

Effect of insulin needle reuse, size and site of injection on the risk of bending and breaking

Theresa Torrance

A retrospective study was conducted using a questionnaire sent to DSNs in the UK to assess reports of needle bending and breakage in people with type 1 and type 2 diabetes who self-inject insulin. The investigation also looked at the advise issued for various needle lengths, injection sites and frequency of reuse and whether or not these variables had any significant impact on the reported frequency of needle bending or breaking.

The first insulin injection was given to 14-year-old Leonard Thompson on 11 January 1922. The needle used was made of steel, sharpened regularly, reused on many occasions and designed for intramuscular injections. Modern-day insulin needles have changed dramatically.

Prior to March 2000, pen needles were unavailable on prescription in the UK and healthcare professionals often advised people to reuse their insulin needles. Thomas et al (1989), Islam and Ali (1990), Schuler et al (1992) and Fleming (1999) all support reuse and report no adverse events. However, there are older studies that predominately examined infection rates and 12.7-mm needles. More recent advice from insulin needle manufacturers states that insulin needles should only be used on one occasion. There would, however, appear to be a lack of evidence from the current literature to support this. It should be noted that healthcare professionals should consider the litigious aspects of recommending reuse if the needle causes

damage.

Reuse of insulin needles still occurs in practise. In a pan-European study involving 1002 participants, Strauss et al (2005) found reuse to be more common with 12.7-mm needles than with 5-mm needles. On average, needles were reused on 3.3 occasions in Europe. Strauss (2002a) suggests that reuse of insulin needles causes micro and macro trauma to the needle tip, resulting in a hook shape (*Figure 1*) that can lacerate tissues, potentiating the release of growth factors and microscopic needle fragments into fatty tissues. It is postulated that growth factors may further trigger the immune response and exacerbate lipohypertrophy. The loss of the silicone lubricant on the shaft of the needle may lead to an increased force required to push the needle through the skin, which may contribute to bending and breaking. Ginsberg and Strauss (2002) suggest that insulin pen needles rarely break: there are reports of breakage in approximately 1 for every 50 million users.

Anecdotal reports from DSNs and experience

Article points

1. Correct insulin injection technique may be as important to good glycaemic control as the type and amount of insulin injected.
2. This study aimed to identify incidence of needle bending and breaking; examine the statistical significance of bending and breaking when compared with needle length and injection site; and identify current insulin injection technique recommendations.
3. It is not clear that reuse increases the risk of bending and breaking in insulin needles, but cases in the literature report bending and reuse as contributory factors.

Key words

- Injection needle
- Bending and breakage
- Needle reuse

At the time of this study Theresa Torrance was a DSN at Perth Royal Infirmary, Tayside. Currently, she is a diabetes nurse for Novo Nordisk.

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1. The correct insulin injection technique may be as important to good glycaemic control as the type and amount of insulin injected.
2. The hypothesis investigated was that a number of pre-defined variables are contributory factors to insulin needle bending and breaking.
3. A questionnaire was developed since no pre-validated tool was identified through the literature. Questions were designed to obtain specific information and were closed questions with a choice of responses.



Figure 1. Reuse of insulin needle resulting in a hook shape.

from the author's own practice would suggest that breakage is under reported. Many anecdotal reports from other DSN colleagues over several years would also suggest that bending and breakage of insulin needles are not isolated incidents. A colleague recently reported a case where an elderly gentleman was found to have five needle ends embedded under the skin of his thigh.

Identifying the problem

The correct insulin injection technique may be as important to good glycaemic control as the type and amount of insulin injected (Bantle et al, 1993; Birkebaek et al, 1998; Strauss, 1998). International guidelines identified the following points as important factors when considering insulin injection technique: injection sites, needle length, age of patient, gender of patient, BMI and pinch up (Strauss, 1998). The use of smaller needles in more recent years is probably explained by the increased availability of literature discussing the importance of injection technique, needle size and site for injection (Uzun et al, 2001; Strauss et al, 2005). Inconsistency of advice within the literature has led to confusion within practise (Strauss, 1998).

