RESEARCH REPORT

PORK SAFETY

Table: Developing Standardization Procedures and Conducting Product Testing for Veterinary-Use Hypodermic Devices, PHASE II – **NPB 01-151**

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Phase II Project Objectives

The project objectives for Phase II were;

1. Investigate needle sharpness retention versus repeated use on all gages and manufacturers of needles tested during Phase I, and,

2. Using representative needle fragments from all 18 and 16 gage needles tested in Phase I, determine needle detectability as a function of needle fragment size and orientation embedded in a consistent cut of pork as it passes through a metal detector used commonly in packing plants.

The results from this Phase II project along with the completed Phase I results will provide a complete Aconsumer=s-report@ statement of the strength, failure mode, sharpness, and detectability for most all manufactured veterinary-use needles used in the swine industry today.

Materials and Methods

The following documents the procedures used for testing both sharpness retention and needle fragment detectability.

<u>Sharpness Testing</u>

Sharpness retention was tested using the test stand developed for static strength analysis for Phase I testing. The specific apparatus used for testing is shown in Figure 1.

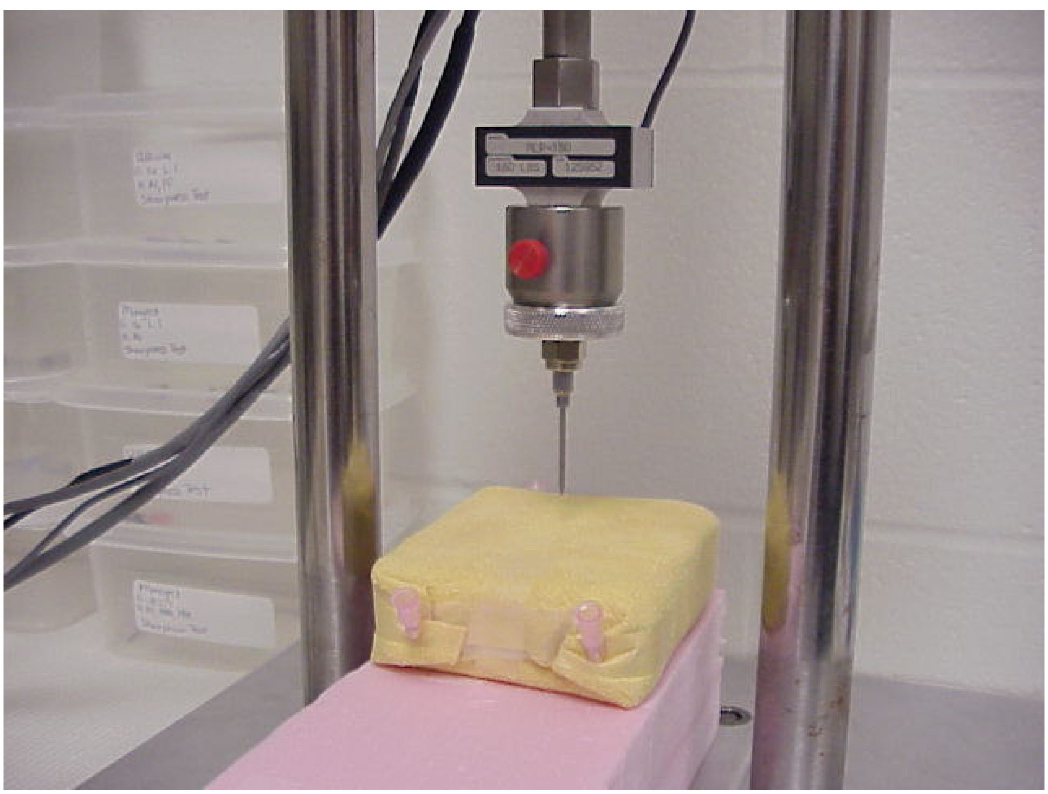


Figure 1. Test stand arrangement used for sharpness testing

New fittings were built for this test stand to accommodate a vertical orientation of a needle. The medium used for evaluating the relative trend in needle sharpness consisted of two layers of chamois over a 1.0 inch piece of high-density rigid insulation board. The needle was allowed to penetrate into this arrangement 1 mm beyond the furthest cut-point of each needle.

Originally, a device constructed specifically for conducting field testing for sharpness was to be used on fresh pig cadavers, but this method proved to be much too variable relative to the method in which a user injects an animal. Several test cases using this device were made on the medium shown in Figure 1 but it was decided that the small force changes due to sharpness reduction were being masked by the variability in injection technique.

