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ORIGINAL ARTICLE

Design and Test Wireless Pedicle Probe for Spine

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ABSTRACT
pedicle screw placement in spinal fixation surgery is a very challenging technique especially for those patients with scoliosis and degenerative diseases, due to variation in the vertebral structure between different levels of the spine and between humans, Also due to the site of placing the screw in the pedicle, it's near the nerve roots of the spine, But recently there was excessive effort to reduce the risk of this surgery by inventing new methods to override these risks, Wireless probe was created in this test by using ESP32 Wifi and Bluetooth development board as a processer, And Raspberry Pi3 Model B+ to display the result, By using Force sensor (FSR 400) and Hall effect sensor (AH49E) to detect bone density variation of the vertebral body and distinguish between cortical and cancellous bone, The test was performed on a three years old calf vertebra from the thoracic region and the result has been taken in a different situation to prove that the probe is working.
Keywords: Screw placement, pedicle probe, force sensor, hall effect sensor.

INTRODUCTION
Posterior vertebral fixation by using rods and screws is the most commonly used method to treat scoliosis, degenerative and deformity cases[1], the accuracy of placing the pedicle screw is challenging as a result of the variability of the vertebra from one region to another, the different in pedicle size and their proximity to the nerve [2].

There are many methods used to reduce the risk of screw perforation but all these methods have drawbacks, Computed tomography (CT) for example is used to give the surgeon an image of the screw position after the screw has been inserted into the vertebra, the repeated exposure of the radiation to the staff and the patient may lead to serious complication after surgery especially for the surgeon, while the use of computer-aided frameless stereotaxis is very complicated method needs to prepare before the surgery which will take time and consume money [3].

There was an attempt to design a probe that depend only on the force sensor (FSR400) to detect the difference in the bone density between the cancellous and cortical bone of the vertebra but our device depend on two sensors to give the surgeon a real-time alarm when any misplacement of the screws happen[4].

System design Hardware design: The Wireless probe design includes a 3D printing cover and electronic parts as shown in Fig. 1

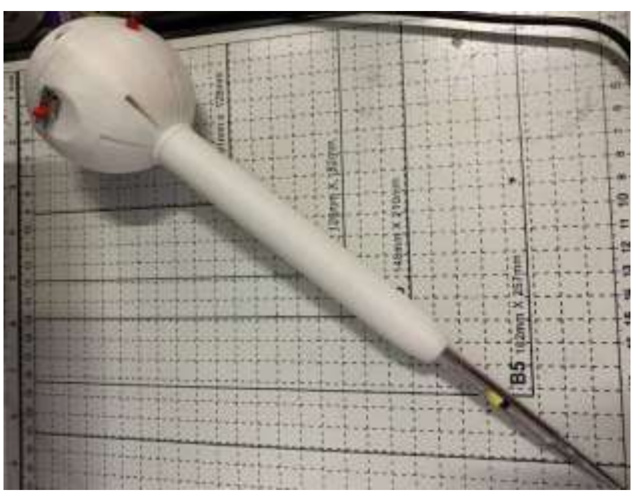

Figure 1: Wireless Probe

The Probe 3D printing cover: which was carefully designed by using a graphic design programming (Blender and Solidworks), It has been adjusted many times and printed using a 3D Printing machine (Balco) and PLA material so the probe will be friendly used in the surgeon's hands and acceptable to contain all the other parts of the probe.

The probe consists of five parts shown in Fig. (2), The first one is a long shaft of 14cm with a toothed head cannulated with 9mm inner diameter and 15mm outer diameter, The Second part is the half bottom sphere which contains a bottom hole for the shaft, Two side upper hole one for the LED and the other for the switch to switch on and off the batteries inside, and from inside the sphere contains four holes for the screws of the upper half of the sphere and sidebars to support the electronic board.

The Third part is a plane plate with 2mm thickness to support the awl and force sensor placing it on the two bars of the half bottom sphere and fixed with two small side screws, While the Fourth part is the upper half of the sphere contains holes for the four screws to be fixed on the bottom half and contain a hole for charging the batteries by using c type wire at the top of the sphere, another hole for programming the ESP32 when it needed to change anything in the programming, And a small hole for the reset bottom of the ESP32.

Long stainless steel tapered awl 26cm cannulated with two holes 4mm each, One at the 4cm from the top and the other is at 7cm from the bottom to pass the hall effect sensor through it, Plastic circular head at the top to be isolated, The circular head used to push the force sensor on the plate.

Figure 2: The Probe Cover

Electronic Parts: The electronic parts consist of ESP32 Wifi and Bluetooth development board connected to Buzzer, LED, Vibrator, Resistor, Force Sensor (FSR400), Hall Effect Sensor (AH49E), Two 200mAh 3.7V Flat Lithium Rechargeable batteries, Lithium battery Charger Board and 1.54.2V To 5V DC-DC Step up conversion Module connected as shown in Fig. (3).