There would appear to be conflicting reports about the incidence of bending and breaking of insulin needles (Ginsburg and Strauss 2002; Strauss 2002b). Actual numbers are unavailable and not known as many appear to be unreported.

Study aims

The hypothesis investigated was that a number of pre-defined variables are contributory factors to insulin needle bending and breaking. The pre-determined variables were insulin needle reuse, site of injection and the size of the needle. The aims of the study were as follows:

- to identify how many people have reported to UK DSNs a problem with needles bending and breaking
- to examine the statistical significance of bending and breaking of needles when compared with pre-determined variables
- to identify present insulin injection technique recommendations.

Methods

A survey approach was chosen as it provides information about the variables under consideration. Patterns can be extracted and comparisons made (Polger and Thomas, 1995). Surveys have been described as a method of easily gathering information economically and efficiently (Bowling, 1999).

It was important to generate a sample large enough to identify the extent of the problem and to maximise response rates. A survey approach was chosen and delivered through postal questionnaire to a random sample of 248 DSNs working in clinical practice in the UK, extracted from *The Diabetes Specialist Nurse Directory* (Diabetes UK, 2003). Exclusions included those working with children only, those employed within the private sector and those listed as facilitators or managers.

A questionnaire was developed since no pre-validated tool was identified through the literature. Questions were designed to obtain specific information and were closed questions with a choice of responses. The content validity was tested over a 3-week period through an expert panel of three diabetes consultants and nine DSNs within the local area. The questionnaire was piloted on two occasions; on the first occasion, to nine DSNs; and on the second occasion, to 20 DSNs across the country over a period of 3 weeks. This increases validity and reduces ambiguity (Castles, 1987). Return rates on each pilot were 100% and 70%, respectively. This was largely due to constant reminders. The final data and results included the results from the second pilot only because changes to the questionnaire design were required. The questionnaires were anonymous, posted first class and contained a stamped addressed envelope addressed to the researcher to try to maximise responses.

The questionnaire was designed to take no more than 5 minutes to complete and was divided into three sections:

- Section one assessed caseload numbers, years in post as DSN and whether or not the DSN recommended single use of insulin and pen needles.
- Section two investigated the recommendations given to patients about the needle size and site for injection.

- Section three looked at the reported incidence of insulin syringe and pen needle bending and breakage.

The DSNs were also asked to identify (retrospectively, through recall) incidences of people with diabetes who had reported to them a problem with needles bending or breaking, along with the site of injection, needle size and details of how the needle was removed.

Data analysis

Data were entered into an Excel database. Using a student t test, P value were generated for the relationship between bending and single use of an insulin needle, needle reuse, site of injection and needle size. Further investigated was needle breakage associated with reuse and site of injection. An ANOVA was used to calculate the significant difference between independent variables and the significant difference between the categories.

Results

A total of 147 questionnaires were returned within the study period of 3 weeks (response rate: 59.2%).

Section one: DSN demographics and their recommendations regarding needle reuse

The total patient sample size as identified by DSNs was 130 670 people. The mean duration of DSN post was identified as 8.13 years. The majority of DSNs (79.6%; n=117) reported that they recommended single use of needles, while just 1.4% recommended unlimited use and 15.0% recommended no more than four injections with the same needle.

Section two: Recommendations for needle size and site of injection

The majority (72.1%) of DSNs suggested the use of 8-mm needles and that with higher BMIs larger needle sizes were recommended. Approximately a third (32.6%) of DSNs recommended 5- and 6-mm needles in people who were considered to be of normal weight (BMI: 20–27 kg/m²). In addition, 44.8% recommended 12.5-mm needles in the obese and 55.7% in the morbidly obese.

The only group for whom DSNs consistently used

5- and 6-mm needles was adolescents (73.4%).

The abdomen, buttocks and legs were recommended as injection sites by 98%, 96% and 96% of DSNs, respectively. Only 46% of DSNs recommended the arms and 1% the calf.

