Received: 16 April 2021 | Revised: 13 June 2021 | Accepted: 14 June 2021

DOI: 10.1111/trf.16582

ORIGINAL RESEARCH

TRANSFUSION

Comparison between a laser lancing device and lancet for capillary blood sampling, capillary blood hemoglobin measurement, and blood typing

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Funding information
Korea Health Industry Development Institute, Grant/Award Number: HR20C0021; Wonju Medical Industry Techno Valley, Grant/Award Number: R210305_54

Abstract

Background: Blood donor screening includes tests using capillary blood, which is usually obtained by finger pricking using a lancet; however, the lancet has some shortcomings, such as skin puncture pain and needle stick injury. Recently, laser lancing devices for finger-prick sampling have been developed. We compared capillary blood Hb (cHb) levels and blood typing results obtained using a laser lancing device with those obtained using a lancet.

Study design and methods: cHb levels, blood typing results, and skin puncture pain scores were assessed in 191 participants. Finger-prick sampling was performed using LMT-1000 (LaMeditech, Seoul, Korea) and a lancet on the same finger on different hands. Paired venous Hb (vHb) levels were assessed in 103 participants using an automated hematology analyzer and compared with the cHb levels obtained using both lancing devices.

Results: The paired cHb results obtained with the laser lancing device and lancet showed a strong correlation ($r = 0.927$, $p < .001$) without any significant difference ($p = .113$) and a substantial agreement ($\kappa = 0.654$) for the identification of participants with a low Hb level (<12.5 g/dl). cHb levels were significantly higher than vHb levels with both lancing devices (mean differences: 0.27–0.43 g/dl). The results of blood typing using the laser lancing device showed 100% accuracy. Use of the laser lancing device showed significantly lower skin puncture pain scores ($p < .001$).

Conclusion: Use of a laser lancing device for capillary Hb measurement and blood typing showed accurate results, with significantly reduced skin puncture pain. Laser lancing devices could be feasible for donor screening tests.

KEYWORDS
capillary blood sampling, donor screening, hemoglobin, lancet, laser, pain

1 | INTRODUCTION

Blood donor screening tests include several laboratory tests performed at the donation site, including measurement of the donor's hemoglobin (Hb) concentration and

Abbreviations: cHb, capillary blood Hb; Er:YAG, erbium:YAG; Hb, hemoglobin; NRS, numeric rating scale; POC, point-of-care; RBCs, red blood cells; vHb, venous Hb.

ABO and Rh blood typing. Hb measurement is performed to protect the donor from developing symptomatic anemia and to ensure an adequate dose of red blood cells (RBCs) and Hb in the collected blood product.[1–3] The lower limit for Hb levels for donor deferral varies across countries,[4] and the acceptable Hb level for blood donation is at least 12.5 g/dl for both male and female whole-blood donors in Korea. Hb is often measured before donation at the donation site using a point-of-care (POC) instrument and capillary blood sample.[5] In addition to Hb measurement, forward ABO and Rh typing can be performed using the capillary blood at the donation site for confirmation.

Finger-prick sampling is a simple and fast method for obtaining capillary blood samples for performing blood donor screening tests at donation sites. The conventional stainless steel needle lancet ("lancet") is a commonly used tool for finger-prick sampling; however, this method has some shortcomings, such as pain during blood sampling. The pain and fear related to capillary blood sampling using a lancet have been suggested as hurdles for successful blood glucose monitoring in patients with diabetes.[6] Capillary blood sampling using a lancet would be challenging in patients with needle phobia, and fear of injections is one of the barriers to blood donation.[7] In addition to lancing pain, needle stick injury during the handling and disposal of lancets remains a serious concern, despite advances in lancet devices.[8, 9]

