Needle coatings to relieve penetration and drag forces of needles

Brian Reilly, Product Director – Healthcare Materials
April Ennis, QA Analytical Chemist

A study comparing penetration forces of uncoated and coated needles was performed to analyze and compare the efficacy of specific NuSil Technology's needle coating materials in lowering the force required to penetrate and pass through a substrate. Testing was performed on a TA.XT.plus Texture Analyzer with a 5-kg load cell. Needles coated with MED-4162 proved to have the largest decrease in penetration and drag forces.

WHITE PAPER

INTRODUCTION

Hypodermic needles and alternate cutting surfaces are often rough and have a high level of surface friction from manufacturing processes and properties of the material. This surface friction negatively interacts with the substrate it contacts during incision or penetration, resulting in a certain level of damage to the substrate surface and discomfort for a patient. In this study, hypodermic needles were coated with various NuSil Technology's silicones to test the silicones' effects on penetration and drag forces. Hypodermic needles are tri-beveled with an elliptical opening, followed by an elongated tube. The shape itself eases penetration and prevents coring effects, but the metal maintains surface friction against the substrate preventing a smooth, comfortable puncture.

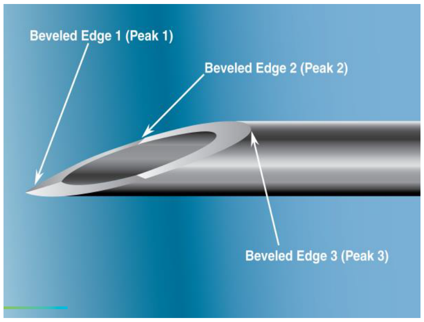

FIGURE 1: Graphic representation of a needle with peak labels

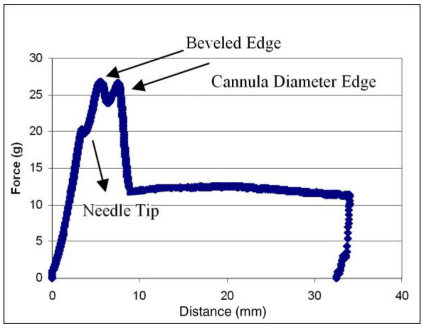

FIGURE 2: Punch results with peak labels at penetration force and distance

Traditionally, lubricants are applied to these surfaces to minimize the effects of surface friction by providing a low coefficient of friction layer between the device surface and its substrate without sacrificing cutting or penetration efficacy. It has even been demonstrated that certain silicone lubricants may relieve stresses on certain devices, preventing bending or breaking of the materials (1, 2). Silicone lubricants are often used as coatings due to the flexibility of control over physical and chemical properties, including biological inactivity, based on sample preparation and formulation.

MATERIALS AND METHODS

Substrate

In order to properly examine and interpret main force outputs of the penetrating hypodermic needle, the appropriate substrate needed to be one which showed 3 initial peaks, expected to appear as the substrate encountered the three beveled edges, and a penetration force distinguishable from drag force as the cannula1 passed through the substrate. MED-6613-2, a silica-reinforced pigmented cured silicone elastomer, was found to be the most effective substrate for discerning forces of interest and reducing noise throughout the experiment. Potential lubrication effects of the cured substrate were controlled for in previous studies, wherein no overall lubrication effect on the needles was observed. Average thickness of the substrate was 0.025" with a Type A durometer of 45.

Needles

Tri-beveled hypodermic needles with a length of 38 mm and an outer diameter of 1 mm were used for the experiment. One end has a Luer-Lok connecter for attaching needles to penetration devices.

Cleaning Process

To control for any initial imperfections or residues left on the needles from the manufacturing process, all needles were cleaned according to the following procedure:

- Needles were suspended, distal side down, in 0.1N KOH in methanol volumetric solution for 2±0.1 hours.
- Needles were removed and rinsed with ASTM Type II water, then allowed to dry at ambient conditions2 for 30 minutes minimum.

- Needles were suspended in acetone, distal3 side down, for 5 minutes, then rinsed with ASTM II water and again allowed to dry at ambient conditions for 30 minutes minimum.
- Methylene chloride was used as the final rinse, followed by a final drying at ambient conditions for 5 minutes minimum.Adites nust es utesto te re plitatur?

