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Analysis and Testing of Plastic Hypodermic Needles

Final Report

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Introduction

This research project studied the design and characterization of plastic hypodermic needles. Finite element analyses (FEA) were performed to determine approximate buckling loads for multiple needle configurations. Variables studied during the FEA included cannula length, taper, and cross-sectional shape. Physical experiments included penetration tests using rubber skin mimics, stiffness and bending resistance, and fluid flow tests.

Finite Element Analysis

FEA tests were performed to determine the loads that caused the cannula to buckle using the ANSYS (versions 10 and 11) software. The first step was to create a solid model of the cannula from their surface models. The models feature a 38.1 mm long cannula, with a 0.72 mm outside diameter and a 70% ID/OD ratio. The needles taper over the length of their cannula, with their OD being 1.2 mm where the cannula intersects the hub. From this original design, multiple models were created, reflecting changes in the design. These models, 28 in all, each featured a different needle configuration, with variations in the cannula taper, length, and cross sectional shape. The cross sectional shape reflected the geometry of the actual needles, which featured an elliptical cross section, as opposed to one that is perfectly round. The end conditions were chosen to reflect those present when a needle penetrates the skin. In the model, the hub was fixed so that no displacement and rotation occurs. The tip was given a fixed displacement during the simulation. With the orientation of the needle aligned so that the length is along the x-axis, the displacement was fixed so the y and z axes were restricted from displacement. This allowed free movement in the x direction, as well as free rotation about any of the three axes. These constraints on the movement of the needle replicated its motion during initial contact with the skin. By fixing the y and z directions, the needle was prevented from sliding along the skin prior to penetration, but the "operator" was free to rotate the needle about the tip's contact point in any direction while applying force directly in the x direction. The FEA works by applying a 1 N force at the tip along its x axis. This loading level was used by the software to "scale" the analysis.

The results from the FEA include a load factor, which is a multiplier that, when multiplied by the applied force (in this case, 1 N), provides the actual load. The FEA conditions and results are summarized in Table 1. For comparison, two tip conditions were simulated – tip present and tip not present. This allowed one to determine the effect of the presence of the tip on the results. Load 1 describes the simulated force with the tip present, and Load 2 is the force with the tip removed.

Table 1 - Buckling FEA Results

Needle	Length (mm)	Cross-Section	Taper	Thru-Hole	Load 1 (N)	Load 2 (N)
3-2	38.1	Circular	Tapered	Round	7.88	4.86
3-3	38.1	Elliptical	Tapered	Round	6.68	3.19
3-4	38.1	Circular	Straight	Round	2.88	1.73
3-5	38.1	Elliptical	Straight	Round	2.94	1.31
3-6	25.4	Circular	Tapered	Round	15.64	11.08
3-7	19.0	Circular	Tapered	Round	26.17	20.12
3-8	25.4	Circular	Straight	Round	6.36	4.11
3-9	19.0	Circular	Straight	Round	11.14	7.76
3-10	25.4	Elliptical	Tapered	Round	13.44	7.33
3-11	19.0	Elliptical	Tapered	Round	24.63	13.42
3-12	25.4	Elliptical	Straight	Round	6.44	3.13
3-13	19.0	Elliptical	Straight	Round	12.92	5.97
3-14	38.1	Circular	(1/3) Tapered / (2/3) Straight	Round	4.01	NA
3-15	38.1	Elliptical	(1/3) Tapered / (2/3) Straight	Round	3.11	NA
3-16	38.1	Circular	(1/2) Tapered / (1/2) Straight	Round	4.46	NA
3-17	38.1	Elliptical	(1/2) Tapered / (1/2) Straight	Round	3.53	NA
3-18	38.1	Trilobular	Tapered	Round	4.81	3.05
3-19	38.1	Trilobular	Straight	Round	1.85	1.09
3-20	38.1	Trilobular	Tapered	Trilobular	4.94	3.27
3-21	38.1	Trilobular	Straight	Trilobular	2.05	1.25
3-22	25.4	Trilobular	Tapered	Round	10.51	6.99
3-23	25.4	Trilobular	Tapered	Trilobular	11.10	7.45
3-24	25.4	Trilobular	Straight	Round	4.04	2.59
3-25	25.4	Trilobular	Straight	Trilobular	4.60	3.00
3-26	19.0	Trilobular	Tapered	Round	20.48	13.15
3-27	19.0	Trilobular	Tapered	Trilobular	21.47	14.07
3-28	19.0	Trilobular	Straight	Round	7.66	4.94
3-29	19.0	Trilobular	Straight	Trilobular	8.69	5.67

The buckling simulations showed many expected trends concerning the effect of the variables. The tapered needles had a buckling strength 125-175% greater than the straight needles of the same length and cross section at the tip. In addition, needles that had a combined straight/tapered cannula (straight at the tip, tapered near the hub) had strengths between those of the straight needles and those of the tapered needles. One interesting phenomenon is found with the changes in the cross sections. For tapered needles, an elliptical cross section has a buckling strength 6-17% lower than the round cross section (here the major axis of the elliptical cannula is the same size as the diameter of the cylindrical cannula). However, for straight needles, the opposite trend exists; the buckling strength is 1-17% higher than the tapered needle's strength. Changing the length also had a large effect on the buckling strengths. Reducing the length from 38.1 mm to 25.4 mm increased the strength 98-120%. Further reducing the length from 25.4 mm to 19.0 mm increased the strength another 68-100%. The simulations also indicated that a needle with a trilobular cross section has a lower buckling strength than one with either circular or elliptical cross sections. With a round thru-hole, a trilobular cross section reduces strength 22-72% compared to a needle with a round cross section. If the thru-hole is also trilobular, the strength increases 2-10% over a trilobular cross section with a circular hole.

Experiments

Penetration Tests

To verify the results of the FEA simulations, buckling tests were conducted on plastic hypodermic needles as per the "Single Needle Testing Protocol" in Appendix A. These were performed by forcing a needle vertically against an aluminum plate at 60 mm/min. The needle was prevented from slipping by a small notch in the plate. The tests showed that buckling occurs at axial force levels of between 4 and 6 N. These are consistent with the results of both the failed penetration tests (discussed below) and the FEA (needle 3-3 from Table 1). Similar results were achieved for the 25.4 mm long needles. The FEA (needle 3-10 from Table 1) predicted buckling at approximately 13 N whereas the actual needles had buckling forces of approximately 10 to 12 N. The 19.0 mm long needles FEA (needle 3-11 from Table 1) prediction was approximately 25 N, whereas the actual needles had buckling forces of approximately 20 to 22 N. These tests validated the results from the FEA simulations for the expected buckling force at each length of the needle.

