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Design and Development of Ligature Force Measurement System for Whipples Surgery

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Abstract—*Pancreatic cancer is the fourth leading cause of death in the world. The standard treatment for pancreatic cancer is Pancreatic resection. The surgical process known as Whipple's procedure for pancreatic cancer involves suturing the part of pancreas with stomach or jejunum is known as anastomosis. The success of anastomosis depends on the ligature force (knot tying force). The failure of anastomosis results in leakage of amylase which leads to mortality and morbidity of the patient. To avoid these complications, optimal force has to be exerted by the surgeon during ligature phase of the Whipple surgery. Hence, this research work aims to design and develop ligature force measurement system. The system indicates the surgeon an audio/visual alarm if the applied force exceeds the optimal range. This system can also be used as a training tool for surgeons to improve their surgical skill.*

Keywords: *Anastomosis, Ligature, Whipple'ssurgery, surgical training.*

1. INTRODUCTION

Pancreatic resection is technically a demanding procedure, where the head of the pancreas, a portion of the bile duct, the gallbladder and the duodenum are removed, usually with part of the stomach. After the removal of these structures, the remnant portions are rejoined to the intestine. Despite significant improvements in the safety and efficacy of pancreatic surgery the morbidity rate remains high in the range of 30%-65%. At present, the single most significant cause of morbidity and mortality after Pancreatico-dudenectomy (PD) is the development of pancreatic leak and fistula.

The development of pancreatic leak and fistula increases the length of hospital stay, cost of treatment and causes life-threatening complications. This necessitates the use of additional investigations and procedures. To avoid these complications, optimal force has to be exerted by the surgeon during ligature phase of the Whipple surgery.

Nobuki Oshima et al., proposed the development of a Suture/Ligature Training system which provides quantitative information of the movement of an artificial skin as well as information of the quality of the suture[1]. The investigations on appropriate knot tying force for endoscopic surgery in dog model was done by determining the relation between the force and wound healing [2]. A method to study the tear-out characteristics of stitched porcine small intestinal tissue as a function of the position of the stitch, using an optical strain measurement system was studied. Furthermore, the hole formation of two different suture materials (monofilament and braided) with a single stitch is examined and compared [3].

Jorge Solis et al., proposed the development of a suture/ligature training system which provides quantitative information of the movement of a dummy skin as well as information of the quality of task[4]. A device to prevent the surgeon from applying excessive force in making suture knots for any kind of surgery using force sensor was proposed by Aqeel F et al, [5]. Jingsi Zhang et al., developed a model for realistic cutting and suture in real-time. For realistic rendering, the response of deformable soft tissue during the cutting and suture process is analyzed and simulated [6] Most of the above reported works have been carried out on models and simulations only. This paper focuses on the development of real time force measurement system for whipple's surgery.

2. MATERIALS AND METHODS

The general block diagram of the proposed system is shown in fig. 1. The system consists of the sensors, signal conditioning circuit, control unit, transmitter and receiver. In this work, flexi force sensor is used and it is shown in fig. 2.

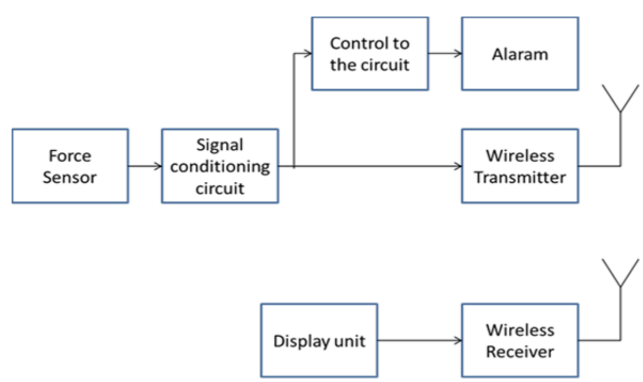

Fig. 1: Block diagram of the developed System

It is used to convert the force into equivalent resistance. The acquired signal is amplified, filtered and transmitted wirelessly.

The received signal is displayed and analysed using software. Also, the measured signal was compared with the optimal force in the control unit and the control signal initiates the alarm, if the force exceeds the optimal range.

Fig. 2: Flexi Force Sensor

3. EXPERIMENTAL SETUP:

The sensor was first calibrated against the standard weights and the characteristic curve was obtained and it is shown in Figures 3& 4.

