Capillary blood sampling: how much pain is necessary?

Part 3: Pricking the finger can be less painful

H Fruhstorfer MD, Head of Department, University of Marburg, Germany
H Lange, Manager, Research and Development, Diabetes Care, Boehringer Mannheim, Germany

Correspondence to: Professor Heinrich Fruhstorfer, Department of Neurophysiology, Institute of Physiology, University of Marburg, Deutschhausstrasse 2, D-35033, Marburg, Germany

Accepted for publication: 1 February 1995

Abstract-

A new lancing device (Softclix®) with an adjustable penetration depth was compared to the Glucolet® which had proven to be the least painful device in an earlier study¹. At the lowest depth setting for obtaining just enough blood for a glucose test (≥20µl), the new device was significantly less painful. This is mainly due to the fact that the Glucolet® lacks low and intermediate depth settings.

Keywords: lancing device; capillary blood; pain; fingerprick; diabetes mellitus

Introduction

On the basis of the results of preceding studies^{1,2}, a new automatic lancing device was developed with the following features: controlled lancet movement, precise guidance of the lancet and a range of easily selectable depth settings (=device B). The precise lancet guidance allows a small cap opening, which brings the actual penetration depth closer to its nominal value and which increases the tissue pressure between cap and bone. This newly developed device was compared to the least painful device (=device A) of an earlier study¹ (see Table).

Both lancets vary in length by approximately ±0.1mm. The Glucolet lancet sold at the time of these experiments (1993) is thinner than the original Unilet lancet used in the earlier studies^{1,2}.

Methods

Fifty healthy subjects, most of them having experience in testing finger-stick devices, participated in these experiments. Methods were principally the same as in an earlier study¹. Puncture sites were the sides of the 2nd to 5th fingertip on both hands. The following data were recorded: Puncture pain (numerical rating scale NRS 0–10); blood volume obtained up to 100µl; and the time necessary for collecting the blood. At the end of the complete experiment the

subject had to indicate on a visual analogue scale (VAS) how much he liked each of the two devices (extremes: 0=do not like it at all; 100=like it very much). All finger-sticks were performed in one session. The devices were used in random order

The subject washed hands with soap and warm water and rated five calibrated pain stimuli. Then he loaded the first device, adjusted it to the lowest penetration depth and pricked one of his index fingers. After rating puncture pain and collecting the blood, he pricked his other index finger with the same penetration depth. Then he adjusted the device to the

next deeper setting and pricked one of his middle fingers, after that the other middle finger. These four pricks tested the two possible penetration depths of device A.

With device B, if the second penetration depth had not twice delivered volumes >20µl blood, the third depth setting was tested on both ring fingers and, where necessary, the 5th depth was tested on both little fingers.

After all punctures with one device had been performed, the subject unloaded and discarded the lancet and began testing the other device, starting again on the index fingers.

Differences in puncture pain at the minimal depth setting for obtaining, twice, a blood volume ≥20µl (=ideal penetration depth), and the subjective ratings of the devices, were determined using the Wilcoxon Signed Rank Test for Paired Replicates with adjustment according to Bonferroni-Holm. The overall threshold was set at p≤0.01.

Results

With device A, which allows the selection of only two depths, the ideal penetration

Table. Comparison of ease of use of two lancing devices (A and B)

	Device A Glucolet® (Bayer Diagnostics)	Device B Softclix® (Boehringer Mannheim)
Lancet movement	ballistic	controlled
Depth adjustment	2 caps	6 settings
Penetration depth	1.05–1.67mm	0.75-2.25mm
Cap opening	6mm	2.5mm
Lancet diameter	0.65mm	0.8mm
Lancet loading	easy	easy
Lancet cocking	by loading lancet	by turning cap
Triggering	button on top	button on side
Lancet unloading	difficult, by pulling lancet	easy, by pressing button on top

Figure 1. Number of subjects for whom a selected penetration depth produced twice a blood volume ≥20µl, or for whom the available depth settings were not sufficient (=ns), together with average puncture pain at ideal depth (blood volume ≥20µl) (n=50)

