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Effects of Microneedle Design Parameters on Hydraulic Resistance

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Abstract

Microneedles have been an expanding medical technology in recent years due to their ability to penetrate tissue and deliver therapy with minimal invasiveness and patient discomfort. Variations in design have allowed for enhanced fluid delivery, biopsy collection, and the measurement of electric potentials. Our novel microneedle design attempts to combine many of these functions into a single length of silica tubing capable of both light and fluid delivery terminating in a sharp tip of less than 100 microns in diameter. This manuscript focuses on the fluid flow aspects of the design, characterizing the contributions to hydraulic resistance from the geometric parameters of the microneedles. Experiments consisted of measuring the volumetric flow rate of de-ionized water at set pressures (ranging from 69-621 kPa) through a relevant range of tubing lengths, needle lengths, and needle tip diameters. Data analysis showed that the silica tubing (~150 micron bore diameter) adhered to within $\pm 5\%$ of the theoretical prediction by Poiseuille's Law describing laminar internal pipe flow at Reynolds numbers less than 700. High hydraulic resistance within the microneedles correlated with decreasing tip diameter. The hydraulic resistance offered by the silica tubing preceding the microneedle taper was approximately 1-2 orders of magnitude less per unit length, but remained the dominating resistance in most experiments as the tubing length was >30 mm. These findings will be incorporated into future design permutations to produce a microneedle capable of both efficient fluid transfer and light delivery.

Keywords

Hollow-core microneedle; hydraulic resistance; fluid delivery

1 Introduction

In recent years, developments in microscale fabrication have enabled the creation of needles on the scale of micrometers. These "microneedles" can be created out of a variety of materials such as polymers, metals, or glass, and are utilized to facilitate highly accurate small volume fluid delivery with minimal tissue disruption. Studies have shown that needle diameter and insertion force are primary determinants of patient pain caused by transdermal injection [1-3]. The small diameter of these microneedles reduces the invasiveness and patient sensation associated with their clinical use. The potential presented by these microneedles for therapeutic and diagnostic applications has led to a significant investment of research attention.

One of the first therapeutic applications utilizing microneedles was increasing the effectiveness of transdermal drug delivery patches by increasing skin permeability with slight penetration (< 1 mm) [4]. Other applications involved using microneedles as electrodes to measure electrical potentials or cause electroporation in tissue [5-7] Other groups have successfully utilized these needles for intrascleral delivery of therapeutic agents

and to inoculate patients against disease [8, 9]. Solid, biodegradable polymer microneedles containing dissolved pharmaceuticals have been developed for time-delayed drug release [10-12]. Due to the lessened patient discomfort associated with microneedles, they have been developed for use in patients with conditions that require frequent infusions, such as diabetics [13]. However, the small diameters of microneedles make delivery of larger volumes difficult. To bypass this difficulty, parallel arrays of microneedles can be utilized. Early developers of this design successfully delivered sufficient insulin to lower glucose levels in diabetic rats [13, 14]. In a more refined variant of the parallel array design, one group developed a microneedle-based transdermal patch device that allowed for the active dispensation of insulin [15]. Microneedles are continuing to receive a great amount of research attention, with new designs being applied to novel applications in many diverse fields.

The research described in this paper focuses on fluid flow characterization through a novel type of hollow-core silica microneedle that allows for several millimeters of tissue penetration and co-localized light and fluid delivery. These microneedles can be made from silica capillary tubing capable of guiding laser light. A device with this dual capability can be readily adapted to several applications, such as treatment of non-superficial, focal cancers by delivery of exogenous chromophores and laser irradiation from the same probe. Cosmetic laser-based applications such as body contouring may also benefit from this technology through simultaneous fat liquefaction and removal from sensitive areas such as the face.

Our fiberoptic microneedle design incorporates tubing of an inner bore diameter of 150 ± 1 μm with a fabricated microneedle tip with diameter ranging between 20-100 μm . The sharpened tip is necessary to lower the force required for penetration and thereby safeguard the structural integrity of the needle, in addition to minimizing patient discomfort [3, 16]. Our design is biomimetic, as the mosquito's proboscis is of similar proportions and is able to painlessly penetrate millimeters into an animal's skin to extract blood [17]. These microneedles can be incorporated into many applications that require accurate localized delivery of small fluid volumes. The experiments performed in this study characterized the fluid flow properties of this transformative microneedle design so that it may be easily integrated into devices for a range of applications. More specifically, the experiments sought to determine the most important factors contributing to the hydraulic resistance to fluid flow in this design.

