

Proof of puncture resistance with non-penetration of medical 23G needles against protective materials for use in gloves - Verification by Pressure Sensors and Accelerometers

Seiji Tada^{1,a,*}, Masaaki Matsubara^{1,b}, Ryosuke Suzuki^{1,c}, Yu Goto^{1,d},
and Kenta Morishita^{1,e}.

¹Graduate School of Science and Technology, Gunma University, 1-5-1 Tenjin-Town, Kiryu City, Gunma 376-8515, Japan

*Corresponding author

^a<t202b005@gunma-u.ac.jp>, ^b<m.matsubara@gunma-u.ac.jp>, ^c<r_suzuki@gunma-u.ac.jp>, ^d<yu-goto@gunma-u.ac.jp>, ^e<t180b094@gunma-u.ac.jp>

Keywords: 23g medical injection needle, en388-2003, non-penetration, acceleration of the motion

Abstract. Medical needles, mainly 23G, have become an indispensable instrument in clinical medicine. The accelerometer enables the user to check the non-penetration to the protective material of the hand, which is one of the most exposed areas of personal protection. With accidental motion energy of $0.0557 \text{ kg m}^2/\text{s}^2$ and a tip penetration of 90° , the microscopic atmosphere of the non-penetrating acceleration was verified.

1. Introduction

Despite the daily improvements in the penetrating ability of medical needles, it is alarming that unintentional puncture injuries are still occurring during use, after use, and after disposal. Moreover, the constant occurrence of medical accidents, not only recently but also in response to the emergence of new viruses, is a problem that needs to be solved, leading to the collapse of healthcare worldwide. The development of hand protection materials that reduce the penetration of these viruses has not progressed due to the inability to measure their non-penetration [1, 2]. In the process of researching the development of a non-penetrating device, we consulted the literature where a measuring device for puncture was presented [3, 4, 5]. The purpose of the development of this device was to verify the non-penetration of materials under certain conditions of energy E , assuming an unforeseen accident. ISO's EN388-2003 test method is not sharp enough for injection needles and is not something that industry can refer to EN374 -2003, which is a virus transmission test for protection against viruses, is a virus transmission test for materials and not a puncture protection assessment test. This study contributes to the development of hand protection materials and confirms the non-penetration of a typical 23G injection needle. The kinetic energy of the hand during the handling of the needle was assumed and reproduced in the device. The non-penetration of the needle was measured using a pressure sensor, but this did not detect any change in position or microscopic atmosphere at the material interface for flexible materials.

However, it was not possible to detect the microscopic behavior of the flexible material. We focused our attention on the fact that the non-penetration occurs at the interface between the materials, and confirmed the non-penetration by changing the acceleration of the motion.

2. Materials and Methods

2.1 23G Injection Needle

In this experiment, we used commercially purchased 23G needles, which are commonly used for muscle injection. The specification was Sterile injection needles, model: 23gauge, material: stainless

steel pipe, needle length: 38 mm, inner diameter: 0.6 mm, outer diameter: 0.65 mm, cutting edge angle: 13° Regular Bevel, manufactured by SHAOTONG China.

2.2 Equipment

Samples were made from Mitsui Dow Polychemical Co.'s ionomer film Hymilan 1855, 100 μm thickness.

2.3 Equipment

The movements that people can make in real work do not involve flailing their arms. In other words, we assumed that accidental accidents often involve a very small arm and finger movements and gentle acceleration. By examining reports of accidental incidents, it is possible to change this assumption in the future [5, 6, 7, 8, 9,].

Measuring instruments such as Instron is suitable for measuring the behavior at constant speed up to the point of fracture, but it was determined that it would be difficult to apply them to this case of no penetration, so an attempt was made to develop a device suitable for this task as Fig.1.

If you think of a glove, there is a human hand inside, exerting internal pressure towards the surface. We tried to reproduce this by applying a pressure of about 0.20 MPa using air pressure. The 0.20 MPa was due to equipment limitations. This value was the limit for maintaining constant pressure with a manual pump, but we proceeded because we could recognize pressure changes even at 0.20 MPa in this way.