Recently, a laser lancing device, LMT-1000 (LaMeditech, Seoul, Korea), has been developed for finger-prick sampling. LMT-1000 uses an erbium:YAG (Er:YAG) monopulse laser for skin perforation. LMT-1000 is a more compact version of the Food and Drug Administration-approved LMT-3000 (LaMeditech, Seoul, Korea), which uses the same laser as LMT-3000 but is smaller, lighter, and more affordable. Compared with a lancet, a laser lancing device (LMT-3000) was reported to significantly reduce puncture pain without any significant difference in POC test results.[10] However, the effect of laser radiant energy on capillary Hb (cHb) levels and blood typing results has not been fully evaluated. This study aimed (i) to compare the capillary blood Hb levels and blood typing results obtained by laser lancing device with those obtained by a lancet, (ii) to evaluate the use of a laser lancing device for identifying participants with low Hb levels (<12.5 g/dl), (iii) to compare lancing pain between the two lancing devices, and (iv) to examine the feasibility of blood donor screening tests at the donation sites.

2 | MATERIALS AND METHODS

2.1 | Study participants

A total of 91 healthy volunteers and 100 outpatients at Korea University Guro Hospital were enrolled in the study from November 2020 to June 2021. Outpatient volunteers were included to assess the reliability of the laser lancing device in measuring various levels of Hb (with low and high values). All participants were subjected to finger-prick sampling on both hands using a laser lancing device and a lancet. Finger-prick sampling was performed on the same finger on different hands, and the order in which the lancing devices were used was random. A total of 96 (50.26%) participants underwent finger-prick sampling using the laser lancing device first (Table S1). Of the 191 participants, 103 also underwent venous sampling for venous Hb (vHb) measurement. This study was approved by the Institutional Review Board of Korea University Guro Hospital (2020GR0330), and all study participants provided informed consent.

2.2 | Study protocol

Capillary sampling was performed based on the World Health Organization guidelines for capillary sampling.[11] The puncture area was disinfected with alcohol swabs and air dried. Finger pricking was performed on the fingertip of the second or third finger with a laser lancing device or lancet, and the first drop of blood was wiped away. Using capillary samples, Hb measurement was performed first, followed by blood typing. A 28-G lancet (Greenlan, Sae Han Med, Ilsan, Korea) with a lancing device (Lanzo, GMMC, Seoul, Korea) was used. Initially, the penetration depth of the lancing device was set at level 2. Venous samples were collected in ethylenediaminetetraacetic acid tubes (BD, Franklin Lakes, NJ), and Hb levels were determined using DxH 900 (Beckman Coulter, Miami, FL).

Capillary sampling using LMT-1000 was performed according to the manufacturer's instructions. LMT-1000 is a portable device that uses an Er:YAG single pulse laser, which emits light with a wavelength of 2940 nm (Figure 1A). The device is powered by a rechargeable battery (3.7 Vdc) and generates pulse energy at three different levels, 100, 140, and 180 mJ, in less time than 1/10,000 s. LMT-1000 shows penetration within a diameter of 500 μm and a depth of 600–900 μm. After turning the device on, the energy level was selected, and the device was charged by pushing the charge button. A disposable cap, which prevented contamination of the device with blood during the sampling procedure, was placed. After the puncture area was properly prepared, skin puncture was performed by pushing the shot button (Figure 1B–F). The laser was emitted only when the sensor on the irradiation area of the LMT-1000 was in close contact with the skin, ensuring safety.

cHb measurement was performed using the POC Hb determination system, HemoCue Hb 301 (HemoCue AB, Angelholm, Sweden). cHb measurement was performed after passing an internal quality control test

