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DEVELOPING AN ELECTRONIC PEN NEEDLE HOLDER USED IN MICROSURGERY

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ABSTRACT

Background: The concept of electrical integrated with surgical instruments (EISI) was first introduced by one of the authors of this paper. It aims to add electronic chips to classical surgical instruments to facilitate the surgeon's work during operation. Another concept called Penization is also utilized to redesign the instruments into pen-like ones to have 360° control by the surgeons' hands. This concept results in the production of the so-called pen needle holder. We tried to add an electrical chip to this innovative needle holder design to solve the problem of passing the needle through hard tissues in delicate microsurgical work, especially in neurosurgery. Method: A hybrid electronic circuit was added to the newly designed needle holder. We designed a circuit with built-in motors to facilitate the pen needle holder's work on tough tissue. The design respects the so-called tunnel principle, which states that we can add any material or devices within the surgical instrument that are not in contact with the organic tissue. The system depends on a pressure sensor circuit located just beneath the index tip of the surgeon so that whenever he has tough tissue, the pressure on the sensor through his index finger will increase to a certain amount; it will stimulate uni-direction vibrators, which will push that tip of the needle holder Onwards. The electrical motors will stop spontaneously whenever resistance stops as the needle passes through the tissue; ten neurosurgeons use this integrated surgical instrument. They answered a special questionnaire designed to compare the use of this pen needle hoarder with the electronic vibrators and without it, and the results were encouraging. Conclusion: The newly designed pen needle holder with an integrated electronic chip is approved to facilitate the surgeon's work, especially with hard tissues. It creates an opportunity to develop further innovations by integrating these electrical chips with other surgical instruments.

KEYWORDS

Eisi, Microergonomic, Redesign, Pen Needle Holder.

1. INTRODUCTION

The technical problems of microsurgery have provided a special opportunity to develop the application of ergonomics to surgery. A new needle holder design is suggested in the presented work because micro suturing in a narrow and/or deep operating space is technically difficult, and traditional micro-instruments, like bayonet microneedle holders, have significant limits. Historically, manufacturers have modified surgical tools based on surgeon requirements, with a strong emphasis on ergonomics (Papaspyros et al., 2015;Stucky et al., 2018;Shimizu et al., 2020). Developing a position that can increase the surgeon's comfort level during surgery was a top priority (Lucas-Hernández et al., 2014; Rajesh and Srinath, 2016). Extreme joint positions extended static postures, precise, repetitive movements, prolonged tension, and excessive force affect standard surgical instruments negatively. Moreover, there is an increased prevalence of musculoskeletal diseases in the back, neck, wrists, hands, and fingers. But when such musculoskeletal disorders are identified in shoulder-arm fatigue and elbow-forearm, along with paresthesia and pain in the wrist-hand-fingers, we incorporate an electronic circuit into the instruments to help lessen the surgeon's continuous tension and effort while also decreasing the likelihood of a musculoskeletal disorder (Lucas-Hernández et al., 2014).

One of the problems with the needle holder is that it hinders its movement in deep areas due to its two shafts with circles for the finger grip that take up space from the target tissue, so they designed 2011 a needle holder with a very long shaft and material of shape memory alloy to reach deeper tissue (Menovsky and De Ridder, 2011). As for what has been recently published regarding this topic, there are some problems in using the needle holder that were found in 2014 by Carl-Fredrik Frimandet al., which are the effort loss of the surgeon and the lack of accuracy in using the instruments of uncontrolled movements and tremors, so they use the traditional needle holder. Still, another technique, which is used as a palm grip, not a finger grip, is called a Frimand needle holder (FNH) that uses a palm grip, and it was used by several surgeons to get their impressions about it (Frimand Rönnow et al., 2014). Atsushi Sato et al. 2022 stated that suturing is most challenging in a limited and deeper field and advanced a needle holder design to be uniaxial and permits the forceps at the tip to be manipulated by operating the rotor in hand. So, the benefit is that it allows opening and closing by fingers without moving the holder (Sato et al., 2022). In 2022, to achieve a balance between efficiency and cost in the management of medical instruments, the microneedle holder was also used to remove sutures and foreign bodies from the cornea, and this is to reduce cost and increase efficiency as we do in our research as the new design (Gao et al., 2022). With our design of an electronic needle holder, the number of instruments in suturing is also reduced, as in our design of the electronic pen needle holder, there is a sharp tip for cutting the suture, eliminating the need to use scissors.