Coating Process

Six silicones were diluted to 2% solids in xylene and mixed for 5 minutes minimum to ensure a homogenous dispersion. The following describe each sample chosen: Ore volupta dendite remodit, cuptatur, is eatem re occusanda auta voloria cullacc upicimporis ad que ipitiam autemqu atiunti oneceat quo consequi dolum, ommollant ipsae ium facia dit mos adipsa

- MED10-4161: Solution containing aminofunctional polydimethylsiloxane copolymer (PDMS) dispersed in xylene
- MED-4159: Silicone dispersion containing aminofunctional polydimethylsiloxane copolymer
- MED10-6671: Silicone elastomer dispersed in tert-butyl acetate
- MED-4162: Solution of polydimethylsiloxane copolymers dispersed in xylene
- MED-4162 + MED-361: Solution of polydimethylsiloxane copolymers dispersed in xylene with 8% inert silicone fluid at 350 cp
- MED-4162 + MED-361: Solution of polydimethylsiloxane copolymers dispersed in xylene with 8% inert silicone fluid at 12,500 cp

A total of 70 needles was prepared for testing: 10 replicates for each material and 10 replicate control needles. Needles were dipped for a single coating, placed into a jig (distal end down) and allowed to cure in an environmental chamber per the manufacturer's recommended cure schedule. Ambient conditions in the environmental chamber remained at 25°C and relative 50% humidity. Control needles were left uncoated but otherwise were processed in the same manner.

RESULTS

Penetration and Drag Forces

For each material, 3 punches per needle replicate were averaged over 10 needles. It was determined that all six coatings resulted in a lower penetration force compared to the uncoated control needles. (See Figure 3.) Statistical analysis established that these results are more characteristic of typical outcomes than enigmatic situations.

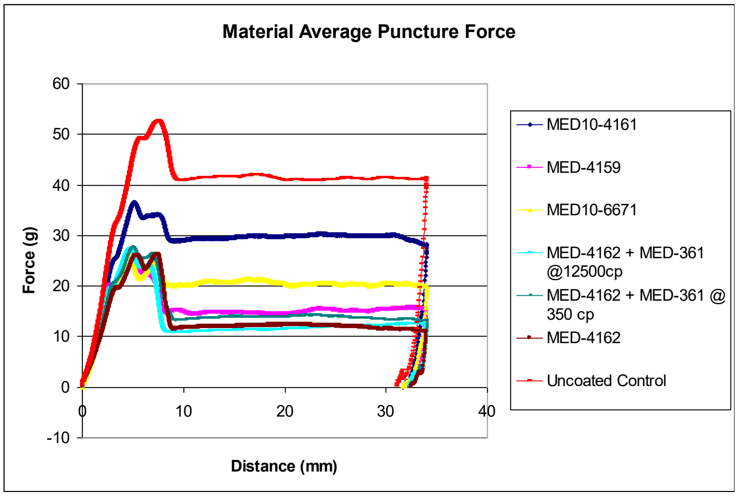

FIGURE 3: Overall comparison of needle penetration replicate and punch averages for each sample.

Coating a needle with any of the sample materials resulted in a significantly lower drag force than the uncoated control needle. MED-4162 and its corresponding solutions with MED-360 (PDMS fluid) maintained equal average drag forces, all of which were lower than the forces recorded for the other samples. It was also observed that 5 of the coatings achieved the same mean peak force, lower than the peak force for MED10-4161. The following is a list of the coatings ordered from lowest to highest drag force:

- MED-4162 = MED-4162 + MED-360 @350 cp = MED-4162 + MED-360 @12500 cp
- MED-4159
- MED10-6671
- 4. MED10-4161

The graph below displays how well MED-4162, a dispersed high molecular weight polymer, reduced the effects of friction (lower puncture force, lower drag force, no rubbing off, and better consistency).

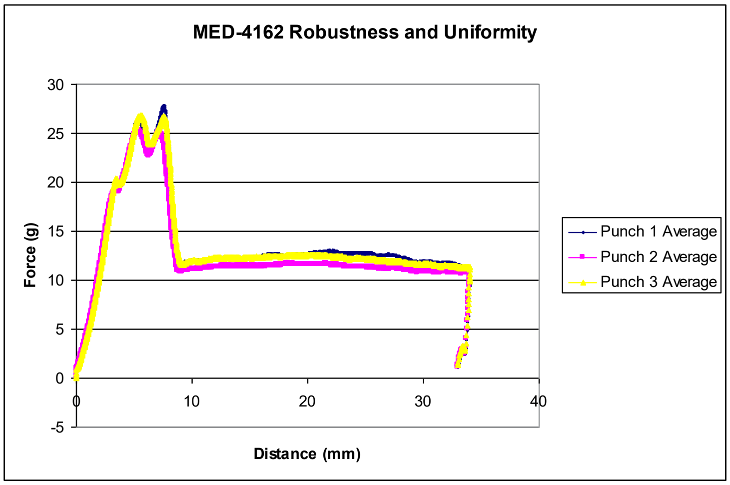

FIGURE 4: The averages of all replicate punches for MED-4162. Material punches are very close and there is very little noise in the data, indicating a smooth and consistent coating.