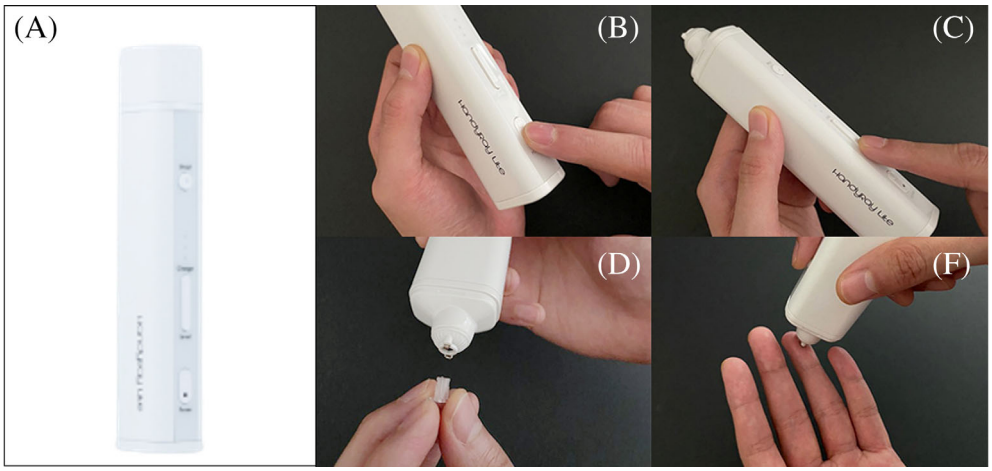

FIGURE 1 The laser lancing device, LMT-1000, and the capillary blood sampling process. (A) Laser lancing device hardware. The capillary blood is obtained by pushing the power button (B), selecting the laser level between levels 1 and 3 (C), charging the device by pushing the charge button (image not shown), placing a disposable cap (D), and performing skin puncture by pushing the shot button (E) [Color figure can be viewed at wileyonlinelibrary.com]

according to the manufacturer's instructions. The microcuvette was filled with capillary blood and placed into a cuvette holder, and the analyzer determined the cHb level.

Capillary blood samples obtained using a laser lancing device and lancet from 191 participants were tested to determine ABO compatibility and Rh blood type using the slide method. A drop of capillary blood was mixed with a drop of reagent antisera (anti-A, anti-B, or anti-D) using an applicator stick. Agglutination was visually examined after 2 min by tilting the slide back and forth.

Skin puncture pain was evaluated and compared between the laser lancing device and lancet using a numeric rating scale (NRS) from 0 to 10. A NRS was graphically presented to the participants, with 0 indicating no pain and 10 indicating the worst imaginable pain. Pain evaluation was performed immediately after skin-prick sampling.

2.3 | Statistical analyses

The comparison of results between the laser lancing device and the lancet was performed using the paired sample *t*-test and Wilcoxon signed-rank tests. The correlations between Hb values were analyzed using Pearson's correlation analysis. A p-value of $<.05$ was considered significant. Agreement was verified using a kappa coefficient; the strength of agreement was defined as follows: Cohen's kappa coefficient (κ) <0 = poor, 0–0.2 = slight, 0.21–0.4 = fair, 0.41–0.6 = moderate, 0.61–0.8 = substantial, and 0.81–1 = almost perfect. The sensitivity and specificity for the identification of participants with Hb values below 12.5 g/dl were evaluated by considering vHb values measured using a hematology analyzer as reference.

TABLE 1 Participants' characteristics

	Total	Men	Women
Total number	191	58	133
Participants with capillary and venous Hb values (%)	103 (53.9)	29 (50.0)	74 (55.6)
Capillary Hb (g/dl)[a]			
Mean ± SD	13.33 ± 2.18	13.69 ± 2.53	13.17 ± 2.00
Venous Hb (g/dl)			
Mean ± SD	12.72 ± 2.29	12.84 ± 2.65	12.67 ± 2.14
ABO/Rh blood type (%)			
A+	56 (29.3)	17 (29.3)	39 (29.3)
B+	59 (30.9)	20 (34.5)	39 (29.3)
AB+	19 (9.9)	3 (5.2)	16 (12.0)
O+	56 (29.3)	17 (29.3)	39 (29.3)
A−	1 (0.5)	1 (1.7)	0 (0)

Abbreviation: Hb, hemoglobin.
[a]Capillary Hb refers to the capillary Hb results obtained using the lancet.

