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SHORT REPORT

A Pain-free Lancet with a Small Needle for Glucose Measurement

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Abstract: A new lancet with an extremely small needle (0.15 mm diameter and 0.75 mm length) mounted on a small pedestal was tested in diabetic patients for blood glucose measurement in a randomized clinical study. A total of 37 diabetic patients were enrolled for the study. A pain scale categorized from 0 to 3 was created to measure the intensity of puncture pain which was explained to patients before testing. The patients' fingers were punctured with their own old style lancets at least 1 hour before the punctures by the new lancets, and puncture pains recorded according to the pain scale. All patients tested with the new lancet reported no pain and recorded the puncture pain as scale 0. Among the total 37 patients tested with their old style lancets, 2 patients (5.40%) reported no pain and recorded the pain as scale 0, thirteen patients (35.14%) recorded as scale 1, 16 patients (43.24%) as scale 2, and 6 patients (16.22%) as scale 3. The average pain scale of the patients who used old style lancets was 1.702 with the standard error 0.133. The chi-square goodness-of-fit test shows that the proportion of the pain scales comes from the claimed distribution with unequal frequencies, and chi-square tests for independence indicate that neither sex nor age of the sample patients is related to the pain scales.
The paired t-test to test the existence of any difference in pain levels between the new lancet and the old style lancet showed; $t = 1.702/0.133 = 12.796$ with p-value < 0.005 ($df = 36$). The average pain level from the old style lancet is significantly higher than from the new lancets. Pain-free needle puncture was achieved by limiting the puncture depth to less than 0.75 mm with a thin needle with a 0.15 mm diameter. By allowing patients to see the new lancets before testing, psychological pain anticipation was minimized as the very thin and short needle is visually less intimidating. With a pain free puncture, better compliance and improved subsequent glucose levels may be achieved.

Keywords: lancet, glucose measurement, pain free, small needle

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Introduction

Great improvements and innovations have been made in the field of diabetes care in recent years, especially in glucose monitoring technology. However, as lancet technology has not been met with the same innovation, many diabetic patients still suffer from needle puncture pain when measuring their blood sugar levels. Lancets, designed 30 years ago, with a thick and long needle used to puncture the finger tip are still being used.

Furthermore, both adults and children use the same size lancets as no lancets suitable for diabetic children are available. A typical stainless steel lancet has a diameter of 0.3–0.8 mm and penetrates 0.7–1.3 mm, with depth of penetration directly related to pain.[1] Although the extent of tissue injury and pain are less from the puncture by a thinner and shorter needle, the puncture by the very small size needle yields less blood volume which may not be sufficient for the glucose measurement. Modern glucose meters require a much smaller blood sample for an accurate measurement, therefore diabetic patients no longer need to use lancets with a large size needle. For example, the FreeStyle© glucose monitor (Abbott Laboratory, Abbott Park, Illinois) requires only 0.3 microliters of blood for testing the glucose level.[2] The pain from the needle puncture discourages diabetic patients to monitor the blood glucose levels as frequently as recommended, which adversely affects the quality of their health. According to a survey of some 6,600 type 1 diabetic patients, to which 1,895 replied, actual testing frequency was less than recommended, mainly because of soreness, pain and inconvenience. The difference between the reported recommended and actual frequency of testing was proportional to the number of hospitalization over the prior two years,[1] which indicated that poor compliance increased complications of diabetes.

A new lancet having an extremely thin and short needle was created and tested in an open randomized clinical study as to whether it causes less puncture pain when compared with old style lancets while producing enough blood volume for glucose testing.

Methods

A total of 37 diabetic patients (3 patients with type 1 and 34 patients with type 2 diabetes) were enrolled in the study (Table 1). The study was conducted at a medical clinic during the period of 2 April 2008 to 31 December 2008. There were 12 females (32.4%) and 25 males (67.6%), and patients ages ranged from 24 to 88 years-old with an average age of 66.6 years. 16 patients were younger than 66 years old, and 21 patients were older than 66 years.

