The Effect of Temperature, Needle Gauge and Wall Thickness on the Force Required for Needles to Puncture Sharps Containers

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Abstract
Healthcare workers sustain sharps injuries in many ways including via needles penetrating sharps containers (SC). Little published data exists on the parameters affecting SC puncturing. This study examined the effect on puncture force of varying 5 needle gauges, three temperatures and three container wall thicknesses. Puncturing was significantly easier with higher temperatures, finer needles and thinner walls. Puncture forces as low as 5.2N indicate that with high temperatures and finer needles, 44% of containers would not meet the 15N required by ISO. Tougher puncture testing procedures need be considered as modern engineering and technology now enable safer SC to be produced.

Introduction
Despite the introduction of safety engineered devices (SED) and implementation of administrative and workplace controls, accidental sharps injuries (SI), with their potential for exposure to bloodborne pathogens, are still occurring among healthcare workers (HCW).[1,2] One subset of these injuries occurs to HCW when needles penetrate the sharps containers (SC) in which they have been disposed. For every thousand sharps injuries reported by HCW, the reported incidence of container puncture injuries (CPI) ranges from 1.4 (USA),[1,2] 2.0 (UK),[3] 4.0 (Canada)[4] and 12.6 (Japan)[5]. In the United States this equates to at least several hundred HCW sustaining a sharps injury from punctured SC annually. Reports of CPI to the US FDA show these injuries may occur when HCW grasp, handle, change, carry, manipulate, lean on, tap or use excess force to insert a sharp into a SC.[6] Commonly, the HCW injured is not the original user of the sharp.[6]

Sharps container standards attempt to limit needle penetration by requiring SC to have a specified puncture resistance when tested with a specified needle gauge at a specified temperature.[7-9] HCW trust that using SC certified to a standard will protect them from CPI however the above Injury rates indicate the protection is falling short of that needed.

Puncture tests were first standardized in 1990 when SC were required to resist a force of 12.5 N applied to a 21G needle at room temperature.[7] This did not eliminate CPI,[3] and the 2012 ISO standard increased this force to 15N [8] and in 2013 Canada adopted the ISO standard but increased the force to 20N.[9] In the deliberations as to what puncture force value should be adopted, it became apparent to technical working group members on many standards that there was no published research on the parameters affecting puncture forces. To this end, this study investigated the effect of temperature, needle gauge and SC wall thickness on the force required for a hypodermic needle to puncture SC.

Method

This study measured the force in Newtons (N) required for hypodermic needles to pierce four disposable SC made of polypropylene (PP) or high density polyethylene (PE) and varying in wall thickness. The SC were sourced from Italy, USA, Australia and UK and ranged in size from 1.8 to 4L.

For each SC, six penetration repetitions were conducted for each of five needle gauges (21G, 23G, 25G, 27G and 30G) and three different temperatures (13^{o}C, 23^{o}C, 43^{o}C) - with the higher temperature being tested with 21G and 30G needles only. The three temperatures were chosen to represent: temperate environments (23^{o}C) as recommended in current SC standards;[8,9] high latitude and high altitude environments (13^{o}C); and warmer world regions (43^{o}C) as per ECRI recommendations.[10]

Penetration was measured using ECRI methodology.[10] In summary, samples of each SC were cut out and placed on a rigid horizontal surface in which a hole was drilled for needle clearance. The supported needle was descended at right angles to the sample at a rate of 100 mm per minute. The maximum force at which the needle fully penetrated the sample was recorded using a Chatillon DFM 50 force gauge (Ametek, Largo FL USA). New needles were used for each sample test. All results were statistically compared using standard t-test as calculated using Microsoft Excel, with significance set at $p \leq 0.05$

Results

A total of 288 puncture tests were performed. Of the four SC investigated, two SC made of PP had wall thicknesses of 1.9 mm, one SC (PE) had walls of 2.4 mm thickness and the fourth SC (PP) had walls of 2.9 mm thickness. The average puncture force (all needle gauges, all temperatures) for the EU and USA 1.9mm PP SC was 16.8 and 18.2N respectively however their penetration force values were not significantly different across the spectrum of tests and the results for these two containers were combined. Averaging all needle gauge sizes and all temperatures, the results with the 2.9 mm PP SC was significantly higher than the 1.9 mm PP results ($p < 0.001$) and the 2.4 mm PE results ($p < 0.001$). The 1.9 mm PP results, although lower than those with 2.4 mm PE, were not significantly different ($p = 0.06$).