3 | RESULTS

Paired finger-prick samples obtained by a laser lancing device and lancet were collected from 191 participants. Capillary blood sampling was successful in all participants at the first attempt. The participants'

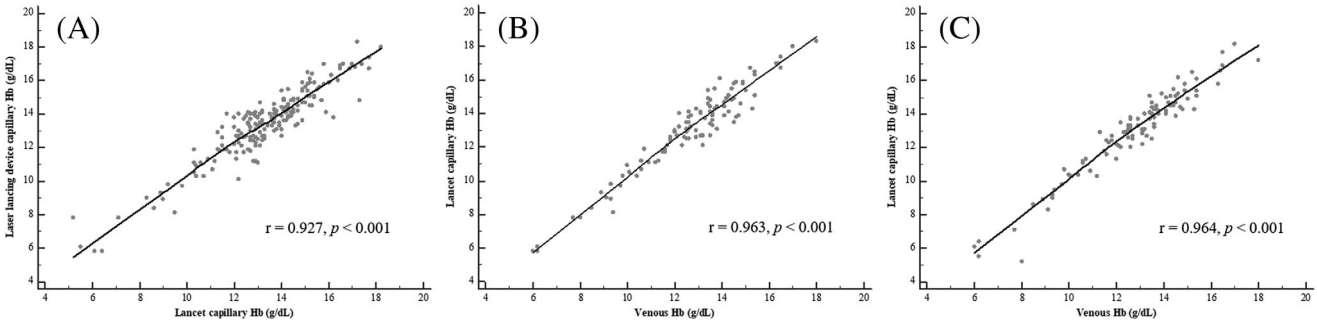

FIGURE 2 Scatter gram showing the correlation between the lancet cHb and laser lancing device cHb levels (A), vHb and laser lancing device cHb levels (B), and vHb and lancet cHb levels (C). cHb, capillary hemoglobin; vHb, venous hemoglobin

TABLE 2 Paired comparison of Hb values obtained using three different sampling methods

	N	Hb (g/dl) (mean ± SD)	Difference in Hb levels (g/dl) (mean)	*r* (Pearson correlation coefficient)	*p*-value	Kappa coefficient[a] (95% confidence interval)
Laser lancing device cHb vs. lancet cHb	191	13.42 ± 2.14 13.33 ± 2.18	0.10	0.927	<.001	0.654 (0.531–0.779)
Venous Hb vs. laser lancing device cHb	103	12.72 ± 2.29 13.15 ± 2.53	0.43	0.963	<.001	0.819 (0.700–0.938)
Venous Hb vs. lancet cHb	103	12.72 ± 2.29 12.99 ± 2.53	0.27	0.964	<.001	0.845 (0.735–0.956)

vHb, venous hemoglobin; cHb, capillary hemoglobin.
[a]Kappa coefficient refers to the strength of agreement between the sampling methods for identifying participants with Hb levels below 12.5 g/dl.

characteristics are presented in Table 1. The order in which lancing devices were used showed no significant differences in cHb or vHb levels or skin puncture pain scores (Table S1).

The paired cHb results obtained with the laser lancing device and lancet were compared, and a high correlation was observed between the values ($r = 0.927$, $p < .001$) (Figure 2A). The mean cHb level was 13.42 ± 2.14 for the laser lancing device and 13.33 ± 2.18 for the lancet (Table 2). The comparison of results obtained by the laser lancing device and lancet did not show any significant difference ($p = .113$). The cHb result obtained using the laser lancing device was 0.10 g/dl (range: −2.5 to 2.6) higher than that obtained using a lancet (Figure 3A). Since the lower limit of the cHb level for donor deferral is 12.5 g/dl for whole blood in Korea, we evaluated the agreement between cHb results obtained using the laser lancing device and a lancet for identifying participants with cHb levels below 12.5 g/dl. The cHb results obtained using the laser lancing device and a lancet showed that 47 (24.61%) and 50 (26.18%) participants had cHb values below 12.5 g/dl, respectively. Substantial agreement was observed between the lancing devices ($\kappa = 0.654$, 95% confidence interval [CI]: 0.531–0.779).