They had all been testing blood glucose levels at home using typical old style disposable lancets from various makers including the OneTouch® (Life Scan, Milpitas, California), AccuChek softclix® (Roche Diagnostics, Indianapolis, Indiana), FreeStyle® (Abbott Laboratory, Abbott Park, Illinois), Ascencia® (Bayer Health Care LLC, Tarrytown, New York), BD Ultrasoft® (BD, Franklin Lakes, New Jersey). The diameter of the lancet needles ranged from 28 gauge to 30 gauge, and the length range was between 2.8 mm to 3.2 mm.

A new disposable lancet, Tiniboy™ (Health Innovation Ideas, LLC, Upland, California) has a needle size of 38 gauge (0.15 mm in diameter) and 0.75 mm in length. A photograph comparing the new lancet, Tiniboy™ with other lancets is shown in Figure 1.

The OneTouch® lancing device (Life Scan, Milpitas, California) was used as a lancing device for the Tiniboy™ lancet, and the capillary blood glucose level was measured with the OneTouch® glucose monitor (Life Scan, Milpitas, California) that requires at least 1.0 microliters of blood for testing. As a control, patients used their own disposable lancets housed in various lancing devices in the way they normally did at home. The punctures by the old lancets were done at least 1 hour before the punctures by the new lancets.

All patients were tested in the fingertip, and the testing sites for the new lancet are comparable to those for the old style lancets.

The finger tip was cleaned with alcohol swab and wiped with sterile gauze, and the lancing was performed by a physician. Patients were allowed to see the new lancet before lancing. The lancing device was opened, and the disposable lancet inserted into the lancet holder. After the lancing device was closed and cocked, it was placed onto the patient's finger tip as usual. Generally the 3rd and 4th finger tips were selected for testing.

At the first attempt, a penetration depth of level 1 out of 9 was set by adjusting the lancing device. If the first attempt failed to produce enough blood for

Table 1. Patient data.

Patient no.	Sex	Age	Brand of old lancet	Pain scale from old lancet	Pain scale from new lancet
P01	M	62	OneTouch	2	0
P02	M	64	Generic	1	0
P03	M	70	AccuChek	2	0
P04	M	68	Ascensia	3	0
P05	M	68	Ascensia	3	0
P06	F	80	AccuChek	1	0
P07	M	67	Generic	3	0
P08	M	57	FreeStyle	2	0
P09	F	70	OneTouch	2	0
P10	M	63	AccuChek	1	0
P11	M	70	OneTouch	2	0
P12	M	70	OneTouch	2	0
P13	F	75	OneTouch	1	0
P14	M	58	AccuChek	1	0
P15	M	62	OneTouch	3	0
P16	F	80	OneTouch	2	0
P17	F	77	AccuChek	2	0
P18	M	78	BD30G	1	0
P19	F	47	AccuChek	2	0
P20	F	49	OneTouch	1	0
P21	M	24	BD30G	1	0
P22	M	61	AccuChek	2	0
P23	M	83	OneTouch	1	0
P24	M	67	OneTouch	2	0
P25	M	88	AccuChek	0	0
P26	F	58	OneTouch	3	0
P27	M	67	FreeStyle	1	0
P28	M	68	Ascensia	3	0
P29	M	62	FreeStyle	2	0
P30	F	61	OneTouch	2	0
P31	F	84	Generic	2	0
P32	M	63	OneTouch	2	0
P33	F	76	OneTouch	0	0
P34	M	70	OneTouch	1	0
P35	F	66	OneTouch	1	0
P36	M	61	AccuChek	1	0
P37	M	71	AccuChek	2	0