Penetration tests were performed using the plastic needles with cannula lengths of 38.1 mm, 25.4 mm, and 19.0 mm, and their performance was compared to that of 22 gage steel needles. The tests were performed on a mechanical testing machine (Instron, model 4466), using the "Single Needle Testing Protocol" in the appendix. The rubber skin mimic was supported horizontally in the base, although elevated to allow the needle to penetrate, and the needle is attached to a 25 N load cell suspended from the crosshead. This setup is shown in Figure 1. Research into other companies' needle penetration testing led to the conclusion that a speed of 100 mm/min and an exposed rubber area of 506.5 mm^2 were the optimal conditions for performing the tests. Prior tests showed that no there was no significant difference in penetration forces for changing speeds or exposed rubber areas; thus, the tests could be performed with those variables held constant. Originally, the needles were tested using photoelastic sheets (Vishay Measurement Co., PS-4) and silicone rubber (McMaster-Carr, #87315K74 (0.04" (1 mm) thickness) and #87314K75 (0.06" (1.5 mm) thickness)) as skin mimics, but these materials were found to be ineffective. As a result, polyurethane film (McMaster-Carr #1446T41, 0.015" (0.37 mm) thickness) was chosen to be the skin mimic used for all penetration tests.

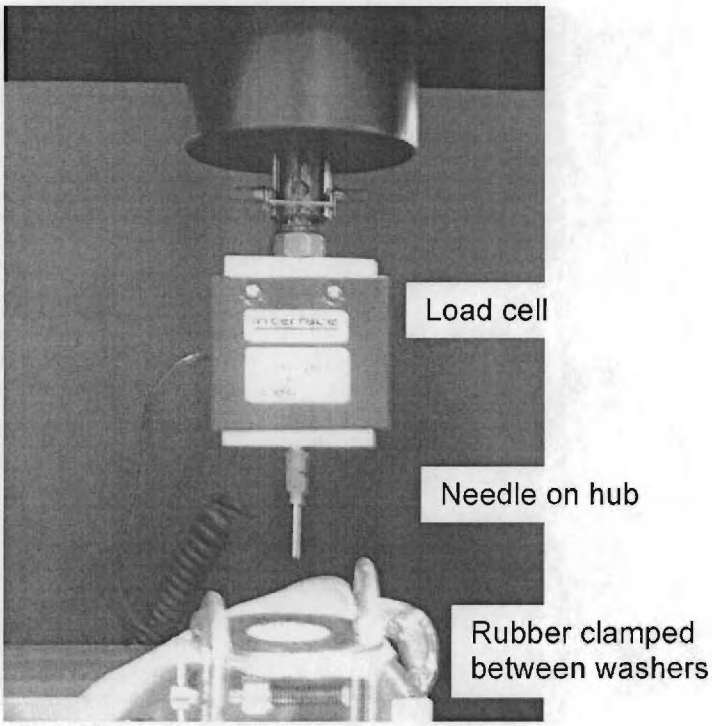

Figure 1 - Penetration test setup

Initial tests with the polyurethane were performed without lubrication. To create the shorter needles, full-length needles were cut, leaving them attached to the hub and removing excess material at the tip end. Tips were crudely recreated at what became the end of the needle (see Figure 2 for a comparison of the tips and Figure 3 for a view of the needle as a whole). As a result of the needles' taper, the diameters for the shorter needles are larger than the diameters of the full-length needles. All of the initial tests run with the polyurethane for full-length (38.1 mm) needles failed, as the needles buckled prior to penetration. The needles cut to 25.4 mm without the original tip also failed, and only two of the eight needles cut to 19.0 mm penetrated the polyurethane. However, the usefulness of the tests run on the shorter needles cannot be determined because of the inaccuracies due to the larger overall diameter and the lack of an appropriate tip. The tests were beneficial in supporting the FEA buckling results, as the failure loads were between the averages of the two loads generated from the FEA for each test.

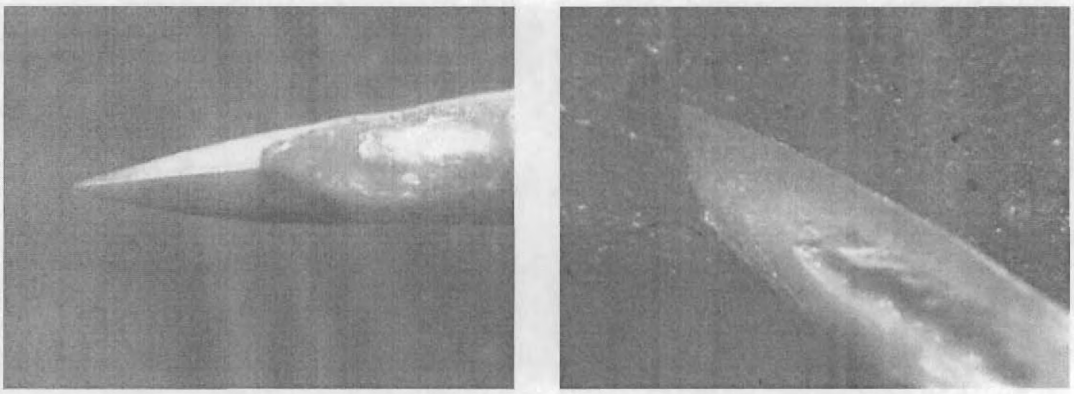

Figure 2 - Needle tip comparison (original tip on left, recreated tip on right)

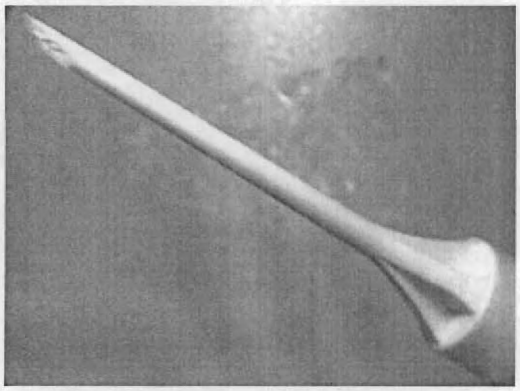

Figure 3 - 19.05 mm length needle

As a benchmark, steel needles (Kendall Monoject Polypropylene Hub Hypodermic Needles, #250222, 22 gage, 25.4 mm length, Lot #421132) were tested in penetration, using polyurethane as the skin mimic. They were tested both as-is (with lubrication) and with the lubrication removed. As expected, the penetration force was lower for the steel needles than for the plastic needles, and removing the lubrication increased both the penetration force and the friction force. The penetration forces for lubricated steel needles ranged from 0.5-0.6 N, and the friction forces ranged from 0.06-0.1N. Comparatively, the penetration forces for unlubricated steel needles were from 0.9-1.7 N, with friction forces from 0.3-1.2 N. Representative graphs comparing the two conditions are shown in Figures 4 and 5.