Of the 191 participants, 103 also underwent venous sampling and Hb measurement using a hematology analyzer. Both cHb values showed significantly high correlations with the Hb value obtained using the hematology analyzer (laser lancing device cHb $r = 0.963$, $p < .001$; lancet cHb $r = 0.964$, $p < .001$) (Figure 2B,C). The vHb result was significantly lower than both cHb results (laser lancing device cHb, $p < .001$; lancet cHb $p = .002$) (Table 2). The vHb results were lower by 0.43 g/dl (range: −2.2 to 1.3) and 0.27 g/dl (range: −1.7 to 2.8) than the cHb levels obtained using the laser lancing device and lancet, respectively (Figure 3B,C). On considering participants with vHb levels below 12.5 g/dl as the "true positive" participants with low Hb levels, the cHb levels obtained using the laser lancing device showed 80.00% ($n = 28/35$, 95% CI: 63.06%–91.56%) sensitivity and 98.53% ($n = 67/68$, 95% CI: 92.10%–99.96%) specificity (Table 3). The cHb levels obtained using a lancet showed 85.71% ($n = 30/35$, 95% CI: 69.74%–95.19%) sensitivity and 97.06% ($n = 66/68$, 95% CI: 89.78%–99.64%) specificity (Table 3). Using Kappa statistics, cHb results obtained using both lancing devices showed almost perfect agreement with vHb results in terms of identifying participants with vHb levels below 12.5 g/dl (Table 2).

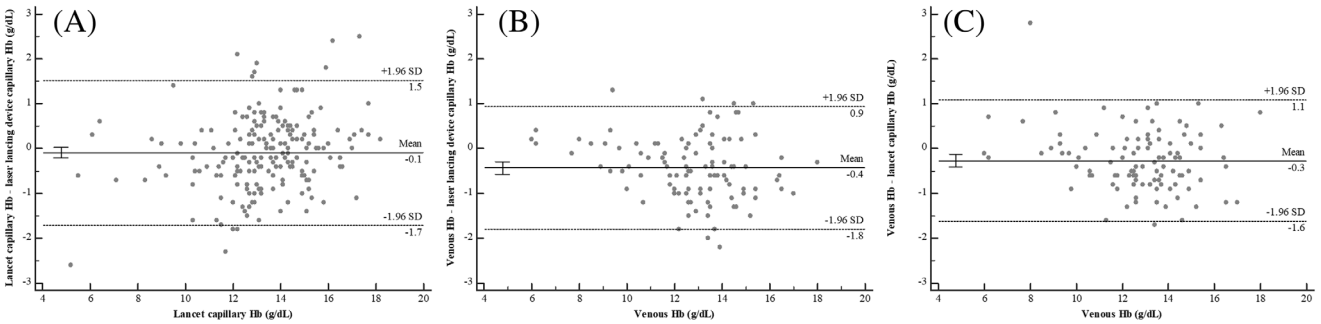

FIGURE 3 Bland–Altman plot of the difference between the lancet cHb and laser lancing device cHb levels (A), vHb and laser lancing device cHb levels (B), and vHb and lancet cHb levels (C). cHb, capillary hemoglobin; vHb, venous hemoglobin

TABLE 3 Number of samples and Hb values obtained using the laser lancing device and lancet according to a venous Hb cut-off level of 12.5 g/dl

