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DETERMINING THE PROFILE OF TISSUE PUNCTURE FORCE IN ORDER TO IMPROVE THE IMITATION OF REALITY BY MEDICAL TRAINING DEVICES

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While the procedure of amniocentesis is considered safe, there are still risks to both the fetus and the mother. The goal of the research was to determine the values and profiles of the forces that occur during the penetration of real tissues with a needle intended for use during amniocentesis. The data on force exerted during puncture was measured in relation to insertion into organic material from domestic pigs, a mammal similar in size and mechanical properties of tissues to humans. The results showed a local increase in the force value when piercing the skin and the uterine wall. The findings prove the usability of measurements done on porcine tissues for at least initial planning of the medical training devices.

Keywords: Force profile, Skin, Adipose tissue, Uterine wall, Amniocentesis.

1. Introduction

To obtain a definitive diagnosis for most genetic disorders during pregnancy, it is essential to undergo prenatal diagnostic testing, such as amniocentesis. After 15 weeks of gestation, amniocentesis is considered the most reliable and widely accepted method for diagnosis [Alfirevic *et al.*, 2017]. While amniocentesis is considered safe and provides valuable medical information about the fetus, there are still risks to both the fetus and the mother [Jindal *et al.*, 2022]. Minimizing the risk associated with this procedure is a significant factor influencing the physical and mental comfort of a pregnant woman and may be important for assuring good health of the fetus (and eventually newborn) in later stages of life. For this reason, all instruments and devices used in the training of surgeons for this procedure should provide the best possible representation of real conditions. For this purpose, force profiles were measured in relation to insertion of a needle into real tissues of a mammal with body proportions similar to that of a

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human (domestic pig *Sus domesticus*) using a specially built device (SilSense Technologies S.A., *vide* Acknowledgement).

2. Purpose of research

The aim of the research was to determine the values and profiles of the forces occurring during the penetration of real tissues (obtained from domestic pigs, as a mammal similar in size and structure of organs/tissues to humans) with a needle intended for use during amniocentesis. Measurements were taken using a device designed for this purpose.

3. Methods

The laboratory stand (Fig.1) used in the research consists of two main functional blocks:

- a device for measuring the profile of the puncture force of the tissue with standard needles used in amniocentesis procedures, installed on the chassis obtained from the Prusa MK3S 3D printer,
- a computer station with software allowing data collection and analysis.

Fig. 1: Laboratory stand; arrow – amniocentesis needle in measuring head.

The repeatable precision of positioning the sample and needle, through the use of 3D printer mechanisms, is not lower than 0.1mm in each axis. For economic and availability reasons, a low-cost compression load cells with a maximum load capacity of 5kg (50N) was used in the device. Their suitability for this research purposes was confirmed through initial calibration using weights of known mass and comparing the obtained values with the readings of the AXIS FC500 dynamometer. The values measured using the described device are within the linear range of the sensors used.

The sampling frequency during the measurement was 10Hz (with 20 consecutive samples being averaged and transmitted to the computer at a frequency of 0.5Hz), and the needle penetration speed into the material was 0.5mm/s. Thanks to this, according to the project requirements, data on the distribution of tissue puncture force with a vertical resolution of 1mm was obtained.

For each measurement, the sample was positioned on the 3D printer bed and the measuring device activated. The connection to the computer was verified and the depth measuring arm adjusted to the starting position. The needle was subsequently positioned over the sample using the 3D printer mechanism, and the measurement program activated from the computer. The printer's Z-axis movement was initiated, and the measurement carried out. The needle was then lifted while the sample was held. Finally, the measurement outcomes were transferred from the serial terminal to an *.xlsx file for additional examination.

In the case of skin with subcutaneous adipose tissue, measurements were made using needles with a diameter of 1.3mm and 1.0mm, while in the case of the uterine wall a needle with a diameter of 1.0mm was used (the diameters given by the manufacturer were confirmed by micrometric measurement). The length of each needle was >100mm.

3.1. Tissue samples

Two main types of tissues were isolated for the study: skin with subcutaneous adipose tissue (Fig. 2) and uterine wall (Fig. 3). The thickness of the dermis, the adipose tissue and the uterine wall was measured as

1mm $^{+}/_{-}$ 0.1, 12mm $^{+}/_{-}$ 1, and 3mm $^{+}/_{-}$ 0.1, respectively. Both structures were measured immediately after isolation.

Fig. 2: Porcine skin with subcutaneous adipose tissue.

Fig. 3: Porcine uterine wall.

3.2. Environmental conditions during measurement

The samples were not refrigerated. At the time of measurement, the ambient temperature was 19°C $^{+}/_{-}$ 1 (66.2°F) and the relative humidity was 60% $^{+}/_{-}$ 5.