Therefore, it was decided to incorporate the apparatus shown in Figure 1 which provided for a consistent injection motion, direction, speed, and puncture depth relative to the bevel cuts unique to each needle tested.

To test needle sharpness retention, a needle was fitted into the test stand shown in Figure 1. Measurements were made of the distance that the needle had to travel to imbed the needle to a point 1 mm beyond the furthest cut-point of the needle. The software controlling needle motion was programmed for this distance to provide consistency in this travel distance. In addition, the needle was instructed via the software control program to puncture 30 repetitions. By hand, the operator moved the puncture medium to a new puncture location for each of the 30 punctures. In this way, each of the 30 punctures by a single needle punctured the medium in a new location. The data acquisition equipment developed for this test stand recorded the loading curve for each of the 30 punctures from which data analysis could be conducted. This testing was conducted for each Phase I needle, by gage and hub material.

Detectability Testing

Detectability testing was conducted using a state-of-the-art metal detector rented from Safeline, Inc. The detector used is shown in Figure 2.

Figure 2. Safeline, Inc *Power Phase* metal detector used to conduct needle detection testing

Detectability testing was conducted for all 18 and 16 gage needles tested during Phase I, by manufacturer and hub material. Needle fragments of ½ and 1 inches were tested and three orientations of each combination were tested. The three orientations conducted were;

Horizontal Back (HB): Needle fragment horizontal in the meat and imbedded in the back of the meat (last to go through the detector) perpendicular to the long axis of the detector.

Horizontal Side (HS): Needle fragment horizontal in the meat and imbedded in the side of the meat parallel to the long axis of the detector.

Vertical Center (VC): Needle fragment vertical in the meat and imbedded in the center of the meat.

The detector had an automated set-up feature that eliminated the effect of the product itself. In other words, if a relatively consistent cut of meat is traveling through the detector at the plant, the detector could be set-up to "correct" for this meat product allowing only fragments of detectable metal to be detected by the machine. This feature was used for all testing which allowed for a consistent method of eliminating the product and concentrating only on the needle fragments alone. The machine could have been further refined for each individual cut of meat, but this would have introduced user bias into the results and thus was not incorporated for this study.

Standard cuts of pork shoulder roasts were purchased from a local grocery store before each testing session. Meats in the range of 3.48 to 3.74 lbs were used in this study. For each test conducted, standard full-size needles were randomly selected and assigned to be either a ½ or 1 inch test and cuts of the needle were made accordingly, leaving the bevel end for testing. The needle was imbedded into the meat at one of the three orientations listed above to a point where the end of the needle was level with the meat outline. This needle fragment was then tested for 15 passes through the detector at each of the three orientations listed above. Four replications were conducted for each of these combinations.

Preliminary Results and Discussion

The following documents the preliminary results for both sharpness retention and needle fragment detectability. The results are preliminary in that not all of the data has been fully analyzed.

Sharpness Testing

Sharpness retention results showed, in most cases, a clear trend of increasing puncture force with repeated use, up to about 10-15 punctures at which point the forced required to puncture the test media leveled off to a relatively constant value. Figure 3 below gives a good indication of a typical needle sharpness test.

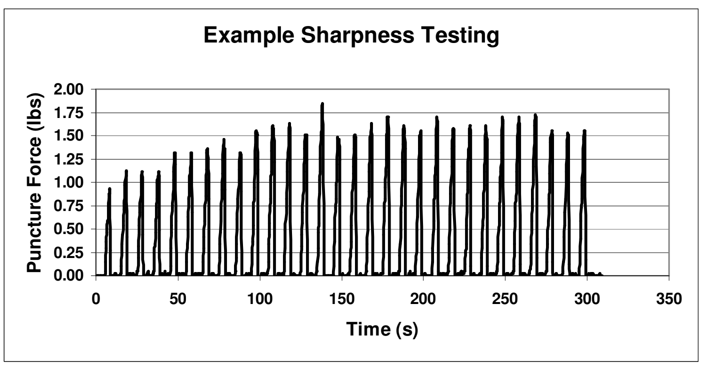


Figure 3. Example plot of 30 punctures and the resulting trend recorded in puncture strength as a function of repetition for the test set-up shown in Figure 1