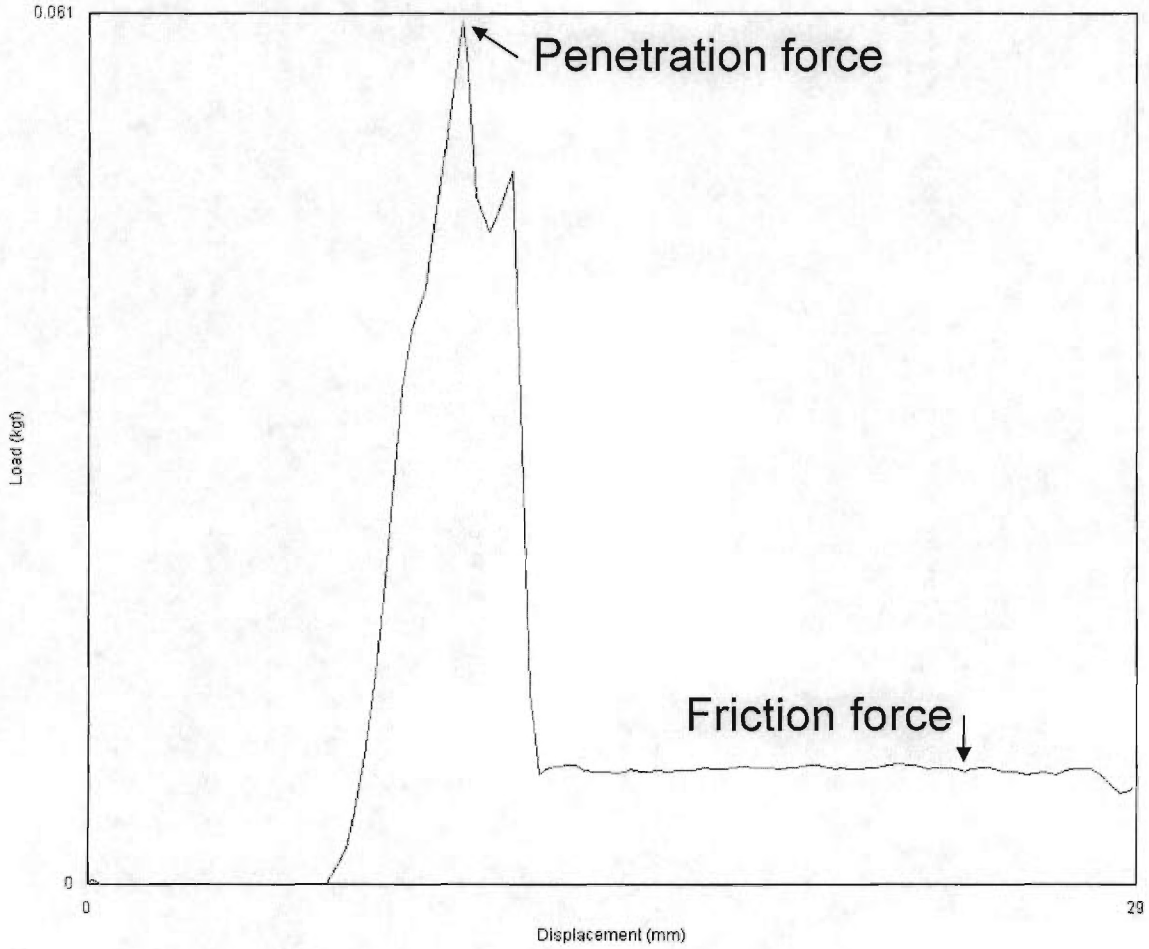

Figure 4 - Lubricated steel needle penetration test result

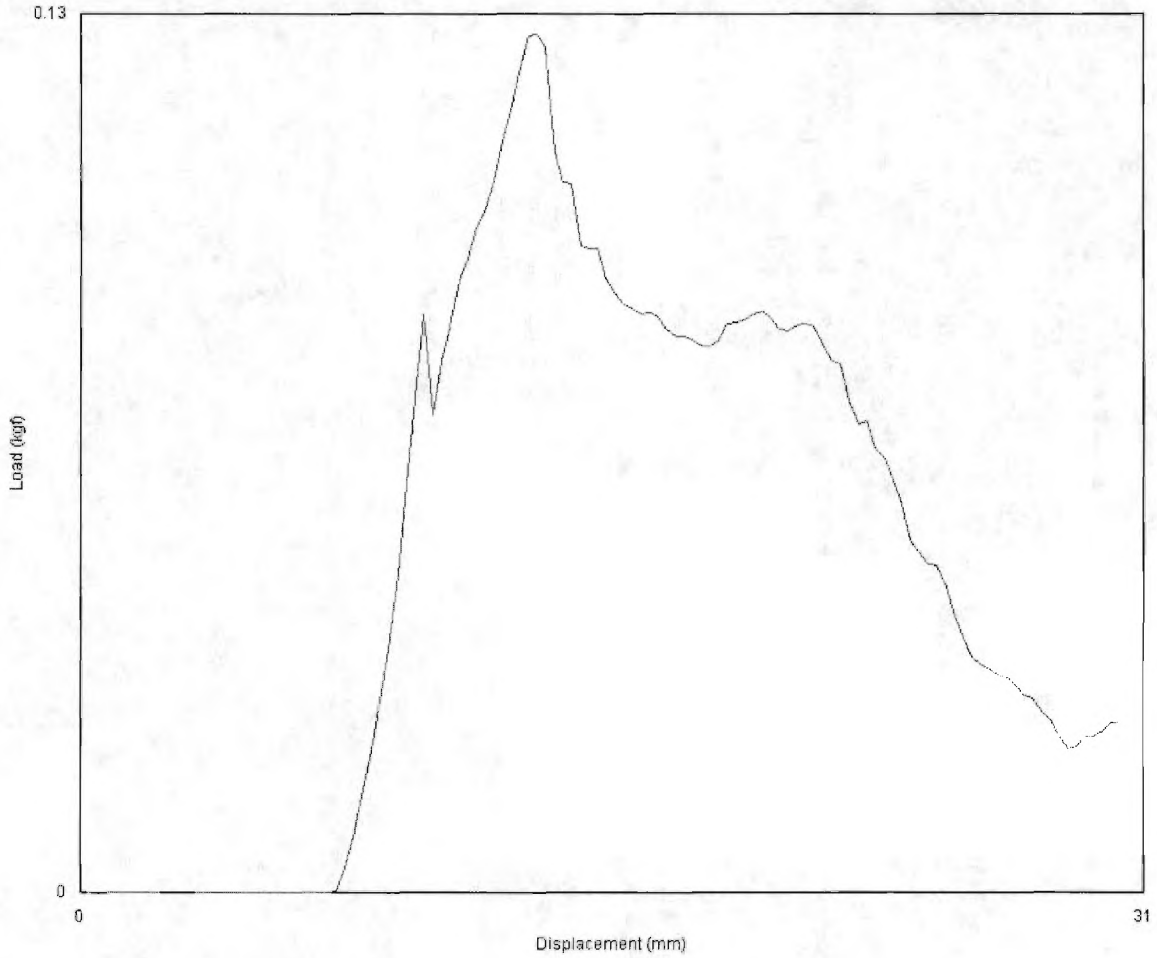

Figure 5 - Unlubricated steel needle penetration test result

Silicone Oil Lubrication

Tests were conducted to determine the influence of lubrication on the penetrative capabilities of the needle. The original hypothesis was that the lubrication would only reduce the frictional forces between the needle and the rubber following penetration and would have no effect on the penetration itself. The first lubricants used were silicone oils with viscosities of 100 cSt and 500 cSt. The oils were applied by dipping the needles into a container of the oil for 5 seconds and then allowing the excess oil to drip off the needles. The needles were immediately loaded onto the load cell, and the tests were performed. These coatings failed to influence the penetration of the needles into the polyurethane; the needles did not penetrate the polyurethane. The oils did produce a minor decrease in the friction force when tested with the silicone rubber, through which the plastic needles could regularly penetrate, even in a dry state. The silicone oil did not bond to the surface and, as a result, was less effective. This was not a realistic portrayal of needle lubrication.

Dow-Corning Lubricant

Dow Corning MDX4-4159, 50% silicone medical grade was used as a lubricant. The MDX4-4159 is a silicone dispersion that chemically bonds to steel needles, keeping them lubricated until use. This is a lubricant used commercially for steel needles. The original, as-received dispersion consists of 50% silicone oil-based material, with the bulk of the material being a solution consisting of a mixture containing 70% mineral spirits and 30% isopropyl alcohol. For the final lubricant, the necessary final silicone component content had to be <5%, so the original solution was diluted using a 70% mineral spirit, 30% isopropyl alcohol