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RESEARCH ARTICLE

ENHANCING DIAGNOSTIC ACCURACY IN ONCOLOGY: THE ROLE OF BIOPSY GUN TECHNOLOGY IN DIAGNOSING MALIGNANCY"

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ABSTRACT

Nowadays, cancer is one of the leading causes of mortality; different varieties of cancer can affect anybody at any age, from young children to the elderly. Different forms of cancer grow depending on the location of aberrant cell proliferation. After 40 years of age, lung and breast cancer are the most frequent types of cancer. The development of cancer has several causes. Because malignant cells seem like normal cells, diagnosing them can be challenging. Although there are other ways to diagnose it, a biopsy is far more accurate than other techniques.By providing an adequate sample for pathological examination, it facilitates accurate diagnostic results for cancer cell analysis, it will also aid in the course of treatment. Different methods are used today to take biopsy samples, but with the aid of a biopsy needle, we can collect samples easily, improving both procedural safety and diagnostic accuracy. We have engineered a biopsy gun that integrates dual linear sliders for enhanced operational precision and control. We have developed a biopsy gun that integrates dual linear sliders for enhanced operational precision and control, guided by the main slider guide, improves ease of use, and the needles design provides additional benefits for the patient. Thus, the current developed device is dedicated to the biopsy gun designed specifically for acquiring biopsy samples to diagnose cancer diseases.

INTRODUCTION

Cancer, characterized by the abnormal proliferation of cells within organs, poses a significant threat to human health, often culminating in organ failure and mortality. This complex disease manifests in various forms, each contingent upon its originating location within the body, with cancerous cells possessing the capacity to metastasize, resulting in widespread organ dysfunction. Major types of cancer, including lung cancer, blood cancer, prostate cancer, breast cancer, and tumours exhibit distinct abnormalities and symptoms.

Despite extensive research, the definitive cause of cancer remains elusive. However, certain factors such as smoking, aging, genetic mutations, chronic inflammation, radiation exposure, and immune system dysfunction have been identified as contributors to cellular abnormalities and the development of cancer.

Breast cancer and lung cancer stand out as the most frequently reported malignancies globally. According to a report from the Indian Council of Medical Research (ICMR) spanning from 2012 to 2019, a staggering 1,332,207 cancer cases were registered from 96 hospitals participating in the National Cancer Registry Programme (NCRP). Among these cases, 51% of females were diagnosed with breast cancer, while 47% of males suffered from cancers attributed to tobacco use. Notably, lung cancer patients exhibited the highest proportion of distant metastasis at presentation, with rates reaching 49.2% in males and 55.5% in females.

In the realm of cancer diagnosis, several methods are employed, including imaging tests, biopsies, blood tests, genetic tests, and endoscopies. Imaging tests such as ultrasound, MRI, and biopsy are commonly utilized for the diagnosis of lung and breast cancers. Biopsy, in particular, plays a crucial role in cancer detection, as it provides definitive evidence of cancer cells. This procedure involves the extraction of tissue samples from suspected tumours or abnormal areas for microscopic

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examination. Different biopsy techniques, including needle biopsy, surgical biopsy, and endoscopic biopsy, cater to specific diagnostic needs.

The present research study endeavors to evaluate the dynamic development of a biopsy gun for the collection of tissue samples in cases of lung and breast cancer. Unlike traditional incision biopsy methods, this innovative biopsy gun boasts a less invasive approach, employing a tissue-cutting needle capable of retrieving larger tissue specimens. This characteristic enhances its diagnostic accuracy, rendering it a widely utilized method in the diagnosis of various cancer types. Furthermore, the precise positioning of the needle tip minimizes the risk of injury to adjacent organs, thereby enhancing patient safety and clinical outcomes.

MATERIALS AND METHODS

The biopsy gun is comprised of distinct components which find application in various medical disciplines such as oncology, gastroenterology, radiology, and dermatology. Prior to the manufacturing process, a prototype is constructed to provide critical insights into the design, functionality, and mechanisms of the product. It also helps to identify any potential errors or issues that may arise during the initial stages. Typically, the device includes a hollow

needle connected to a spring-loaded mechanism. The present research article provides a comprehensive description of components utilized in the biopsy gun. Specifically, the biopsy needle operates on a spring-loaded mechanism, with two springs employed in the biopsy gun. One spring is affixed to the cannula holder, which secures the cannula, while the other is attached to the stylet holder, which holds the stylet.

Slider Guide:

The slider guide is a critical component of the biopsy gun, serving as the outer body that houses the full assembly and enables easy handling by physicians. It is molded in two parts, with both the springs and holders placed inside and assembled together. The slider guide features two individual sliders connected to the surface, guiding both needle holders according to the requirements of the operation.

