Detection of needle puncture to blood vessel using puncture force measurement

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Abstract—*Although blood sampling is frequently performed, a system to take blood samples automatically has not yet been developed. In the paper, as a first step towards automatic blood sampling, an examination of an automatic method for puncturing blood vessels is described. The force waveforms produced by puncturing rabbit ear veins were measured. A characteristic peak, possibly associated with the needle piercing the vessel wall, was observed in each waveform of ten successful cases of 14 trials. An algorithm that allowed the detection of this peak was developed, and parameters of a filter to improve the accuracy of the algorithm were determined. Using this algorithm, automatic needle punctures were performed in a rabbit ear vein and then were simulated using the data derived from manual needle puncture on four other rabbits. The results gave 30 fully successful cases of 33 trials of needle puncture and showed that measurement of the puncture force may be important for automatic needle puncture of blood vessels.*

Keywords—*Needle puncture, Puncture force, Automatic blood sampling*

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1 Introduction

NEEDLE PUNCTURE of a blood vessel is a very frequently performed medical procedure for blood sampling, blood donation, injection, intravenous drip and cannulation. Even if the relative incidences of medical mishaps such as internal haemorrhage are low, the total number could be considerable. Improving technique through increased clinical experience reduces these accidents. Simulators that model skin and blood vessels are available for clinical training (GLOBAL INDUSTRY ANALYSTS, INC., 2002). However, the models allow only limited skill acquisition, because the model cannot fully reflect differences in the hardness and elasticity of skin and blood vessels between individuals

On the other hand, experienced operators can sense the subtle changes in resistance that are met when the blood vessel is punctured, before visual confirmation of blood flow into a syringe through the needle. This information may help to control the penetration. The possibility of using changes in puncture force to improve control has been evaluated using the simulated skin and blood vessel model (ZIVANOVIC and DAVIES, 2000). In this paper, the use of puncture force to control needle movement during venepuncture in a rabbit ear is evaluated.

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2 Methods

2.1 *Experimental set-up for measuring the puncture force*

Fig. 1 shows a schematic diagram of the system for measuring the puncture force. A force sensor* and a disposable tube were installed inside a transparent cylinder (diameter 22 mm, length 55 mm). The maximum load, error of non-linearity and natural frequency of the force sensor were 9.81 N, less than 0.5% and 17.5 kHz, respectively. The axial force of puncture acting on the needle tip was transmitted to the force sensor through the cylindrical bearing guide. Fig. 2 shows a schematic diagram of the experimental set-up.

The output of the force sensor was fed through an amplifier†, sampled every 10 ms and then recorded on a personal computer. The accuracy of an analogue-to-digital (AD) converter was 12 bits of the length. The cutoff frequency of the force sensor amplifier was set to 10 Hz. The cylinder on which the force sensor was mounted was an ultrasonically driven linear stage‡. At 1 kg of the load, movement range, resolution and maximum velocity of the linear stage were 60 mm, 1 μm and 180 mm s^{-1}, respectively. The linear stage was controlled manually or by programmed operation with the computer interface. The speed and the needle angle were held constant, at 2.5 mm s^{-1} and 15° to the skin surface, respectively. A method was developed to determine the point at which the needle punctured the blood vessel.

Disposable needles** were used in all experiments. These had an outer diameter of 0.40 mm and length of 19 mm, and

*LM-1KA-P, Kyowa Elec. Inst., Tokyo
†DPM-611A, Kyowa Elec. Inst., Tokyo
‡USL-A106Y-P150, SUN-SYN Co., Tokyo
**NEOLUS® 27G, TERUMO Co., Tokyo

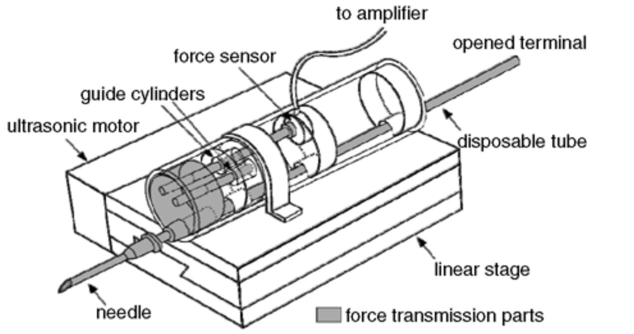

Fig. 1 *Schematic diagram of mechanical set-up for measuring puncture force. Force acting at tip of needle is transmitted to force sensor by guide cylinders. When needle punctures vessel, blood flows into needle and disposable tube. Device is mounted on linear stage that is driven by ultrasonic motor*

