Using insulin pen needles up to five times does not affect needle tip shape nor increase pain intensity

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Abstract

Aims: Reusing insulin pen needles could help to reduce the increasing economic burden of diabetes. We tested the hypothesis that reusing insulin pen needles leads to needle tip deformity and increased pain. Methods: Three blinded reviewers assessed 123 electron microscope pictures analyzing needle tip deformity of insulin pen needles used up to four times by diabetic subjects and up to five times by blinded non-diabetic volunteers. The estimated frequency of needle use was correlated to the actual number of needle use. Pain intensity and unpleasantness of each injection were measured by a visual analogue scale and their differences analyzed by Kruskal–Wallis analysis of variance. Results: Unused needles could be differentiated visually from used needles. However, there was no correlation between the actual and guessed number of times a needle was used (r = 0.07, P = 0.2). Evaluating all 270 injections, neither pain intensity nor unpleasantness increased with repeated injections of the same needles in people with diabetes (P = 0.1 and 0.96) and in the volunteers (P = 0.63 and 0.92). Conclusions: Using pen needles four to five times does not lead to progressive needle tip deformity and does not increase pain intensity or unpleasantness, but could increase convenience and lead to substantial financial savings in Europe of around EUR 100 million/year.

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1. Introduction

In Western Europe, the yearly cost per patient with type 2 diabetes mellitus is estimated at EUR 2800 [1].

Abbreviations: ADA, American Diabetes Association; ANOVA, analysis of variance; NS, not significant


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About 5 million insulin injections are performed every day in Europe. The American Diabetes Association (ADA) [2] and health care providers in general do not favour needle reuse and allude to potential issues such as the risk of bending the thin needle tip to form a hook, which could lacerate tissue or break off to leave needle fragments within the skin, and to a small risk of infection. Manufacturers of pen needles make reference to unpublished studies showing damage to the needle after repeated use. Potential medical consequences might be an increase in lipodystrophy [2], or thickening of the subcutaneous tissue leading to erratic absorption of insulin.
Nevertheless, a large proportion of people with diabetes do reuse their needles [3,4]. In one retrospective study, using older and thicker disposable syringe-needle units three times did not increase pain [5].

We aimed to investigate prospectively the effects of reusing insulin pen needles on needle shape and on the sensation of pain and unpleasantness prospectively in people with diabetes as well as in blinded non-diabetic volunteers.

2. Materials and methods

2.1. Subjects and design

We consecutively recruited 15 insulin treated people with diabetes from our Outpatient Clinic. They were between 23 and 78 years old, [11] were males and their BMI ranged from 18 to 46 kg/m². They had been taking insulin for a median of 19 years using 10–85 units/day. Five of them injected NPH insulin, the others insulin glargine. Six diabetic subjects were habitual reusers of insulin pen needles. A group of four non-diabetic volunteers was recruited. They were healthy subjects aged 33–58 years, of whom two were female.

People with diabetes were instructed to inject their usual long-acting insulin in their thighs using insulin pen needles one to four times. They were each given four different pen needles in distinct bags. They injected once with the first needle, twice with the second, three times with the third and four times with the fourth needle. Thus, each diabetic subject completed a total of 10 injections. Eight of the people with diabetes were randomly assigned to use BD Micro-Fine® (0.25 mm × 8 mm, Beckton Dickinson GmbH), the others to use Novofine® (0.3 mm × 8 mm, Novo Nordisk Pharma) needles. After every use, needles were recapped with the small cap so the pen could be closed. Needles were not cleansed with alcohol.

The volunteers used insulin pen needles one to five times in a blinded manner injecting the equivalent of five units of isotonic saline into their abdomen. In total, one needle was used once, the second twice, the third three times, the fourth four times and the fifth five times, but in a random fashion. As every volunteer used both BD Micro-Fine® and Novofine® insulin pen needles, everyone completed 15 injections with needles from each of the two manufacturers, making a total of 30 injections per volunteer. Every morning the volunteers received four number-coded pen needles in a container. They themselves with each of the four needles, capped it with the small cap, put it back in the container and returned it to the study nurse. Apart from the first time, volunteers were blinded to how many times a specific needle in the container had been used previously.

After each injection, volunteers and people with diabetes noted the intensity of pain (sensory-discriminative component) and unpleasantness (motivational-affective component) on a 10 cm horizontal visual analogue scale, a frequently used and well validated tool to measure pain intensity [6–8].

For each intensity scale, the anchor point on the right was “no pain or unpleasantness at all” and on the left “the most intense I could imagine”. All participants gave written informed consent. The university human research ethics committee of the University of Basel approved the study.

2.2. Scanning electron microscope and examination of the needles

All 123 needles were mounted on specimen targets with carbon paint (LeiC by Goecke—Conductive Carbon Cement, Neubauer Chemikalien, Münster, Germany). The examination of the needle ultrastructure was performed with a scanning electron microscope (Philips XL 20, Eindhoven, Holland) with the beam at the secondary electron mode (SE), a magnification of 260, and an accelerating voltage of 10.0 kV. The examiner was blinded to how many times the needles had been used. For each non-diabetic volunteer 12 needles, including two unused ones, were utilised. For each person with diabetes, five needles, including an unused one, were utilised. The scale ranged from zero (no needle tip deformity, integrity of edges, no detritus) to five (severe needle tip deformity, worn edges, abundant detritus).
2.3. Statistical analysis

Data of sensation of pain or unpleasantness for each injection were read off the visual analogue scale. Means of all the first injections of one individual were calculated and they were set as 100%. Next, every single injection of each participant was expressed as percent of this mean to account for inter-individual differences in perception of pain and unpleasantness. Differences in pain or unpleasantness with increasing number of injections were analyzed by non-parametric Kruskal–Wallis analysis of variance (ANOVA). Spearman rank correlations were used to assess the relationship between true and estimated frequencies of needle use, between estimated frequencies and pain sensation and, to establish an association between the examiners’ estimates to validate the results, between the estimates of all three different reviewers. Two-tailed \( P \) values <0.05 were considered statistically significant. Data were analyzed using Statistic for Windows (version 6.0, StatSoft Inc., Tulsa, OK, USA).