mixture to obtained the desired silicone component content. In addition to lubricating the needles, a procedure to clean them was developed. This was important because dirt and other particles could prevent the lubricant from fully contacting the needle, resulting in a poor coating. The procedures for both cleaning and lubricating the needles are detailed in the appendix, "Cleaning Protocol" and "Lubrication Application Protocol".

The results for these penetration tests are summarized in Table 2 for successful penetrations and Table 3 for unsuccessful tests. The lubrication was successfully coated on the plastic needles, at concentrations of 2.5% and 5% silicone content, and enabled the plastic needles to penetrate the polyurethane. On average, 50% of the lubricated needles at 38.1 mm length were able to penetrate the polyurethane with both 5% and 2.5% silicone content in the dispersion. These numbers increased to 75% penetration for 25.4 mm with 5% silicone content, and 50% of the 19.1 mm needles also penetrated. With 2.5% silicone content, only 25% of the needles at 25.4 mm penetrated, and 0% of the needles at 19.1 mm penetrated. The differences between pre-cleaning the needles and not pre-cleaning them were not noticeable. These results are significant because they demonstrate that the plastic needles are capable of penetrating the polyurethane film. The lubrication is able to accumulate, although not visibly, at the tip of the needle because the needle is suspended vertically immediately after the dispersion is applied. As a result, the dispersion contacts the rubber prior to the needle tip contacting the rubber. This reduces the force required for penetration, and as a result, the needles have an increased rate of penetration. Examples of successful and failed tests are shown in Figures 6 and 7. This also showed that lubrication does affect penetration, countering the original hypothesis that lubrication would have no effect.