In this study, we tried to solve the problem of suturing tough tissue by making the needle pass easily. By using an electronic chip with embedded motors that work as a hammer effect when the pen needle holder reaches a hard tissue, and this is helpful in various precise surgical operations, such as operations at the base of the skull, cerebrovascular surgery, spine operations, and neurosurgical operations known as keyhole operations. In addition to overcoming the problems of tremors and difficulty of controlling the needle holder movements with accuracy, especially during long operations and deep sites by making the new design like a pen, writing is the work most practiced by the hand with years of experience so with the use of the needle holder as pen; we can move it precisely in any direction and efficiently without much effort.

2. ELECTRONICS INTEGRATED WITH SURGICAL INSTRUMENTS EISI CONCEPT

The technological challenges associated with microsurgery have created a unique possibility to advance the use of ergonomics in surgery. Since almost all surgical tools were built with the target tissue in mind, an ergonomic analysis regarding the instruments could be utilized to modify them to be used more successfully through the adaptation of their design to the surgeon's hands. The target tissue and methods for manipulating it were considered in the design of most surgical instruments (Seagull, 2012). Unfortunately, the manufacturers have not focused on developing the instruments with the user's hand arrangement in mind. The emphasis of this new EISI concept is on the fact that certain electronic tasks could be carried out through specialized electronic circuits that are affixed to the surgical instrument

3. NEEDLE HOLDER; WITH THE EISI CONCEPT

As seen in Fig.1, the pen needle holder resembles a pen and is intended to be readily controlled through the surgeon's hand. The base has scissors so the surgeon can cut the notes by themselves, and it has a tip for gripping the needle, including an electronic circuit that will pound the needle's tip to make it pass through tough tissues more readily and assist the surgeon in not using as much force when gripping the needle holder.

4. METHODOLOGY

First, we need to measure the force of the surgeon's thumb finger exerted on the instrument tissue; second, a specific motor programmed to this measured force of thumb, so in the case when the needle goes through tough tissue, the motors vibrate the microneedle to make it pass through the tissue more simply.

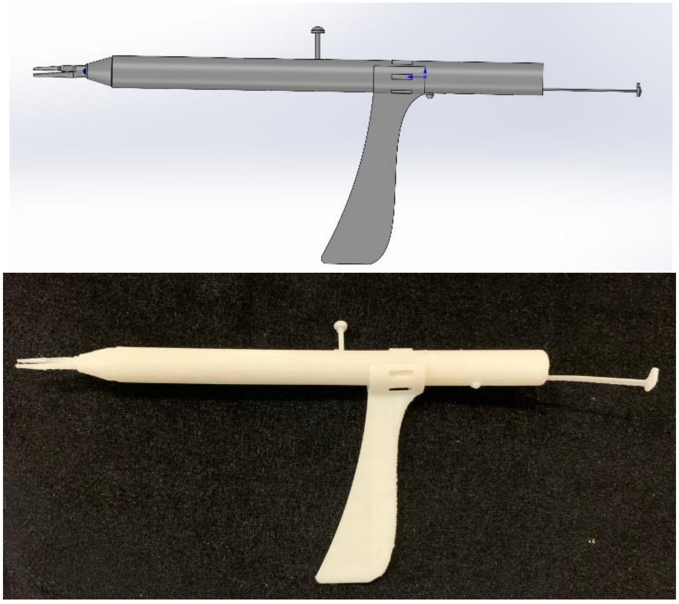

Fig. 1. The Pen Needle Holder (a) design in SOLIDWORKS 2022 (b) 3D printing prototype

4.1. Thumb finger force measurements by Force Sensor Resistive FSR

FSR connected to Arduino by wires, one hooked up to positive 5 V on the Arduino, and the other hooked up just like a button through a 10 K resistor and jumped the resistor to the Arduino ground pin, as shown in Fig. 2.

