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HISTOLOGICAL STUDY OF TISSUE DAMAGE DUE TO COMPOSITE-COATED NEEDLE INSERTION

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ABSTRACT

Reducing the force required during needle insertion is vital to minimize tissue damage in percutaneous procedures. A composite coating of Polydopamine, Polytetrafluoroethylene, and Activated Carbon materials was applied to the needles to address this challenge. The coating reduces needle surface friction, which eventually helps to decrease the insertion force and minimize tissue damage. In this study, measuring the insertion and extraction forces inside a bovine kidney showed that the coated needles decreased the insertion force by 49% and the extraction force by 30%. In addition, a histological analysis was conducted to compare the tissue damage caused by coated and bare needles. The results revealed that coated needle insertion reduced tissue damage by 39.6% compared to bare needles. These findings highlight the potential of this composite coating approach to improve the safety and precision of percutaneous procedures.

Keywords: Needle surface enhancement, Insertion force reduction, Histology.

1. INTRODUCTION

Surgical needles are essential for specific medical procedures, such as biopsy, brachytherapy, thermal ablation, drug delivery, and blood sampling. However, tissue damage and deformation caused by the insertion force can significantly affect the precision of these procedures. Therefore, reducing the required insertion force is necessary to improve accuracy and minimize tissue damage and deformation [1].

Various methods can be used to decrease the insertion force of the needle, such as reducing the speed of needle insertion [2], modifying the design of the needle [3], coating the needle surface [4], and using different insertion techniques [5]. In the mentioned cases, coating the needle surface enhances its surface properties and helps to preserve the original needle design and geometry, which is crucial in numerous surgical interventions. Medical researchers have investigated the use of polymer and composite coatings on medical devices to minimize friction and lower tissue damage during medical procedures. Materials such as silicone [6], diamond-like carbon (DLC) [7], thin-film metallic glass (TFMG) [8], and composites of DLC and Parylene [9] coatings have been used to enhance the surface of medical devices, particularly needles, by improving their sharpness and durability.

In this research, a new coating was introduced for needles using a combination of Polydopamine (PDA), Polytetrafluoroethylene (PTFE), and activated carbon (C). These materials were selected based on their unique properties, like biocompatibility, low friction, antimicrobial properties, and resistance to chemicals and drugs. In addition, experiments were performed to measure the insertion-extraction forces of coated and bare needles in bovine kidney tissue.

To test the hypothesis that reducing the insertion force can reduce tissue damage [10], histological analysis was performed on bovine kidney tissue samples with needle insertion holes, comparing the tissue damage caused by coated and bare needles. The images were then analyzed using image analysis software to evaluate the tissue damage. Overall, this research highlights the importance of using composite coatings for surgical needles to decrease the insertion force, minimize tissue damage, and improve the success of medical procedures.

2. MATERIALS AND METHODS

The research comprises two parts: needle coating impact on the insertion-extraction forces and tissue damage analysis. This section explains the needle coating process, the experiments conducted to observe the coating effects, and the histological experiment used to analyze tissue damage in bovine kidney tissue. The bovine kidney tissue was procured from the local butcher store, and it was prepared for the experiments using a tissue fixation solution called formalin.

2.1 Experiments to Study the Needle Coating Effect

This research analyzed two types of needles: (i) stainless-steel needles without any coating and (ii) stainless steel needles coated with PDA-PTFE-C. The needles used throughout this research are solid trocar tip needles (Vita Needle Company, Boston, MA, USA) with a diameter of 1.27 mm, as shown in Figure 1. The two distinct parts of the needle, namely the shaft and the tip, are illustrated in Figure 1 with a sketch. The coating process involved submerging the needles with the clamping laboratory stand in a PDA solution for 24 hours at room temperature (20°C), after which any excess PDA was removed using deionized water. Next, the PDA-coated needles were dipped in a PTFE-C solution using a dip coating machine (Custom-fabricated using the Velmex UniSlide® MA40, Velmex, INC, Bloomfield, NY, USA) and cured at 373°C in a furnace. After cooling, the coated needles were ready for the experiment [4].

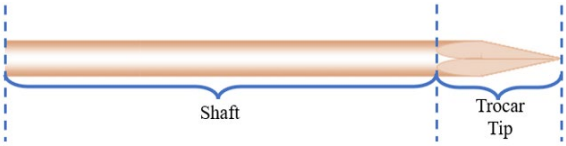

FIGURE 1: SKETCH OF THE STAINLESS-STEEL TROCAR TIP NEEDLE.