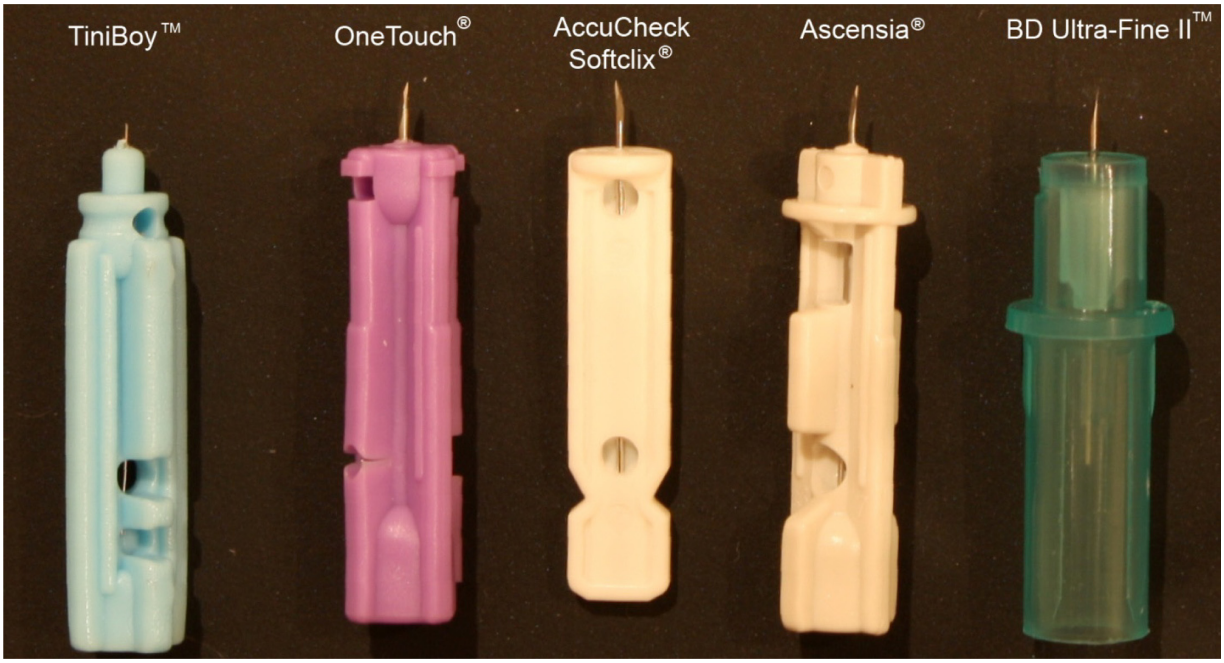

Figure 1. The new lancet, Tiniboy™ in comparison with other old style lancets.

glucose testing, the second attempt was done with an increase of the penetration depth to level 2 with the same lancet. Likewise, if the second attempt failed, the third attempt was made with another increase to the level 3.

A simple pain scale (Table 2) was created; and depending on the intensity of puncture pains, it was categorized from 0 to 3 (0 = no pain, 1 = minimal pain, 2 = mild pain, and 3 = moderate or severe pain). The pain scale was explained to the patient before testing. After testing with the new lancet, patients were asked to score their pain sensations, and their results were recorded. Similarly, their pain sensations with their own old style lancets were recorded.

Results

Sampling success at the first attempt was obtained in 19 patients (51%), second attempt sampling success in 17 patients (46%) and the third attempt in 1 patient (3%).

Table 2. Pain scale.

Scale	Intensity of pain
0	No pain
1	Minimal pain
2	Mild pain
3	Moderate or severe pain

All patients tested with the new lancet reported no pain and recorded the puncture pain as scale 0 (Table 3a). Among the total 37 patients tested with their old style lancets, 2 patients (5.40%) reported no pain and recorded the pain as scale 0, thirteen patients (35.14%) recorded as scale 1, 16 patients (43.24%) as scale 2, and 6 patients (16.22%) as scale 3 (Table 3b). The average pain scale of the patients who used old style lancets was 1.702 with the standard error of 0.133.

The chi-square goodness-of-fit test (Table 3) showed sufficient evidence at the 5% level of significance

Table 3. Goodness-of-fit test.* **a**) Percentage of patients according to pain scale using the new lancet.

Pain scale	0	1	2	3
Frequency	37	0	0	0
Percentage	100%	0%	0%	0%

Table 3b. Percentage of patients according to pain scale using the old style lancets.

