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Original Research Article

Quantitative Evaluation of Venipuncture Training Models: A Study Using a Puncture Force Testing Device

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ABSTRACT

Background/Objectives: This study introduces a quantitative assessment of venipuncture training models using a customized puncture force testing device. The device, engineered to quantify the force and torque exerted during a puncture under regulated speed and angle conditions, aims to augment the authenticity and efficiency of medical training models. In Japan, a diverse group of medical professionals receive training in venipuncture, utilizing models in a variety of educational environments. However, the existing models often fall short of replicating the physiological realism of human tissue, which limits the effectiveness of the training.

Methods: To address this issue, the study employed a puncture force testing device that includes a needle, syringe, load test stand, and digital force gauge, among other components. This arrangement facilitated the precise control and recording of puncture force at varying speeds and angles. Three distinct venipuncture models (Models A, B, and C), filled with water to mimic venous blood, were tested under these regulated conditions.

Results: The findings revealed notable differences in puncture force among the models, with Model C closely resembling human tissue because of its lower maximum puncture force.

Conclusion: The study also observed a variation in the force required at different puncture speeds, thereby enhancing our understanding of model behavior under diverse conditions. Moreover, the use of a mechanically controlled puncture device eliminated the variability associated with individual technique, allowing for a more quantitative and reproducible evaluation. In conclusion, the study proposes a more quantitative and objective approach for evaluating venipuncture models. This progress is vital for refining these models to more accurately simulate human tissue, consequently improving the quality of medical training in venipuncture procedures.

Keywords—*Clinical skills, Intravenous injection, Nursing students, Public health nurses, Venipuncture.*

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INTRODUCTION

In Japan, a broad spectrum of medical professionals, including physicians, dentists, public health nurses, midwives, nurses, licensed practical nurses, clinical laboratory technicians, radiology technicians, and clinical engineers, are trained in intravenous injection and blood sampling. These professionals acquire venipuncture skills through various training schools and clinical practice. Simulation education, exemplified by skills laboratories, is actively conducted primarily in medical schools. Ishikawa et al. reported that at least 74 out of 80 faculties in Japan had a skills laboratory at the time of their survey.¹ Suzuki et al. reported that an intravenous blood collection and injection model was used in 53 faculties, with more than 300 sets available.²

These models are utilized not only in training schools but also in postgraduate education to enhance clinical skills across various professions. Training facilities for medical professionals in Japan comprise 81 medical schools,³ 1 medical doctor training programs at a ministerial university, 828 three- or four-year training schools for nurses, and 180 training schools for licensed practical nurses.⁴ In addition, there are 103 clinical technologist training schools,⁵ 55 training schools for radiology technologists,⁶ and 88 training schools for clinical engineers who are members of educational associations nationwide.⁷

A comparative study of cannulation training for veins in nursing students observed no statistically significant differences in performance between groups of students trained with each other and with a rubber mannequin.⁸ Jones et al. suggested that student-to-student and mannequin training are equally effective. They also noted that the use of mannequins can reduce risk.⁸ Despite the widespread use of these models, it has been noted that the skills acquired from training on a mannequin are limited because of their unique characteristics that differ from those of the human body.⁹⁻¹¹ To address this issue, we attempted to measure the force and torque applied when puncturing a model to establish a quantitative evaluation method to improve the quality of these models.^{12,13} However, the methods used in previous studies are dependent on the human technique, which remains a challenge.

In this study, we developed a puncture force testing device capable of testing puncture speed and angle under specific conditions. We conducted tests on a product similar to the model used in the previous study to compare it with conventional methods.

METHODS

Puncture Force Testing Device

We constructed a puncture force testing device, which incorporates a force gauge and a load test stand, to assess the venous blood collection and injection model. This device allows for the evaluation of the model under consistent puncture speed and angle (Figure 1).