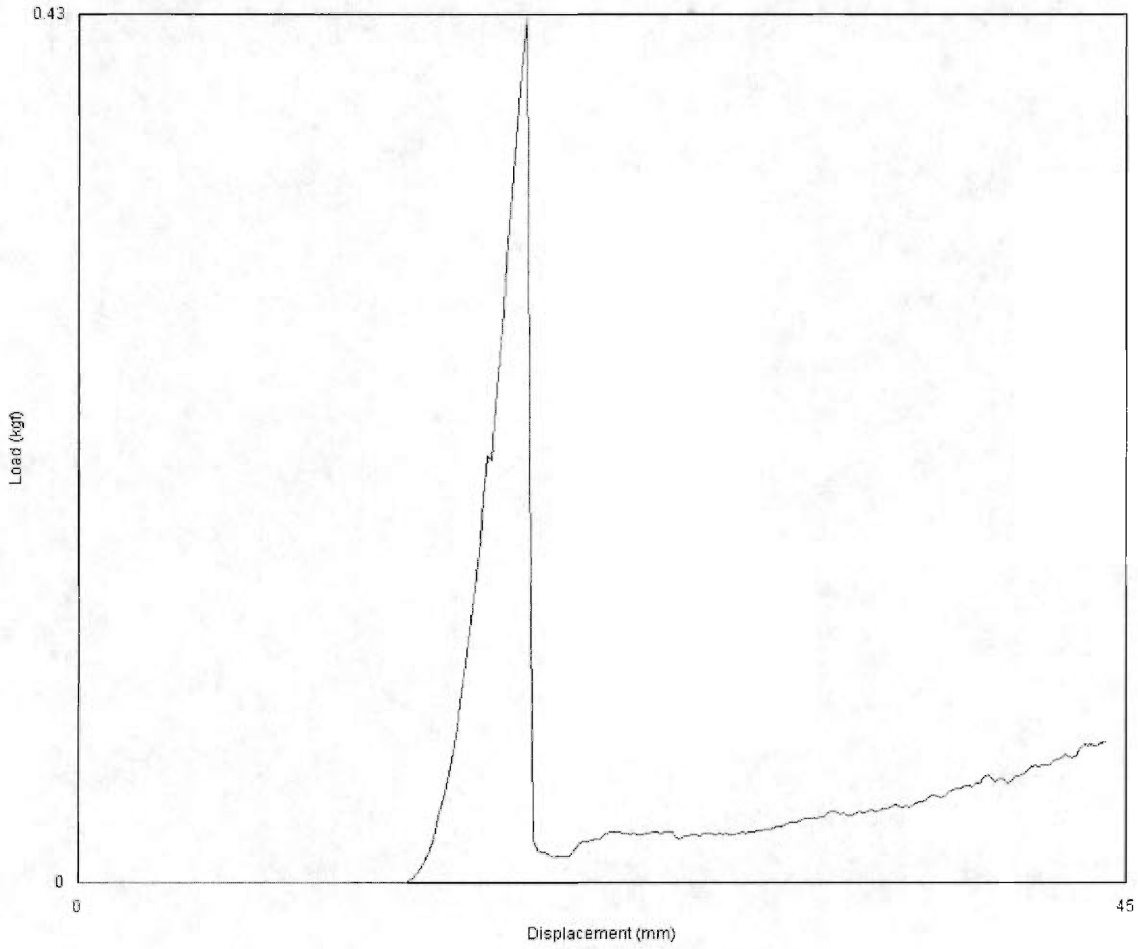

Figure 6 - Successful plastic needle penetration test

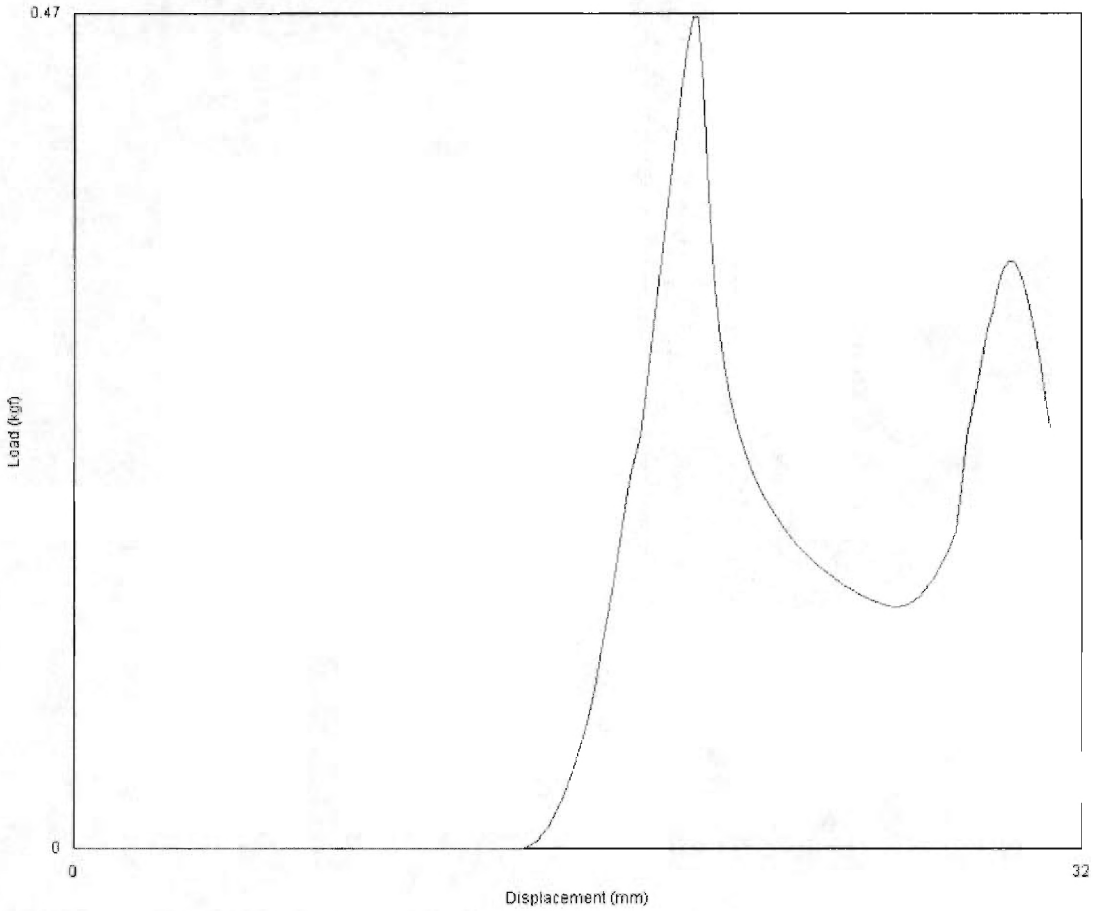

Figure 7 – Unsuccessful plastic needle penetration test

Table 2 – Successful penetrations with lubricated needles

Solution	Cleaned	Length (mm)	Avg. Penetration Force (N)
5%	N	38.1	2.96
5%	Y	38.1	3.65
2.50%	N	38.1	3.30
2.50%	Y	38.1	3.50
5%	N	25.4	6.88
5%	Y	25.4	8.30
2.50%	N	25.4	6.00
2.50%	Y	25.4	10.00
5%	N	19	5.65
5%	Y	19	8.05
2.50%	N	19	did not penetrate
2.50%	Y	19	did not penetrate

Table 3 - Failed penetrations with lubricated needles

Solution	Cleaned	Length (mm)	Avg. Buckling Force (N)
5%	N	38.1	4.53
5%	Y	38.1	4.55
2.50%	N	38.1	4.70
2.50%	Y	38.1	4.50
5%	N	25.4	no needles buckled
5%	Y	25.4	8.60
2.50%	N	25.4	8.33
2.50%	Y	25.4	9.40
5%	N	19	9.80
5%	Y	19	9.75
2.50%	N	19	12.68
2.50%	Y	19	12.05