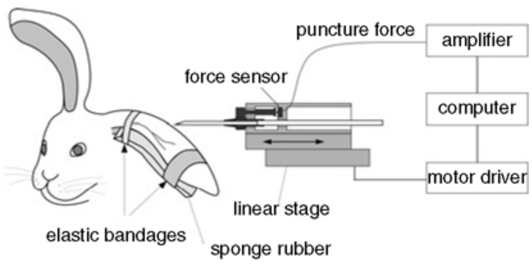

Fig. 2 *Schematic diagram of puncture force measurement set-up. Output of force sensor is fed through amplifier and sampled every 10 ms. It is then recorded on personal computer. Cylinder with force sensor was fixed to ultrasonically driven linear stage. Linear stage was controlled by personal computer or manually via computer interface*

the needle tip (bevelled in three planes) was about 1.7 mm long. The measurement set-up was tested with five needle punctures through an elastic rubber membrane, measuring about 5×5 cm by 0.1 mm in thickness. These tests showed that the output of the force sensor increased when the needle tip touched the surface of the rubber membrane and then decreased suddenly when the needle tip pierced the rubber membrane. Waveforms of puncture force with a saw-tooth shape were obtained.

2.2 *Subjects*

Five Japan White female rabbits, weighing from 1.7 to 4.5 (2.5 ± 1.2) kg, were used. The experimental protocol was designed to minimise pain, conforming to the guidelines for animal experimentation at the Tokyo Medical and Dental University. The rabbit's head was gently immobilised at the palate and occipital regions using a cylindrical fixation device, without anaesthesia. The rabbit's ear was fixed to a magnetic base with an elastic bandage on a bed of sponge rubber, which was moulded to fit the ear. The position of the rabbit's ear was adjusted by a linear manipulator attached to a magnetic base.

2.3 *Measurement of puncture force to rabbit ear vein in manual operation*

The puncture force was measured by making punctures on the *vena auricularis rostralis* in one rabbit. The outer diameter of the vein was estimated using a vernier caliper held against the skin surface. It was briefly compressed with an elastic bandage and then allowed to expand from 1.2 to 1.5 mm before each puncture. The needle was placed at the same height above the ear and over the target vein. Puncturing was stopped when the operator confirmed that the needle tip had entered the vein, who then determined success or failure of the puncture by the observation of blood flowing into the disposable tube. Both ears of the rabbit were punctured a few times in one day, with another session performed after a week's recovery. Fourteen manually driven punctures were performed on the ear vein in rabbit *A*.

2.4 *Parameters of second-order low-pass filter for peak detection of puncture force*

Automatic needle control should be possible by detection of the peak in the puncture force. An algorithm that would stop the needle movement when the time differential of the puncture force became negative was developed for use with the personal computer. The puncture forces were filtered with a second-order low-pass filter (2nd LPF). The optimum combination of cutoff frequency (f_c) and damping coefficient ζ was determined so that peak force could be detected, with less delay after the actual peak, using a peak detection algorithm on the puncture force measurements from the manual operation.

2.5 *Automatic puncture of the vein*

Thirteen automatic needle punctures were carried out to the vein of rabbit *A*, under the same conditions as used for the measurements of puncture forces in the manual penetrations. Two experimental sessions, separated by an interval of 7 days, were performed a month after the manual puncture experiments. To evaluate further the peak force detection algorithm, automatic needle punctures were simulated using the data derived from manual needle puncture to four other rabbits (*B–E*). In these simulations, five automatic needle punctures were performed on each rabbit.

