surfaces meeting at obtuse angles and therefore, upon injection, such cutting edges tend to spread or stretch rather than cut a membrane or tissue.

An object of the present invention is to provide an improved hypodermic needle which has extremely sharp cutting edges and which cuts a relatively large opening as it is urged into a tissue, membrane, etc. Another object is to provide a pointed hollow needle which has relatively low penetration force characteristics and which is less likely to cause pain upon insertion into the body than needles heretofore known in the art.

Other objects will appear from the specification and drawings in which:

FIGURE 1 is a perspective view of a needle embodying the present invention;

FIGURE 2 is an end view of the needle shown in FIGURE 1;

FIGURE 3 is a transverse sectional view taken along line 3—3 of FIGURE 1;

FIGURE 4 is a transverse sectional view of the needle taken along line 4—4 of FIGURE 1;

FIGURE 5 is a perspective view of a needle constituting a second embodiment of the invention;

FIGURE 6 is an end elevational view of the needle shown in FIGURE 5;

FIGURE 7 is a transverse sectional view taken along line 7—7 of FIGURE 5;

FIGURE 8 is a sectional view taken along line 8—8 of FIGURE 5;

FIGURE 9 is a graph representing the penetration force pattern for a conventional lancet;

FIGURE 10 is a graph illustrating the penetration force characteristics of the needle illustrated in FIGURES 5—8;

FIGURE 11 is a graph illustrating the penetration force characteristics of the needle represented in FIGURES 1—4.

One aspect of the present invention lies in the recognition that the pain of needle injection is associated with a pressure threshold and therefore, unless a threshold

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force level is reached, a patient may feel no pain at all when a needle is inserted into his body. While this threshold value may vary depending upon the area of injection and also varies for different individuals, it is nevertheless significant that a needle which has extremely sharp cutting edges and which cuts a relatively large opening will also have a relatively low penetration force peak and may, in many instances, produce painless injection.

Referring to the drawings, FIGURES 1 through 4 illustrate a needle 10 constituting a first embodiment of the invention. Unlike a conventional hypodermic needle, needle 10 is formed from tubing of triangular cross section. Preferably, the lumen 11 is also of triangular shape, resulting in top and side walls 12 and 13 of uniform thickness, although a lumen of non-triangular cross section might be provided without appreciably affecting the penetration force characteristics of the needle.

Needle 10 has top and side faces 14 and 15 which extend parallel with the needle's longitudinal axis and which meet along longitudinal edges 16. As shown in the drawings, edges 16 are slightly rounded as a consequence of limitations in the tube drawing operation and while these edges may be sharpened thereafter such sharpening is not essential for the purpose of reducing the needle's penetration force requirements.

The needle is formed by carefully grinding or otherwise treating a selected length of triangular tubing to form a substantially planar front face 17. The front face extends along a plane meeting the bottom edge of the needle at an acute angle, approximately 14½ degrees in the illustration given. Also, the illustrated needle has a cross section in the shape of an equilateral triangle although it is to be understood that other triangular shapes (preferably isosceles) may be provided. Furthermore, various other acute angles might be formed between the needle's bottom edge and front face 17, although an angle within the range of 10 to 20 degrees is particularly desirable.

Two cutting edges 18 diverge along straight lines from the tip 19 of the tapered needle. The maximum distance between these straight cutting edges occurs at the top of the needle and is substantially the same as the needle's maximum width. Cutting edges 18 also extend the full height of the needle from the bottom ridge 16 to the top surface 14 thereof. When the needle is viewed in cross section (FIGURES 3 and 4), it will be observed that the front and side surfaces 17 and 15 meet at acute angles to form the needle's cutting edges and that such angles are uniform along the entire length of each cutting edge. Therefore, the cutting edges are uniformly sharp along their entire length and, since such cutting edges are formed by the meeting of adjacent surfaces at acute angles (60 degrees in the illustration given), a relatively high degree of sharpness is obtained.

Referring now to the graph of FIGURE 11, line 20 represents the penetration force curve for a triangular needle as shown and described, the specific test needle being of 10 magnification (of an 18 gage needle) and being tested by urging it through a polyethylene film of 15 mil. thickness. Point 21 on the graph represents the force required to cause puncture of the film and, from the time of such puncture until full penetration of the needle point (peak 22), it will be seen that the driving force increases only slightly.