Section three: Needle breakage and bending

There were 1135 reports from patients to DSNs of needles bending in addition to 108 needle breakages; which in total is equivalent to 0.95% of the studied population. *Figure 2* shows the sites where DSNs reported needle breakages. DSNs were also asked to identify how the needle was removed from the individual following the breakage. A hospital visit for the needle end to be removed was required by 24 individuals (22% of those affected, see *Table 1* for other methods used). Bending was reported in 0.32±0.69% of cases of needle reuse.

Twenty-five DSNs had experience of patients having a problem with a broken needle when using their abdomen as the injection site. There was no statistically significant relationship between needle bending and injection site ($P=0.912$). This was assumed to be due to DSNs being unable to identify the usual site of injection. The results were unable to demonstrate a significant relationship between bending and single needle use, nor between bending and needle size (with bending based on a continuous variable and needle size based on a categorical variable).

Discussion

Of the DSNs who responded to the questionnaire, 79% recommended single use of insulin needles. It is postulated that this figure is now higher as people with diabetes no longer have to buy

Page points

- A total of 147 questionnaires were returned within the study period of 3 weeks (response rate: 59.2%).
- The majority of DSNs (79.6%; n=117) reported that they recommended single use of needles, while just 1.4% recommended unlimited use and 15.0% recommended no more than four injections with the same needle.
- The majority (72.1%) of DSNs suggested the use of 8-mm needles and that with higher BMIs larger needle sizes were recommended.
- There were 1135 reports from patients to DSNs of needles bending in addition to 108 needle breakages.

Table 1. Reported methods and frequency of insulin needle removal (n=108).

Self removed	3 %
Removed by minor operation	3 %
Removed at A&E	8 %
Removed under general anaesthetic	11 %
Left in-situ	11%
Removed using tweezers	22%
Method unknown	42%

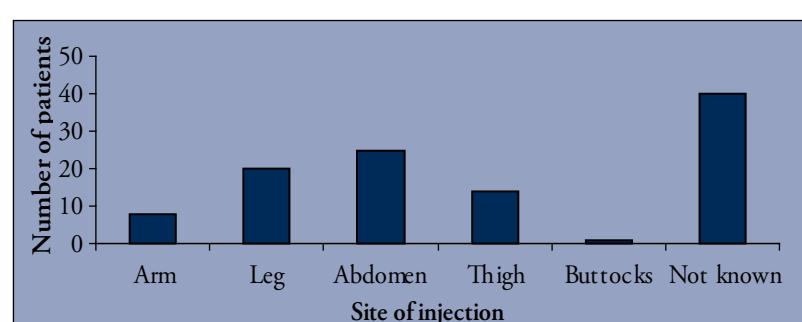


Figure 2. Reported site of injection on needle breakage.

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1. With the significant shift of overweight people with type 2 diabetes onto insulin, the reuse and size of needle used may be very relevant as these factors may be linked to needle damage.
2. There may be many reasons for the higher incidence of needle breakage when injecting into the abdomen, including difficulty reaching the site – particularly in people who are very overweight.
3. It has been suggested that the safest injection technique involves the use of a 6-mm needle used at a 90 degree angle with a lifted skin fold.
4. The lack of statistical significance in the analyses conducted was disappointing to the researchers and may have been affected by the abundance of variables that may affect needle bending and breaking.
5. Patient injection technique should be assessed at every opportunity.

needles for their insulin injections. Needle length may impact significantly on rates of bending and breaking, but it was not possible to demonstrate this within the limitations of this study.

With the significant shift of overweight people with type 2 diabetes onto insulin, the reuse and size of needle used may be very relevant as these factors may be linked to needle damage. The recommended sites for injection are the abdomen, thigh and buttocks (King, 2003), which matches well to the recommendations from insulin manufacturers: these additionally identify that the arms may be less than ideal as a primary injection site owing to their very thin layer of subcutaneous fat (Becton Dickinson and Company, 2001).