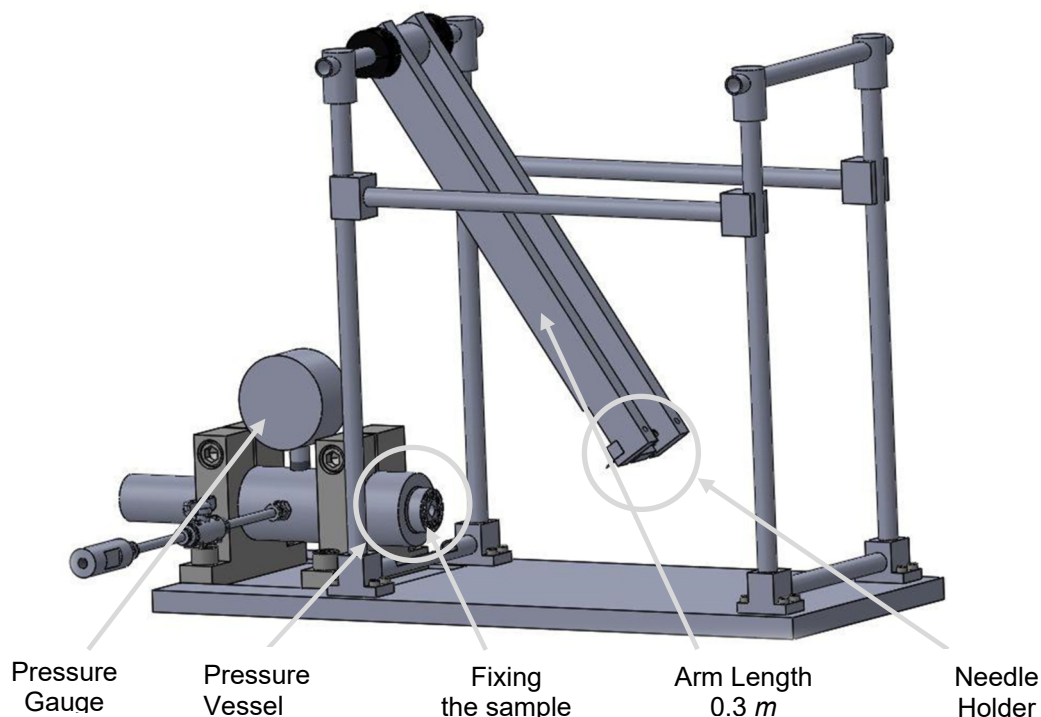
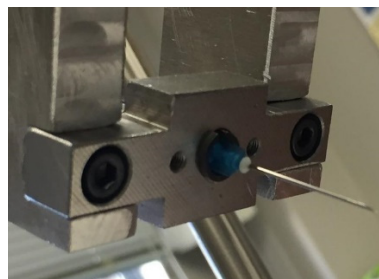
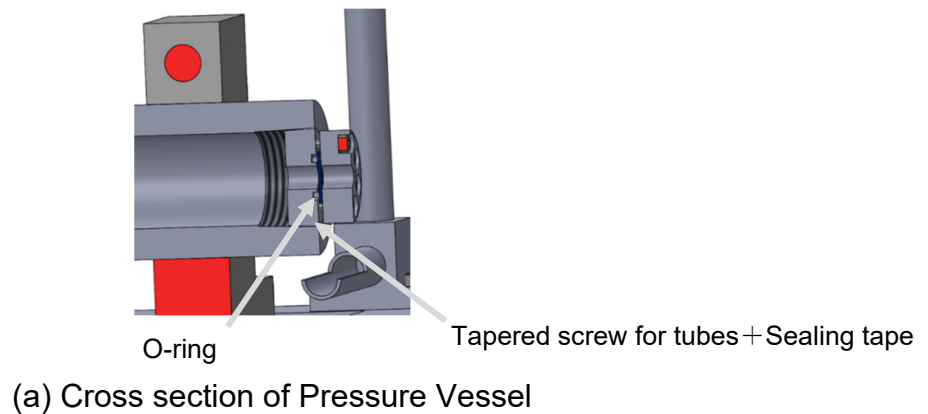


Fig. 1. Full view of the equipment.