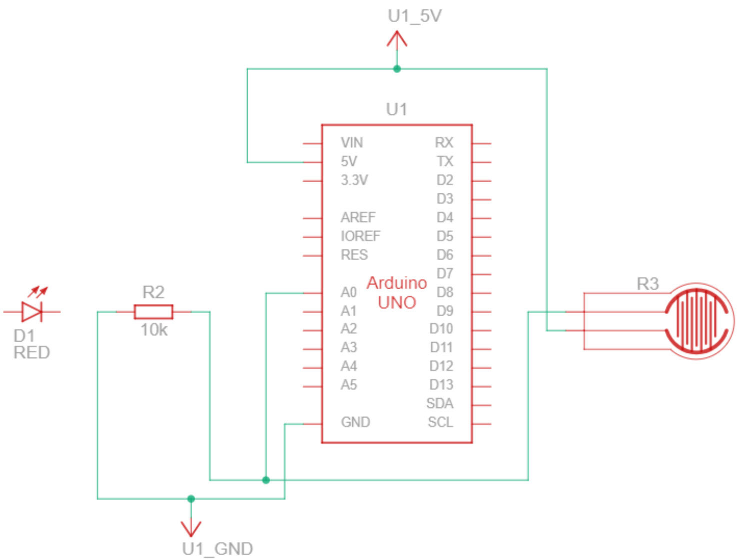

Fig. 2. Schematic view of the electronic circuit used to sense finger force

FSR was placed on the pen needle holder to measure the force of the surgeon's thumb finger on the instruments 4N for thumb and for tough tissue, the thumb force is 8N, so from these results, the motor programmed in Arduino to vibrate at 8N force sensed by FSR when pressed by surgeon, this vibration works as hammering effect on the needle and it forced the needle in suturing path without the need to strain the surgeon's hand.

4.2. The design of the hammering effect electronic circuit

The FSR is connected to a measuring resistor in a voltage divider configuration for force-to-voltage conversion, as shown in Fig. 3.

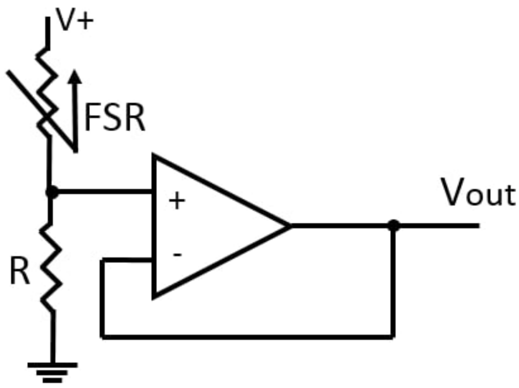

Fig. 3. FSR voltage divider

The equation describes the output.

$$V_{OUT} = \frac{R_M V+}{(R_M + R_{FSR})}$$

In the illustrated arrangement, the voltage at the output rises in tandem with force. If there is an interchange between R_{FSR} and R_M (The resistor employed for measurement), the extent of fluctuation at the output will diminish as force is amplified.

Adding a flat vibration motor "mobile motor "to the previous circuit in Fig. 2, which is programmed with the FSR as stated in Fig. 4 and Fig. 5.