Figure 3 shows the trend of 30 repeated punctures in new areas of the puncture media in time. There existed in this example result, and most all that were conducted, a gradual trend of increasing puncture force, representing a decrease in sharpness, up to about 12-14 punctures. This trend was fairly consistent throughout testing. The sharpness data has not been fully analyzed yet so final conclusions can not be drawn but the trend is that after about 15 punctures the puncture forced peaked and remained fairly consistent for the remaining punctures. An example of this trend with the additional variable of needle gage is shown in Figure 4. Figure 4 summarizes the puncture force and sharpness retention for a single manufacturer as a function of gage. As expected, the higher the gage, the less the puncture force and this is especially evident if one compares the 22 versus 16 gage plots. Also, the puncture force increases quite dramatically for the first few punctures until an upper limit average is reached, occurring after about 15 punctures.

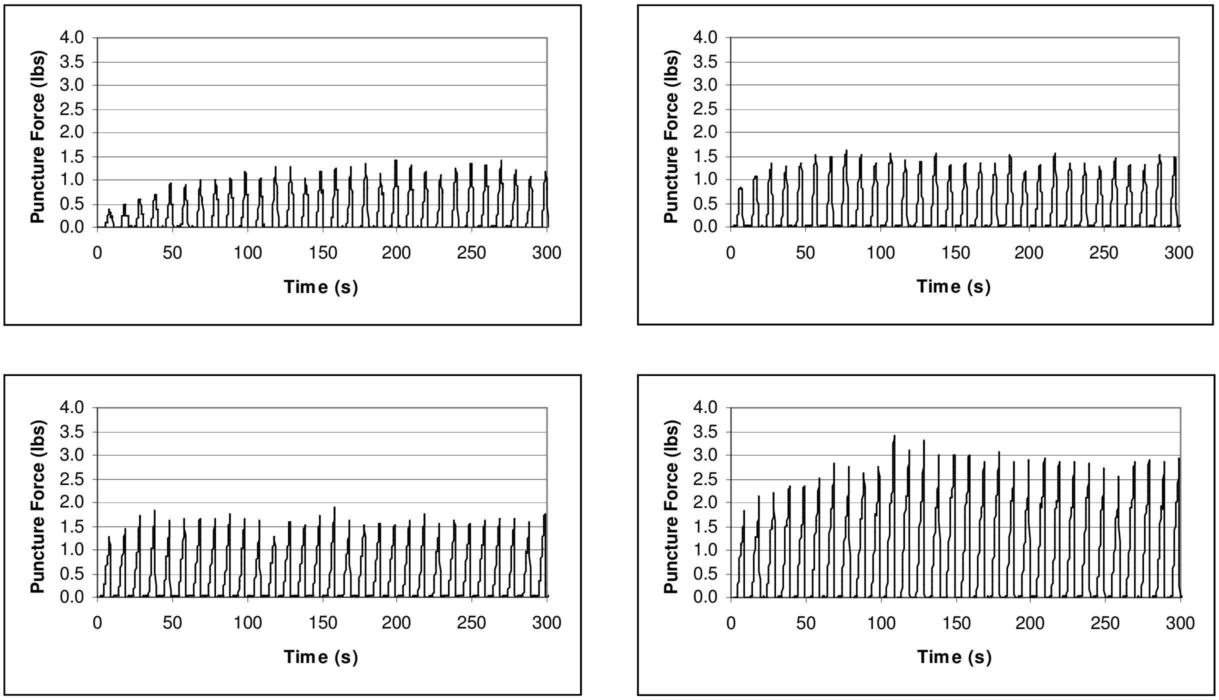


Figure 4. Example sharpness testing result for a single manufacturer and the effect of gage on puncture strength and sharpness retention. (a) 22 gage, (b) 20 gage, (c) 18 gage, and (d) 16 gage.

What has been become more interesting is the relatively large differences in puncture force recorded between manufacturers. As an example, Figure 5 shows the differences between two manufacturers (right side versus left side) and by gage (16, 18, 20, and 22) respectively. For the manufacturer shown on the left, the maximum puncture force measured was 1.5, 1.1, 0.8, and 0.6 lbs for gages 16, 18, 20, and 22 respectively. For the manufacturer shown on the right, the maximum puncture force measured was 3.5, 1.8, 1.6, and 1.5 lbs for gages 16, 18, 20, and 22 respectively. Clearly, the bevel design between these two manufacturers resulted in vastly different puncture forces required. It is interesting to note also that the manufacturer with the highest puncture force throughout had a clear trend of increasing puncture force with increasing punctures.