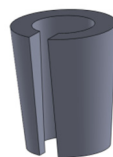
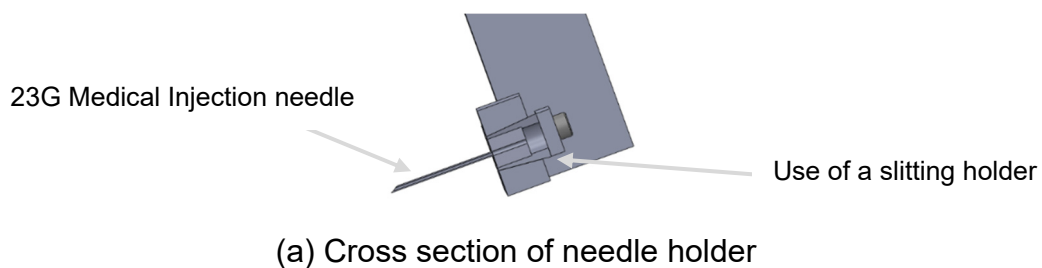
The arm length was 0.3 m and the deadweight load was 0.726 g. The kinetic energy could be determined at any amount by the adjusting swing angle of the arm. The needle was fixed vertically, and the idea is to observe the resistance when penetrating vertically into the skin is minimized and the resistance when penetrating obliquely can be encompassed. The shape of the hand has many curved surfaces, but its resistance to penetration is minimized when it is perpendicular to the tangent of the surface.

Initially, this pressure behavior was used to fine-tune the penetration, but it did not capture the non-penetration behavior. Sealing was done to keep the pressure constant as shown in Fig. 2. The needle was fixed with a slit cup holder as shown in Fig.3.



(b) photograph of Needle Holder

Fig. 2. Details of Pressure vessel seals.



(b) slitting holder

Fig. 3. Section of needle holder.

3. Reproduction of the kinetic energy of the hands and fingers

Depending on the size of the human body, the kinetic energy of the swing of the hand will vary, but we have considered the weight of the one arm is 5% of a very ordinary person weighing 60 kg [10]. In fact, prosthetic arms and legs also refer to this kind of body balance, and the weights of body parts were public knowledge in comparison. Many injuries have been caused by stabbing fingers other than the dominant hand. However, the injuries were very slow and unintentional, not as fast as swinging

down a hammer. From person itself, people also assumed that the velocity of the needle touching me was really slow and that the angular velocity from 30 degrees on this device was sufficient.

The length of the arm of a person of that build is 0.65 m. We decided to reproduce it with the device at an angular velocity of 0.785 rad/s and kinetic energy of 0.392 kg m²/s². As the working length of the arm with the apparatus is 0.3 m, the mass of the dead weight is specified as 134 g and the measurement is started. The following Fig. 4 illustrates the process of thinking.

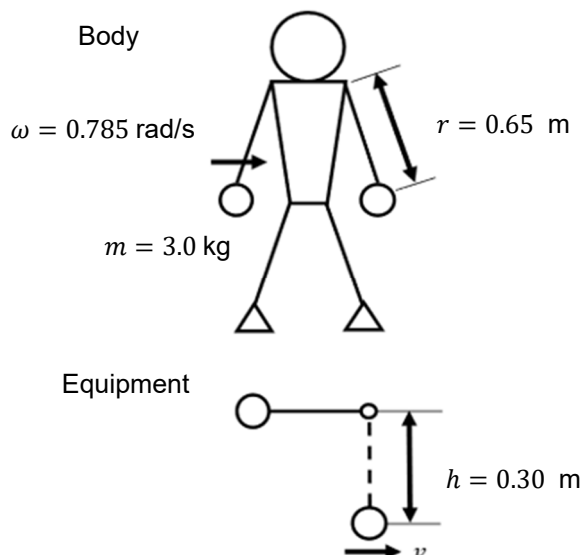


Fig. 4. Illustrates for the Reproduction of the kinetic energy of the hands and fingers.