2 Methods

2.1 Manufacturing Process for Hollow-Core Microneedles

Commercially available flexible fused silica capillary tubing was utilized in the characterization of the fluid properties for our design. The fused silica capillary tubing had an outer diameter of 363 ± 4 μm , an inner diameter of 150 ± 1 μm , and a coating thickness of 40 μm (Polymicro Technologies, Phoenix, AZ). The microneedle fabrication method outlined below is similar to that described in a previous publication by this group for solid-core microneedles [16]. To begin the fabrication process, the protective polyimide jacket (40 μm coating) was removed from the silica tubing through soaking in a warmed sulfuric acid ($\sim 130^\circ\text{C}$) bath for 15 minutes. The silica was drawn into a microneedle geometry by simultaneously heating the tubing with a CO_2 laser (wavelength, $\lambda = 10.6$ μm) to silica's melting temperature ($\sim 1650^\circ\text{C}$) while stretching it with a linear stage providing uniaxial tension ($\sim 0.2 - 1$ mm/s, manually translated). The drawing speed was intentionally varied to fabricate tip diameters ranging from 30-75 μm . Microscope images of several representative hollow-core microneedles are shown in Fig. 1 and 7.

2.2 Hydraulic Circuit Analysis

In order to determine the most important factors contributing to hydraulic resistance, an experimental approach utilizing two successive stages was developed. Stage I consisted of characterizing the hydraulic resistance of the tubing that would precede the microneedle, while Stage II sought to characterize the resistance of the microneedle itself. This approach can be modeled via hydraulic circuit analysis as outlined by Kirby [18]. In Stage I, the hydraulic resistance of the flat cleaved tubing (150 μm inner diameter) was tested. The experiment consisted of using pressured CO_2 to drive deionized water through the tubing into atmospheric pressure. Laminar internal flow through a pipe is described by Poiseuille's Law as

$$R_{\text{TUBE}} = \frac{\Delta P}{Q} = \frac{128 \mu L}{\pi D^4} \quad (1)$$

where R_{TUBE} is the hydraulic resistance ($\text{Pa}\cdot\text{s}/\mu\text{L}$), ΔP is the pressure difference (Pa), Q is the volumetric flow rate ($\mu\text{L}/\text{s}$ or mm^3/s), D is the pipe's diameter (mm), μ is the dynamic viscosity ($\text{N}\cdot\text{s}/\text{m}^2$), and L is the length of the pipe or tube (mm). The hydraulic circuit analytical model of a tube with a single (lumped) resistance is represented in Fig. 2. To facilitate better physical understanding and ease of calculation, the units for hydraulic resistance were input pressure divided by the measured volumetric flowrate ($\text{Pa}\cdot\text{s}/\mu\text{L}$) and were reported as such in this manuscript.

In Stage II, the hydraulic resistance of a length of tubing with an attached microneedle was tested via the same method as Stage I. As the resistance provided by the initial tubing (R_{TUBE}) would be understood after the completion of Stage I, the series resistance provided by the microneedle (R_{NEEDLE}) could be isolated and quantified (depicted in Fig. 3). The total hydraulic resistance can then be described mathematically by

$$R_{\text{TUBE}} + R_{\text{NEEDLE}} = \frac{\Delta P}{Q} = R_{\text{TOTAL}} \quad (2)$$

where R_{TUBE} describes the resistance to flow due to the tubing length preceding the microneedle, R_{NEEDLE} is the resistance provided by the microneedle, and R_{TOTAL} is the total resistance. Assuming these resistances are linear and ideal (no capacitance or inductance), this equation should describe the ideal case of flow defined by viscous forces alone (limited inertial effects) through the microneedle design.

To correctly interpret results obtained via this experimental model, an understanding of the flow turbulence in the tubing and microneedles was important. The dimensionless Reynolds number describes this effect, and is calculated for internal pipe flow by:

$$\text{Re} = \frac{QD}{\nu A} \quad (3)$$

where Re is the Reynolds number, ν is the kinematic viscosity (m^2/s), and A is the cross-sectional area of the pipe (m^2). For Stage II, the Reynolds number increased along the length of the needle towards the tip as the diameter decreased.