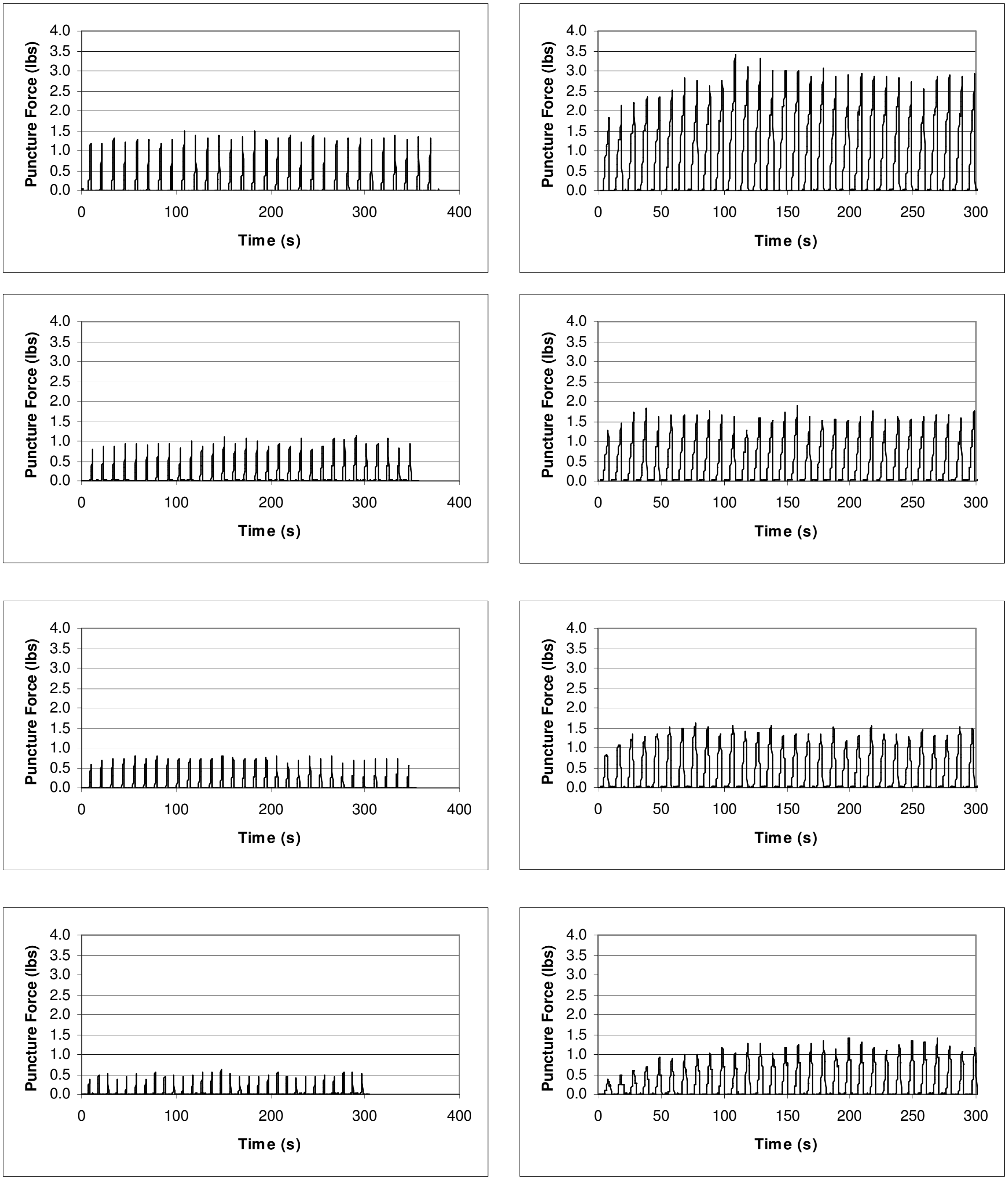


Figure 5. Differences found in puncture force for two manufacturers (left versus right) organized by gage from top to bottom as 16, 18, 20, and 22 gage respectively.

