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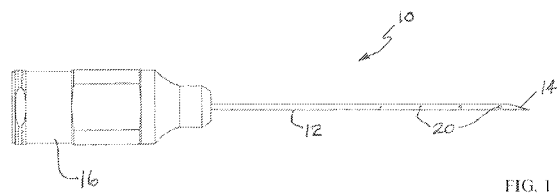
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(54) Title: MULTI-PORTED SYRINGE NEEDLE



(57) Abstract: A multi-ported syringe needle comprises a hollow tube having a proximal end, a distal tip, a sidewall and a lumen. A plurality of side ports are provided in the sidewall in communication with the lumen. The side ports increase in size from the proximal end toward the distal tip. In one embodiment the side ports are provided in a single roll along the sidewall. In another embodiment the side ports are provided in two rows along the sidewall. The two rows may be radially separated by an included angle of between 10 and 35 degrees. In another embodiment the two rows are radially separated by an included angle of between about 175 and 180 degrees.

## MULTI-PORTED SYRINGE NEEDLE

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/608,217, filed March 8, 2012, the full disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present device relates to syringe needles. More specifically, this system relates to a multi-ported syringe needle utilized for the trans-dermal injection of substances such as fillers and anesthetics.

BACKGROUND

[0003] To date various needles have been developed incorporating shafts with side ports. Examples of such needles are disclosed in, for example, U.S. Patents 4,308,875 to Young; 4,989,614 to Dejter, Jr. et al; 5,019,039 to Anderson; 5,199,441 to Hogle; and 5,817,074 to Racz. While these prior art documents teach providing side ports on a needle in one or more rows, the side ports are only provided adjacent the tip and all side ports are of the same diameter no matter where they are positioned along the length of the shaft.

[0004] The present device relates to an improved needle incorporating a shaft with side ports that increase in size from the proximal end of the shaft to the distal tip. This new needle enables more controlled transdermal delivery of fillers such as hyaluronic acid, beneath the wrinkles as well as upwards toward the skin while under and along the fold. The different size side ports allow for more even distribution of the injectable substance transdermally for more direct delivery along the length of the wrinkle in substantially equal amounts while minimizing lumping. Advantageously this achieves a more aesthetically pleasing result. Further this result is achieved with less patient discomfort as the need for serial puncturing and needle manipulation under the skin is substantially reduced and in some cases even eliminated.

SUMMARY

[0005] A multi-ported syringe needle comprises a hollow tube having a proximal end, a distal tip, a sidewall and a lumen. A plurality of side ports are provided in the sidewall in communication with the lumen. The side ports increase in size from the proximal end toward

the distal tip. In one embodiment the side ports are provided in a single row along the sidewall. In another embodiment the side ports are provided in two rows along the sidewall. The two rows may be radially separated by an included angle of between 10 and 35 degrees. In another embodiment the two rows are radially separated by an included angle of between about 175 and 180 degrees. In still another embodiment more than two rows of side ports are provided. In still yet another embodiment the side ports are provided in a rowless, random arc spacing along the sidewall or shaft of the needle.

[0006] More specifically describing the needle, the side ports increase in size by 5% to 100% from a first side port to a second side port. In another embodiment the side ports increase in size by 5% to 20% from a first side port to a second side port. In either of these embodiments the relative increase in size from one side port to the next side port is constant. In yet another alternative embodiment the relative increase in size from one side port to the next side port varies.

[0007] In one embodiment each side port has a diameter of less than or equal to a diameter of the lumen. In another embodiment each side port has a diameter of less than the diameter of the lumen. In yet another embodiment each side port has a diameter of between about 50% and 5% of the diameter of the lumen.

[0008] In one embodiment the distal tip is open. In another embodiment the distal tip is closed. In yet another embodiment the distal tip is partially closed. In any of the above embodiments the proximal end of the needle includes a syringe connection structure.

[0009] In accordance an additional aspect a method is provided for transdermal injection. The method comprises steps of inserting a needle so as to penetrate a target area of a patient and evenly distributing an injectable substance transdermally while minimizing needle manipulation using a needle as set forth and described above.