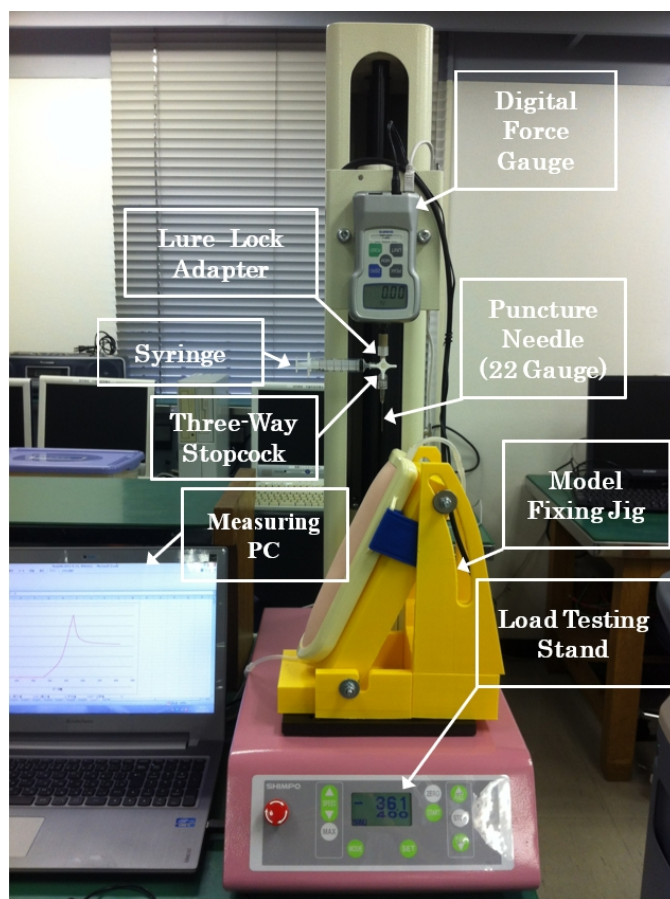


FIGURE 1. Puncture force testing apparatus utilizing a load test stand.

In contrast to our previous study,¹² which employed a syringe-type force sensor operated manually by participants—potentially introducing variability associated with individual technique—the device developed in the present study enables puncture under controlled conditions with a fixed speed and angle.

This system offers improved reproducibility and eliminates inter-operator variability, thereby enhancing the reliability and objectivity of the puncture force measurements.

The apparatus comprises a needle (NN-2232S: Terumo), a Luer–Lock adapter (PS6608: ISIS), a three-way stopcock (394900: BD), a syringe (SS-05SZ: Terumo), a force test stand (FGS-100VC: Nidec-Sympo), a digital force gauge (FGP-1: Nidec-Sympo), a personal computer (ideapad Z500: Lenovo), and a jig made of acrylonitrile-butadiene-styrene (ABS) resin produced by a 3D printer for securing the model.

The puncture force tester can move a digital force gauge up and down at a variable speed (10–400 mm/min) by either automatic or manual operation. When a puncture is performed with the load test stand, the puncture force is transmitted to the measurement axis of the digital force gauge via the needle. The measured data can be continuously recorded by a personal computer connected to the digital force gauge. The force waveform obtained by the digital force gauge is smoothed by an integrated measurement filter. In the experiments, the 90% response time to step input was set to 3 ms, and the sampling frequency was 100 times per second.

A three-way stopcock was attached to verify whether the needle tip was inserted into the model's blood vessel after puncture with the load test stand. If the puncture was successful, water filled in the model's blood vessel could be aspirated from the port of the three-way stopcock by a syringe. The puncture needle is a sterile disposable needle commonly used for blood collection in adults (22G, short bevel type). The Luer–Lock adapter, made of polyetheretherketone (PEEK) resin, is used to screw the puncture needle into the device. The tool adheres to

the same standard as the method used to secure needles in actual clinical practice, allowing the puncture needle to be changed according to the application. The jig for securing the model, made of ABS resin, is used to puncture the model at an angle suitable for blood collection and puncture. The jig was fabricated using a 3D printer (Replicator2X: Makerbot).¹²

Figure 2 provides an example of a puncture force waveform measurement and the items measured. In Figure 2, " F_{\max} " represents the maximum puncture force.

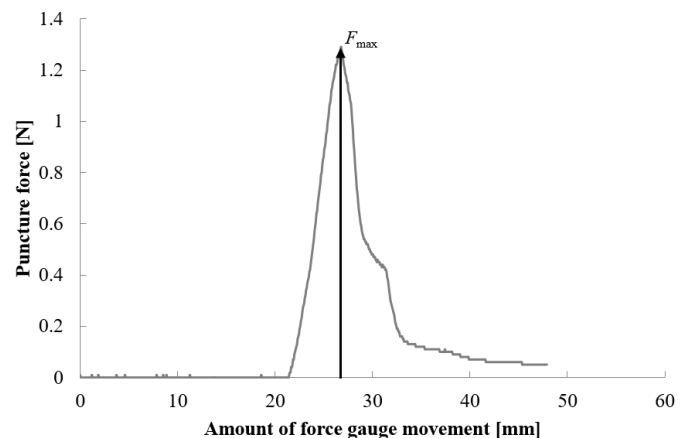


FIGURE 2. Puncture force waveform measurement and the corresponding measured item (The puncture force waveform was smoothed using a low-pass filter built into the force gauge. The filter parameters were set such that the 90% response time to a step input was 3 ms).