Venous Hb value			Laser lancing device				Lancet			
			cHb <12.5 g/dl		cHb ≥12.5 g/dl		cHb <12.5 g/dl		cHb ≥12.5 g/dl	
	N	Median vHb (g/dl) (range)	N	Median cHb (g/dl) (range)	*N*	Median cHb (g/dl) (range)	*N*	Median cHb (g/dl) (range)	*N*	Median cHb (g/dl) (range)
vHb <12.5 g/dl	35	10.6 (6.0–12.4)	28	10.4 (5.8–12.4)	7	12.9 (12.6–14.0)	30	10.4 (5.2–12.4)	5	12.9 (12.7–13.5)
vHb ≥12.5 g/dl	68	13.7 (12.5–18.0)	1	12.1	67	14.3 (12.5–18.3)	2	12.1 (12.0–12.2)	66	14.3 (12.5–18.2)

cHb, capillary hemoglobin; vHb, venous hemoglobin.

All 191 capillary blood samples were successfully classified into the ABO and Rh blood groups. The ABO and Rh blood group distributions of the participants are presented in Table 1. For all participants, the ABO and Rh blood typing results obtained using the laser lancing device were in accordance with the results obtained using lancets (100%, $n = 191/191$).

Evaluation of skin puncture pain revealed that the mean NRS scores of the laser lancing device and lancet were 1.70 ± 1.55 and 2.66 ± 1.69, respectively. The laser lancing device showed significantly lower skin puncture pain scores than the lancet ($p < .001$) (Figure 4).

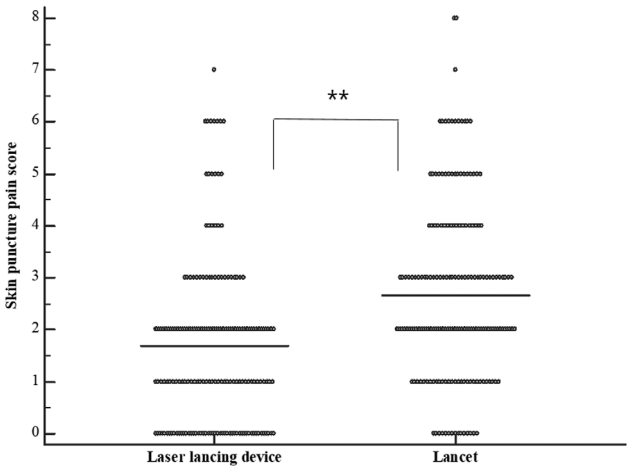

FIGURE 4 Distribution of skin puncture pain scores using the laser lancing device and lancet. The horizontal line represents the mean skin puncture pain score for the two lancing devices. Comparison of scores between the two lancing devices was performed using the Wilcoxon signed-rank test: $^{**}p < .001$

4 | DISCUSSION

In this study, we attempted to assess the accuracy of Hb measurement and blood typing using capillary blood samples obtained using the laser lancing device and examined the feasibility of blood donor screening tests using this device at donation sites. Capillary blood samples obtained using the laser lancing device could be used for Hb measurement and ABO and Rh typing. Compared with a lancet, the laser lancing device showed comparable performance for anemia detection, with significantly reduced pain levels.

Capillary sampling using a laser lancing device had some advantages. First, it resulted in significantly less pain than sampling using a lancet, consistent with the findings of previous studies.[10, 12] The Er:YAG laser energy is strongly absorbed by water due to high absorption of light with a wavelength of 2940 μm and can cause

selective ablation at a very limited depth in skin tissue with minimal thermal damage.[13] Pulse duration is an important factor in the generation of thermal effects;[13–15] with the generation of pulse energy in less time than 1/10,000 s, LMT-1000 minimized thermal damage. A laser lancing device has a penetration depth lower than that of a lancet, and this has been postulated to be a cause of less pain. Considering the lower depth of penetration, sampling using a laser lancing device would only involve the papillary dermis without involvement of the reticular dermis, which has abundant free nerve fibers.[10] The depth of lancet penetration is associated with puncture pain.[16] Second, needle stick injury during the handling and disposal of lancets was avoided during capillary sampling, which would be helpful at donation sites.