[0010] In the following description there is shown and described several different embodiments of syringe needle. It should be realized, this syringe needle is capable of still other different embodiments and its several details are capable of modification in various, obvious aspects. Accordingly, the drawings and descriptions will be regarded as illustrative in nature and not as restricted.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0011] The accompanying drawings incorporated herein and forming a part of the specification, illustrate several aspects of the present multi-ported syringe needle and together with the description serve to explain certain principles thereof. In the drawings:

[0012] Figure 1 is an elevational view of a first embodiment of syringe needle with an open bevel at the end;

[0013] Figure 2 is a detailed elevational view of the syringe needle embodiment of Figure 1 illustrating a pattern of ports in a single row;

[0014] Figure 3 is an elevational view of a second embodiment of syringe needle with a closed end;

[0015] Figure 4 is a detailed elevational view of the syringe needle of Figure 3 illustrating a pattern of ports in a single row;

[0016] Figure 5 is a detailed elevational view of yet another syringe needle embodiment illustrating ports in two separate rows spaced by an arc of about 10-20 degrees; and

[0017] Figure 6 is a detailed elevational view of still another syringe needle embodiment illustrating staggered ports in two opposed rows arc spacing of 180 degrees.

[0018] Reference will now be made in detail to the present preferred embodiment of the invention, examples of which are illustrated in the accompanying drawings.

DETAILED DESCRIPTION

[0019] The disclosed syringe needle 10 provides a means for transdermal injection of substances such as fillers and anesthetics (eg. dermal filler solution and hyaluronic acid). Effective transdermal distribution of substances across a target area often requires manipulation of the inserted needle. Sub-dermal manipulation of a needle, as when a local anesthetic is injected during a dental procedure, can result in tissue damage and pain while the anesthetic is being injected at various points. Insufficient sub-dermal manipulation during procedures such as the injection of collagen can result in uneven distribution appearing as collagen lumps beneath the skin.

[0020] The syringe needle 10 is a formed hollow tube, or cannula 12. Processes to make small tubes and hollow needles are quite old, and almost always begin by forming a large tube. Hypodermic needles are normally made from a stainless-steel tube through a process known as tube drawing where the tube is drawn through progressively smaller dies to make the needle. The tube may also be formed by rolling a sheet of metal into a tube and welding the seam, or by taking a solid billet of metal and boring a hole through the center while the metal is heated (creating "seamless tubing"). The end 14 is beveled to create a sharp pointed tip letting the needle easily penetrate the skin.

[0021] The needle 10 consists of the shaft 12 including a sidewall, a lumen within the sidewall, a proximal end 15 and distal tip a bevel 14. Needles vary in length, size of the shaft and size of the lumen. The shaft is the metal's length and is usually chosen depending upon the route and site of administration, physical mass of the client, and the thickness or viscosity of the medication. Syringes come with a number of designs for the area in which the needle locks to the syringe body. The most common needle-syringe connection 16 is the Luer-lock style, which simply twists the two together. Slip tips, catheter tips, and eccentric tips are additional connection types. The piercing end of the bevel 14 is called the lancet. Many different styles of lancet can be cut; which one is selected depends upon the application. The bevel 14 may also be open (note opening 18 of first embodiment illustrated in Figures 1 and 2) or sealed (note closed end 14 in second embodiment illustrated in Figures 3 and 4).

[0022] The diameter of the needle shaft 12 is indicated by the needle gauge. Various needle lengths are available for any given gauge. There are a number of systems for gauging needles, including the Stubs Needle Gauge, and the French Catheter Scale. Needles 10 in common medical use range from 7 gauge (the largest) to 33 gauge (the smallest) on the Stubs scale. 21-gauge needles are most commonly used for drawing blood for testing purposes, and 16-or 17-gauge needles 10 are most commonly used for blood donation, as they are wide enough to allow red blood cells to pass through the needle without rupturing (this also allows more blood to be collected in a shorter time). Larger-gauge needles 10 (with smaller diameter) will rupture the red blood cells, and if this occurs, the blood is useless for the patient receiving it. Although reusable needles remain useful for some scientific applications, disposable needles are far more common in medicine.