Solid Needles

Solid needles were tested. These had a slightly different design than the earlier version of needles, with a narrower, but sharper tip. The solid needles experienced lower buckling loads than the older needles; they were consequently unable to penetrate the polyurethane. The change in the tip design had a large effect on the overall needle strength. These newer needles always buckled at the hole prior to cannula buckling, as seen in Figure 8. The earlier version of the needles had a ridge near the tip behind the hole, which the solid needles did not. This comparison is demonstrated in Figure 9. This ridge provided extra strength and prevented the tip from buckling before the cannula. The tip on the earlier version of the needles would occasionally crush, such as during buckling tests, but generally held its overall shape. It is difficult to determine whether the lack of a thru-hole had any effect on the strength. A solid needle should have more strength due to the greater amount of material present, the needle may be weakened due to the properties of the LCP; its strength is reported to increase with decreasing wall thickness. This situation may not be present in actual needles because they will have holes, so drawing conclusions from these needles' resistance to buckling would not be conclusive.

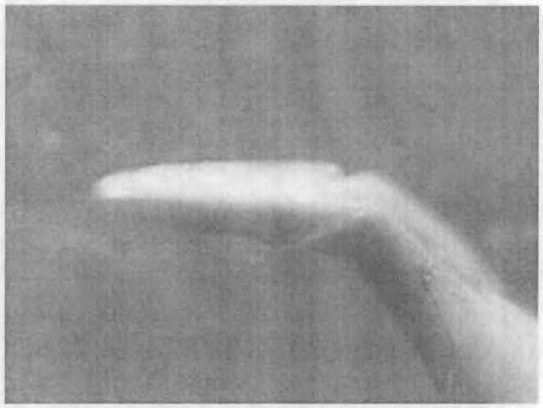

Figure 8 - Broken Solid Needle Tip

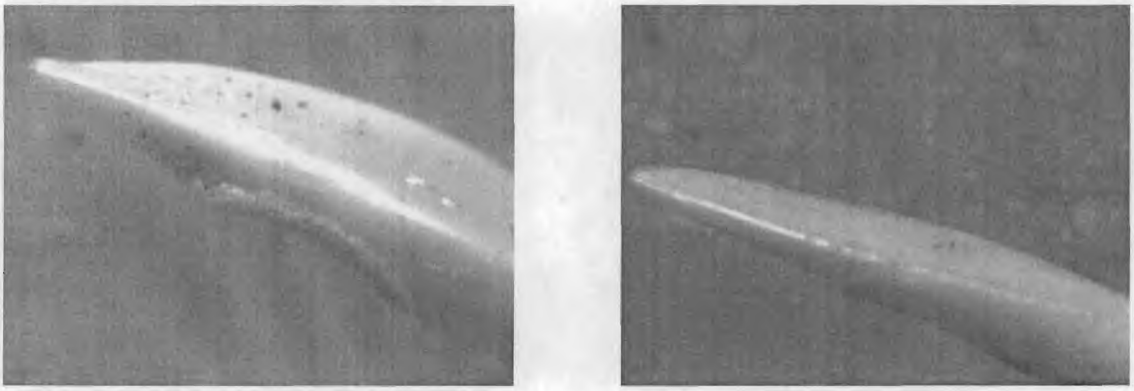

Figure 9 - Earlier needle tip (left) and later needle tip (right)

Fluid Flow Tests

Fluid flow tests also performed on the needles. The test was performed by affixing a syringe to the base of the Instron testing machine with the plunger extending upwards. The load cell was forced down onto the plunger, expelling the liquid (in this case, water) while measuring the force required to push the plunger. Two different syringe are used, with volumes of 1 ml (Becton-Dickinson 1 ml Luer-Lok Syringe, #309628) and 3 ml (Becton-Dickinson 3 ml Syringe, Slip Top, #309586), and two speeds were tested, 20 mm/min and 200 mm/min. The full-length plastic needle was tested against both a steel needle and a plain syringe without a needle. The results are summarized in Table 4. The results showed that at 20 mm/min, a force of 0.12-0.54 N was necessary to push the 1 ml syringe, while 0.79-1.49 N was needed for the 3 ml syringe, with an initial force slightly higher. These results depended on the syringe size. The needle had no effect on the forces. For each of the three setups (plastic needle, steel needle, no needle), the forces that both the smaller syringe and the larger syringe require to expel the water were statistically similar. This indicates that the plastic needles are equally capable of expelling liquid as steel needles at 20 mm/min. However, at 200 mm/min, the forces required to press the syringes increased, and they become dependent on the presence of a needle on the syringe. The plastic needles do not perform differently from the steel needles on the 1 ml syringe, but the forces are higher for the 3 ml syringe.

Table 4 - Fluid Flow Testing Results (Forces in N)

	No Needle	Steel Needle	Plastic Needle
1 ml syringe			
20 mm/min	0.12-0.34	0.14-0.54	0.16-0.51
200 mm/min	0.62-0.90	0.78-1.40	0.90-1.34
3 ml syringe			
20 mm/min	0.67-0.85	0.62-1.05	0.88-1.49
200 mm/min	1.60-2.28	2.09-2.95	3.28-3.78

Stiffness and Perpendicular Force Tests

The needles also were tested in accordance with ISO 9626, including cannula stiffness tests and perpendicular force (resistance to breakage) tests. The conditions for the stiffness test

are described in the appendix, "Stiffness Testing Protocol", and ISO 9626, Annex C. For the 22 gage plastic needles, the span is 15 mm, and the bending force is 10 N. This is the force that the needle must withstand with only a maximum deflection of 0.45 mm. The tests were performed on the Instron machine, and the setup was exactly as described in the ISO document and is shown in Figure 10. As expected, the needle was unable to withstand a 10 N force applied perpendicular to the length of the cannula at its midpoint. The maximum force applied was approximately 3 N, after which, the cannula continued deflecting without the load increasing. The test was stopped when the included angle formed by the bending cannula reached ~90°, and the needle had not broken by this point. By comparison, the steel needles were able to withstand the 10 N force, but not within the 0.45 mm maximum deflection that the standard allows. The perpendicular force test, outlined in Appendix A, "Resistance to Breakage Testing Protocol", and ISO 9626, Annex D, tests the needle's ability to withstand breakage when a fluctuating load is applied at the tip perpendicular to the axis of the cannula. This test also was performed on the Instron mechanical testing machine, with the needle supported from the hub, extending horizontally. A piece was attached to the crosshead which enabled the needle to bend vertically as the crosshead was moved. The test setup is shown in Figure 11. The needles were bent 25° from the horizontal in each direction, creating a 50° included angle, over 20 complete cycles. The needles did not break during this test due to the flexibility of the LCP, and thus passed the test. This test was not performed on the steel needles.