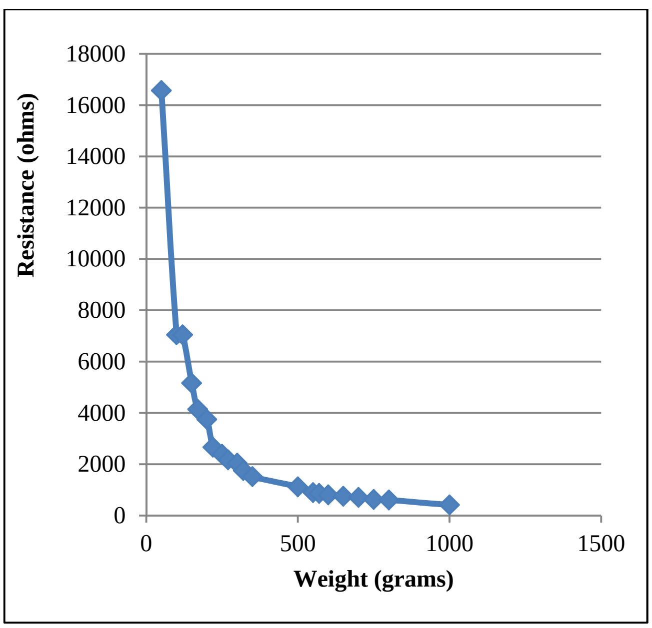

Fig. 3: Weight vs Resistance

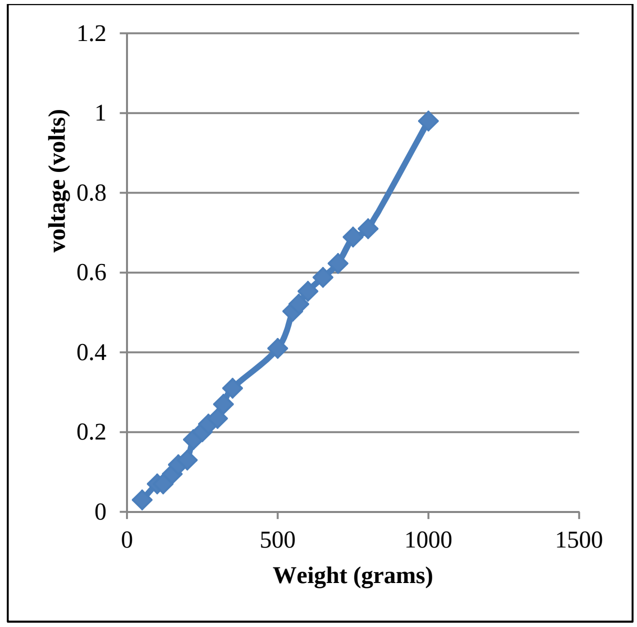

Fig. 4 Weight vs Voltage

The sterilized sensors were placed on the index fingers of the surgeon (Fig. 5) during the ligature phase of the whipple's surgery. The anastomosis of Whipple's procedure is almost performed for about 30 minutes to 1 hour. During this procedure, the knot tying force of the surgeon is measured continuously. The acquired signal is processed using data acquisition system and it is transmitted wirelessly. The receiver unit is kept away from the operating area and suture data is displayed and stored for further analysis.

Fig. 5: Sensor Placement

4. RESULTS AND DISCUSSION:

The developed system was initially used for a pilot study to measure the ligature force during surgery after obtaining the ethical clearance from the hospital. The measurement was taken from the surgeons during the ligature phase of the surgery. Fig. 6 shows the measurement of force during the whipple's surgery.

Fig. 6: Measurement during the Surgery

The ligature force data was collected for 33 surgeries that includes soft, firm and hard pancreas. Force applied during pancreatic anastomosis varies depending on the texture of pancreas such as soft, firm & hard and also on the different surgeons involved. Table 1 shows the optimal knot tying force for different surgeons.

Table 1: Optimal knot tying Force

Surgeons	Knot Tying Force (N)		
	Soft Pancreas (24)	**Firm Pancreas (8)**	**Hard Pancreas (1)**
Senior	3-6	3-7	4-12
Junior	4-7	4-7	-

The post operative study was carried out to analyze the amylase leakage. Based on the analysis, the optimal force range was determined and it was used for controlling the applied force. It was observed that the force applied during pancreatic anastomosis varies between 4-12 N based on the nature of pancreas such as soft, firm and hard. Most of the pancreases are soft in nature and the optimal force range for soft pancreas varies between 3-7 N. The optimal force range determined was set as a threshold and the system indicates the surgeon an audio/visual alarm if the applied force exceeds the optimal range.

5. CONCLUSION

The suture knot tying force measurement system for Whipple surgery was developed successfully and this system is used in real time. The Force data was collected for 33 surgeries. This system prevents the surgeon by applying excessive force during the suture. In future, the developed system will also be tested for other surgeries. This system can also be used as a training tool for surgeons to improve their surgical skill.

6. ACKNOWLEDGEMENT

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