2.3 Hydraulic Resistance Experiments

A simple fluid deployment device (FDD) was fabricated as shown in Fig. 3 to allow for variable input pressures and have negligible hydraulic resistance relative to the tubing or microneedles being tested. The individual components of the device consisted of brass and stainless steel piping, ball valves, inline filter (10 micron in-line filter, FloLok®, Twinsburg, OH), a Luer Lock adapter (1/4 NPT male to Luer Lock, Ellsworth Adhesives, Germantown, WI), and an 18G hypodermic needle (0.838 mm inner diameter). The filter minimized clogging of the needles, and the adapter enabled rapid removal and replacement of different tubing sections and microneedles. The volumetric flow rate of water through the FDD was measured by timed collection and weighing of DI water exiting the FDD. The resistance through the FDD alone (without tubing or microneedle attached) was calculated to be between 2 and 3 orders of magnitude less than the test resistances, which was further observed experimentally. This evidence indicated that the FDD presented an insignificant series resistance that would be constant across all experiments. The different lengths of flat cleaved tubing and microneedle-tipped tubing were epoxy-bonded into 18 gauge hypodermic needles (1.067 mm inner diameter) for interface with the FDD. Excess tubing length extended through the Luer-Lok adapter into the setup, ensuring that the syringe needle did not contribute to the hydraulic resistance of the system. The bonding epoxy served to both fix the tubing in the hypodermic needle and prevent potential leaks. Any leakage from the device or hypodermic immediately invalidated the relevant experiment.

The experimental preparation was identical for Stages I-II. De-ionized water was added to the FDD (10-15 mL) and any air was bled from the system. Next, the FDD was pressurized to the desired experimental level by a CO₂ tank and regulator setup. For both stages, the weight of a small beaker (50 mL volume) was tared on an analytical balance with 0.1 mg (or 0.1 µL of water) accuracy. The beaker was used to capture flow through the test resistance. Once the empty beaker was in position, the valve directly adjacent to the test resistance was opened, allowing fluid flow through the resistance and into the beaker.

Exiting water was captured for a set time (30 s) and then immediately taken to the balance for weighing to determine the fluid flow rate. While evaporation was insignificant (around 0.8 µL/min) relative to total captured volume (2-5 mL), rapidly weighing the beaker immediately after timed capture ensured that the effect of evaporative water loss was minimized. The experimental test pressures used for both stages ranged from 69 to 621 kPa (10-90 psi). For Stage I, 6 different tubing lengths were tested at each of the experimental pressures 3 or more times. For Stage 2, 15 different microneedles with different tubing length precursors were tested 5 or more times at each experimental pressure.

Both partial and complete clogging of the needles was observed infrequently during the Stage II experiments. Microneedles were observed under a microscope prior to experimentation to detect any flow obstruction. The experiments were conducted on each microneedle with incrementally increasing pressure, so any sudden drop in flow rate caused by flow obstruction was immediately evident. Any microneedle observed to have an obstruction was immediately removed from testing and cleared through deployment of a solvent (ethanol or acetone) through the needle. The previous data was discarded and the relevant experiments repeated for the cleared microneedle.

3 Results

3.1 Stage I

Flow rate was measured through different lengths of flat-cleaved tubing to measure the hydraulic resistance (R_{TUBE}). By conducting the experiments over a range of input pressures, graphs of flow rate versus pressure were generated and are presented in Fig. 4.

Using the experimental data, resistance values were calculated for the different tubing lengths and compared to resistances predicted by Poiseuille's Law. Calculation of the tubing resistance from the pressure and flow rate data using Eqn. (1) yielded the results shown in Table 1.

3.2 Stage II

Pressure versus volumetric flow rate for tubing with attached microneedles are provided in Fig. 5. The selected microneedles represent the range of volumetric flow rates measured. The total hydraulic resistance of tubing with microneedle tips was calculated from this experimental data.

The hydraulic resistance associated specifically with the microneedle tip could be determined from Eqn. (1) ($R_{\text{NEEDLE}} = R_{\text{TOTAL}} - R_{\text{TUBE}}$), where R_{TUBE} is theoretically predicted using Poiseuille's Law. For Microneedles 1-15, the needle resistance ranged from 990 to 8230 Pa·s/μL at 207 kPa. High resistance correlated moderately with decreasing tip size.

Geometric parameters of fabricated microneedles (including length and taper angle) were described previously by this group [16]. The microneedles generally resembled straight-sided cones with linearly decreasing cross-sections. Needle measurements were taken from images recorded with a Leica DMIL LED light microscope (Leica Microsystems, Wetzlar, Germany) on the brightfield setting. Both sideview and *en face* images were measured and compared to ensure accuracy as shown previously in Fig. 1. The geometric parameters and experimentally measured resistances for the different microneedles are shown in Table 2.