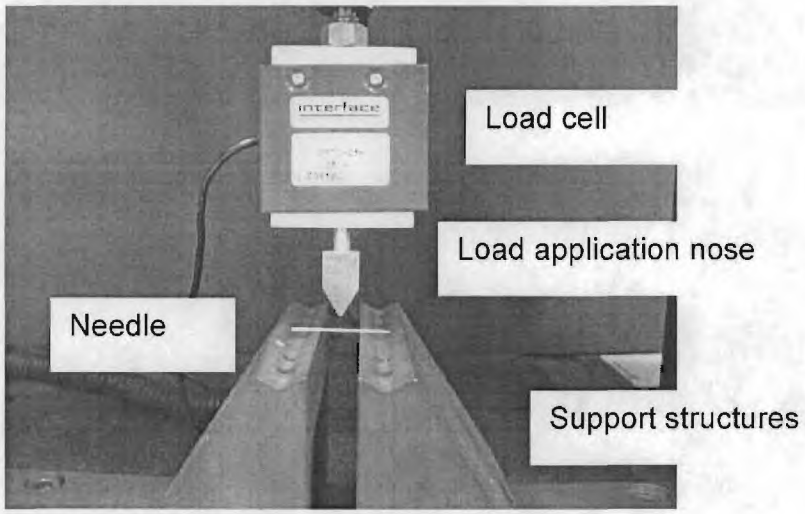

Figure 10 - Stiffness test setup

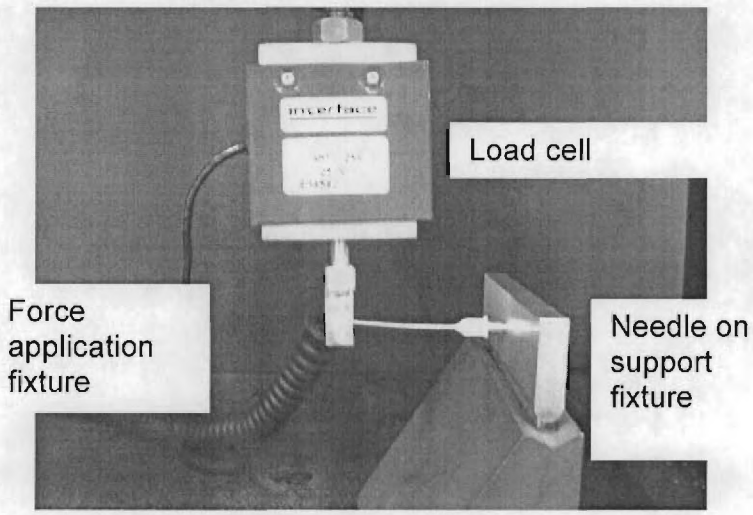

Figure 11 - Perpendicular force test setup

Summary

These experiments and simulations studied the penetration of plastic needles into a rubber skin mimic. The FEA predicted the buckling loads of the needles and helped determine which length and construction is most favorable to avoid buckling. The results of the FEA were confirmed by both buckling tests and failed penetration tests, in which the needles buckled prior to penetration. The penetration testing indicated that lubricating the needles using a silicone-based dispersion is the most effective way to assure penetration through the polyurethane skin mimic. Supplemental testing was performed on the needles to study stiffness and perpendicular force resistance. Finally, fluid flow testing showed that fluids can pass through the plastic needles just as easily as through the steel needles.

Georgia Tech Needle Testing Protocols

DRAFT version 1 – October 11, 2007

This document contains the protocols for test procedures for hypodermic needles as performed at Georgia Tech for the SSB research.

Cleaning Protocol

Objective: To clean needles before testing and before application of lubricant.

Materials:

Ultrasonic bath
KOH (CAS 1310-58-3), 0.5 N, in Ethanol (CAS 64-17-5)
Acetone (CAS 67-64-1)
Isopropyl alcohol, 91%, in water
De-ionized water

Procedure for steel needles:

1. To remove lubrication, immerse the needle in KOH for at least 2 hours.
2. Rinse outside and inside with deionized water.
3. After drying, soak in acetone for 5 minutes.
4. After drying, ultrasonically clean in isopropyl alcohol for 2 minutes.
5. After drying, rinse outside and inside with deionized water.
6. Allow to air dry without touching.

Procedure for plastic needles:

1. Soak in acetone for 5 minutes.
2. After drying, ultrasonically clean in isopropyl alcohol for 2 minutes.
3. After drying, rinse outside and inside with deionized water.
4. Allow to air dry without touching.

Lubrication Application Protocol

Objective: To apply lubricant to bare needles.

Materials:

Mineral spirits (e.g., Barr, #QKSP94005)
Isopropyl alcohol (e.g., 91%, in water)
Dow Corning MDX4-4159 50% Medical Grade Dispersion
Vacuum Oven (e.g., Napco E Series Model 5861)

Procedure:

1. Mix approximately 50 ml of solution comprising 70% mineral spirits, 30% isopropyl alcohol.
2. Add the appropriate amount of MDX4-4159 to form the solution with 2-5% final silicone content, keeping in mind that MDX4-4159 has 50% silicone content.
3. Before lubricating, inspect each needle visually and under magnification (60x) for any noticeable defects. Do not use if defects are present. Also, note any curve in the shape of the needle. Do not use if too curved.
4. Dip each needle individually into a small vial containing the solution so the entire cannula is covered. Hold for approximately 5 seconds and then remove.
5. Place the needles so they hang vertically in an oven, with only the hub supported, and take care to not allow the cannula or tip to contact anything.
6. Set the oven to 70°C, with <55% humidity, and allow it to run with the needles inside from 3-7 days to allow the solution to fully cure. Keep the oven sealed to maintain the moisture constant.

Single Penetration Testing Protocol

Objective: To test needles once through skin mimics to quantify penetration and friction forces.