3. Results

A total of 270 injections were performed and all 123 needles analyzed. There were no incidents related to recapping of the needles and there were no local complications at the injection sites. No needles were visually deformed or clearly noticeable blunt, and no needle tips broke off.

Looking at the printed electron microscope pictures, unused needles could regularly be visually differentiated from used needles, at least in part because of the lack of detritus on the unused needle. When looking at needles which had been used at least once, the true number of injections did not correlate to the estimated number of injections assessed by needle tip deformity by all three reviewers (\( n = 300; \ r = 0.07, P = 0.2 \), Fig. 1). In addition, there was no correlation between the estimates of each individual reviewer and the true number of injections (all \( P < 0.0001 \)). Fig. 2 shows that reusing insulin pen needles did not increase either sensation of pain or unpleasantness in both people with diabetes (Fig. 2A, \( P = 0.1 \) and 0.96, respectively) and volunteers (Fig. 2B, \( P = 0.63 \) and 0.92, respectively). There were no differences between the needles from the two manufacturers in both people with diabetes and non-diabetic volunteers and within the group of people with diabetes, there was no difference between habitual reusers and non-reusers of insulin pen needles (data not shown). In addition, there were no specific individual needles that hurt more than others (data not shown).

In addition, there was no correlation between pain sensation and needle tip deformity expressed as the number of injections estimated by all three reviewers (\( n = 300; \ r = 0.03; P = 0.57 \)).

![Fig. 1. Guessed number of needle use by inspection of electron microscope pictures of insulin pen needles used one to five times.](image-url)
Fig. 2. Pain and unpleasantness with repeated injections in people with diabetes (A) and non-diabetic volunteers (B). Values are median, interquartile ranges and 20% ranges.

Fig. 3. Illustration of an insulin pen needle used once (left) and five times (right).

As an example, an insulin pen needle used once and five times, respectively, is shown (Fig. 3).

4. Conclusion

Our study shows for the first time in a prospective controlled setting that using insulin needles up to five times does not increase needle tip deformity, and repeated reuse of needles does not increase sensation of pain or unpleasantness, both in people with diabetes and blinded non-diabetic volunteers. The needle tip, however, was slightly affected by the initial injection, as, after a 260-fold magnification, unused needles could often be visually differentiated from used needles, partly due to lack of detritus. Needles used once could not be differentiated from those used more than once. Furthermore, we did not find a correlation between needle tip deformity and pain perception.

No needles broke off to leave fragments within the skin. To our knowledge, there are hardly any reports of such incidents, though it is a concern mentioned in the most recent ADA guidelines [2].

Reusing pen needles is not only attractive from a financial point of view, but leaving the needle attached to the pen for several injections is also more convenient. In addition, frequent needle change potentially increases the risk of shaving off pieces from the rubber stopper into the insulin cartridge. A recent report found that 73% of the cartridges contained rubber pieces that are expelled during injections and might be injected into the subcutaneous tissue with unknown long-term effects [9].

Reusing needles two to 200 times, overseeing over 560,000 injections, found no signs of infection and only rare cases of slight redness in diabetic patients with proper personal hygiene [3,4,10–14]. Accordingly, in our study, we observed no local complications such as redness, tenderness or infections.

Reusing needles may remove the silicone coating and potentially increase pain sensation [2], though this effect was not noticeable in our study.

A further concern of reusing pen needles, derived from earlier studies looking at much thicker needles, is the appearance of a blunt sensation after 3–5 injections [10–12,15]. In contrast, repeated needle use up to five times did not lead to bluntness of the needles in this study.
The ADA recommends that needles should be re-capped after their use. Recapping needles requires a certain dexterity and patients should be instructed how to do it. Leaving the pen needle stuck in the cartridge increases the presence of squamous or epithelial cells in the needle and in the cartridge, underlining the need for strict individual use of the needle and of the cartridge [16]. Furthermore, air could enter the cartridge, leading to reduced delivery of insulin [17].

Inspite of official statements it is assumed that up to 50% of patients in Europe are reusing their needles [3,4]. Based on our results, we do not have a rationale to advise our patients to stop reusing their needles. We acknowledge the limitations of the study as it has a relatively small sample size and lacks information on possible long-term effects, including lipodystrophy. In general, lipodystrophy is probably much more influenced by other factors such as repeated injections in the same area but there is clearly a need for repeated audit of the effects of reusing insulin pen needles, as there is hardly any recent data.

As a general precaution, needles should be changed if there is any local reaction at the injection site or the needle feels blunt. Furthermore, patency of the needles should be ensured by performing air shots. Despite the fact that people with diabetes injected in the thigh and non-diabetic volunteers in the abdomen, the results were similar in both groups, suggesting that these results are valid for at least the two most frequently used sites.

Assuming a pen needle price of EURO 0.15 and a daily rate of 5 million injections by the over 15 million diabetic people living in Europe, then using pen needles up to five times in those 50% of patients, who are not currently reusing their pen needles, would amount to financial savings in Europe of around EUR 100 million/year.

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References