3 Results

3.1 *Puncture force to rabbit ear vein in manual operation*

A typical result of needle puncture is shown in Fig. 3. After the needle tip touched the skin of the rabbit ear, the puncture force increased gradually. Before the needle movement was stopped at the point indicated by the vertical line, the puncture force decreased. In ten cases of 14 trials, the operator confirmed that the needle tip had entered the vein, and blood was observed to flow into the needle. A similar peak was

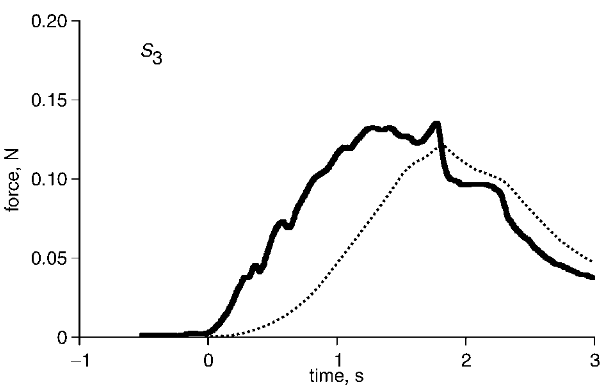

Fig. 3 *Typical example of puncture force for successful puncture in rabbit A. Needle punctured rabbit ear vein at speed of 2.5 mm s^{-1} and at angle of about 15° to skin surface. Operator stopped needle at point shown by vertical line. The dotted line shows the output of second-order low-pass filter*

observed in the puncture force waveform just before the needle was stopped in all of the cases with successful penetrations.

In the other four cases of the 14 trials, the operator could not confirm the needle puncture by visual observation. Fig. 4 shows the waveforms of the puncture force for the manual failures. The needle movement was stopped at the vertical line. In cases F_1 and F_2, neither blood flow into the needle nor a peak in puncture force was observed. In cases F_3 and F_4, the operator judged that the needle did not puncture the blood vessel, but blood flow into the needle was observed a few seconds after needle movement had stopped.

3.2 *Optimum parameters of 2nd LPF*

To determine the optimum combination of f_c and ζ, the peak detection algorithm was applied to the force measurements in all successful punctures. The combination of 0.4 Hz for f_c and 0.5 for ζ achieved the most successful peak detection. The average time required for peak detection of 0.08 s was shorter than the operator's reaction time of 0.28 s to stop the needle movement.

3.3 *Automatic puncture to the vein*

In needle punctures for rabbit A, the needle was successfully stopped automatically, with blood flow into the needle, in ten cases. In three further cases, the needle was manually stopped without blood flow, with the needle tip missing the blood vessel (confirmed by transdermal observation in each case). Fig. 5 shows typical results for the successful cases of automatic puncture. On each graph, the vertical line indicates the point where the needle stopped automatically; the needle stopped just after the peak of the puncture force in all successful cases. The means and standard deviations of the peak puncture forces and the time at which the peak appeared were 0.18 ± 0.04 N, 2.16 ± 0.30 s, respectively. The mean time required for peak detection was 0.06 ± 0.04 s. Although the magnitude and time of the peak puncture force were higher and later than in the experiments of manually driven punctures, the waveforms were similar, and the detection time of the peak became rather shorter.

In five numerical simulations of automatic needle puncture in four other rabbits, the algorithm succeeded in detecting the puncture force peak using the parameters determined from the data obtained for rabbit A. The average and standard deviation of peak value, and detection time of the puncture force are shown in Table 1. The times required for peak detection were longer, 0.08 ± 0.05–0.16 ± 0.10 s, on average in rabbits B–E; however, the needle successfully punctured the blood vessel automatically, without penetration, in all cases. The maximum and minimum peak forces and the time until the peak appeared were 0.28/0.11 N and 2.87/1.51 s, respectively.