By way of comparison, reference is now made to FIGURE 9 where line 23 represents the penetration force necessary to drive an enlarged mode (10 magnification) of an 18 gage conventional lancet into a 15 mil. polyethylene film. The main bevel of the lancet extended at 12 degrees with reference to the needle axis, the side bevels extended at 15 degrees with reference to that axis,

and the needle was rotated at 90 degrees in grinding the side bevels. The dip behind the first peak 24 indicates the slight reduction in applied force occurring the moment the sharpened tip of the needle breaks into the membrane. Thereafter, the force progressively increases until maximum force at peak 25 is applied. This major peak in applied force occurs when the needle heel is about to pass through the opening in the stretched membrane.

The increasing force for needle penetration, as represented by the steeply sloping portion of curve 23 between points 24 and 25, is believed to arise because of the failure of a conventional lancet to cut an opening sufficiently large for needle penetration without stretching or tearing of the membrane or tissue. As brought out above, the surfaces defining the rear portions of each side cutting edge of an ordinary lancet meet at obtuse angles and therefore the edges defined by these lines of meeting are relatively dull. Furthermore, the "cutting" edges of such a lancet do not diverge sufficiently to cut an opening large enough to accommodate the cylindrical portion of the needle without at least some stretching or tearing of the membrane.

In contrast to the graph in FIGURE 9, the curve shown in FIGURE 11 is relatively flat between points 21 and 22. This flatness and the low level of the penetration force peak obtain because the sharpened edges 18 of the triangular needle cut a relatively large slit and do not tend to stretch or tear the tissue or membrane. The cutting edges extend from the tip to the heel of the needle and are of substantially uniform sharpness along their entire extent because the angle of meeting of the side and front faces is substantially uniform. This angle, as noted above, is an acute angle resulting in extremely sharp cutting edges.

It is believed evident from the foregoing that because of its sharp cutting edges and the large size of an opening cut by those edges, the triangular hollow needle of FIGURES 1-4 is particularly suitable for hypodermic use and, by reason of its low penetration force characteristics, is less likely to cause pain of injection than conventional hypodermic needles. These important advantages are obtained while at the same time providing a needle which is relatively inexpensive to manufacture. Assuming any differences in the costs of drawing triangular and circular tubing to be insignificant, the triangular tubing requires only one grinding or processing operation in forming a needle point while the manufacture of a conventional lancet from cylindrical tubing requires three such operations.

Like the embodiment disclosed in FIGURES 1 through 4, the needle 10' illustrated in FIGURES 5 through 8 has side faces 15' which meet the front face 17' along straight rearwardly diverging cutting edges 18' of substantially uniform sharpness along their entire length. However, needle 10' is formed from cylindrical tubular stock rather than triangular tubing and, therefore, the triangular cross sectional configuration (FIGURES 7 and 8) of the point or cutting end portion of the needle is

obtained by grinding to form planar faces or surfaces 15' and 17'.

FIGURE 10 illustrates the penetration force curve for the back beveled needle of the second embodiment. While some rise in line 29' will be noted between points 21' and 22', the slope is gradual and the maximum force for penetration is still relatively low. This curve was obtained by testing a model needle of 10 magnification (of 18 gage) having a front face extending at an angle of 10½ degrees and side surfaces extending at 3 degrees with reference to the needle's longitudinal axis. The angle of rotation in grinding the side surfaces 15', and hence the angle between those surfaces along the back edge 16' of the needle, was 90 degrees, as in the structure illustrated in the drawings. The test procedure was identical to the procedure described in connection with the graphs of FIGURES 9 and 11.

While in the foregoing we have disclosed two embodiments of the invention in considerable detail for purpose of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the spirit and scope of the invention.

We claim:

1. A hypodermic needle formed from cylindrical stock having a lumen of uniformly cylindrical cross section extending axially therethrough, said needle having an inclined front face merging at its rear edge with the cylindrical outer surface of said needle and having a pair of side faces meeting said front face at acute angles to define a pair of sharp side edges, said side faces also meeting each other to form a sharp bottom edge extending along a line angled slightly with reference to the needle's longitudinal axis, said side edges and said bottom edge converging to define an extremely sharp needle point having low puncture and penetration force characteristics.

2. A hypodermic needle formed from cylindrical stock and having a lumen of uniformly cylindrical cross section extending axially therethrough, said needle having an inclined planar front face merging along its rear edge with the cylindrical outer surface of said needle and having a pair of planar side faces each extending along a plane inclined with respect to the axis of said needle and each meeting said front face at an acute angle to define a pair of forwardly converging side cutting edges, said side faces also meeting each other along the bottom of said needle to define a sharpened bottom cutting edge extending gradually upwardly and forwardly and merging with said side cutting edges to form a sharp needle point, thereby providing a needle having relatively low puncture and penetration force characteristics.

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