A specially-designed test setup was used to regulate needle velocity and insertion depth for the insertion-extraction force measurement experiment (Figure 2). The setup included a linear motor actuator (Velmex Unislide® MA40, Velmex, INC, Bloomfield, NY, USA), the force sensor (Nano17®, ATI Industrial Automation, Apex, NC, USA, resolution: 1/160 N, maximum range: 17 N), and a needle holder connected to a force sensor. The test setup also includes a data acquisition system (National Instruments Corporation, Austin, TX, USA) and a custom tissue holder.

This experiment maintained the needle insertion and extraction velocity at 5 mm/s, with a maximum insertion depth of 35 mm, controlled by the motor controller (Velmex, VXM™ controller, Velmex, INC, Bloomfield, NY). Five insertions and extractions were performed with each of the three coated and bare needles at room temperature (20°C). To ensure accuracy and consistency in measuring forces, the force sensor was programmed to start recording as soon as the needle made contact with the tissue. After each procedure, the tissue holder was relocated to a minimum distance of 2 cm from the previous insertion site in preparation for the subsequent insertion and extraction. This method aimed to diversify the measurement sites and prevent any particular area of the tissue from experiencing excessive damage or distortion. The maximum average force of each needle was exclusively used for comparative analysis in Table 1 because maximum forces result in more tissue damage [1].

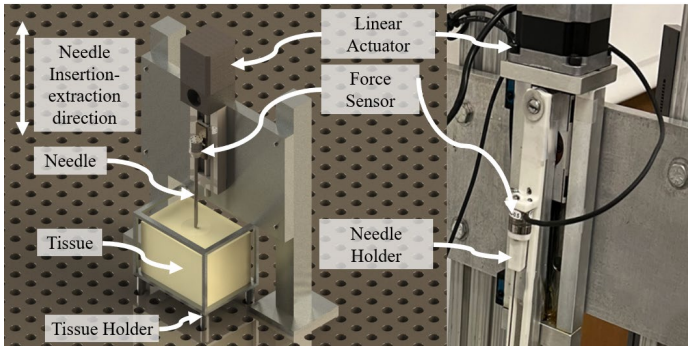

FIGURE 2: NEEDLE INSERTION AND EXTRACTION TEST SETUP.

2.2 Tissue Damage Analysis

Three tissue samples for each bare and coated needle were placed in the modified cassettes shown in Figure 3(a). These cassettes have rectangular holes where the needle was inserted and extracted at room temperature (20°C). After extraction, the tissue samples were placed in a container with 10% formalin to fix them at room temperature (20°C). The cassettes were soaked in the formalin solution for 48 hours before being transferred to 70% isopropyl alcohol to remove any remaining water.

After dehydration and clearing, the tissue is embedded in paraffin wax for proper infiltration. Next, a microtome is used to section the tissue, with tissue sections trimmed to a size of 2 cm x 2 cm and a thickness of 5 mm. Two thinly sliced sections from each sample were mounted on glass slides.

The tissue slides that had been previously sectioned and mounted on slides underwent a dehydration process, which involved immersing them in xylene and a 50:50 mixture of xylene and ethanol for 5 minutes each. Graded alcohols ranging from 70% to 100% were then sequentially used to soak the specimens for 5 minutes each, ensuring complete dehydration. Afterward, the slides were stained with hematoxylin and eosin (H&E). Specifically, they were first treated with a 10% (v/v) hematoxylin solution in water for 5 minutes, followed by two rinses with tap water. Then, they were exposed to a 1% (v/v) eosin Y solution in water for 20 seconds, followed by another two rounds of rinsing with tap water [10]. Once the slides were air-dried and ready for microscopic image analysis, as shown in Figure 3(b).

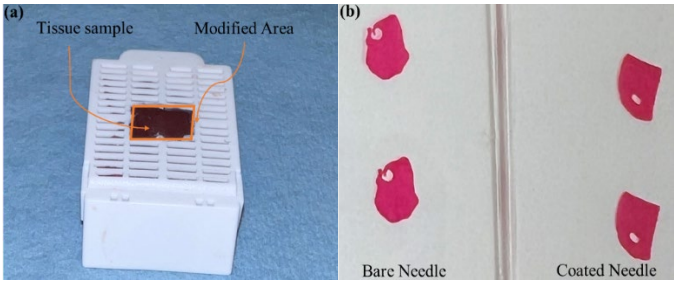

FIGURE 3: **(a)** MODIFIED CASSETTE FOR NEEDLE INSERTION **(b)** H&E-STAINED SLIDES OF BOVINE KIDNEY TISSUE SAMPLE.