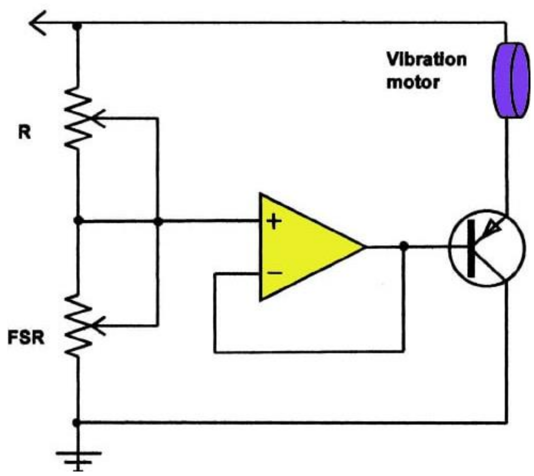

Fig. 4 The electronic circuit

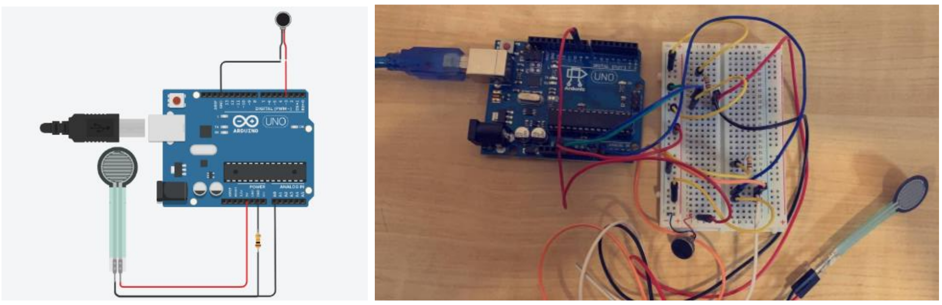

Fig. 5. Representation of the hammering effect electronic circuit

According to the force values measured by the surgeon's finger by writing certain code in Arduino, as shown in Fig. 6 to make the motor vibrate when the sensor is pressed to a tough tissue force by the surgeon's finger and gives a hammering effect so that the needle passes smoothly and easily through the tough tissues without the effort of the surgeon and gives more comfort to the hand joints.

Arduino Uno

sketch_nov11a.ino

```
const int fsrPin = A0;        // Analog pin connected to FSR
const int motorPin = 3;      // Digital pin connected to vibration motor

void setup() {
  pinMode(motorPin, OUTPUT);
  Serial.begin(9600);
}

void loop() {
  int fsrReading = analogRead(fsrPin);

  // You might need to adjust these threshold values.
  int threshold = 500;  // Adjust this value based on FSR sensitivity.

  if (fsrReading > threshold) {
    // Apply PWM to the motor for vibration.
    analogWrite(motorPin, 255);  // Full speed, you can adjust this value.
  } else {
    // Turn off the motor.
    analogWrite(motorPin, 0);
  }

  Serial.println(fsrReading);  // Print FSR reading to the serial monitor for debugging.
  delay(100);  // Adjust the delay to control the update rate.
}
```

Fig. 6. Writing code in Arduino

So, the setup of the final system includes the electronic circuit, Pen Needle Holder, and laptop for Arduino software, as stated in Fig. 7.

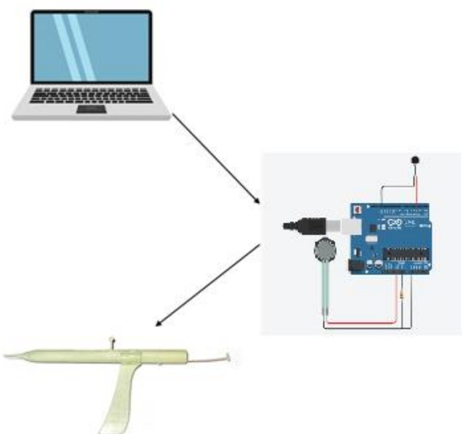

Fig. 7. Block diagram of the system

The sensors are attached to the instruments in the surgeon's grip place, as in Fig. 8. When the surgeon reaches a tough tissue, he will press the sensor harder with the maximum force measured by his thumb and index.