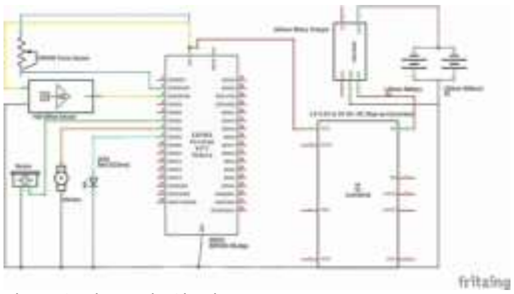

Figure 3: Electronic Circuit

The software part: C++ language was used to program the ESP32 to give a real-time alarm after collecting data from the sensors after being connected to Raspberry Pi 3 Model B+ with the same Wifi username and password and IP address.

System process operation: Using ESP32 Wifi and Bluetooth development board as processer that was connected to Force Sensor (FSR400) and Hall Effect Sensor (AH49E) as analog inputs and give the alarm to the Buzzer, LED and Vibrator, Also a use of Raspberry Pi 3 Model B+ as a display device to make a comparison with the first design so we can play both probes and have resulted at the same time.

The Wireless probe was programmed by C++ Language on Windows 8 system on the ESP32 Wifi and Bluetooth development board that was programmed to send the result to the Raspberry Pi 3 Model B+ when we apply the same Wifi username and password and the IP address of the Raspberry to the ESP32, By using specific code on the terminal of the Linux system the result will appear, A block diagram of the system is shown in Fig. (4).

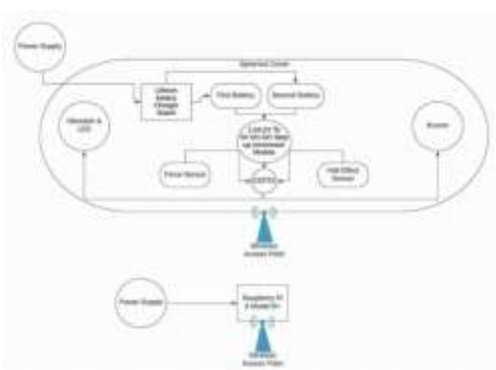

Figure 4: Block Diagram of the Wireless Probe design

With this probe, The surgeon can detect any error in placing the screw through the pedicle without needing any x-ray or other complicated devices with low cost, small size, Portable probe that friendly use in the hand of the surgeon.

DISCUSSION

The Wireless probe gives more flexibility and portable use of the probe in the surgery and also gives the availability for reuse of the probe and makes it sterilizable in the future.

The use of a hall effect sensor was new thought that will give us another indication if there is any misplacement of the screw but here the reading was not accurate and cannot be reliable because the test was done on a dead calf and the magnetic field is different between living and dead body because of the fluids and movement of the living body will increase or decrease the magnetic field [6].

The Test was performed on six-hole in six vertebras of a calf in the pedicle region, Dividing the holes into three in the correct position of placing the screw in the vertebral body and three was deviate in the wrong way one in the spinal canal and one in the vertebral disc and one in the cortical (Vertebral Wall) to test if the probe gives the alarm or not.

As shown in the Table (1) and (2) the result of the force sensor and hall effect sensor gives the same indication when the probe passes through the cortical bone of the vertebral wall the reading is high and the alarm is on, While the second reading is less than the first because the probe pass through the cancellous bone of the vertebral body, The First hole enters through the spinal canal so there is no force to read on the force sensor but the reading have some error percentage so the reading was 405N while the hall effect sensor still read the magnetic field in the body, especially because the spinal cord is still there in the spinal canal so the reading in the cord is higher than the bone.

Table 1: Force sensor Result of Wireless Probe

Number of the Vertebra	First Reading	Second Reading	Placement of the Reading
First Hole	3558	405	In Spinal Canal
Second Hole	4095	3869	In Vertebral Body
Third Hole	4095	4095	In Cortical (Vertebral Wall)
Fourth Hole	3171	2874	In Vertebral Body
Fifth Hole	4095	3869	In Vertebral Body
Sixth Hole	4095	2541	in the vertebral disc

Table 2: Hall effect sensor Result of Wireless Probe

Number of the Vertebra	First Reading	Second Reading	Placement of the Reading
First Hole	2238	2543	In Spinal Canal
Second Hole	4095	3829	In Vertebral Body
Third Hole	4095	4095	In Cortical (Vertebral Wall)
Fourth Hole	3139	2849	In Vertebral Body
Fifth Hole	4095	3829	In Vertebral Body
Sixth Hole	4095	3538	in the vertebral disc

In the Second, Fourth, and Fifth reading the force sensor read high at approximate 4095N then low at approximate 3000N as it inserts in the correct place in the vertebral body, The Third reading gives the same reading at the beginning then when it reaches the cortical wall it gives another high reading and causes the alarm to start in both force and hall effect sensor.

The final reading in the vertebral disc that does not give the normal reading of the cancellous bone is lower and indicates the wrong placement of the probe into the pedicle.

CONCLUSION

The probe has been tested and gives the expected result with error percentage first because there is a difference between calf and human bones structure and density, Second the sensitivity of the Hall effect sensor and its effect on living and dead bodies, But overall we obtain a device that can give us a correct indication on the right placement of the screw through the pedicle of the spine.

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