Twenty-five DSNs had experience of patients having a problem with a broken needle when using their abdomen as the injection site. There may be many reasons for the higher incidence of needle breakage when injecting into the abdomen, including difficulty reaching the site – particularly in people who are very overweight. Other problems may include dexterity, tremor or poor injection technique. The pressure applied to puncture the skin when giving an injection has been raised as a possible problem. Reuse, loss of the silicone lubricant and blunting of the needle tip may all add to the increase in pressure required (Strauss, 2002a).

It has been suggested that the safest injection technique involves the use of a 6-mm needle used at a 90 degree angle with a lifted skin fold

(Strauss, 1998). There are, however, significant differences in fat distribution, not only with age, but between men and women, which means that recommendations for site and technique cannot be standard across patient groups (Throw and Home, 1990). It is also important to consider that 65% of people injecting insulin are reported to have injection site problems from using a small area repeatedly (Strauss, 1998).

The lack of statistical significance in the analyses conducted was disappointing to the researchers and may have been affected by the abundance of variables that may affect needle bending and breaking. However, the information collated does identify a significant problem with needle breakage in practise that requires further investigation. Within recent years, there has been discussion and study around the area of injection sites and techniques. Effects on the patient are unknown, but it is not unreasonable to anticipate significant physical and psychological morbidity. There could also be an effect on hospital services and admissions.

Implications for practice

Vigilant reporting through insulin needle manufacturers will highlight the problem further and may stimulate more research in the field. It should also be advised that adverse event reporting is a way of identifying faults and problems with products.

Using data collected as part of this study, we were able to compare how many DSNs were following the recommendations from the medical technology company BD for needle size. See *Table 2*. These data may indicate that further education of DSNs is required.

There are a number of practice considerations such as the continuation of injection technique education. Further identification of at-risk groups is also important. People with lipohypertrophy, the very overweight, the elderly and those with dexterity or visual problems have already been identified as high risk for insulin delivery difficulties (Strauss, 1998). Healthcare professionals should also try to identify ways of recognising and minimising risk. Patient injection technique should be assessed at every opportunity. People who have been on insulin for long periods

Table 2. Comparison between the recommendations made by Becton Dickinson and Company (2001) for needle size and age or BMI and recommendations made by UK DSNs participating in study (N=147).

BMI (kg/m ²)	BD recommended needle length	DSNs following recommendations
Adolescent	5–6 mm	108 (73.4 %)
<20	5–6 mm	134 (91.1 %)
20 – 27	5–6 mm	48 (32.6 %)
	8 mm	106 (72.1 %)
>27	12.7 mm	32 (21.7 %)
>30	12.7 mm	66 (44.8 %)
>35	12.7 mm	82 (55.7 %)

of time should be targeted and assessed, as many of these individuals may be experiencing problems.

Limitations

Using a survey approach rarely demonstrates causal relationships. However, it is a good way of finding out facts, which was the primary aim of the study. A further weakness in the design may have been that the questions were superficial and reflect the bias of the researcher. Retrospective data, as reported by people with diabetes to DSNs, are less accurate, especially when recall of information is required, although it could be argued that recall of a significant event – such as needle breakage – is less likely to be forgotten or misinterpreted.

Conclusion

This study has identified a significant problem with needles bending and breaking. Therefore, further independent study is required. It is not clear that reuse increases the risk of bending and breaking in insulin needles, but cases in the literature report bending and reuse as contributory factors and these, therefore, cannot be ignored. Statistical analysis has failed to identify a relationship between pre-determined variables, but the study provides a platform for further investigation. The incidence of needles breaking shown in this study suggests that the problem is under-reported within the literature and to needle manufacturers (Ginsberg and Strauss, 2002).

As healthcare professionals, we are aware that people with diabetes can have difficulty with injecting insulin on a daily basis. There are those who may have already experienced problems with bending or breaking. This may contribute to increased anxiety, avoidance behaviours and concordance with medication. This knowledge allows practitioners and their patients to explore the potential problem in more detail. There may be particular groups who are more at risk, but unfortunately, this study does not identify these specific risk factors. ■

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Page points

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2. Statistical analysis has failed to identify a relationship between predetermined variables.
3. The incidence of needles breaking shown in this study suggests that the problem is under-reported within the literature and to needle manufacturers.