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INNOVATIVE STATION FOR DETERMINING THE PROFILE OF TISSUE PUNCTURE FORCE USING A NEEDLE USED IN AMNIOCENTESIS PROCEDURES

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Abstract: *In this paper we present the results of design works aiming to create a new, functional device that would allow testing the amount of force required for a amniocentesis needle to puncture tissue. The device was supposed to take form of an addition to a standard, market-available 3D Printer and allow collection of data about relation of force to depth of penetration. The device was assembled, made of easily accessible components and 3D printed parts and initial tests proving its functionality were performed. The construction of the device was presented and tests were carried out to verify the functionality of the device on the basis of puncture through selected materials. The results confirm the usefulness of the construction in determining the needle penetration force through human and animal tissues.*

Keywords: Amniocentesis, puncture testing, puncture resistance.

1. Introduction

Amniocentesis is a procedure used for purpose of prenatal diagnosis and therapy (Jindal et al., 2022*)* It usually is performed on women between 15th and 20th week of pregnancy, and consists of insertion of long, thin needle into woman's abdomen under ultrasonographic control and collection of amniotic fluid containing cells of the fetus. Although amniocentesis is considered as not dangerous and valuable in terms of obtaining medical knowledge about fetus condition (Obstetrics & Gynecology, 2016), the procedure being done on pregnant women still holds risk to the fetus and/or mother. Consultations with gynecologists gave us insight into how the procedure is done, and lack of equipment that would allow inexperienced gynecologists prepare for real patients was reported. Our aim was to create a device that would allow collection of data regarding forces that are usually used during amniocentesis procedure in order to help minimize the risk of harming the fetus and/or mother, and later help beginner gynecologists

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gain insight into procedure characteristics before performing it on pregnant women. In this paper a project of such device is presented, its tests are described and results are discussed.

2. Purpose of research

The aim of the work is to develop a construction of a device enabling the registration of the puncture force profile of human or animal tissue with the use of needles used in amniocentesis procedures. The action is part of the project of implementing a simulator that uses VR and force feedback to train doctors for amniocentesis.

3. Design

The implementation of the assumed goal required defining the assumptions for the project, then developing the structure and preparing the software and conducting tests. At the beginning the prerequisites were set, and they were: possibility of measuring of the force applied to the needle used during amniocentesis procedure while puncturing different biological materials, force measuring range between 0 and 30N, force measuring resolution of 0,1N or better, possibility of measuring of the force on different depths of puncture, needle penetration range up to 3cm, needle depth recording resolution 1mm or better, possibility of using of needles of different lengths and sizes. Additionally the entire device had to be designed in a manner that would allow easy replacement of broken parts, consist of easily accessible components and co-function with market available 3D printer. In order to accomplish those aims an ATMEGA328p microcontroller was selected, which was a part of Iduino Nano board. This was done in order to avoid unnecessary soldering and implementation of custom-made part. Pre-uploaded bootloader was erased from the FLASH memory of microcontroller, and ISP interface was used for purposes of programming with USBasp programmer. Internal program of the microcontroller was written in BASCOM programming language. To measure the force acting on the needle two 26x26mm tensometric pressure sensors with measuring range of 50N were used. In order to gather data that would be possible for further processing a HX711 amplifier was used. To avoid thermal drift affecting pressure sensor two were used and they were placed “back to back” – therefore, when one was changing its geometry, the other was counteracting to that change and allowing a compensation of returned data changes. In order to measure the depth of the needle an 3D printed ringed arm was designed and connected to a linear potentiometer. The further the needle was penetrating a sample, the further the potentiometer was slid, changing the value of recorded voltage. Linear characteristic of potentiometer allowed us to measure the voltage at its full extension and contraction, and from simple proportion it was possible to precisely measure depth of the tip of the needle.

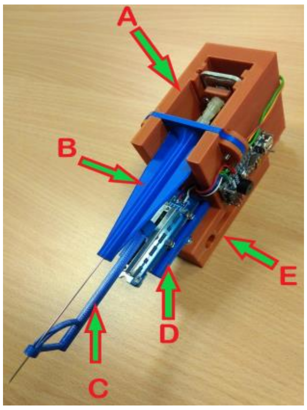

Fig. 1: Mechanical components of the designed device.