3. RESULTS AND DISCUSSION

This section presents a detailed analysis of the results from experiments conducted to compare the insertion-extraction forces of coated and bare needles. Moreover, the tissue damage caused by coated and bare needles is thoroughly compared and examined.

3.1 Needle insertion-extraction forces

The experiments were conducted on bovine kidney, and the maximum average insertion and extraction forces of the needles with standard deviations are shown in Table 1. The bare needles had an average maximum insertion force of 3.54N (standard deviation: 0.054N), while the coated needles exhibited an average maximum insertion force of 1.82N (standard deviation: 0.024N). Similarly, the average maximum extraction force for the bare needles was -0.72N (standard deviation: 0.048N), whereas the coated needles had a lower average maximum extraction force of -0.50N (standard deviation: 0.025N).

A paired two-tailed t-test resulted in p-values of 0.0010 for insertion forces and 0.018 for extraction forces. These values rejected the null hypothesis, affirming a statistically significant difference between the insertion forces of the coated and bare needles and between their extraction forces.

Figure 3 presents a graph of average insertion-extraction forces versus insertion-extraction depth. It shows that the force required for needle insertion is greater than extraction. This difference arises because, during insertion, force is applied between both the needle shaft and the tissue (friction force) and the needle tip and the tissue (cutting force). In contrast, during extraction, only the needle shaft encounters the tissue (friction force), and it follows the path created during insertion.

TABLE 1: AVERAGE MAXIMUM INSERTION AND EXTRACTION FORCES WITH THE STANDARD DEVIATIONS.

Samples	Maximum Insertion Force (N)		Maximum Extraction Force (N)	
	Bare	Coated	Bare	Coated
1	3.56	1.81	-0.74	-0.45
2	3.60	1.79	-0.78	-0.51
3	3.47	1.85	-0.62	-0.49
Average	3.54±0.054	1.82±0.024	-0.72±0.048	-0.50±0.025

The nonlinearity observed in Figure 3 of the force graph reflects the heterogeneous nature of bovine kidney tissue. During the insertion phase, the diverse properties of the bovine kidney become more evident as the needle cuts through different sections of tissue and experiences friction force. However, during the extraction phase, the needle primarily experiences friction force. Additionally, the graph illustrates that the bare needle generates higher insertion and extraction forces compared to the coated needle. This increase can be attributed to greater surface friction and temporary tissue adherence, both of which are more pronounced in bare needles due to the absence of a coating [8,11].

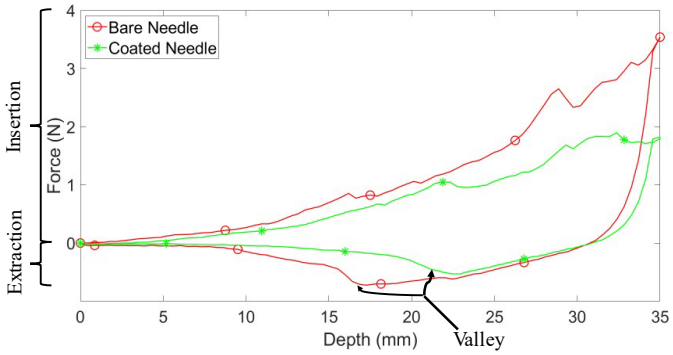

FIGURE 4: NEEDLE INSERTION-EXTRACTION FORCES IN THE BOVINE KIDNEY, MAXIMUM AVERAGE INSERTION FORCE OF BARE NEEDLES 3.54 ± 0.054N, MAXIMUM AVERAGE INSERTION FORCE OF COATED NEEDLES 1.82 ± 0.024N, MAXIMUM AVERAGE EXTRACTION FORCE OF BARE NEEDLES -0.72 ± 0.048N, MAXIMUM AVERAGE EXTRACTION FORCE OF COATED NEEDLES -0.50 ± 0.025N.

This adherence is particularly noticeable during extraction, as the tissue moves upward with the needle, creating a valley in the extraction force graph (Figure 4) [11]. This phenomenon occurs because, during needle extraction, there is a maximum surface contact length of 35mm with the tissue, leading to increased adherence. In contrast, during insertion, the needle contact surface length gradually increases, preventing the formation of a noticeable valley [8,11]. The valley observed for the coated needle during extraction is smaller compared to the bare needle. This indicates that the coating reduces the temporary adherence of the needle to the tissue, making the needles less sticky. So, the coating of PDA-PTFE and C on the needle helps in reducing the insertion force by reducing the friction force and making the needle less likely to stick to tissue. From the results, it is determined that the coated needle decreased the insertion force by 49% and the extraction force by 30% compared to the bare needle.