Subjects and Methods of Experiments

We prepared three models, designated as Model A, Model B, and Model C, similar to those used in the previous study (Figure 3).^{9,10} Models A and B are designed to be worn on the arm of the training collaborator, while Model C is shaped like an arm. The simulated vessels of the models were filled with tap water to mimic blood, and a drop pressure was applied to simulate venous blood pressure, as per the models' instruction manual.

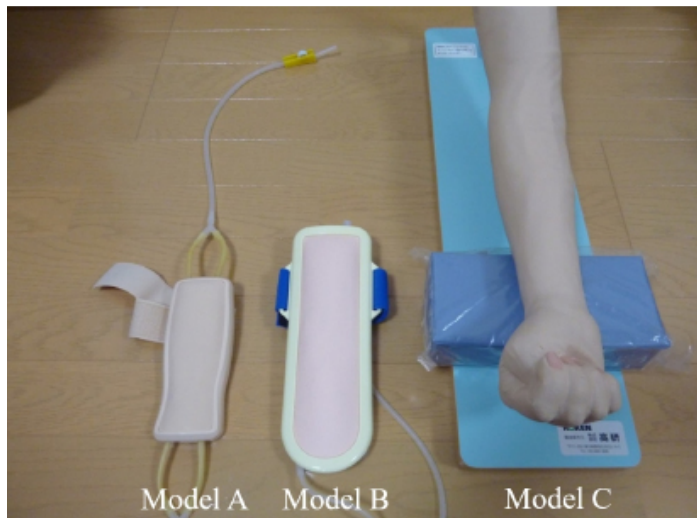


FIGURE 3. Intravenous blood sampling practice model.^{12,13}

During the puncture test, the puncture angle was mechanically fixed at 25° using a jig, in accordance with the standards specified in the blood collection method guidelines.¹⁴ We also set the puncture speed at 200 mm/min and 400 mm/min. We used two different puncture speeds to examine the model’s dependence on speed, as it has been reported that the puncture reaction force decreases as the speed increases when puncturing the biological tissue.¹⁵

We conducted 12 tests for each model at a sampling frequency of 100 Hz. The needle was manually advanced into the model’s simulated blood vessel using the stand, and the stand was stopped when the needle reached the vessel. We replaced the needle used for the puncture after each test. A puncture was deemed successful when water could be aspirated from the three-way stopcock by a syringe. The number of tests was set to 12 to allow for comparison with our previous study,^{12,13} in which the same model was used and experiments were conducted with 12 participants.

RESULTS AND DISCUSSION

The average of the maximum puncture force is presented in Figure 4. An analysis of variance revealed a significant difference ($p < 0.05$) between the groups with a puncture speed of 200 mm/min and those with a puncture speed of 400 mm/min. Furthermore, multiple

comparisons using Fisher’s protected least significant difference (PLSD) indicated significant differences in all combinations, except between Model A and Model B in the group with a puncture speed of 200 mm/min ($p < 0.05$). Notably, Model C exhibited a significantly lower maximum puncture force than the other models at all puncture speeds ($p < 0.05$). The puncture speed dependence test results showed that only Model B exhibited a dependence on puncture speed ($p < 0.05$).

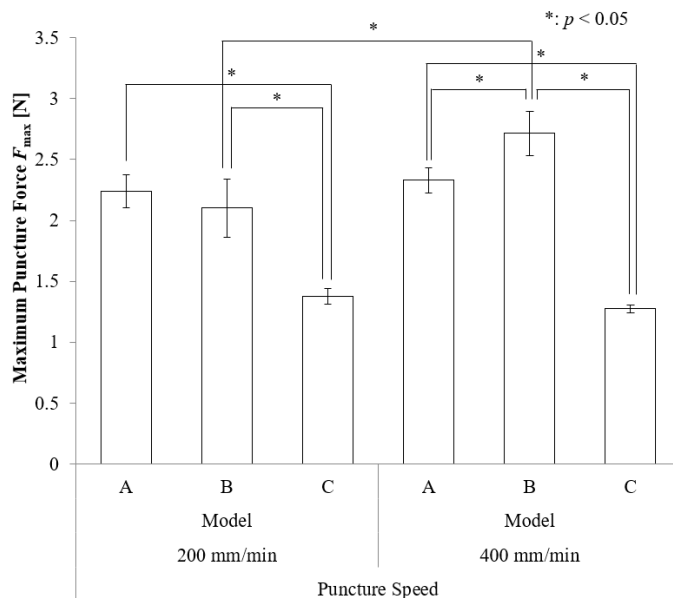


FIGURE 4. Average maximum puncture force (mean ± standard error; $n = 12$)