Sliders:

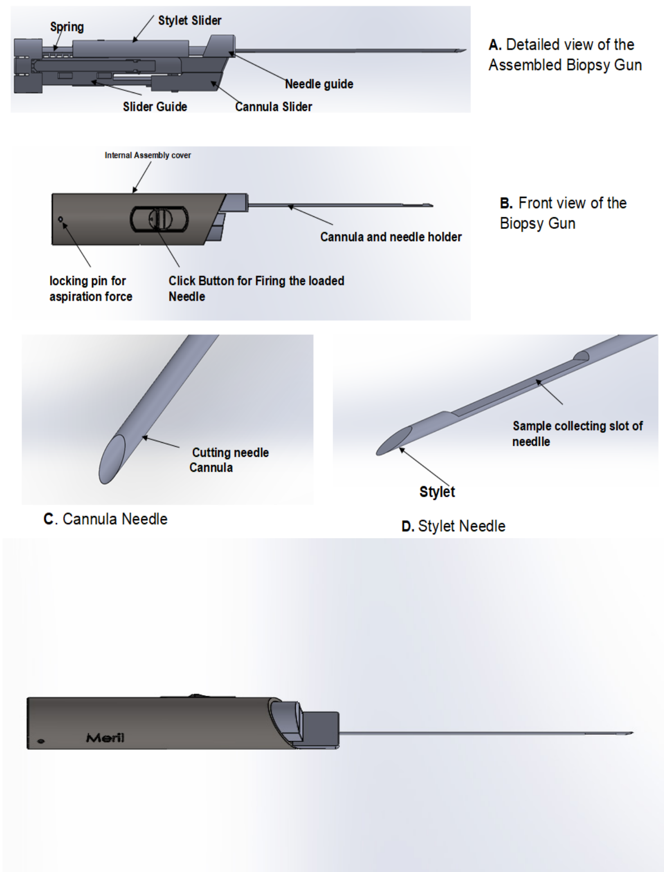
To operate the hole assembled biopsy gun there are two sliders attached to the needle holder in such a way that the needles can operate as per the need and separated by their size. The first slider is a big slider which holds the cannula holder and the other one is small slider which holds the stylet holder. Big slider is used to load the stylet needle, which retrieves the tissue sample, where small slider has an access for cannula needle which is intended to direct towards the desire tissue.

Manufacturing of Needles:

The Biopsy Gun consists of two crucial components: the Outer Needle and the Inner Needle. The Outer Needle, also known as the Cannula needle, is a hollow needle known for its ergonomic design and sharp tip, which enables it to penetrate tissue smoothly and cut precisely during sample extraction. On the other hand, the Inner Needle, or Stylet needle, is a solid component with a dedicated passage designed for collecting tissue samples at the distal end, ensuring efficient and controlled retrieval within the biopsy process. Both needles are made of medical-grade materials, including stainless steel 304, stainless steel 316, and Nitinol. The sample collecting slot is specifically designed to accommodate a maximum volume of 13.6 mm^3, the range can be in between 7 to 13.6mm^3. Sometimes the amount of tissue collection can be uncertain depending upon the tissue collection area and type of the tissue. The amount of tissue collected with a biopsy gun can indeed vary depending on the type of needle used. Different needle sizes and designs can affect the volume and quality of the tissue sample obtained. Usually smaller gauge needles can yield larger tissue samples, which can be more suitable for specific diagnostic purposes. It's important to choose the appropriate needle based on the specific requirements of the biopsy procedure and the characteristics of the tissue being sampled.

Prototype Construction:

Prior to mass production, it is imperative to ensure the compatibility and design accuracy of the biopsy gun's prototype model. To achieve this, the entire structure undergoes careful design and drafting utilizing computer graphics. The computational graphical prototype of a biopsy gun is depicted in the figure 01. Subsequently, prototype parts are fabricated using 3D printing technology. These 3D-printed components are meticulously crafted from Polypropylene material and coated with Teflon for enhanced grip and durability. Once all parts are 3D printed (figure 02) and assembled, the prototype undergoes rigorous testing to assess its functionality and performance.



E. Graphical Portrayal of a Biopsy Gun Prototype
Figure 1: Computational graphical prototype of a biopsy gun, illustrating its key components and design features.

RESULTS AND DISCUSSION

Efficacy, Functionality, and Tissue Sampling Quality:

To evaluate the efficacy and functionalities of the biopsy gun, we conducted multiple tissue sampling tests on raw pork meat shown in the figure 03. These tests provided valuable insights into the biopsy process, leading to the following observations:

Figure 2 3D printed parts of the biopsy gun prototype before assembly and testing.