Assume that the mass m of the arm is concentrated on the tip of the arm. The arm length is r , the angular velocity when swing the arm is ω , and E is the energy when the hand touches.

$$\begin{aligned}
 E &= \frac{1}{2}m(r\omega)^2 \\
 &= \frac{1}{2} \times 3.0 \times (0.65 \times 0.785)^2 \\
 &= 0.392 \text{ (kgm}^2/\text{s}^2)
 \end{aligned}$$

Velocity at the bottom

$$v = \sqrt{2gh} = \sqrt{2 \times 9.8 \times 0.3} = 2.42 \text{ (m/s)}$$

Mass of the equipment weight

$$m = \frac{2E}{v^2} = \frac{2 \times 0.392}{(2.42)^2} = 0.134 \text{ (kg)} = 134 \text{ (g)}$$

4. Results of needle non-passage by the pressure sensor

A pressure sensor was used to measure the non-penetration of the specimens. The specification of the pressure sensor is Model: FP101-C-31-L20A*B, Manufacturer: Yokogawa Electric, 1 to 5 VDC output, Gauge pressure measurement, Typical range: 0 to 1 MPa (gauge pressure), Mounting screw: R1/4, Power supply: 12 to 30 VDC. Fig. 5 shows the network diagram with the pressure sensor.

The measurement results of Fig. 6 by the pressure sensor were different between penetration and non-penetration, but the capture of microscopic behavior of the change point was insufficient to confirm enough the fine non-penetration.

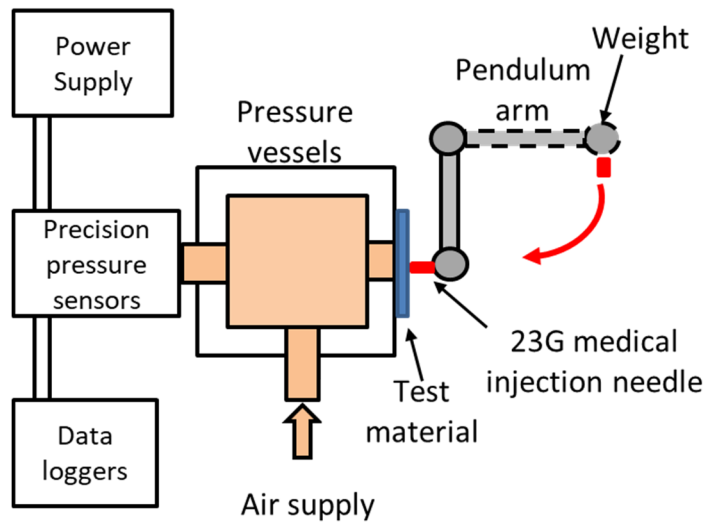
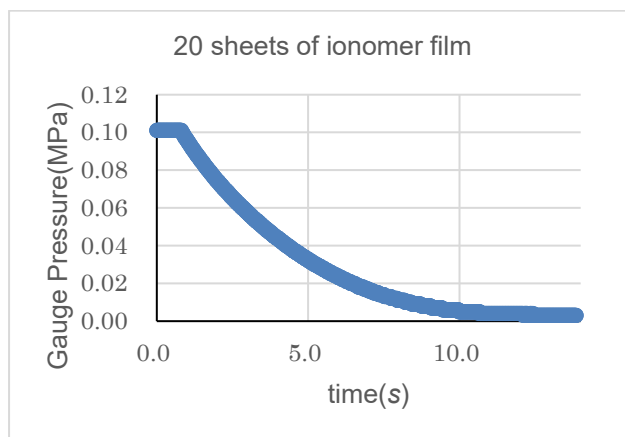
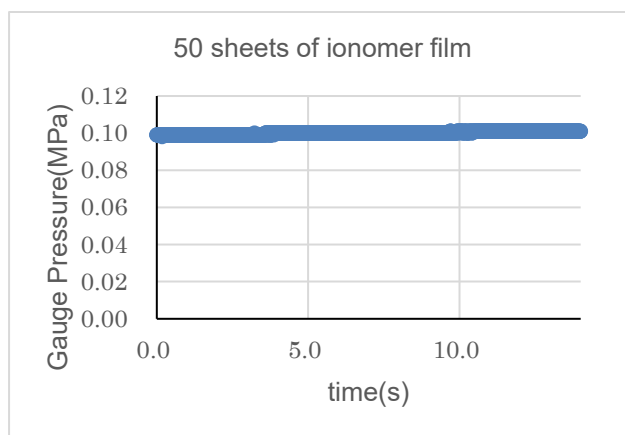


Fig. 5. The network diagram with the pressure sensor.