3.2 Histological Analysis

This section explains histological analysis to investigate the extent of tissue damage caused by coated and bare needles in bovine kidney tissue samples. The Olympus GX-71 microscope (Olympus Corporation, Shinjuku City, Tokyo, Japan) with 5X magnification was used, which was calibrated with a micrometer calibration slide to examine the H&E-stained tissue samples. The analysis of the tissue damage area for both coated and bare needles tissue samples was performed using the ImageJ software (National Institutes of Health, Bethesda, MD, USA). To make selecting the tissue damaged area easier, the images were converted to grayscale (8-bit), and calibrated the software with a reference line of 250µm. Then, the irregular tissue damage area was selected and calculated using the wand tool. Table 2 presents the area of tissue damage for each individual sample, along with the mean value and associated standard deviation. The damage inflicted on tissue by the bare needle insertion-extraction

averaged at 956.47mm², with a standard deviation of 85.3mm². On the other hand, the needle with coating inflicted a mean damage of 582.11mm², exhibiting a standard deviation of 94.5mm². The data rejects the null hypothesis according to the two-tailed t-test, with a p-value of 0.00089, which shows the statistically significant difference between the bare and coated needles tissue damage area.

TABLE 2: TISSUE-DAMAGED AREAS OF BARE NEEDLE AND COATED NEEDLES IN (mm^2).

Samples	Damaged area (mm^2)	
	Bare	Coated
1	1051.78	670.68
2	972.93	615.33
3	844.71	448.34
Average	956.47±85.3	578.11±94.5

Furthermore, Figure 5 displays microscopic images of six bovine kidney tissue samples, with the tissue damage areas superimposed for both the coated and bare needles. The damaged area is distinguished by prominent white region, indicating the extent of tissue damage. Due to friction and adherence, the bare needles caused more damage than the coated ones, as shown in Figure 5 with the superimposed images.

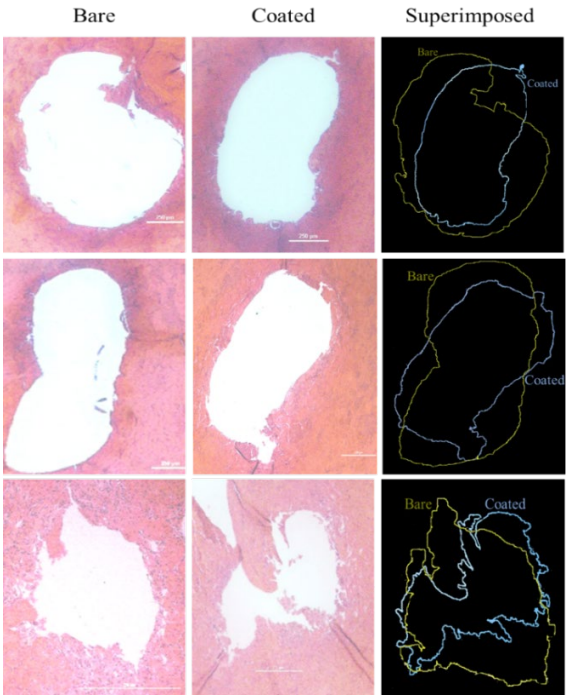

FIGURE 5: MICROSCOPIC IMAGES OF TISSUE DAMAGE CAUSED BY BARE AND COATED NEEDLE INSERTION AND SUPERIMPOSED IMAGES OF DAMAGED AREAS OF BARE (YELLOW) AND COATED (BLUE) NEEDLE INSERTION-EXTRACTION.

According to the data presented in Table 2, the coated needles caused, on average, 39.6% less tissue damage than the bare needles. Based on the results, it can be interpreted that using a PDA-PTFE-C coated needle results in less tissue damage during insertion and extraction. These significant results support the hypothesis of this research.

CONCLUSION

PDA-PTFE-C coated needles can decrease tissue damage during insertion and extraction compared to bare needles by reducing insertion force to 49% and extraction force to 30% at 35mm insertion depth. Moreover, the histological analysis also supports this conclusion by demonstrating 39.6% less tissue damage with coated needles. Future work involves developing a comprehensive analytical model that considers various parameters affecting the needle insertion process and precisely predicts the insertion force.

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