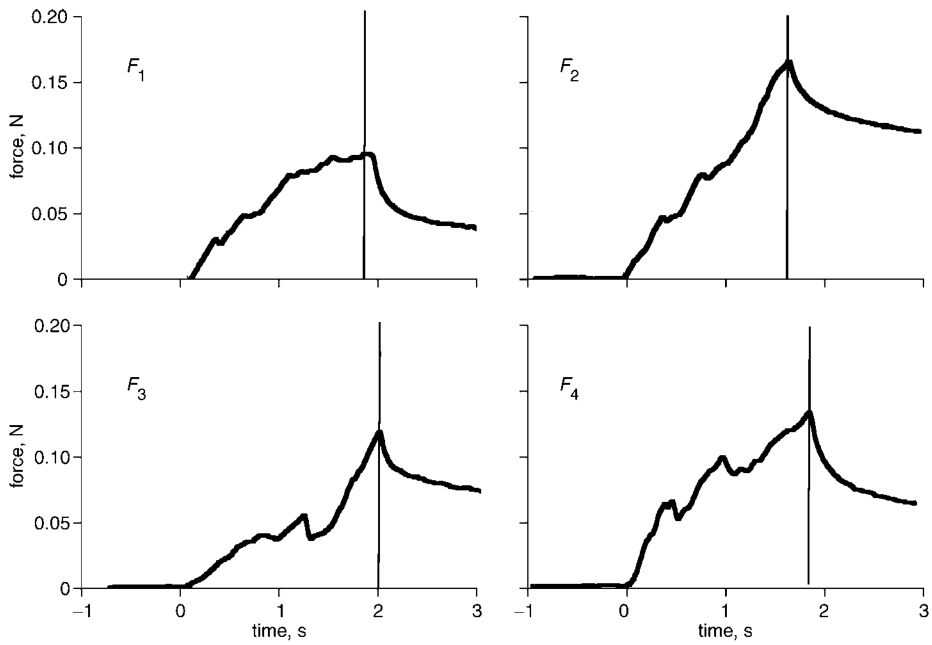

Fig. 4 *Examples of waveform of puncture force in four failed cases of manual operation*

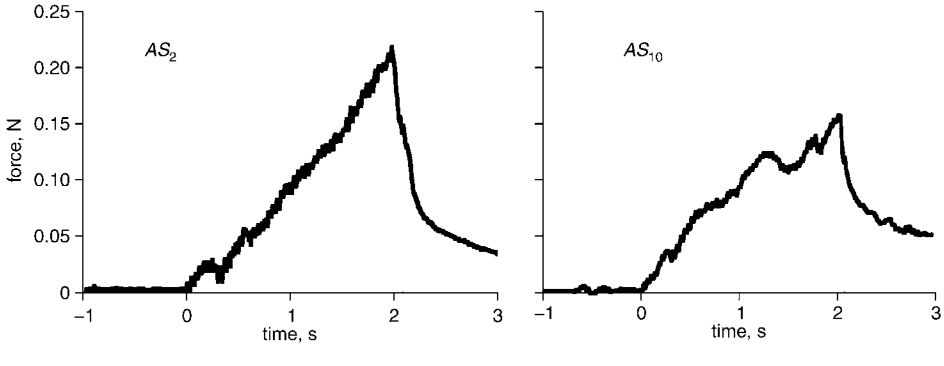

Fig. 5 *Examples of successful blood aspiration in rabbit A. Needle was automatically stopped at vertical line*

Table 1 Results of successful peak detection of puncture force. Average and standard deviation of ten trials in rabbit A and five trials each in other rabbits

Rabbits	Peak force, N	Peak time, s	Peak detection time, s	Peak detection required time, s	Number of trials
A	0.18 ± 0.04	2.16 ± 0.30	2.22 ± 0.28	0.06 ± 0.04	10
B	0.20 ± 0.05	2.30 ± 0.41	2.46 ± 0.40	0.16 ± 0.10	5
C	0.14 ± 0.03	1.83 ± 0.45	1.91 ± 0.41	0.08 ± 0.05	5
D	0.15 ± 0.02	2.02 ± 0.52	2.09 ± 0.38	0.13 ± 0.08	5
E	0.20 ± 0.03	2.46 ± 0.45	2.55 ± 0.44	0.09 ± 0.07	5

4 Discussion

4.1 *Reproducibility in waveforms of puncture force*

We proposed using the force at the needle tip to control automatic needle puncture of blood vessels (OKUNO *et al.*, 1998). Successful manual puncture of the vein was achieved in ten out of 14 cases, as evidenced by blood flow into the needle. In these cases, we consistently observed that the puncture force suddenly decreased on penetration. In addition, continuous decreases in the force caused by reductions in the tension of the skin and/or the vessel wall could be measured.

