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Determination of Needle Size Based On Measurements of Punctures in Pharmaceutical Vial Stoppers

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The US Food and Drug Administration's Forensic Chemistry Center (FCC) analyzes a wide variety of FDA-regulated products, including those that are suspected of having been tampered. The FCC is frequently summoned to examine pharmaceutical vials for evidence of tampering and illegal manipulation. With the rise in the abuse of controlled substances, there has also been an increase in the theft of pharmaceutical products by health care workers. One analytical approach is to look for punctures in the rubber vial stoppers, which might indicate that a hypodermic syringe needle was used to access the contents.

Previous research, which was a result of collaboration between the FCC and the Indiana State Police Laboratory, developed a method for the determination of syringe needle punctures in rubber vial stoppers using stereoscopic light microscopy (1). In addition to the method, this research showed that punctures produced by trocar-style hypodermic needles usually resemble one of two characteristic shapes (Figure 1). The method developed from this research has become the official procedure used by the FCC for analysis of suspected punctures.

Often, investigators request the laboratory analysts to determine the size of the needle that was used to create the puncture, and this information may help provide an investigative lead or corroborate a witness's or suspect's statement. Preliminary research explored the relationship between needle size and puncture size, using both light microscopy and Scanning Electron Microscopy (SEM) over a wide range of needle sizes (2). The needles were inserted into rubber stoppers at a 90 degree angle to the stopper surface, and punctures were examined on both the top and bottom stopper surface. Results of this research indeed found a correlation between the needle size and puncture size (Table 1), and also described another characteristic shape of trocar-style hypodermic needle punctures (Figure 2). Further, it was determined that measurements of the puncture on the bottom surface of the stopper were more precise than those from the top surface, and that there was no significant difference between measurements made using a digital light microscope and an SEM.

As a continuation of previous research, we present a more robust examination of many commercially-available needle sizes, to include sizes that were not initially examined. Further, real world use of needles prompts an examination of the effect on puncture size when the angle of needle insertion is varied. Here we will present our findings which will include the range of measurements of punctures at extreme angles and their correlation to needle size.

References:

1. S. F. Platek *et al*. J Forensic Sci 2002;47(5):986-992.
2. S. F. Platek and S. L. Kremer. Presentation SPIE – Scanning Microscopies 2014: Monterey, CA, September 17, 2014.

Figure 1. Characteristic shapes of punctures produced by trocar-style hypodermic needles. This image, taken using a light microscope, shows both the “bird in flight” and “smile” shaped characteristic punctures.

Needle Gauge	Sigma/ Aldrich Needle OD (mm)	Digital Calipers Needle OD (mm) $\bar{x}$ (n=5)	DLM Needle OD (mm) $\bar{x}$ (n=5)	DLM Top-Horizontal Puncture OD (mm) $\bar{x}$ (n=20)	DLM Bottom-Horizontal Puncture OD (mm) $\bar{x}$ (n=20)	SEM Top-Horizontal Puncture OD (mm) $\bar{x}$ (n=20)	SEM Bottom-Horizontal Puncture OD (mm) $\bar{x}$ (n=20)
16	1.65	1.63	1.63	1.2860	1.1569	1.1726	1.1504
20	0.91	0.88	0.89	0.6895	0.5733	0.7115	0.5479
21	0.82	0.76	0.82	0.6263	0.5430	0.6386	0.4638
22	0.72	0.68	0.71	0.5660	0.4821	0.5718	0.4792
23	0.64	0.63	0.63	0.5111	0.3868	0.5241	0.3839
25	0.51	0.50	0.51	0.3775	0.2944	0.3917	0.2947
27	0.41	0.38	0.40	0.2757	0.2485	0.2877	0.2347
28	0.36	0.33	0.36	0.2710	0.2086	0.2495	0.2056
29	0.34	0.32	0.33	0.2652	0.1762	0.3059	0.1777
30	0.31	0.30	0.31	0.1646	0.1560	0.1712	0.1634

Table 1. Puncture measurements compared to needle gauge/size. This table shows the comparison between needle gauge/size, average measured puncture size on the top and bottom surface of the stoppers, and measurements taken using digital light microscopy and SEM.

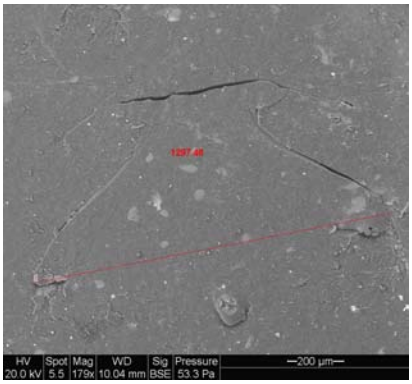

Figure 2. SEM image of a puncture produced by 16 gauge needle. This SEM image shows a newly described characteristic “pi” shape of punctures produced by trocar-style hypodermic needles and the measurement end points.

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