Higher temperatures, finer needles and thinner container walls lessened the puncture resistance of the SC. (Table 1). Of the 36 combinations, 12 (33%) had one or more repetition results less than 15N and 21 (58%) had one or more repetition results less than 20N (Table 1). Extrapolation using a trendline at 43^{0}C in Figure 1 to estimate results using 23G, 25G and 27G needles, indicates that 44% of replicates would have results <15N, and 67% would have results <20N.

Table 1. Mean (range) of force (N) required for penetration of sharps containers (p values shown in comparison with next largest bore needle to left)

Temperature, wall thickness and polymer		Needle gauge				
		21G	**23G**	**25G**	**27G**	**30G**
13^{o}C	**2.9 mm PP**	54.9 (51.6-60.0)	42.5 (38.6-47.2) p < 0.001	31.7 (29.8-35.6) p < 0.001	23.7 (22.0-26.6) p < 0.001	14.7 (13.4-15.8)*^ p < 0.001
	2.4 mm PE	32.0 (30.4-34.4)	27.9 (21.0-30.6) p = 0.03	24.5 (21.6-25.8) p = 0.06	18.2 (16.2-18.4)^ p < 0.001	13.4 (11.8-15.4)*^ p < 0.001
	1.9 mm PP	30.0 (27.0-33.3)	27.3 (25.8-31.0) p = 0.009	21.6 (20.4-23.0) P < 0.001	17.5 (15.8-20.0)^ P < 0.001	12.4 (10.4-14.4)*^ P < 0.001
23^{o}C	**2.9 mm PP**	42.5 (39.2-46.4)	34.0 (30.4-36.4) p < 0.001	24.0 (23.2-25.2) p < 0.001	19.1 (18.0-20.6)^ p < 0.001	12.6 (11.2-13.8)*^ P < 0.001
	2.4 mm PE	29.8 (28.6-30.8)	22.5 (19.6-24.6)^ p < 0.001	18.0 (16.8-18.6)^ p = 0.002	15.0 (14.4-15.6)*^ p < 0.001	9.7 (9.2-10.4)*^ p < 0.001
	1.9 mm PP	21.5 (19.8-23.2)^	19.2 (18.4-19.8)^ p < 0.001	16.7 (15.4-17.6)^ p < 0.001	13.7 (12.6-15.2)*^ p < 0.001	9.1 (8.0-10.6)*^ p < 0.001
43^{o}C	**2.9mm PP**	29.8 (29.0-31.8)	NT	NT	NT	8.4 (7.6-9.2)*^ p < 0.001
	2.4 mm PE	15.7 (15.2-16.2)^	NT	NT	NT	6.8 (6.2-7.0)*^ p < 0.001
	1.9 mm PP	15.0 (13.8-15.8)*^	NT	NT	NT	6.2 (5.2-6.8)*^ p < 0.001

N Newtons; G gauge; PP Polypropylene; PE High Density Polyethylene; p Probability.
*Tests results below 15N; ^Test results below 20N:

The effect of higher temperatures on the ease with which needles puncture container walls was consistent across all needle gauges (Figure 1) and container wall thicknesses (Figure 2). SC walls were more easily penetrated by finer needles than by wide-bore needle. Results indicated that for each container type the mean force required for wall penetration was lower with increasing needle gauge, irrespective of whether the tests were conducted at 13^{o}C, 23^{o}C or 43^{o}C (Figure 1).