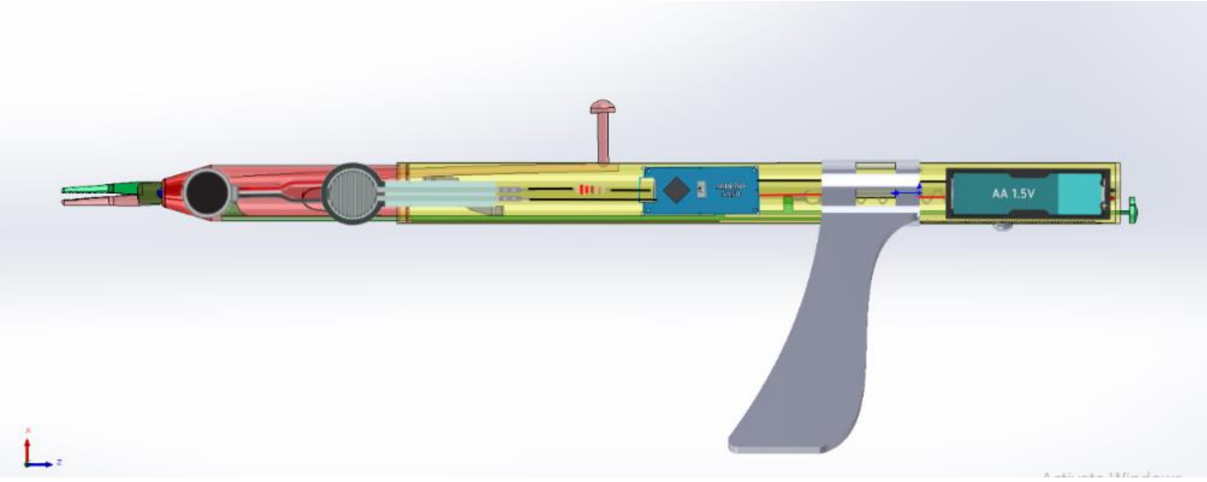

Fig. 8. Connecting the entire electronic circuit to the tool

5. THE RESULTS

After determining the medical problems of the traditional needle holder instrument and the extent of developing a Microsurgical Pen Needle Holder Instrument, the new instrument was signed according to several specifications that guarantee ease of use, accuracy, safety, and reliability. As a design of any Instrument, it was necessary to conduct simulations to determine how much it practically matches its objectives and improves performance. A simulation of the new instrument used in SOLIDWORKS 2022, where several models were designed until the final design was reached.

Ten surgeons specializing in neurosurgery used the new surgical tool, and videos were recorded for each surgeon using the traditional needle holder and the latest electronic pen needle holder as a comparison between them. The decision was made through filling questionnaires by each surgeon, as stated in Fig. 9. For a higher promotion response rate, the same survey was repeated for the traditional needle holder instrument.

The questionnaires were built based on three categories: (1) details about the surgeon, (2) evaluation of the surgical insinstinstrument3) other numerical assessments such as the rate of agreement opinion from (1-5) about time, precision, hand comfortability, instrument control and problems encountered in use. Thus, the total number of questions is 27 for each new and traditional instrument. The procedures were performed on animal tissue, as shown in Fig. 10, using the new instrument with a motor, a sensor, and a laptop to program the Arduino using the code.

Summarized Version of the Questionnaire about Pen Needle Holder

Category 1

Participant details	
Sex	
Age	
Years of experience	
No. microsurgical procedures as the first surgeon	
Hours per week performing microsurgical surgery	
Surgical glove size	
Specialty	
Body posture in interventions when using the needle holder	
Uses the right or left hand	

Categories 2

How do you consider the handle size?	
How do you find the position of the instrumental use?	
During the use of needle holder, do you take any uncomfortable or forced posture?	
How much effort did you put into working with tough fabrics and what is your comment on why?	
How much time does it take?	
How do you see the accuracy?	
How do you see the orientation of needle hold?	
Indicate the causes of the problems in parts of the body?	
Indicate the elements that need improvement, and if you want, indicate any proposals to improve or solve the current problems	
Rating the traditional needle holder and pen needle older instrument	
Indicate other measures or assessments of the surgical instrument you consider necessary	
Specify other contributions you want to record	
Realism of the instrument	
Instrument movement	