To assemble functional device 5 parts had to be designed and manufactured through use of 3D printing technique (Fig 1):

A- Main body with slot for pressure sensors

B- Stiffener keeping the needle straight during measurements

- C- Ringed arm allowing measurement of depth of penetration of needle
- D- Potentiometer housing
- E- Back cover

All parts had to be designed in a way that would allow the entire device to co-work with a Prusa MK3S+ 3D printer. After assembling and setting the entire device up it looked as presented in (Fig 2).

Fig. 2: Measuring station during test measurements.

After assembling the device a custom gcode was written to operate the 3D Printer in a way that would allow performing initial test measurements.

4. Verification methods

To test complete device two measurements were performed. Test samples consisted of one new sponge, which was a control sample, and one with a paper sheet placed on top of it. Testing consisted of placing the sample in the centre of the printer's bed, starting up the printer with custom gcode, starting up the laptop with serial port monitor turned on, moving the measuring head to the sponge as close as possible, so the ringed arm was touching the sponge, but no pressure to the measuring device nor to the sponge was applied, starting data recording on the laptop, and starting the measurement sequence of movements on the printer. The measurement sequence consisted of pressing the control knob on the printer, which played a warning beep sound and began moving the Z axis (up-down) down 30mm at speed of 0.5mm/s. After the movement was done, a double beep sound was played and the printer was waiting for second knob press. After the knob was pressed, the measuring head was beginning to move upwards 30mm and ending the sequence. Next it was necessary to move the ringed arm downwards to starting position and so the device was ready for next sample. At beginning of each measurement the ring was few milimetres below the tip of the needle. This design solution was used in order to assure collection of useful data with a safety margin, not to lose data on force value.

5. Results

Measured was relation between force, that had to be exerted in order to keep penetrating the sample at steady speed, and depth of puncture. Presented are results in Fig 3

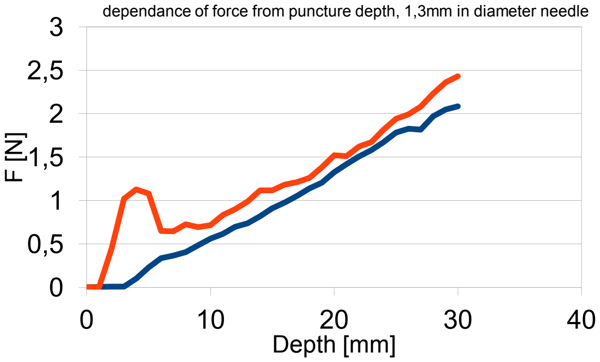

Fig. 3: Results of test measurement done on sponge (blue graph) and sponge with a sheet of paper (red graph).

Initial increase in depth without increase in registered force is a result of using two independent components for measuring the depth and force – while the ringed arm was projecting translation to the potentiometer from the beginning of the measurement, the needle pushed by tensiometers had to travel few milimeters before reaching the sample. Difference in registered values of force between samples in first 5mms of penetrating is noticeable, reaching over 1.1N in sample with sheet of paper on it, while in the same range registered force for sample without paper was 0.3N. After penetrating the sheet of paper a drop in exerted force is recorded, which did not happen in sample without sheet of paper on it. Final recorded force was also higher in sample with sheet of paper on it, reaching 2.5N, than in control sample, which exerted 2.1N

6. Discussion and conclusions

The aim of this study was creation and testing of a simple, easy to create, and cheap device that would allow adapting an already available device in form of a 3D Printer to purpose of measuring of puncture resistance of chosen sample with an amniocentesis needle, and all goals have been achieved. Performed tests allowed us to verify that created device is promising and can be used for performing initial tests of puncture resistance of materials which can be proven by comparing our results to those presented by Gerwen et al., 2012. Analyzed in their work reports also present constant increase in puncturing force, resulting from increase in surface area friction forces are acting on with increase in depth of puncture done with a needle. Results gathered from testing the sponge with a sheet of paper allow us to believe that although greatly simplified, it can serve as initial simulation of penetrating tissues, as the force-depth characteristics are similar to those reported in Gerwen et al., 2012 with initial increase resulting from increase in energy amount gathered in skin before puncture, sudden release of that energy after the skin layer gets punctured, and steady increase in force required to increase the depths of the needle in the sample. Created device can serve as a form of cheap alternative to expensive, market-available devices when there is no necessity for resolution greater than 0.1N. Further tests of created device were performed in work done by the same authors.

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