[0023] As an example, Becton, Dickinson and Company ("BD"), a large manufacturers of syringes, makes syringes using 3/4-inch-wide stainless steel rolled and welded into a 1/4-

inch diameter tube, then heated, drawn, and finally cold-drawn to its final size. For typical insulin syringes, sizes include:

<b>Needle gauge</b>	<b>Outside diameter, inches</b>	<b>Inside diameter, inches</b>	<b>Nominal wall thickness, inches</b>
27	0.0160 – 0.0165	0.0075 – 0.0095	0.004
28	0.0140 – 0.0145	0.0065 – 0.0080	0.0035
29	0.0130 – 0.0135	0.0065 – 0.0080	0.003
30	0.0120 – 0.0125	0.0055 – 0.0070	0.003
32	0.0090 – 0.0095	0.0035 – 0.0050	0.002

[0024] The needle 10 of the present invention possesses a plurality of side ports 20 along the shaft 12 of the needle for distribution of fillers or anesthetics or the like along the shaft of the needle. The purpose of multi-porting is to avoid the withdrawal and reinsertion or lateral sub-dermal manipulation of the needle to achieve a desired distribution of the injectable substance. The bevel 14 is either closed (as illustrated in Figures 3 and 4) to ensure maximum delivery through the side ports 20, or open (as illustrated in Figures 1 and 2) to permit delivery through the opening 18 at the tip as well as the side ports 20. The tip opening 18 may be partially closed so as to restrict delivery and force more injectable substance through the side ports 20. The needle gauge selected will depend on the viscosity of the injectable substance, but may be smaller than ordinarily chosen to increase the internal pressure within the cannula 12 so as to direct more of the injectable substance through the side ports 20 or a thicker wall thickness may be utilized with a smaller interior or lumen diameter to achieve a similar effect.

[0025] The pattern of ports 20 along the shaft depends largely on the wall thickness since the addition of ports may affect the tensile strength of the needle. A pattern of linearly aligned cannula side ports 20 along the shaft can be arranged in one or more rows. The use of a single row of cannula side ports 20, as illustrated in Figures 1-4, can be useful for the controlled delivery of an injectable substance in one direction away from the shaft 12 of the needle 10 and yield a stronger needle shaft than one with multiple linear rows along the shaft.

Delivery of injectable substances around the shaft 12 can be accomplished through the manual rotation of the syringe. Alternatively, an offset pattern of ports (see Figure 5 and 6) can achieve a wider distribution of an injectable substance and result in a stronger needle 10. The different rows of ports 20 may be radially spaced through an arc of between about 10 and about 180 degrees. Smaller arc spacing (eg. an included angle of about 10 to about 35 degrees) as illustrated in Figure 5 will allow for a more evenly spread transdermal delivery or distribution of filler or anesthetic along one side of the needle 10. Advantageously, this reduces the need to manipulate and move the needle 10 under the skin for this purpose. In contrast, an arc spacing of or included angle of about 175 to 180 degrees as illustrated in Figure 6 results in the transdermal delivery of filler or anesthetic to opposite sides of the needle 10.

[0026] In Figure 5, the ports 20 in the two rows are aligned. In Figure 6, the ports 20 in the two rows are staggered. Either arrangement may be used, similarly, it should be appreciated that while only two rows of ports 20 are illustrated in Figures 5 and 6, more rows of ports may be provided if desired. Further, rowless, random arc spacing of side ports 20 is also a possibility.

[0027] It should also be appreciated that the ports 20 may vary in size. For example, as illustrated in Figures 1-4, the ports 20 increase in size from the proximal end or connection end of the needle to the distal or beveled end 14. This better allows for even transdermal distribution of filler or anesthetic along the length of the shaft 12. The size of the ports 20 may increase between about 5% and about 100% from one port to the next. In one possible embodiment the side ports 20 increase in size by 5% to 20% from one port to the next. Further, the relative percentage increase in size may be the same from one port to the next or may vary.