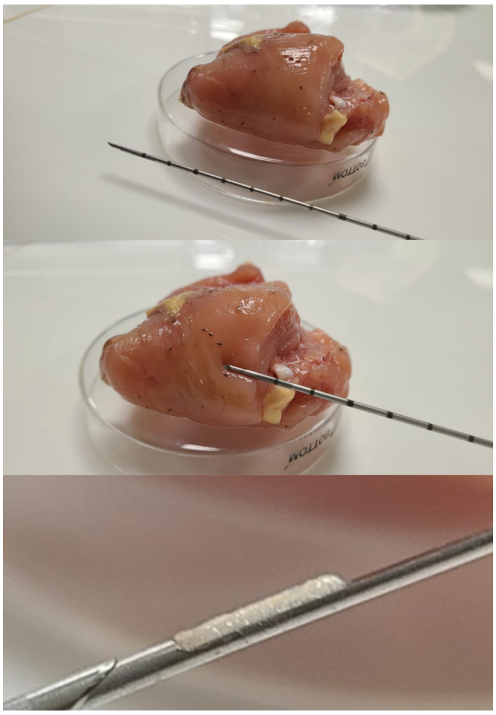


Figure 3: Tissue sampling tests on raw pork meat to evaluate the efficacy and functionalities of the biopsy gun.

Performance and Accuracy

The biopsy gun was subjected to extensive testing to evaluate its performance and accuracy. These tests involved diverse tissue samples to assess both the precision of tissue extraction and the overall functionality of the device.

Precision of Tissue Extraction

The biopsy gun consistently achieved a high precision in tissue extraction, with accuracy . The extracted tissue samples were of adequate size and quality for pathological examination, ensuring reliable diagnostic outcomes.

Operational Consistency

The developed biopsy gun demonstrated excellent operational consistency, with minimal variation in performance across different test scenarios. This consistency is crucial in clinical applications, where the ability to replicate results is paramount.

User-Friendliness

The user-friendly and intuitive design of the biopsy gun ensures ease of use. Its lightweight construction and smooth operation enhance operator comfort during procedures, reducing the learning curve for new users.

Mechanical Properties

The mechanical properties of the biopsy gun, including the force required for tissue penetration and the stability of the extraction mechanism, were thoroughly evaluated.

Penetration Force

The permissible range of average penetration force for manual operation typically falls between 3 N and 7 N. This range ensures efficient operation, minimizing strain on the operator while maintaining effective performance. After conducting several tests, we determined that an average force of 5.0 to 5.4 N is required for effective sampling with our biopsy gun.

DISCUSSION

The development of the biopsy gun has yielded promising results, highlighting its potential as an invaluable tool for medical professionals. Below is an overview of the findings and their significance:

Performance and Accuracy

The tissue extraction is done with increased accuracy demonstrating the device's effectiveness in acquiring sufficient tissue samples for diagnosis. This high accuracy rate reduces the risk of repeat procedures due to inadequate sampling.

Tissue Quality

The extracted samples are of sufficient size and quality for pathological examination, ensuring reliable diagnoses. This highlights the biopsy gun's ability to maintain tissue integrity during sampling.

Minimal Variation

The consistent performance across different test scenarios demonstrates the gun's reliability in clinical settings. Reliable results are crucial for accurate diagnosis and minimize the risk of errors due to device variability.

Needle Compatibility

Testing the gun's compatibility with various needle types and sizes broadens its applicability for different biopsy procedures. This flexibility enhances the device's utility in diverse clinical settings.

In summary, the biopsy gun has demonstrated high precision, operational consistency, user-friendliness, and optimal mechanical properties, making it a promising tool for clinical biopsy procedures.

CONCLUSION

Overall, the biopsy gun's combination of high precision, operational consistency, user-friendliness, and optimal mechanical properties makes it a promising tool for clinical biopsy procedures. The device achieved great accuracy in extracting tissue samples, ensuring sufficient size and quality for pathological examination. Its consistent performance across various test scenarios, coupled with an intuitive design, enhances ease of use and operator comfort. These features are crucial for reliable diagnostic outcomes and minimizing the need for repeat procedures. The development of this biopsy gun represents a significant step forward in improving the safety and accuracy of cancer diagnosis, ultimately leading to better patient care and outcomes. However, further clinical testing and validation are necessary to confirm these findings and fully integrate the device into medical practice. Our future research will be focusing on in-vivo applications to evaluate the biopsy gun's performance in real-world clinical settings. This will help to understand its efficacy in different types of tissues, under various conditions, and across a wider range of patient demographics. Successful in-vivo trials will be performed towards establishing the biopsy gun as a standard tool for cancer diagnosis and potentially other medical applications, enhancing diagnostic accuracy and patient outcomes even further.

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