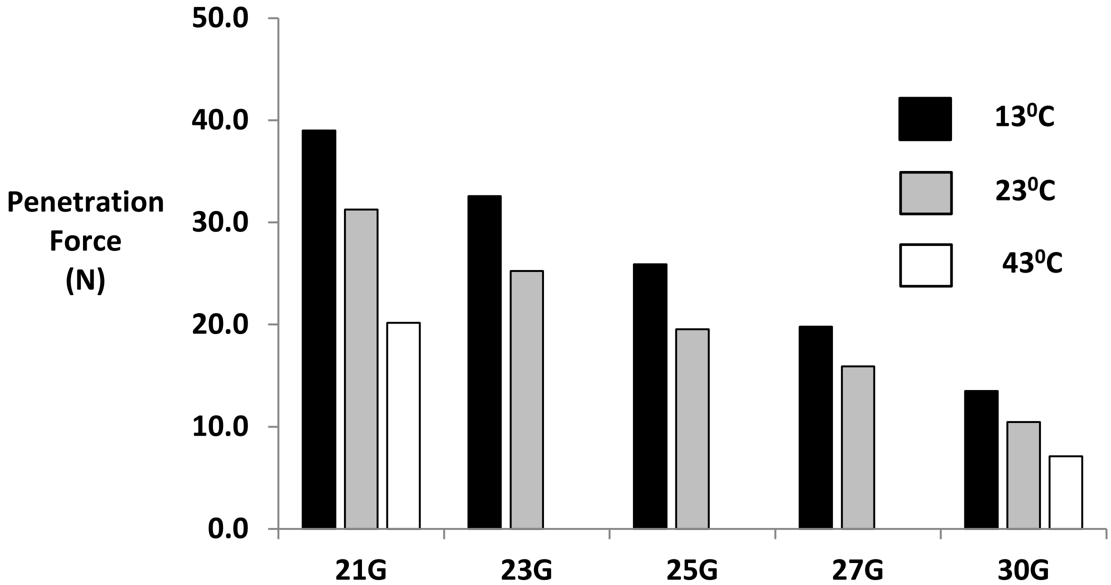

Figure 1. The effect of temperature on the ease of puncturing sharps containers with needles of different gauges (average of all wall thicknesses).

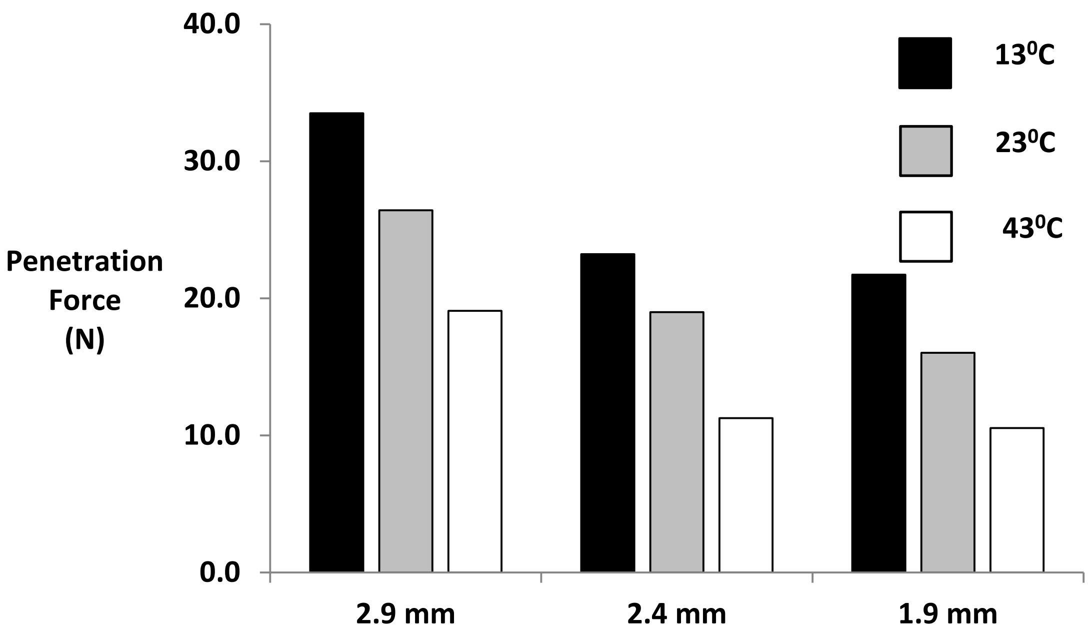

Figure 2. The effect of temperature and container wall thickness on force required to puncture sharps containers (average of all needle gauges).