[0028] The size, number, spacing and pattern of ports 20 is determined by a number of factors including but not limited to medical application of the needle 10 and substance to be injected. Higher viscosity substances typically require larger ports 20. Typically, the side ports 20 each have a diameter between about 50% and 5% of the diameter of the lumen. For example, a needle 10 used for administration of dermal filler into a cheek might include open ports 20 and an open bevel 14 as illustrated in Figure 5. A needle 10 as illustrated in Figures 1 and 2 might be used to fill nasolabial folds as well as in the area of the jaw line. For creating the most natural appearance in the lips, one might use a needle 10 with ports 20

spaced in arcs all the way around the needle. In contrast, when seeking to outline the lips along the vermillion border one might use a needle 10 as illustrated in Figures 1-4 with ports along only one side or row.

[0029] The present invention enables the approach of controlled transdermal delivery of fillers, such as hyaluronic acid, beneath wrinkles as well as upward toward the skin while under and along the fold. This approach yields a more direct assault on the wrinkle and avoids the use of a serial puncture technique employed along the length of the wrinkle, resulting in less discomfort for the patient and a more aesthetically pleasing result because of the controlled delivery which avoids the formation of lumps. Presently such lumps are either massaged as flat as possible or filler is retrieved transdermally by syringe. A more direct delivery along the length of the wrinkle in substantially equal amounts minimizes lumping and avoids these corrective measures.

[0030] The needle 10 preferably possesses a shaft 12 approximately 0.5 to 1.0 inch in length. In a preferred embodiment, four lateral cannula side ports 20 are serially aligned in a row down the entire length of the shaft. In one embodiment, one side port 20 is closer to the proximal end 15 (the point where the shaft 12 enters the syringe connection structure 16) of the needle 10 than the distal tip 14. In another possible embodiment, between 10% and 50% of the side ports 20 provided on the sidewall or shaft 12 are closer to the proximal end of the needle than the distal tip. An exemplary needle would have an outer diameter of approximately 0.018 inches and an interior or lumen diameter of approximately 0.010 inches. The cannula side ports are approximately  $0.010 \pm 0.002$  inches in diameter and substantially annular in shape. The cannula side port proximal to the bevel is centered approximately  $0.20 \pm 0.010$  inches from the tip of the bevel which possesses an angle of inclination of approximately  $15^\circ$  and possesses a closed piercing tip.

[0031] While the use of stainless steel is a preferred embodiment, the use of advanced composites with greater tensile strength than stainless steel permits the inclusion of additional cannula side ports. Many advanced composites would also be less brittle than stainless steel and permit easier boring of the cannula side ports as well as tapered bores within the cannula itself. In addition, other types of metal may be used. One particularly useful metal providing an excellent combination of flexibility and strength is nitinol.

WHAT IS CLAIMED:

1. A multi-ported syringe needle, comprising:  
a hollow tube having a proximal end, a distal tip, a sidewall and a lumen; and  
a plurality of side ports provided in said sidewall in communication with said lumen, said side ports increasing in size from said proximal end toward said distal tip.
2. The needle of claim 1 wherein said side ports are provided in a single row along said sidewall.
3. The needle of claim 1, wherein said side ports are provided in two rows along said sidewall.
4. The needle of claim 3, wherein said two rows are radially separated by an included angle of between 10 and 35 degrees.
5. The needle of claim 3, wherein said two rows are radially separated by an included angle of between 175 and 180 degrees.
6. The needle of claim 1, wherein said side ports are provided in a rowless, random arc spacing along said sidewall.
7. The needle of claim 1, wherein said side ports increase in size by 5% to 100% from a first side port to a second side port and at least one side port of said plurality of side ports is closer to said proximal end than said distal tip.
8. The needle of claim 7, wherein said relative increase in size from one side port to a next side port is constant.
9. The needle of claim 7, wherein said relative increase in size from one side port to a next side port varies.
10. The needle of claim 1, wherein said side ports increase in size by 5% to 20% from a first side port to a second side port and at least one side port of said plurality of side ports is closer to said proximal end than said distal tip.
11. The needle of claim 10, wherein said relative increase in size from one side port to a next side port is constant.