4 Discussion and Conclusion

Based on the experiments determining the flow rate through the hollow tubes, we calculated the Reynolds numbers for each experiment to determine the validity of Poiseuille's Law as a model for our tubing. The range of Reynolds numbers for the Stage I experiments varied from 50 to 1675, indicating that flow through the shortest tubing lengths at the highest pressures exhibited both viscous and inertial traits. As our Poiseuille's Law model is based on ideal laminar pipe flow, its prediction of the hydraulic resistance should be less than that observed experimentally. As Table 1 indicates, Poiseuille's Law was not an accurate predictor (>5% deviation) for the flow resistance through tubing (without a microneedle tip) at Reynolds numbers greater than 700. In contrast, the high resistance provided by microneedles kept the flow in the tubing preceding the needle within a lower Reynolds number range ($100 < \text{Re} < 500$) in all of the Stage II experiments, allowing Poiseuille's Law to be an accurate model for the tubing.

For the Stage II experiments, the hydraulic resistance for the microneedles increased significantly with increased pressure, with an average increase of 33% from 69 to 620 kPa. This was likely due to increased turbulence in the fluid flow near the sharpest point of the needle, as the Reynolds numbers at the microneedle tips approached 3600 (well above the onset of transitional flow at $\text{Re} = 2100$) for the smallest tip diameter (30 μm) at the highest pressure (621 kPa) [19]. Hydraulic resistance at 207 kPa was chosen as the metric with which to compare different microneedles, as flow at 69 kPa was not continuous (dripping) for some of the higher resistance needles and pressures greater than 207 kPa exhibited increasingly transitional flow. In addition, Reynolds numbers calculated for the tubing sections at this pressure in Stage II fell within the range of 50-500 Pa·s/μL, indicating laminar flow and adherence to Poiseuille's Law. Comparing the hydraulic resistances at 207 kPa allowed for better isolation of the direct effects of geometry on fluid flow.

Entrance length for each tubing and microneedle were calculated to determine its effects. An approximate value for entrance length of developing flow can be calculated with Eqn. 4

$$\left(\frac{\text{Entrance Length}}{\text{Hydraulic Diameter}} \right)_{\text{Laminar Flow}} = 0.05 \text{ Re} \quad (4)$$

which relates the entrance length, hydraulic diameter, and Reynolds number for laminar internal pipe flow [20]. For the Stage I experiments, the longest entrance length (25 mm tube, 620 kPa) was found to be 12.7 mm. Using flow analysis outlined by Zahn et al., the pressure drop along this entrance length was found to be ~13 % of the total pressure drop, suggesting entrance effects significantly contributed to the discrepancies between Poiseuille's Law predictions and the experimental measurements in the Stage I experiments [21]. However, due to the higher overall resistance added by the microneedle tips in Stage II and the chosen comparison pressure of 207 kPa, the longest entrance length among the microneedles was found to be 3.7 mm. Since tubing with attached microneedles were ≥ 25 mm in length, these calculations suggest that the entrance effects for the Stage II experiments were negligible as the flow reaches a fully-developed state preceding the microneedles, thus supporting the use of Poiseuille's Law as a model for the straight tubing portion of the microneedle.

Data gathered in this study was consistent with the established literature on the flow behavior in conically-tapered microneedles in that small forces (such as capillarity) did not influence flow behavior significantly [22, 23]. As hydraulic resistance was most sensitive to tip diameter, future design iterations may include a conically beveled microneedle tip. Fortunately, the data gathered in these experiments should also predict flow from a beveled tip, as the diameter of the closed tube before the spread of the bevel should behave similarly to the flat microneedle tips from this study.

Poiseuille's Law predicts a tubing hydraulic resistance of 80.7 Pa·s/μL per mm for the straight tubing used in these experiments. Thus, the total tubing resistance theoretically varies from 2100 to 15000 for lengths between 25 and 185 mm. The microneedle hydraulic resistance values measured in Stage II ranged from 990 to 8230 Pa·s/μL at 207 kPa. This finding indicates that fluid flow through the tubing should be kept at a minimum length as this design continues in development, an important concept as some tubing length may be necessary for successful coupling of both light and fluid into the same microneedle.