Materials:

Instron model 4466 with 25 N capacity load cell
Polyurethane Rubber Film (McMaster-Carr, #1446T41, 0.03" (0.76 mm) thickness, Shore hardness 85A)
2 washers, 1" (25.4 mm) ID
Clamps
Testing rig
Microscope

Procedure (in accordance with DIN 13097 Appendix C; Sherwood Medical Test Protocol: Insulin Needle Penetration):

1. Mount the 25 N load cell and needle hub fixture onto the Instron. Plug the load cell into the Instron.
2. Clamp the test rubber between two washers.
3. Load the clamped washers and rubber into the testing rig.
4. Load the testing rig in the base of the Instron directly beneath the load cell. Make sure that the rubber is perpendicular to the direction of the needle.
5. Inspect the needle prior to the test. Examine the surface under a magnification of 60x, and note any defects. Do not use the needle if defects visible without magnification are present, such as bent tip or bent cannula. Take a picture of the needle under magnification, and record the initial state of the needle.
6. Load the needle into the fixture on the 25 N load cell in the Instron. Be sure not to overload the load cell.
7. Visually inspect the tip of the needle to assure that you have not dulled the tip or bent the cannula.
8. Run the Instron so the needle penetrates the rubber in the center of the washers at a speed of 100 mm/min.
9. Record the force required for both penetration and frictional forces.
10. Inspect the tip under magnification and record any changes from before the test. Look for tip damage and rubber in the needle hole. Take a picture of the needle.
11. Inspect the rubber around the hole for the shape, inspecting under magnification, and record findings.
12. Keep at least ¼" (6 mm) between punctures of the rubber to ensure that the rubber is not compromised in the location of the puncture.
13. Repeat with a steel needle of the same size, and compare the results.

Double Penetration Testing Protocol

Objective: To test needles once through a vial stopper and once through skin mimic to quantify penetration and friction forces.

Materials:

Instron model 4466 with 25 N capacity load cell
Polyurethane Rubber Film (McMaster-Carr, #1446T41, 0.03" (0.76 mm) thickness, Shore hardness 85A)
2 washers, 1" (25.4 mm) ID
Clamps
Testing rig
Microscope
Glass vial, 20 ml, 20 mm diameter top
Vial stopper, 20 mm, gray butyl (Shore hardness 40A)
Vial stopper ring (20 mm, flip-off)

Procedure (in accordance with DIN 13097 Appendix C; Sherwood Medical Test Protocol: Insulin Needle Penetration)

1. Mount the 25 N load cell and needle hub fixture onto the Instron. Plug the load cell into the Instron.
2. Clamp the test rubber between two washers.
3. Load the clamped washers and rubber into the testing rig.
4. Load a vial with stopper in the base of the Instron directly beneath the load cell. Make sure that the rubber is perpendicular to the direction of the needle.
5. Inspect the needle prior to the test. Examine the surface under a magnification of 60x, and note any defects. Do not use the needle if defects visible without magnification are present, such as bent tip or bent cannula. Take a picture of the needle under magnification, and record the initial state of the needle.
6. Load the needle into the fixture on the 25 N load cell in the Instron. Be sure not to overload the load cell.
7. Visually inspect the tip of the needle to assure that you have not dulled the tip or bent the cannula.
8. Run the Instron so the needle penetrates the rubber in the vial stopper at a speed of 100 mm/min. Stop the test before the needle contacts the bottom of the vial.
9. Record the force required for both penetration and frictional forces.
10. Inspect the tip under magnification and record any changes from before the test. Look for tip damage and rubber in the needle hole. Take a picture of the needle.
11. Load the testing rig in the base of the Instron directly beneath the load cell. Make sure that the rubber is perpendicular to the direction of the needle.
12. Run the Instron so the needle penetrates the skin mimic rubber in the center of the washers at a speed of 100 mm/min.
13. Record the force required for both penetration and frictional forces.
14. Inspect the tip under magnification and record any changes from before the test. Look for tip damage and rubber in the needle hole. Take a picture of the needle.

15. Inspect the rubber around the hole for the shape, inspecting under magnification, and record findings.
16. Keep at least ¼" (6 mm) between punctures of the rubber to ensure that the rubber is not compromised in the location of the puncture.
17. Repeat with a steel needle of the same size, and compare the results.

Stiffness Testing Protocol

Objective: To determine the stiffness of the tubing and the deflection when placed under a load perpendicular to the length of the needle.

Materials:

Instron with 25N load cell
Testing rig
Microscope

Procedure: (in accordance with ISO 9626 Appendix C)

1. Inspect the needle prior to the test. Examine the surface under a magnification of 60x, and note any defects. Do not use the needle if defects visible without magnification are present. Record the initial state of the needle.
2. Place the needle as indicated on the appropriate testing apparatus with the correct span and locations.
3. Lower the plunger at a speed of 1mm/min until the appropriate bending force is achieved, as indicated in the ISO document.
4. Remove the needle from the apparatus. Measure the resulting deflection of the tubing. Inspect the needle under magnification, and record any damage.

Resistance to Breakage Testing Protocol

Objective: To determine the needle's resistance to breakage through repeated alternating perpendicular loads, causing a specified repeated deflection.

Materials:

Instron with 25N load cell
Testing rig
Microscope

Procedure: (in accordance with ISO 9626 Appendix D)

1. Inspect the needle prior to the test. Examine the surface under a magnification of 60x, and note any defects. Do not use the needle if defects visible without magnification are present. Record the initial state of the needle.
2. Fix one end of the needle into the base of the Instron so that it is extending horizontally.
3. Apply a force to the free end so that it bends 25° from its initial position. Record the force.
4. Apply this force in the opposite direction, creating a 50° included angle.
5. Complete 20 cycles at 0.5 Hz.
6. Remove the needle from the apparatus. Examine the needle for breakage under magnification. Record any damage found.

Additional Tests

Vial stopper fragmentation testing procedure

To be performed in accordance with ISO 7864:1993(E), Appendix B; DIN 13097 Appendix B

Bond between hub and needle tube

To be performed in accordance with ISO 7864:1993(E), section 13.1

Patency of lumen

To be performed in accordance with ISO 7864:1993(E), section 13.2

Other tests may need to be run on the material, depending on whether it is approved for the specific application. These are outlined in ISO 7864 and ISO 9626