12. The needle of claim 10, wherein said relative increase in size from one side port to a next side port varies.
13. The needle of claim 1, wherein each side port of said plurality of side ports has a diameter less than or equal to a diameter of said lumen.
14. The needle of claim 1, wherein each side port of said plurality of side ports has a diameter less than a diameter of said lumen.
15. The needle of claim 14, wherein each side port of said plurality of side ports has a diameter between about 50% and 5% of a diameter of said lumen.
16. The needle of claim 1, wherein said distal tip is open.
17. The needle of claim 1, wherein said distal tip is closed.
18. The needle of claim 1, wherein said distal tip is partially closed.
19. The needle of claim 1, wherein said proximal end includes a syringe connection structure.
20. A method for transdermal injection, comprising:
  - inserting a needle so as to penetrate a target area of a patient; and
  - evenly distributing an injectable substance transdermally while minimizing needle manipulation using a needle as set forth in claim 1.

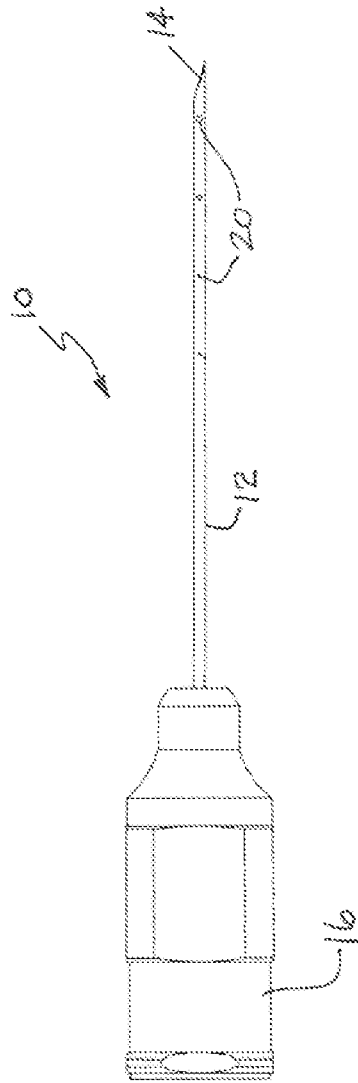


FIG. 1

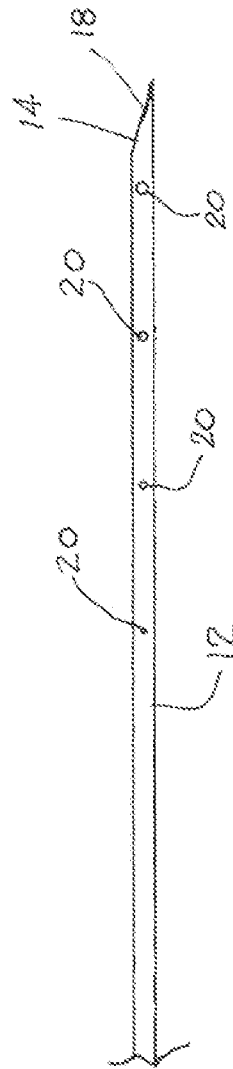


FIG. 2

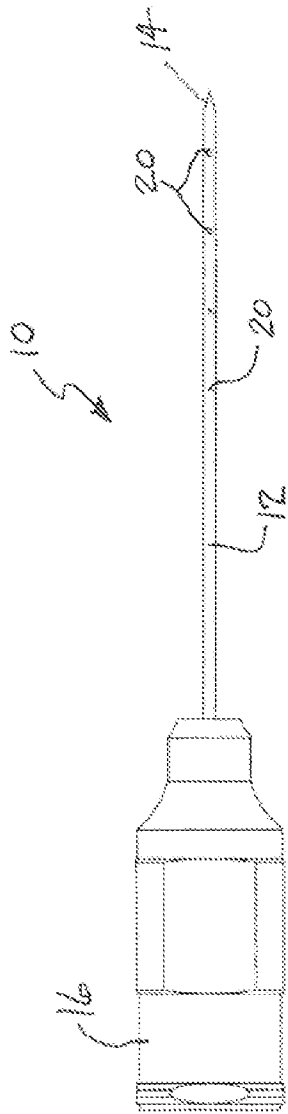


FIG. 3