Pain scale	0	1	2	3
Frequency	2	13	16	6
Percentage	5.40%	35.14%	43.24%	16.22%

*The chi-square goodness-of-fit test gives $\chi^2 = 13.270$ with p-value < 0.01. Hence, the null hypothesis was rejected, concluding that the proportion of SCALEs varies with unequal frequencies.

that the proportion of the pain scales comes from the claimed distribution with unequal frequencies; chi-square = 13.270 with p-value < 0.01.

Chi-square tests for independence (Table 4) were performed to determine whether there is an association between sex and pain scale (Table 4a) as well as age and pain scale (Table 4b). Small values of chi-square statistics with large p-values indicate that neither sex nor age of the sample patients is related to the pain scales (Table 4c).

The paired t-test to test the existence of any difference in pain levels between the new lancet and the old style lancet showed; $t = 1.702/0.133 = 12.796$ with p-value < 0.005 ($df = 36$). This concludes that average pain level from the old style lancet is significantly higher than that from the new lancets.

Discussion

Among many difficulties and problems encountered by diabetic patients, daily experience of pain and soreness of the finger cannot be underestimated. Although the pain itself may not be a serious medical condition, it is indirectly associated with dire complications of diabetes. Patients' reluctance to test blood glucose levels due to the fear of puncture pain is a well known cause of poor compliance among the diabetic patients. As confirmed in this open randomized clinical study, by reducing the lancet size to the 38 gauge and limiting its penetration depth to not more than 0.75 mm, needle puncture pain was virtually eliminated, and the amount of blood produced by a puncture with this very thin and short needle was at least 1.0 microliters, which was sufficient for the glucose test when patients use a modern glucose monitor. Recent advancement of technology even permits a glucose monitor to measure an accurate blood glucose level with only 0.3 microliters of capillary blood.[2]

The basis for using this painless needle puncture can be perceived from both a biological and psychological perspective. The Tiniboy™ lancet has an unusually thin and short needle that causes a very shallow and narrow puncture, probably hitting the capillaries in the superficial dermis thus sparing the pain nerve fibers below.

Anticipation of puncture pain can be minimized by using an extremely small needle, as a smaller needle is less intimidating to patients.

The skin consists of the epidermis and the dermis. Underneath the epidermis which has no blood vessels and negligible pain nerve innervations, the dermis is divided into two layers, the papillary layer above and the reticular layer below. Typically, the superficial portion of the papillary layer is arranged into ridge-like structures, the dermal papillae, which contain microvascular and neural components that sustain the epidermis. A vascular plexus, the rete subpapillare, demarcates the lower limit of the papillary dermis.[3]

The normal thickness of the epidermis of the middle fingers is about 0.3 mm, and that of the dermis 1.5 mm.[4] The papillary layer has about 0.3 mm to 0.4 mm thickness.[3]

The Merkel's cells in the epidermis and the Morgagni's corpuscles in the papillary layer are nerve receptors for touch sensation.

Therefore, if a lancet needle penetrates the finger skin at 0.6 mm to 0.7 mm depth, it can hit the rete subpapillae, the superficial vascular structure of the papillary dermis without going deeper to the reticular dermis where abundant free nerve fibers are present. By penetrating up to the papillary dermis only, the

Table 4. Independence test.* **a**) Sex versus pain scale.

Pain scale	0	1	2	3
Male	1	9	10	5
Female	1	4	6	1

Table 4b. Age versus pain scale.

Pain scale	0	1	2	3
≤66 years	0	7	7	2
>66 years	2	6	9	4

Table 4c. Chi-square statistics, p-values and contingency coefficient.

Category	Chi-square statistics	p-value	Contingency coefficient
Sex vs. pain scale	1.1661	0.761	0.1748
Age vs. pain scale	2.3610	0.501	0.2449

*The chi-square independence tests showed very small values of χ^2 with large p-values. **Although the powers of the test are not significantly higher due to the relatively small sample size in the experiment, it is worth noting that the pain scales are not related to either age or sex.** The values of contingency coefficient show very weak relationships among SCALE and Sex or Age, and they support the results of chi-square independence tests.

lancet needle may hit the nerve receptors such as Merkel's cells and Morgagni corpuscles, and patients feel something touching instead of unpleasant pain.