Category 3

Place × to the option you see appropriate	1	2	3	4	5
Indicate your rate of agreement, from 1 (very short are caused) to 5 (very long are caused), for the time of suturing					
Indicate your rate of agreement, from 1 (very preciseare) to 5 (inaccurate), for the precision					
Indicate your rate of agreement, from 1 (no discomfort are caused) to 5 (very severe discomfort are caused), for hand comfortability					
Indicate your rate of agreement, from 1 (very easy are caused) to 5 (comfortable), for instrument control					
Indicate your rate of agreement, from 1 (no discomfort are caused) to 5 (very severe discomfort are caused), the level of problems generated					

Fig. 9. Form of the surgeons' questionnaire

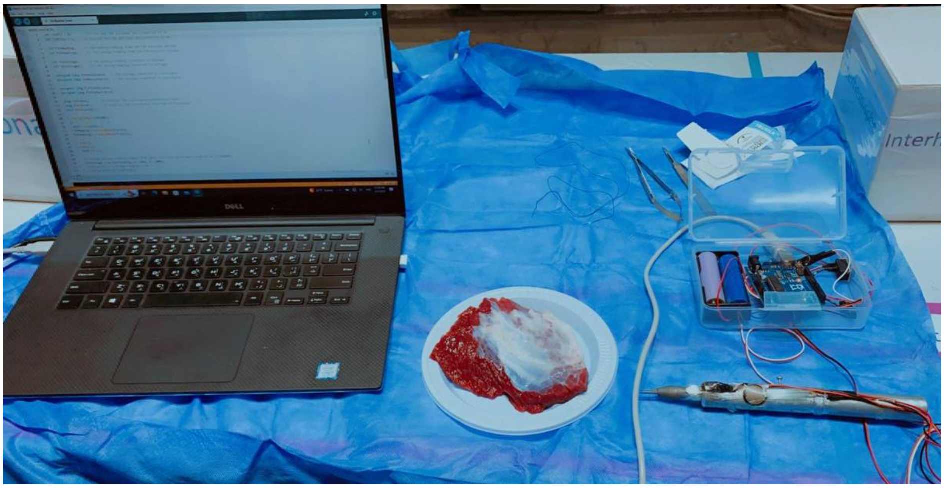

Fig. 10. Set up of the electronic needle holder instrument

The surgeon used a microsurgical needle with tissue at more than an angle and in several long orientations. As shown in Fig. 11, the surgeon picks up the microneedle and inserts it into the tissue. When he feels that he has reached a tough tissue, he presses the sensor, which turns on the motor, gives a hammering effect, and facilitates the passage of the needle through this tough tissue. These suturing stitches were repeated several times and in more than one place in the tissue.