(a) Needle penetrating case



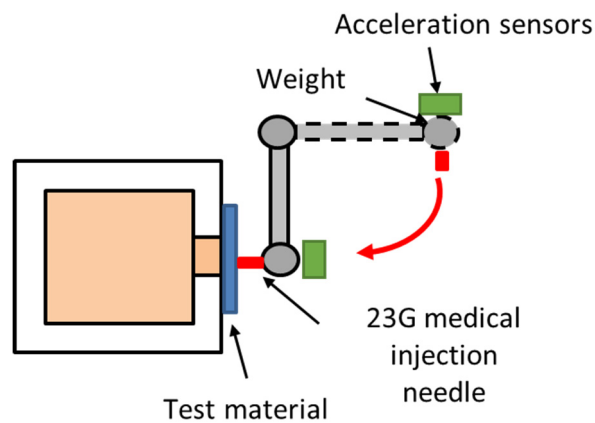
(b) Needle non-penetrating case

Fig. 6. Experimental results for pressure parameters.

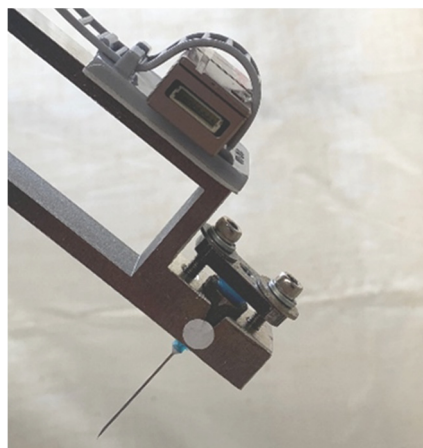
5. Results of needle non-passage by accelerometer

Noting that the acceleration of the hand motions in response to the movement of the hand when the needle penetrates, we attempted to capture the non-penetrating behavior of the specimen by adding an accelerometer. Fig.7 shows the network diagram with the Acceleration sensor. The needle makes point contact. In this case, the acceleration in the case of penetration maintains at least a positive direction. In the case of non-penetration, the acceleration is in the opposite direction, i.e., negative.

The specification of the accelerometer was by Syscom Ltd., Co., Ultra-compact acceleration logger, Product name: AccStick6, Dimensions: W21.2 x D32.5 x H10.5 mm, Weight: 15 g, Range: 2 G to 400 G, Sampling frequency: 0.1 to 1600 Hz. For the purpose of varying the E due to the deadweight, we verified the change in acceleration with arm angles of 30, 45, 60 degrees, etc. In the case of penetration, the acceleration varied within positive values. In the non-penetrating case, negative acceleration was created, albeit for a very short time. In addition, we considered that E at an angle of 30 degrees was sufficient for E in actual inadvertent accidents.



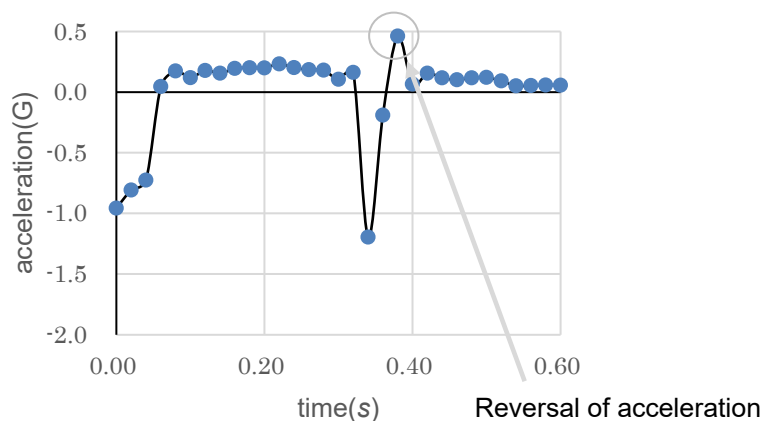
(a) The network diagram with the Acceleration sensor