The limited penetration depth (maximum 0.75 mm) by the very thin needle (38 gauge) of the Tiniboy™ lancet is conjectured to be the reason why tested patients consistently reported no pain. The Tiniboy™ lancet's revolutionary structure, employing a small pedestal, enables the functionality of the extremely thin and short needle. Commercially available lancing devices have an exit opening (where the lancet needle protrudes to puncture the skin) of about a 3 mm diameter, with a side wall of about 1 mm-thickness. Therefore, with the use of available lancing devices, a traditional lancet needle shorter than 1 mm cannot hit the skin; as such, therefore currently available lancets have about 3 mm-long lancet needle. However, the Tiniboy™ lancet is structured with a small pedestal of 2.25 mm height and 1.75 mm diameter at the distal end of the lancet body on which a 0.75 mm needle is mounted (Fig. 1). When the Tiniboy™ lancet needle penetrates the skin during the lancing procedure, the small pedestal, not the needle, passes through the exit opening. Because the total length of the Tiniboy™ (including the needle, pedestal and lancet body) is commensurate to that of traditional lancets, it can be used interchangeably with old style lancets in conjunction with standard lancing devices.

The length of a needle also influences the thickness of a needle. When the needle is very thin and long, it bends and can even break when it hits the skin, especially hard callused skin. Because of the pedestal's ability to pass through the exit opening of a lancing device, the lancet needle can be shorter than 1 mm, and as a result, the needle is able to be very thin without the risk of bending or breaking.

Another possible reason for the painless puncturing is less total dwelling time of the lancet needle inside the skin after the lancing actuation because of the smaller total surface area of contact between the skin and the lancet body and needle due to the smaller distal surface of the pedestal in contact with the skin as well as the less total surface area of the thinner and shorter lancet needle. Simply the friction between the skin and the lancet needle and body is less. If the surface area of the distal end of the pedestal is larger, patients may experience more puncture pain because the increased friction between the skin and the lancet body.

One can not underestimate the psychological aspect of pain when measuring the intensity of pain. Pain perception is influenced not only by the actual wound size but also by psychological factors. Anticipating pain is perceived as actual pain.[5] It is especially true when diabetic patients puncture the finger skin themselves.

The psychological aspect of pain anticipation was considered as an important factor in measuring the pain intensity in this study. Therefore, patients in this study were allowed to see the TiniBoy™ lancet before puncturing the skin as it was anticipated the pain could be less than with the control lancets, although, in general, it is preferable to design a randomized study using a double blind method.

This study has clearly demonstrated the advantage of the new lancet, which seems long overdue. However, the lack of a control group in the study may limit the validation to some degree. Nevertheless, the new lancet is significantly smaller and will undoubtedly produce less pain and be more practical to use in children. Strikingly, all 37 patients claimed no pain. Future study can aim to test whether improved compliance and better blood glucose control can be achieved by measuring the hemoglobin A1C in a randomized control trial using the new Tiniboy™ lancet.

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Stanley Kim is the inventor of the TiniBoy™ lancet, and is the founder of the Health innovation Ideas, LLC at 421 East 25th Street, Upland, CA 91784, USA.

Disclosure

This manuscript has been read and approved by the author. This paper is unique and is not under consideration by any other publication and has not been published elsewhere.

References

1. Bloomgarden ZT. Treatment Issues in Type 1 Diabetes. *Diabetes Care*. 2002;25:230–8.
2. Company product information. www.abbottdiabetescare.com
3. Cormack D. *Ham's histology*. 9th Edition. Philadelphia: J.B. Lippincott. 1987.
4. Moore, et al. Seventeen-point dermal ultrasound scoring system; a reliable measure of skin thickness in patients with systemic sclerosis. *Rheumatology*. 2003;42:1559–63.
5. Porro, et al. Does Anticipation of Pain Affect Cortical Nociceptive Systems? *J Neurosci*. 2002;22(8):3206–14.