Detectability Testing

Needle fragment detection testing results are currently summarized in 19 various categories, called "cases". These 19 cases are defined below:

Case	Summarized Results
1	All Tested 18 and 16 ga Needles
2	All Currently Used Needles*
3	All Air-Tite and PDN Needles**
4	All Monoject Needles
5	All Allison Needles
6	All Jorgenson Economy Needles
7	All Jorgenson Harvard Needles
8	All Jorgenson Henke Needles
9	All Super Vet Needles
10	All Air-Tite Needles
11	All PDN Needles
12	All 18 ga Needles
13	All 18 ga Currently Used Needles*
14	All 18 ga ½" Needle Fragments
15	All 18 ga 1" Needle Fragments
16	All 16 ga Needles
17	All 16 ga Currently Used Needles*
18	All 16 ga ½" Needle Fragments
19	All 16 ga 1" Needle Fragments

*Currently used needles are those that have been commonly used in practice (excludes Air-Tite and PDN needles)

**Needles excluded from "currently used" list of products

A summary of the results for these 19 cases is given in Table 1 and Figure 6.

Table 1. Percent detection by "case"

		Orientation		
Case	HB	HS	VC	Combined
1	41.2	15.7	18.0	25.0
2	30.5	5.0	7.0	14.2
3	86.4	60.7	64.3	70.5
4	36.7	4.4	8.0	16.4
5	23.0	0.0	0.0	7.7
6	35.7	21.4	21.4	26.2
7	33.3	2.8	2.8	13.0
8	20.0	0.0	0.0	6.7
9	33.3	8.3	16.7	19.4
10	76.3	31.3	37.5	48.3
11	100.0	100.0	100.0	100.0
12	35.0	8.7	11.7	18.4
13	29.1	4.3	6.4	13.3
14	33.3	9.5	11.9	18.3
15	36.8	7.7	11.4	18.7
16	48.8	24.2	25.6	32.9
17	32.4	6.0	7.7	15.4
18	37.0	18.2	18.2	24.4
19	60.6	30.3	32.9	41.3

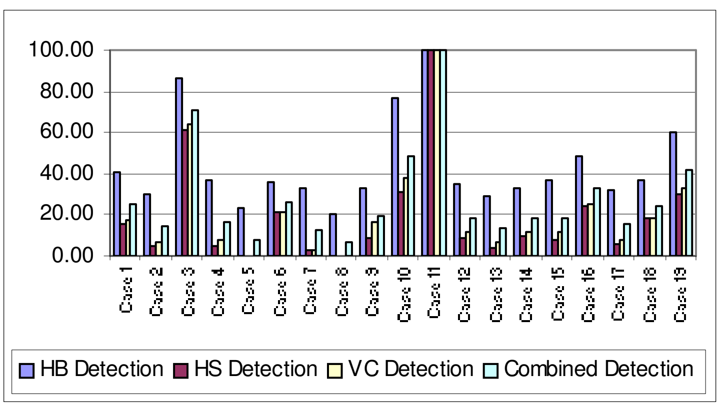


Figure 6. Summary graph of percent detection for the 19 cases summarized

There is a very clear trend that the HB orientation through the detector resulted in significantly more detections for both the ½ and 1 inch needle fragments. In most cases, these detections were from 1.5 to 10 times higher. Comparing HS and VC detections, these were both consistently nearly the same but nevertheless far less than the HB detections, except for the PDN needles which were 100 percent detectable in all orientations, for both gages and needle fragment lengths.

Figure 7 summarizes the trend between manufacturers. Clearly, large differences exist in detecting needles that originate from different manufacturers. Two of the manufacturers tested, Air-Tite and PDN, had detection levels that far exceeded the other manufacturers. One manufacturer, PDN, had a 100 percent detection level regardless of fragment length, gage, or orientation.