4. Results and Analysis

The measurement results for skin with subcutaneous fat are shown in Fig.4 and Fig.5. respectively for needles with diameter 1.3mm and 1.0mm. In turn, results for the uterine wall can be seen in Fig.6.

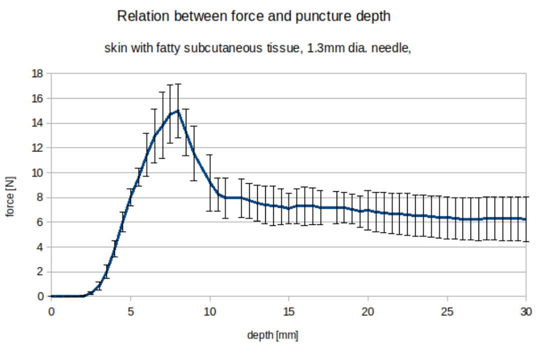

Fig. 4: Force profile; skin with adipose tissue, 1.3mm dia. needle; vertical bars: standard deviations.

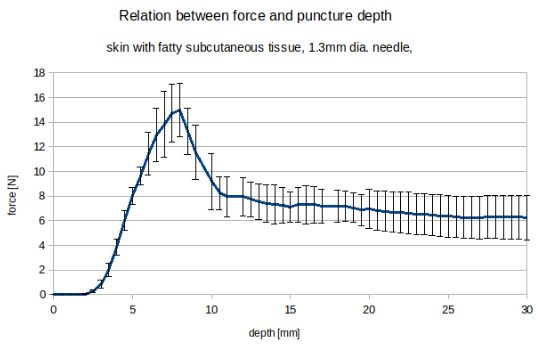

Fig. 5: Force profile; skin with adipose tissue, 1.0mm dia. needle, vertical bars: standard deviations.

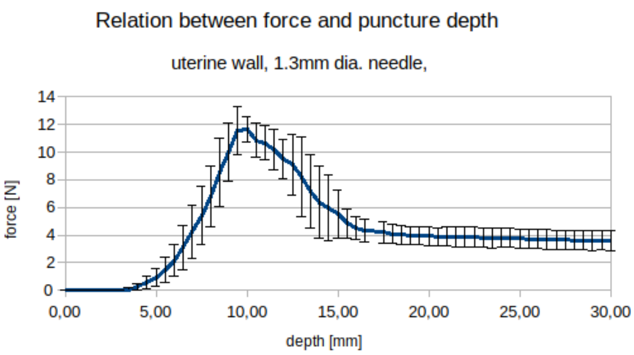

Fig. 6: Force profile; skin with adipose tissue, 1.0mm dia. needle; vertical bars: standard deviations.

In each case, the needle was inserted into the biological material to a depth of 30 mm $^{+}/_{-}$ 1 with 1 mm measure resolution. The results were averaged for 10 series – each series of measurements were performed at different (but quite close to each other) locations on the sample. It was noted that tissue heterogeneity (granulations) sometimes caused problems with single measurements at certain depths. When determining the described relationships, the averaged results from at least 8 measurements out of 10 were taken into account, which is quite a strict assumption. For some measurement points, it was not possible to collect 8 or more measurements, so they were not averaged and included in the graph. Instead, the graph was extrapolated at these points from neighboring points. As a measure of the dispersion of results, standard deviations were determined for each population of samples (marked on figures).

5. Conclusions

Analyzing the obtained data, it is possible to observe a local increase in the force value (average 14.9N $^+/_-$ 2.2 and 11N $^+/_-$ 1.1 for needles with a diameter of 1.3mm and 1.0mm, respectively) at moment of skin puncturing. Afterwards, the force value remained relatively? constant during the penetration of adipose tissue, which is reflected in other works [Gerwen *et al.*, 2012]. It is worth noting that the force needed to pierce the tissues seems to be proportional to the diameter of the needle, at least in the tested range; when the diameter of the needle was reduced by ~23%, the measured forces decreased by ~24.7%. Also in the case of the uterine wall, a local increase in the force value (approximately 1.2N $^+/_-$ 0.1) is visible at the time of piercing the uterine wall; it is a relatively thin and stretchy tissue. The value of force needed to pierce in this case is noticeably lower than for the skin.

Interestingly, the skin seems to show greater differences during needle puncture than subcutaneous adipose tissue, as evidenced by a greater dispersion of the standard deviation values before puncture and after needle insertion into the tissue, what is corresponding with findings of [Mittal, 2019]. On the other hand, the uterine wall does not show this behavior: the scatter of results occurs both before and after the puncture.

Usefulness of measurements on porcine tissues for at least initial planning of the device for human use due to similarity in terms of mechanical properties and dimensions is proved which has also been confirmed in the works of other researchers. [Gerwen *et al.*, 2012] [Mueller F., 2011]. The obtained data will be treated as preliminary in order to determine the direction of further research.

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