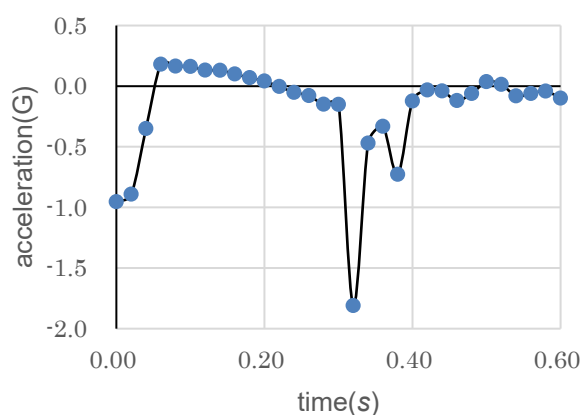
(b) picture of improved needle mount

Fig. 7. The network diagram with the Acceleration sensor and picture of improved needle mount.

Fig. 8 shows a typical change in acceleration. In the case of non-penetration, there is a reversal of acceleration that is not seen in the case of penetration. This phenomenon was used to confirm that the needle had not penetrated the material.



(a) Needle penetrating case



(b) Needle non-penetrating case

Fig. 8. The graph comparing the case of penetration and non-penetration of the specimen by the accelerometer.

6. Conclusion

For the development of materials to be used in gloves, we believe that this accelerometer measurement is useful to understand the behavior of needles that do not penetrate. The pattern of acceleration behavior after contact with the specimen could be distinguished between non-penetrating and penetrating cases.

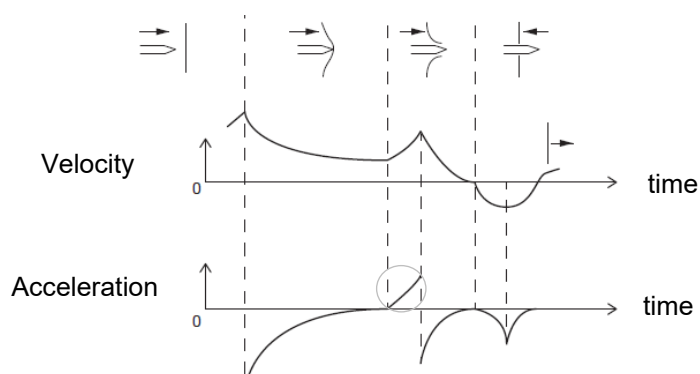
Figure 9 provides a clearer conceptual illustration of how the acceleration obtained in Figure 8 remains at least positive during penetration and then reverses, i.e., becomes negative, in the case of non-penetration.

We thought that capturing the negative acceleration during non-penetration, although for a short period of time, might provide proof of non-penetration with respect to the material.

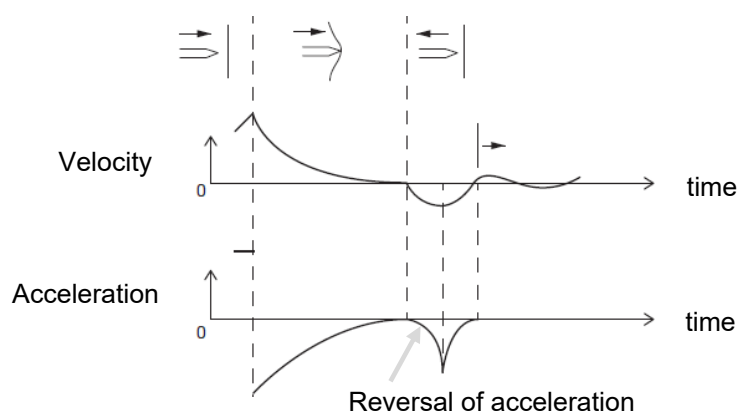
In the future, we will attach a sensor to the backside of the non-penetrating object to ensure further proof of penetration by electric current. We considered it impossible to formulate the post-collision acceleration change because it varies from sample to sample. We also considered it impossible to set an absolute standard for G-values because G-values at the time of collision vary from sample to sample.