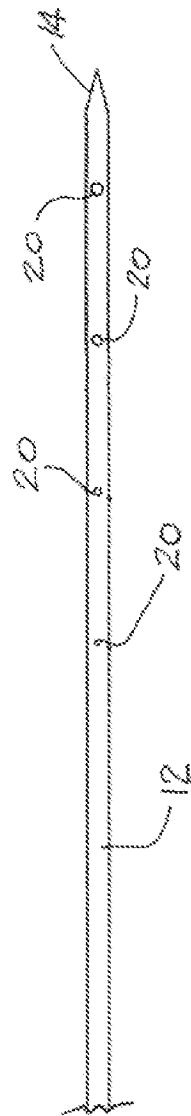


FIG. 4

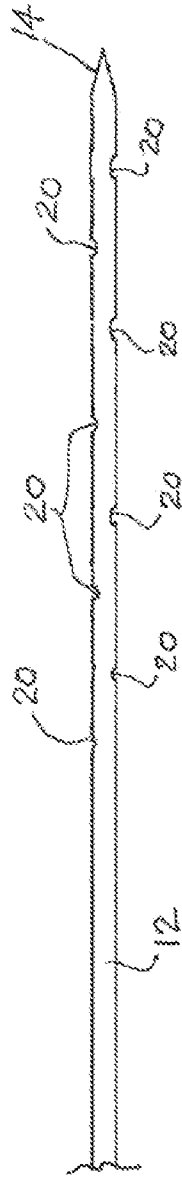


FIG. 6

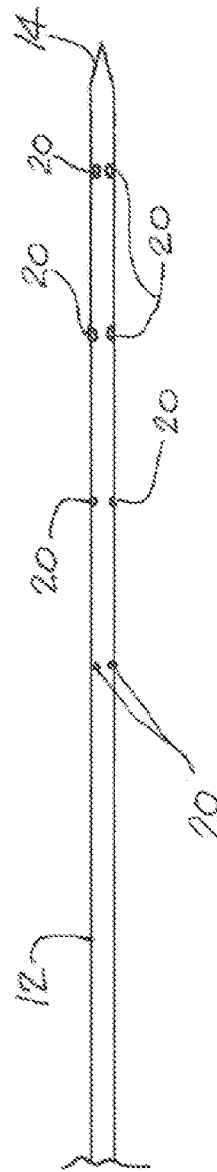


FIG. 5

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2013/029606

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61M 5/178 (2013.01) USPC - 604/30 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61M 5/00, 5/178, 5/31, 5/315, 5/50 (2013.01) USPC - 604/28, 30, 48, 93.01, 191, 236 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC - A61M 5/00, 5/48, 5/48.2, 5/48.4, 5/48.8 (2013.01) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Orbit, Google Patents, Google Scholar		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2003/0009132 A1 (SCHWARTZ et al) 09 January 2003 (09.01.2003) entire document	1, 2, 6, 13-20 ----- 3-5, 7-12
Y	US 2010/0185117 A1 (LYON) 22 July 2010 (22.07.2010) entire document	3-5
Y	US 2009/0149774 A1 (SIMON et al) 11 June 2009 (11.06.2009) entire document	7-12
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
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Date of the actual completion of the international search 06 May 2013		Date of mailing of the international search report <b>21 MAY 2013</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774