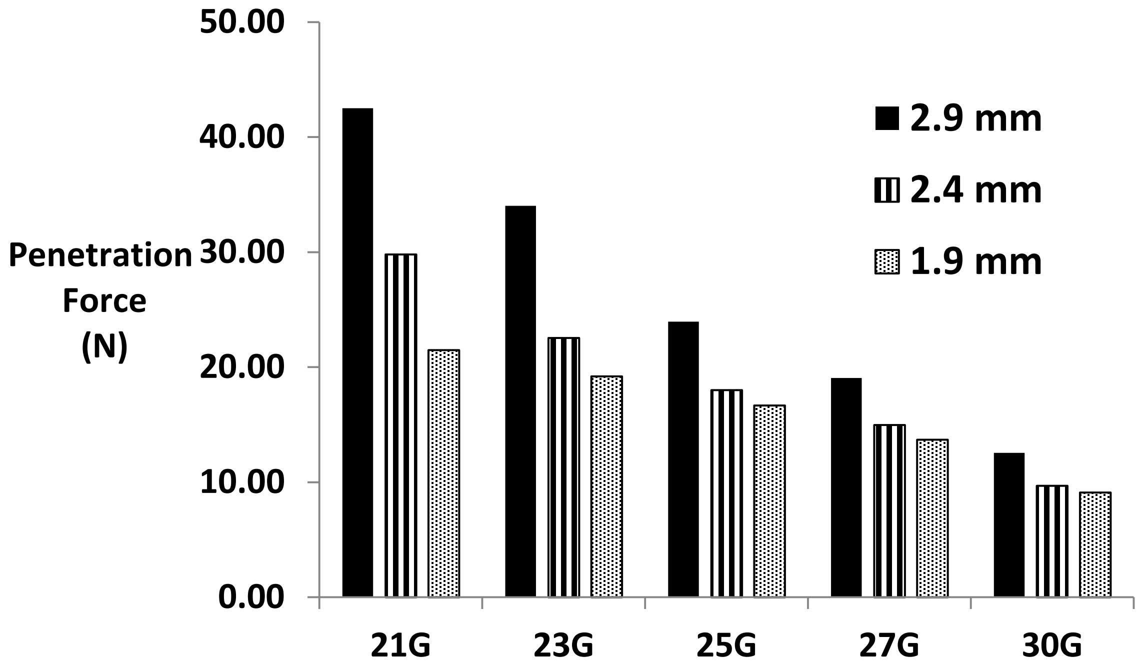

Figure 3. The effect of needle gauge on puncture resistance of three container wall thicknesses at 23°C.

At 23°C, the finest needles (30G) required 58% to 70% less force than 21G needles to puncture the SC walls, with the relationship of puncture force and needle gauge being almost linear for all three wall thicknesses (figure 3).

Discussion

The range of needle gauges (21G to 30G) was chosen because 21G is the gauge currently required in national and international sharps container standards [7-9] and (in 2009) 21G-30G encompassed 66% of all needles used in USA hospitals and alternate sites[11] and 82% of needles used in UK hospitals.[12] Sharps container sizes under 4L were used for testing as sharps containers under 5 L represent 63% of the penetration SI reported to FDA since 2002 and 1 L is the most common size implicated in CPI.[6] The inclusion of three container-wall thicknesses was to illustrate the range of SC wall thicknesses seen in SC less than 4L.

Effect of Higher Temperatures

With higher temperatures resulting in easier container wall puncturing by needles, there are implications for the handling of SCs and also for the standards currently used for puncture resistance tests. The necessity to store and transport full SC outside healthcare facilities (HCF) means they could encounter higher temperatures than an 'ambient' 23°C. Containers transported or left in vehicles in the sun, or those used in non-air-conditioned healthcare facilities in warmer countries, may be handled at temperatures considerably higher than 23°C. In addition, in developing countries where fewer safety engineered devices (SED) are employed, the effect of temperature increases the risk of CPI from non-SED and SED for which the safety mechanism (needle shielding) has not been activated by the user (both devices are always 'sharp' at disposal). In this study, SC penetration tests conducted at 43°C showed penetration with fine needles could occur with a force as low as 5.2N. With an estimated 44% of all results being <15N, this indicates that 4 out of every 9 containers are able to be punctured at 43°C at forces below that required in 15N standards, and 6 out of 9 would be punctured at forces less than that required in 20N standards. The study results indicate that testing (only) at 23°C is inadequate for assessing puncturability in warmer regions. The ECRI recommends additional SC puncture-testing be conducted at 43°C to cater for such regions[10] and it would be fitting for all national standards to recommend testing at higher temperatures.

Effect of Finer Needles

At 23°C, two-thirds of penetration force tests with 27G needles and all tests using 30G needles produced values that were <15N. Of note is that even at 13°C, none of the SC met a 15N or 20N standard with a 30G needle. In speaking with HCW internationally, the author has ascertained that HCW commonly believe that a thicker gauge needle (i.e. a 'stronger' one) will puncture SC more easily, but these study data show that the opposite is the case. Finer needles penetrate SC walls more easily than wider bore needles, irrespective of temperature or wall thickness (Figures 1 and 2). In the author's experience, gauges of finer than 21G are more commonly involved in CPI. Needle gauge is rarely mentioned in CPI databases so it is difficult to obtain published data on the gauges involved. Certainly, smaller SC are more frequently cited[6] and the author, in corresponding with the author of a paper on CPI ascertained that needle gauges of 23G or finer were involved.[13] Advances in technology and materials have enabled the development of finer and sharper needles, and because their use lessens pain and trauma to patients their distribution is likely to be widespread and increasing, thus the potential for an increase in CPI is real, particularly in countries with low use of SED.