We believe that this device can be used to contribute to the development of materials that are non-penetrating, but require conflicting properties for ergonomic flexibility, such as gloves, and to the development of protective equipment that can safely respond to puncture accidents of medical devices.

As the next research, we would like to apply materials made by combining modified ionomer films and dense fabrics of high-strength fibers impregnated with resin and nano powders to the development of flexible and puncture-resistant materials from this accelerometer-based measurement device.



(a) Needle penetrating case



(b) Needle non-penetrating case

Fig. 9. Conceptual diagram of the change in acceleration for needle penetrating case and the needle non-penetrating case.

Acknowledgements

We would like to thank Prof. Shohji, Prof. Hangai and Prof. Rin for their guidance at Gunma University. Also, we express thank Mitsui-Dow Polychemical Co., Ltd. and Kuraray Co., Ltd. for providing us with sample materials for further research and development.

References

- [1] Sumathi Muralidhar, Prashant Kumar Singh, R.K. Jain, Meenakshi Malhotra, and Manju Bala, "Needle stick injuries among health care workers in a tertiary care hospital of India", *Indian J Med Res*, Vol.131, pp.405-410, 2010.
- [2] Sabine Wicker, Jindrich Cinatl, Annemarie Berger, Hans W. Doerr, Rene' Gottschalk, and Holger F. Rabenau, "Determination of Risk of Infection with Blood-borne Pathogens Following a Needlestick Injury in Hospital Workers", *Ann. Occup. Hyg.*, Vol.52, No.7, pp.615-622, 2008.
- [3] D. Zhu, L. Szewciw, F. Vernerey, and F. Barthelat, "Puncture resistance of the scaled skin from striped bass: Collective mechanisms and inspiration for new flexible armor designs", *Journal of the Mechanical Behavior of Biomedical Material*, Vol.24, pp.30-40, 2013.

- [4] L. Jiang, Y. Huang, C. Pan, J. Ling, J. Li, Z. Chen, J. Fu, and Y. Wen, “Research on Insertion Process of Medical Needle”, *Proceedings of the 2016 3rd International Conference of Materials Engineering, Manufacturing Technology and Control: ICMEMTC 2016* (Taiyuan, China) February 2016.
- [5] E. Triki and C. Gauvin, “Analytical and experimental investigation of puncture-cut resistance of soft membranes”, *Mechanics of Soft Materials*, Vol.1, No.6, pp.1-11, 2019.
- [6] *Studies and Research Projects R-753, Needlestick Resistance of Protective Gloves Development of a Test Method*, Toan Vu-Khanh, Patricia Dolez, C. Thang Nguyen, Chantal Gauvin, and Jaime Lara (Montreal, Canada), 2012.
- [7] Jessie B. Mayo, Jr., Eric D. Wetzel, Mahesh V. Hosur, and Shaik Jeelani, “Stab and puncture characterization of thermoplastic-impregnated aramid fabrics”, *International Journal of Impact Engineering*, Vol.36, pp.1095–1105, 2009.
- [8] A. D. Resnyansky, “Ballistic and Material Testing Procedures and Test Results for Composite Samples for the TIGER Helicopter Vulnerability Project”,
<https://www.researchgate.net/publication/235085636>
- [9] Bao Limin, Sato Shunsuke, Wang Yaling, Wakatsuki Kaoru, and Morikawa Hideaki, “Development of Flexible Stab-proof Textiles Impregnated with Microscopic Particles”, *Journal of Textile Engineering*, Vol.63, No.2, pp.43 – 48, 2017.
- [10] Noriko Kurata, Sumiko Kurata, Tadao Kurata, “Measurement Method of Seven Body Region Weights by Use of Body-region Separately Weight System”, *Japanese Society for Medical and Biological Engineering*, Vol.50, No.6, pp.637-644, 2012.