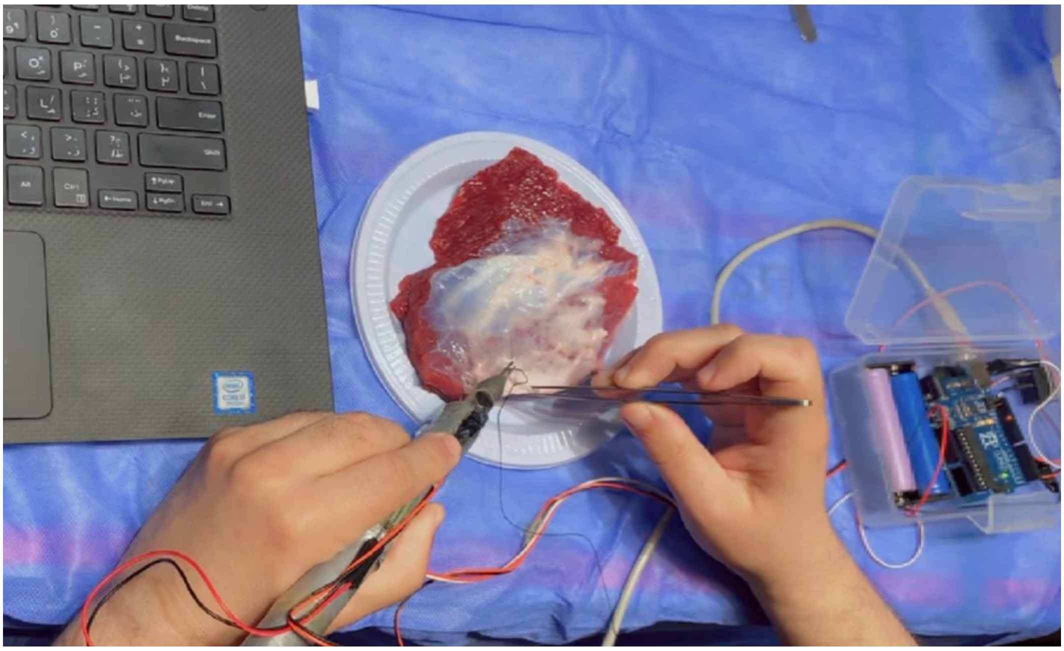

Fig. 11. Neurosurgical surgeons use the electronic pen needle holder for suturing.

6. DISCUSSION

The surgeons' answers to the questionnaire and the comparison between the traditional and New Electronic Needle Holders revealed that the accuracy of the Electronic Pen Needle Holder Instrument is much greater than conventional Instruments. It is almost free of error and is more focused in the desired place because it does not need effort from the surgeon, as by the surgeon pressing the FSR sensor, the effort required to suture the tough tissue will be generated directly from the motor to make needle easily passing, diverting the effort of the surgeon responsible for performing the surgical intervention to be more accurate in determining the location of the target instead of trial and error. Also, surgical interventions that take long periods lead to the stress that traditional instruments may cause, causing a continuous deterioration in quality.

This electronic circuit is placed inside the pen needle holder so that a new concept will appear: "Tunnel Concept," defined as any utilities in the instrument in direct contact with the organic tissue, as shown in Fig.12.

Also, with the use of this new instrument, surgical suturing, musculoskeletal abnormalities in the shoulder-arm and elbow-forearm regions are remarkably comparable, where paresthesia and pain in the wrists, hands, and fingers, together with shoulder-arm weariness, are identified as annoyances that must be eliminated or reduced in surgical equipment.

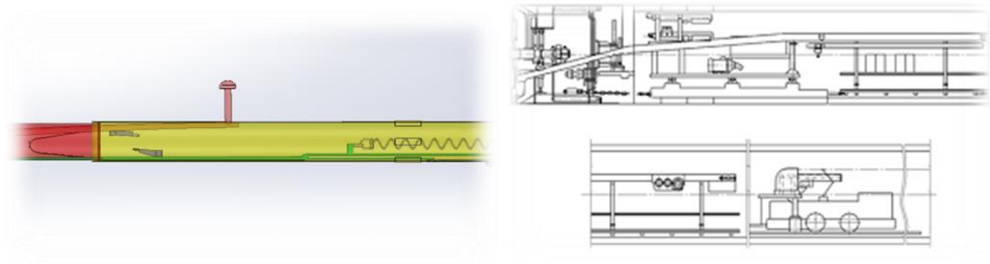

Fig. 12. Tunnel concept

7. CONCLUSION

Integrating electronic circuits with classical surgical instruments will soon be a new revolution in the design of medical instruments.

Our innovative design of using a pressure sensor in a classical surgical instrument like the needle holder facilitates the passing of the needle through hard tissues. This instrument was used by ten neurosurgeons when using it, and the traditional instrument showed that it shortened suturing time by 40% from the conventional and more precision by roughly 60% with more hand comfort and made the maneuverer of suturing with less effort.

We hope to use this pressure sensor with other instruments, such as a brain tractor, to measure the pressure produced by these retractors on the brain tissue to avoid any harmful brain ischemic effects created by them.

8. ACKNOWLEDGMENT

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