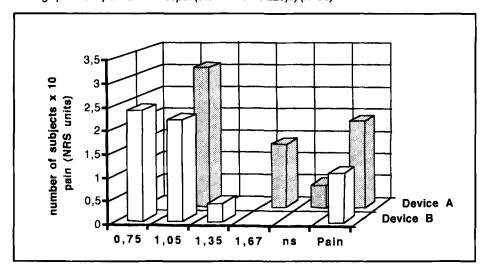
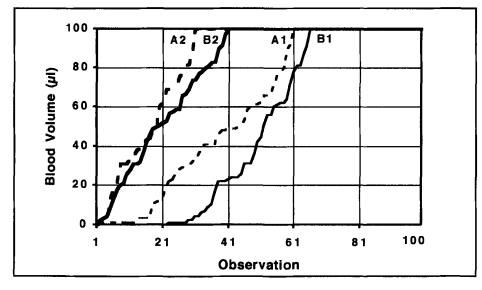


Figure 2. Distributions of blood volumes obtained with device A (broken line) at a nominal penetration depth of 1.05mm (A1) and 1.67mm (A2) and with device B (unbroken line) at 0.75mm (B1) and 1.05mm (B2). For each curve, blood samples are arranged according to increasing volumes. Each of the four curves contains 100 observations



depth was 1.05mm in most subjects (*Figure 1*). The depth setting of 1.67mm was, however, not always sufficient to obtain ≥20µl blood twice. With device B, the ideal depth was 0.75mm in the majority of the subjects, and only four subjects needed a depth of 1.35mm.

At the ideal depth, average puncture pain with device A was nearly twice as high as with device B (Figure 1); this difference was significant, and it existed similarly in both pain-sensitive subjects (high pain scores) and in those with a tough skin (great depth values). At the same depth setting of 1.05mm, puncture pain was comparable for both devices (device A 1.49 NRS units; device B 1.44 NRS units), but with device A many blood samples were below 20µl (22 out of 100;

see Figure 2). At this depth setting, the time needed to collect the blood was, for both devices, on average between 30 and 40 seconds.

Both devices differed significantly in their preference ratings by the subjects (device A 34.4±26.2 VAS units; device B 80.1±17.6 VAS units).

Discussion

With the new device B, puncture pain for obtaining a sufficient volume of blood from the fingertip is significantly smaller than with device A which, in an earlier study¹, was the least painful of six lancing devices. One reason for this is evident from *Figure 1*: device A lacks low and intermediate depth settings, therefore the punctures have to be deeper than

necessary and hence are more painful. The other reason is clear from *Figure 2*: both devices set to the same nominal depth of 1.05mm (ie A1 and B2) deliver different volumes of blood at comparable levels of pain. Although in device A the actual puncture depth could be greater due to the larger cap opening, the blood volumes are nevertheless smaller. This indicates that the lancet of device A does not penetrate into the skin to its full possible depth. There could be several reasons for this phenomenon:

- Differences in the course of lancet movement.
- Differences in lancet force.
- Differences in tissue pressure due to the different cap openings.

The failure to fully penetrate the skin also becomes evident in the finding that, in some of the subjects, device B delivered enough blood at 1.35mm, whereas device A failed at 1.67mm. For a person with a thick horny layer (eg a frequent finger pricker) device A might fail, whereas device B provides more settings for deeper punctures up to 2.25mm.

The high degree of acceptance of device B by the subjects was probably due to the ease of handling, the possibility of penetration depth control and the design. Difficulty in unloading the lancets was disadvantageous for device A.

If one compares the results of the present study with those of earlier tests of automatic lancing devices^{1,3}, it becomes evident that during the last ten years lancing pain has been reduced considerably. It is the patient with diabetes who mainly benefits from this development.

References

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Part 4: Comparison of lancets for automatic lancing devices will appear in a subsequent issue of Practical Diabetes International.

Part 1: Comparison of existing finger stick devices appeared in the March/April 1995 (Vol. 12, No. 2) issue.

Part 2: Relation between penetration depth and puncture pain appeared in the July/ August 1995 (Vol. 12, No. 4) issue.