We further proposed that detecting the instant of puncture into the blood vessel by measuring the changes in force acting on the needle tip would be possible. We performed 13 automatic punctures in the same rabbit following the manual attempts, and reproducible measurements of the force with the manual approach were obtained in ten cases with successful punctures. The mean peak values of the puncture forces were about 60% greater in the automatic punctures than in the manual punctures. Because the same conditions of puncture speed and puncture angle were used for each, differences could be due either to stiffening of the skin and/or blood vessels occurring between experiments, or inadequate compression by the elastic bandage. The medical needles are manufactured collectively under stringent quality control and have uniform shape and size. Therefore the mechanical characteristics during puncture are expected to be uniform (LEHTINEN and OKSALA, 1979; LEHTINEN, 1983; VON FRAUNHOFER *et al.*, 1988). Thus we believe that the peak form of puncture force depends only on the strength and tension of the skin and blood vessel. We observed that similar waveforms could be obtained reproducibly and detected using simple signal processing techniques, when the speed and the angle of needle puncture were the same.

In this study, the peak detection method for puncture force was evaluated in animal experiments. In needle puncture to the human vein, differences in the mechanical properties and structure of the tissue, such as a fat layer, may affect the puncture force. However, even if the parameters of the low-pass filter would require optimisation using puncture force measurements from humans, it seemed that the change in puncture force would be similar when the needle tip penetrated the vessel wall, and it would be possible to detect, as experienced operators could sense it.

4.2 *Analysis of puncture failures*

In this study, we carried out 14 manual and 13 automatic puncture tests on ear veins in rabbit *A*. There were four manually driven and three automatic puncture failures. In failure cases F_1 and F_2 of the manually driven punctures, neither blood flow into the needle nor a peak in puncture force was observed. These results show that the needle tip missed the target blood vessel, and the blood vessel became distorted and then moved laterally during the puncture of the overlying skin tissue. Similar waveforms of puncture force were observed in those cases of failure during automatic puncture. We believe that the reason for failure in the automatic puncture cases was probably an error in the setting of one of the initial conditions, such as the positioning of the needle, rather than an error in the peak detection produced by the algorithm.

In failure cases F_3 and F_4, the operator judged that the needle did not puncture the blood vessel, but blood flow into the needle was observed a few seconds after needle movement stopped. There were some small peaks of puncture force at about 1 s after the beginning of needle puncture in each of these cases. These results could be explained if the needle damaged the blood vessel or penetrated the other side of the blood vessel.

However, the peak detection algorithm cannot be determined from an analysis of puncture force alone, whether the needle tip actually penetrates the blood vessel or merely injures it, in failure cases. Additional information such as the detection of blood flowing into the needle should be included in the analysis (SAITO and TOGAWA, 1999).

4.3 *Prospects for automatic blood sampling*

Automatic blood sampling requires the locating of a suitable blood vessel to sample, puncturing of the blood vessel with optimum speed and needle angle, removal of the blood, and then removal of the needle. Mechanical manipulators exist on the market with sufficient accuracy for positioning the needle on the target blood vessel. Vacuum pumps have been used in blood donation. Automatic selection of the sampling location and control of the actual needle penetration have not been technically solved.

In the present study, the method for controlling needle puncturing has been addressed as a first step towards realising automatic blood sampling; puncture force was examined for suitability as a source of control information. Further studies of blood vessel puncture in a large number of subjects are required for failsafe functional control. However, through detection of the peak of the puncture force, the needle can be controlled to keep the needle tip within the vascular lumen without penetrating the other side of the blood vessel.

To select the blood sampling spot, a tactile sensor used for palpation (ZIVANOVIC and DAVIES, 2000) and an image processing method using graphical data acquired by a CCD camera (ICHIKI *et al.*, 1993) may be useful. The integration of these techniques will realise the automatic blood sampling. Moreover, integrating the automatic blood sampling system with the blood testing system would optimise both systems. A less invasive method of blood sampling may be to use a thin needle, mimicking the blood-sucking proboscis of the mosquito.

5 Conclusions

The examination of an automatic puncture method for blood vessels is reported as a first step towards realising automatic blood sampling. In this paper, the forces on the needle punctures in a rabbit ear vein were evaluated for use in controlling needle movement. The changes in force measured at the needle tip as the needle penetrated the blood vessel were consistent and reproducible. These results show that the measurement of puncture force could be used in the future to assist in the control of blood vessel puncture in automatic blood sampling systems.

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Author's biography

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