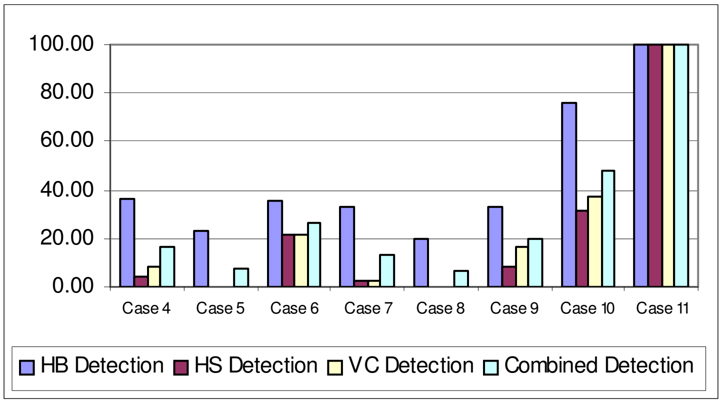
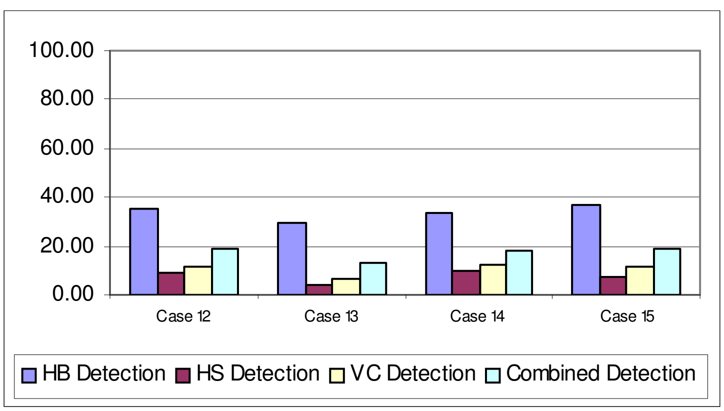


Figure 7. Summary graph of percent detection for each of the individual manufacturers

Figure 8 summarizes the trend between needle gage. Figure 8a summarizes the detection level for all 18 gage needles tested and Figure 8b summarizes the detection level for all 16 gage needles tested.



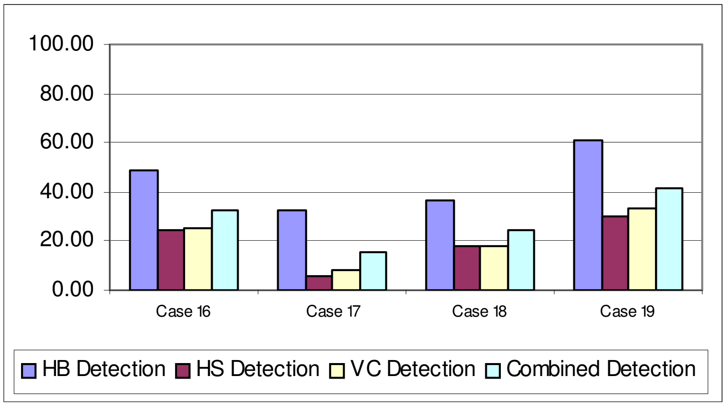


Figure 8. Detection percentages for all (a) 18 gage and (b) 16 gage needles tested.

Comparing the combined detection results, cases 16 and 19 exhibited a clear trend where the 16 gage needles had a higher detection percentage versus 18 gage needles, where cases 17 and 18 had nearly identical combined detection percentages regardless of the gage.

Figure 9 summarizes the detection percentages for all manufacturers needles for the data set containing their 18 and 16 gage needles as affected by needle fragment orientation. Figure 9a compares detection for the HB orientation, Figure 9b compares detection for the HS orientation, Figure 9c compares detection for the VC orientation, and Figure 9d compares detection for all three orientations combined. Clearly, a needle orientation that is horizontal and perpendicular to the long axis of the detector (HB) had the highest chance of being detected. Detection percentages ranged from a low of 20 percent (case 8) to a high of 100 percent (case 11). Except for cases 10 and 11, all other cases resulted in an HB detection percentage at or below 38 percent. When the needles were oriented horizontal and parallel to the long axis of the detector (HS) or vertical (VC), the detection percentages fell off sharply, except for cases 6, 10, 11. Except for these three cases, detection percentages ranged from a low of 0 percent (cases 5 and 8) to a high of 18 percent (case 9). In these orientations, case 11 was 100 percent detectable with case 10 at 32 percent, and case 6 at about 21 percent. With all of the orientations combined in one set of data (Figure 9d), the overall detection percentages ranged from a low of 6 percent (case 8) to a high of 100 percent (case 11).