Hydraulic resistance tended to be highest for needles with small tip diameters. This is illustrated in Fig. 6. The average resistance for needles with tip diameters between 30-55 μm was approximately 4270±2260 Pa·s/μL, while average resistance for needles between 55-90 μm was 1680±510 Pa·s/μL. As can be seen in Fig. 6, the resistance for tip diameters less than 55 μm tends to be higher, but the data has significantly more spread. This data spread can be attributable to the greater influence of surface irregularities on the inner bore surface of the needle or the increased flow alteration due to minor clogging. The microneedles with <55 μm tip diameters were shown to be of significantly greater in hydraulic resistance than the microneedles with >55 μm by a Welch's t-test with 95% confidence.

This paper presents a transformative microneedle design capable of co-delivering fluid and light several millimeters beneath a tissue's surface. Parallel work to characterize the light delivery capacity of these microneedles is currently underway. This manuscript focuses on experiments investigating the needles' hydraulic resistance to fluid flow. For straight tubing with an inner bore of 150 μm and a length greater than 50 mm long, Poiseuille's Law was shown to be accurate within 12% of experimental data for the pressure range of 69-517 kPa.

This silica tubing was also shown to have similar hydraulic resistance to microneedles fabricated from the tubing through our proprietary method. Comparison between different needle design geometries indicated that tip diameters $<55\text{ }\mu\text{m}$ cause a significant increase in hydraulic resistance. Tubing length should be kept to a minimum and tip diameter should be increased to the largest possible size to reduce overall resistance. Future investigations should also consider the resistance to flow by the tissue at the microneedle tip, as this is important for future clinical translation. Similar experiments with these microneedles *in vivo* will accelerate translation of their use to clinical practice. To achieve reasonably low hydraulic resistances in clinical practice, parallel arrays of these microneedles could deliver fluids simultaneously at lower pressures. This concept has been demonstrated by other groups, and could be easily incorporated into our design [13, 15].

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Figure 1.

Left) Three sample hollow-core microneedles. The scale bar represents 500 μm . Water within the needle's bore can be seen in the image of microneedle 8. Right) *En face* images of the tips of a) flat-cleaved tubing b) needle 10 c) needle 11 d) needle 113. Scale bar represents 100 μm .

Figure 2. Hydraulic circuit analytical model representation of resistance in a) a capillary tube (Stage I) and b) tube with a microneedle tip (Stage II).

Figure 3.

The left image shows the fluid deployment device (FDD) with specific components labeled. The right image shows a schematic of the microneedle coupling. The microneedle is epoxy-bonded into an 18G syringe needle, which couples to a Luer-Lok to 1/4" NPT adaptor at the distal end of the FDD.

Figure 4.

Graph of pressure versus volumetric flow rate for different lengths of straight tubing in Stage I. Both experimental data and theoretical values predicted by Poiseuille's Law are shown. Experiments were conducted at N=5 for each length of tubing.

Figure 5.

Measured flow rate versus pressure for tubes and microneedles. Error bars are included on all points, but do not extend outside the marker in some cases. Experiments were conducted with N=5 for each microneedle.

Figure 6.
Hydraulic resistance of the fourteen microneedles plotted against their tip diameters.

Resistance values calculated from Stage I experiments compared to the theoretically predicted values provided by Poiseuille's Law. Resistance units are in Pa·s/μL.

Table 1

Tube Length	185 mm	125 mm	85 mm	70 mm	50 mm	25 mm
Experimental R _{TUBE}	15647	10764	7305	6010	4577	3439
Poiseuille R _{TUBE}	14926	10085	6858	5406	4115	2072
% Difference	4.83%	6.72%	6.51%	11.2%	11.2%	66.0%

Table 2

Geometric parameters and the experimentally measured resistances of the fourteen microneedles tested.

Needle #	Tube Length (mm)	Needle Length (μm)	Tip Diameter (μm)	Taper Angle (degrees)	R _{Needle} @ 207 kPa (Pa·s/μL)
1	70	410	75	5.2°	990
2	30.5	496	59.7	5.2°	1100
3	77.5	1015	68.3	2.3°	1180
4	83	1116	40	2.8°	1800
5	60.5	307	75.3	6.9°	1860
6	69.5	683	61.5	3.7°	1920
7	68	1152	66	2.1°	2040
8	77	516	70	4.4°	2110
9	69.5	997	71	2.3°	2270
10	56.5	698	38.1	4.6°	3280
11	60	701	38	5.5°	4130
12	46.5	541	40	5.8°	4880
13	38	634	50	4.5°	5690
14	58	724	30	4.7°	8230