Compared to the results of multiple comparisons in a previous study by the authors, the current study demonstrated significant differences in all pairs at a puncture speed of 400 mm/min. This suggests that the differences in model characteristics are equally or more detectable.¹²

In the previous study, 12 using the same models, puncture experiments were conducted by 12 participants with a syringe-type force sensor. While that study found statistically significant differences between most model pairs, no significant difference was observed between Model A and Model C. In contrast, the present study, which employed mechanically controlled puncture conditions and the same number of trials ($n = 12$), revealed significant differences among all models at a puncture speed of 400 mm/min.

These findings suggest that the method developed in this study enables more sensitive and consistent detection of differences in model characteristics.

Okuno et al. reported that the puncture force for the median cubital vein on a volunteer was 0.64 ± 0.23 N (21 G, regular bevel).¹⁶ Consequently, all models were deemed stiffer compared to the human body, aligning with the observations in the authors' previous studies.^{12,13} In a subjective evaluation, Model C was assessed to be the most similar to the human body, although there were opinions that the skin and blood vessels were slightly stiff.¹² In the experimental results of this study, Model C was the closest to the human body among the three models. Therefore, the subjective evaluations of the models by previous studies¹² and the quantitative evaluation by the current method are in agreement, and the results are considered to be reasonable.

Several factors could account for the variation in results, even when punctures are performed under specific conditions. Given that blood vessels have a cylindrical shape, their thickness can vary depending on the position of the puncture. Moreover, the blood vessels themselves are not uniformly manufactured. Consequently, the large standard error in Model B might be because of the nonuniform thickness of the blood vessel compared to other models or the blood vessel being stiffer than in other models. These tendencies are more pronounced.

However, when compared to the experimental results using the syringe-type puncture force waveform measuring device, the smaller standard error and the independence of this experimental system from human techniques suggest the possibility of a more quantitative evaluation.^{12,13}

Since the number of trials in both the previous study¹² and the present study was the same ($n = 12$), the comparison based on standard error is considered appropriate. Therefore, the smaller standard error observed in this study reflects reduced variability and supports the potential for more consistent and quantitative evaluation.

In addition, an investigation of puncture speed dependence by Naemura et al. reported that the higher the puncture speed, the higher the peak value, up to a region of 600

mm/min or less. The trend became more pronounced with increasing needle diameter, and differences in the needle tip shape were considered to contribute to variations in its magnitude.¹⁷ Lorenzo et al. demonstrated that during needle insertion, the cutting force at the needle tip changes markedly when penetrating tissue, while the shaft friction force increases proportionally with insertion depth but does not change abruptly at penetration.¹⁸ These reports suggest that the maximum puncture force increases when the incision force of the needle is insufficient relative to the puncture velocity. Since Model B was considered the stiffest model in previous studies, it is possible that this tendency was significantly observed.^{12,13}

CONCLUSION

In this study, we sought to evaluate the model using a puncture force test device that allows for puncture under specific conditions. Multiple comparisons of the average maximum puncture force indicated that the model was capable of detecting differences in model characteristics to an equal or greater extent than the method using a syringe-type puncture force waveform measuring device. Furthermore, the results, which had a small standard error, and the device that enabled puncture force measurement under certain conditions eliminated the need to consider the effects of individual differences among experiment participants. This facilitated a more quantitative evaluation of the model. However, the maximum puncture force of the model was higher than the results of puncture experiments on the human body reported in previous studies, including a study by the authors.^{12,13} Therefore, it is necessary to innovate materials for the skin and blood vessels by developing synthetic materials with lower elasticity in order to enhance the model's resemblance to the human body.

AUTHOR CONTRIBUTIONS

Conceptualization, N.N., K.H. and K.A.; Methodology, N.N.; Validation, N.N.; Formal Analysis, N.N.; Data Curation, N.N.; Writing–Original Draft Preparation, N.N.; Writing–Review & Editing, N.N., K.H. and K.A.

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DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors on request.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Part of the findings were presented at the 27th Annual Conference of Biomedical Fuzzy Systems Association (Japan), 2014.

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