PDMS fluid is often used as a lubricant by itself. MED-4159 was the only material with a trending increase in penetration force after each punch, indicating that the lubrication decreased a given amount every time the needle passed through the substrate. This was attributed to the coating rubbing off the needle upon contact with the substrate, causing the needle to be more and more exposed. MED-4159 is considered to be a much less robust coating than MED-4162 for applications requiring repeated use.

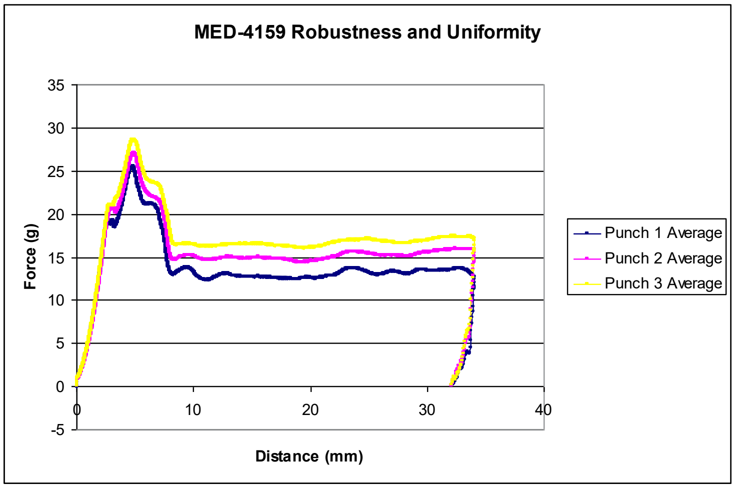

FIGURE 5: The averages of all replicate punches for MED-4159. Each punch rubbed off a certain amount of lubricant, increasing the force required to penetrate the substrate for the next punch.

CONCLUSIONS

It is beneficial to use coatings with the ability to maintain integrity over multiple uses, as well as those which result in smooth and uniform coatings. Inert PDMS fluid dispersions are generally used as generic lubricants for various penetration and cutting surfaces in the medical industry (1, 3). In addition to its primary (higher molecular weight) polymers, the MED-4159 formulation includes a modest loading of inert PDMS fluid. The expectation is that the PDMS improves lubricity, but this only seems to be the case with one-time use lubricants (Figure 5). According to this study, a more favorable formulation for reducing penetration friction and maintaining lubricity over multiple punctures is MED-4162.

MED-4162 is primarily composed of a dispersed high molecular weight polymer which, by comparison, dwarfs the chain length/average molecular weight of the primary polymers of all the other products in this study (MED-4159, MED1-4161 and MED10-6671). In addition, the coating application results in a smooth and virtually uniform coating along the needle cannula, as seen in the steady drag forces the material produces (Figure 4). An explanation of its adhesive success may be attributed to the fact that the extensive polymer chain entangles itself around the needle surface and is reinforced by surface intermolecular forces as the solvent flashes off, resulting in a strong adhesion to the needle.

Future Studies

Analysis of the penetration force graphs for MED-4162 with the two PDMS addition solutions (Figure 3) suggests that adding longer PDMS chains to this particular material may lower the penetration force required for puncture; however, this observation is not supported statistically in this study.

Although the number of punches per replicate was not high enough for solid conclusions to be made about the adhesion strengths of the MED-4162 and its mixtures with inert PDMS, it seems as though including PDMS in this formulation may prove beneficial for decreasing forces without undermining the adhesion strength of the material to the desired surface. It would be beneficial to design another experiment to determine the effects of PDMS chain lengths on friction reduction efficiency by adding varying chain lengths of PDMS to a control material, puncturing the surface several times, and verifying if trending exists.

In certain circumstances a needle may need to be used repetitively before its discard. For example, a physician stitching a lesion or incision together may apply multiple punctures, and the same may be required for a novice phlebotomist to properly penetrate a patient's vein. For such cases, the continued adhesion of the coating to the needle becomes necessary for maintaining a reduced level of discomfort. In a preliminary study the uncoated control needle was used to puncture our substrate 20 times, each time on a fresh part of the substrate, and no trending was observed over the consecutive punctures. In this study, integrity of the coatings was generally stable over 3 punctures (Figure 4 and Figure 5). It would be of interest to further study NuSil Technology's needle coatings over a greater number of punches to look for any trending or signs of the coatings rubbing off.

References

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24524-MR-KK

0320 Lit. No. 931062W