Standard puncture resistance testing specifies the use of 21G needles,[8,9] and, with the exception of WHO recommendations of 23G,[14] this has not changed since 1990.[7] The 21G may have been adopted because it is the most commonly used needle in UK.[12] However, data presented by SC manufacturers at recent ISO standards SC technical working group meetings shows that in UK hospitals 31% of purchased needles are finer than 21G and in USA hospitals and alternate sites, 60% are finer than 21G. The study showed that using 21G needles at 23°C, all wall thicknesses passed a 15N requirement (1 failed 20N) but with 30G needle at 23°C all failed both 15N and 20N. If 'worst case' scenarios were adopted for CPI elimination, the study results indicate that current testing requirements do not reflect the increased risk of CPI with finer needles. Simply put, 'certified' SC may be easily punctured by a good proportion of the needles used in healthcare.

Effect of Container Wall Thickness (and Polymer)

The study shows that, within the PP containers, the 2.9mm walls were significantly more resistant to needle puncture than 1.9mm walls but as needles become finer the impact of wall thickness lessens (Figure 3).

The overall average results for the 1.9 mm PP and 2.4 mm PE containers were not significantly different (Table 1) and may indicate that polypropylene is more puncture resistant than polyethylene, that is, puncture resistance may be improved by changing polymers and leaving wall thickness unchanged. The effect of polymer quality was not assessed in this study although industry comment indicates this can significantly affect puncture resistance. A dilemma faced by SC manufacturers is that SC standards also require SC to pass drop (impact) tests and the polymer parameters needed to pass impact tests may be at odds with those needed to pass puncture tests.

Cost is another dilemma faced by manufacturers (and HCF) as containers with thicker walls, or higher grade polymers mean increased production costs. With HCF facing reduced financial resources, the cost of HCW safety becomes an important issue and the cost of CPI should be considered when assessing the relative cost of purchasing SC with higher puncture-resistance.

Even with containers certified to a higher penetration requirement, needles can still puncture SC if HCW use or create excessive force in disposing of needles or handling SC.[10] Reports to US FDA confirm excessive force can result in SC puncture but it appears not to be the mechanism in the majority of CPI incidents.[6] The author has ascertained from HCW representatives on standards committees that they do not believe excessive force is a common factor in CPI.

Current Puncture-Test Standards

The ease of needle-penetration of a sharps container is an indirect measure of the risk of container penetration by discarded needles, and in turn, a measure of the potential risk of CPI to HCW.

These results raise the question as to whether the currently employed puncture-resistance tests and standards are suitable for real world requirements or are they falling short in protecting HCW. The study's evidence that higher temperatures and finer needles increase the penetrability of SC suggests that the commonly used standard of '21G at 23^{o}C' may indeed no longer be appropriate.

In 1993 ECRI, in commenting on 15N, stated, *"Even this value should be reviewed in the future and may be adjusted upward as…objective information is obtained."*[10] Jagger in 1995 stated, *"It is possible to eliminate (punctures) by requiring all sharps containers to have high puncture resistance; this is a readily achievable goal*".[15] Two decades have elapsed since these statements yet '15N with 21G at 23^{o}C' remains the norm. Whilst "worst-case scenario" (puncture-proof) SC may be cost-prohibitive, it is clear from CPI incidence rates that penetration tests need be tougher. Based on the study results and discussion above, tougher tests could either use a 21G needle and raise the puncture force, or, retain 15N and specify a finer needle. One or the other is urgently needed. Hopefully the objective information in this study will enable informed discussion on the issue.

The study was limited in that it did not examine multiple polymers or polymer grades and only examined 4 of the many hundreds of small SC available worldwide. Study strengths were in the number of replicate samples tested and the number and range of needle gauges tested and these choices were supported by the linearity of test results over the range of needle gauges, temperatures and wall thicknesses tested.

Conclusion

The current incidence of CPI is unacceptable and with the modern engineering and polymer technology now available to manufacturers, safer SC are possible. Current SC standards need strengthening to give greater protection to HCW as the standards do not accommodate the increasing use of finer and sharper needles or the impact of warmer environments on CPI. The cost of safer SC, as with needle SED initially, is an issue but as with needle SED, these costs must be weighed against HCW safety and the cost of treating SI. Llike SED, the cost of safer SC will decrease with time and uptake. Tougher standards on SED markedly reduced SI;[16] tougher container penetration standards would ensure the same occurs with CPI.

While Clinical Engineering has not traditionally focused on waste disposal bins, this is an area where technical understanding and analysis can contribute to the selection of safer products.

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