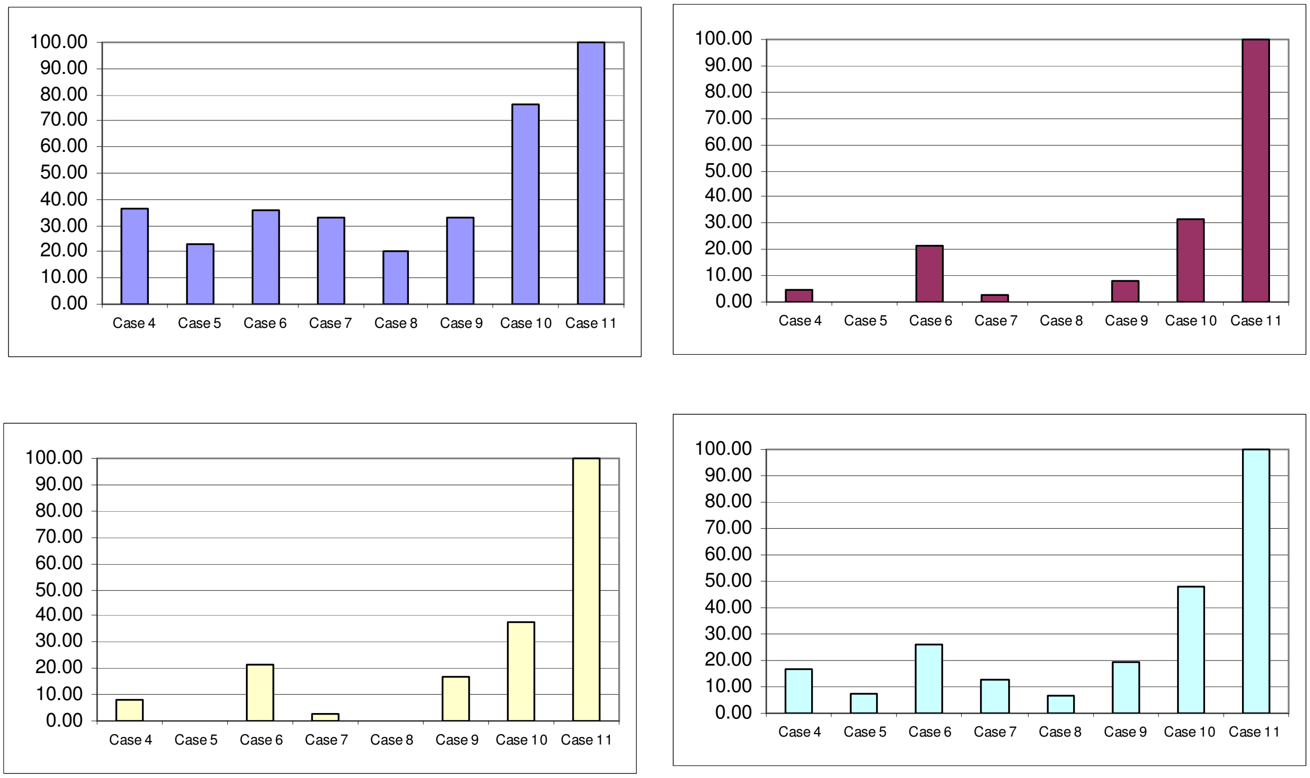


Figure 9. Detection percentages compared for each manufacturer tested at the (a) HB orientation, (b) HS orientation, (c) VC orientation, and (d) all orientations combined.

Summary of Findings

In terms of needle sharpness, small trends were found for some of the needles tested that indicated a certain level increasing puncture force with repeated use, especially with needles that consistently resulted in the highest puncture force. Very large relative differences, on the order of three to four times, were found between puncture force characteristics between manufacturers, and these appear to be consistent gage-by-gage. For those needles that showed a clear trend of increasing puncture force with repeated use, the trend tended to level off to a consistent value after about 12-15 punctures.

Needle detection results indicated vast differences between manufacturers in the ability to detect needle fragments of ½ and 1 inch. Orientation of the needle as it passes through the detector was a large factor, except for the PDN needle that was always detected regardless of orientation. If the needle was horizontal and perpendicular to the long axis of the detector, a much better chance of detection was found. If the needle was vertical or horizontal with the needle parallel to the long axis of the detector, a much lower chance of finding the needle existed. Pooling all needle fragments, orientations, and gages together and grouping by manufacturer, indicated that a range of detection between 6.7 and 100 percent was measured. For the needles most predominantly used today in the market place (excludes cases 10 and 11), the range of detection was between 6.7 and 26.2 percent. The average detection level for all predominantly used needles (cases 4 to

9) was 14.9 percent (average of combined results). If all of the predominantly used needles today (cases 4 to 9) entered the detector either vertically or horizontal and parallel with the detector axis, the range of detection would be from 0 to 21.4 percent, or an overall average of 7.2 percent detection.