In the 191 participants, cHb levels measured using the laser lancing device and a lancet were not significantly different and showed a high correlation ($r = 0.927$). The magnitude of difference in Hb levels was relatively small, with a mean difference of 0.10 g/dl. To the best of our knowledge, only one other study has evaluated a laser lancing device for cHb measurement. Fonseca et al. reported that there was no significant difference in cHb levels between a Er:YAG laser lancing device and a lancet; however, the mean Hb value was lower for the Er:YAG laser lancing device than for a lancet, contrary to our findings. We believe that the direct effect of the laser on Hb measurement was minimal because absorption peaks around 418 nm, 530–545 nm, and 577–595 nm for Hb molecules,[17] which could result in a strong correlation with a relatively small difference in Hb levels.

Compared with vHb values, cHb values obtained using both a laser lancing device and lancet were significantly high, with mean differences ranging from 0.27 to 0.43 g/dl. These results are consistent with those of previous studies, wherein the cHb levels measured with HemoCue were significantly higher than the vHb levels, regardless of the use of a hematology analyzer for vHb measurement. The mean differences varied between studies, ranging from 0.15 to 0.68 g/dl).[18–22] Donor deferral based on cHb values, either using a laser lancing device or lancet, should consider this difference for the donor's safety. In our study, when considering the vHb level as the reference Hb level, two participants showed false-negative results (values higher than the lower limit) for referral with the use of both lancing devices (vHb: 12.2 g/dl; laser lancing device cHb: 14.0 g/dl; lancet cHb: 13.5 g/dl and vHb: 12.4 g/dl; laser lancing device cHb: 12.6 g/dl; lancet cHb: 12.9 g/dl). Based on the laser lancing device and lancet cHb levels, five and three additional participants showed false-negative results, respectively. Of the eight participants who showed false-negative results in laser lancing device cHb or lancet cHb levels, six showed vHb levels of 12.0–12.4 g/dl. Of the remaining two participants, one with a vHb level of 11.8 g/dl had a false-negative result based on a laser lancing device cHb result (12.6 g/dl), and the other participant with a vHb level of 11.3 g/dl had a false-negative result based on a lancet cHb result (12.9 g/dl). The difference in performance between laser lancing devices and lancets for identifying participants with low Hb levels requires further evaluation, with the inclusion of more participants with low Hb levels for confirmation.

This study has some limitations. First, the number of participants with low Hb levels was small. However, on performing analysis only including samples with low Hb levels, the results were almost the same as those obtained using the total number of samples (data not shown); we were able to show statistical significance despite the small number of samples with low Hb levels. Second, additional finger-prick sampling was not performed. Since cHb assessments are prone to preanalytical and analytical variations, repeat finger-prick sampling in participants with borderline cHb values (between 12.5 and 13.0 g/dl) can enable us to clearly evaluate the differences between the laser lancing device and lancet in the detection of low Hb levels.

In conclusion, use of a laser lancing device for capillary Hb determination and blood typing showed accurate results with significantly reduced skin puncture pain, compared with those obtained using a lancet. The cHb level obtained using a laser lancing device showed high correlations with both lancet cHb and vHb results and good performance for the identification of participants with low Hb levels. All ABO and Rh blood typing results were in accordance with those obtained using a lancet. Our findings have shown the feasibility of using a laser lancing device for donor screening tests, especially at donation sites.

ACKNOWLEDGMENTS

This study was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HR20C0021) and a grant from the Wonju Medical Industry Techno Valley (grant number: R210305_54).

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Kim J, Yoon S-Y, Lim CS, Yoon J. Comparison between a laser lancing device and lancet for capillary blood sampling, capillary blood hemoglobin measurement, and blood typing. Transfusion. 2021; 1–7. https://doi.org/10.1111/trf.16582