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High velocity pulse biopsy device enables controllable and precise needle insertion and high yield tissue acquisition

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ABSTRACT

Minimally invasive biopsies are a cornerstone of breast cancer management with ultrasound being the preferred guidance modality. New developments in breast cancer management and advances in imaging technologies bring new challenges to current biopsy methodologies. A new biopsy device (NeoNavia® biopsy system, 14 G) was developed. It incorporates a pneumatic needle insertion mechanism that is intended to provide better control of needle progression and enable stepwise insertion without noticeable deformation or displacement of surrounding tissue as visualized under ultrasound. A new method of tissue acquisition was designed to achieve a sampling yield higher than standard methodologies. Needle dynamics was assessed on a specifically designed test bed and sampling performance was compared to a Magnum® biopsy instrument (Bard, Covington, GA, USA) in representative tissue models. The histological quality of samples obtained *ex-vivo* was evaluated. A pneumatic pulse was measured to accelerate the needle to a maximum velocity of 21.2 ± 2.5 m/s on a stroke length of 2.5 mm, achieving significantly higher acceleration, maximum velocity and power than current biopsy devices. Mean weight of samples obtained by the NeoNavia device were 3.5, 4.6, and 4.3 times higher when sampling was performed in turkey breast, calf thymus and swine pancreas, respectively, as compared to samples obtained with the Magnum instrument. *Ex-vivo* analysis indicates that the method of tissue acquisition has no apparent negative impact on the histopathologic quality of obtained samples.

1. Introduction

Minimally invasive biopsy is a well-established method of obtaining samples from breast tissue that demonstrates suspicious lesions on imaging. As many as 1.7 million such procedures are performed each year in the US alone [1]. Minimally invasive biopsy of breast and axillary lymph nodes enables assessment of tumor biology and staging for an individual treatment of breast cancer patients [2,3]. Various studies have substantiated the diagnostic value of core needle biopsy (CNB) and vacuum-assisted biopsy (VAB) procedures [4] which have become the gold standard method for the initial assessment of suspicious breast lesions [5]. For minimally invasive biopsies of lesions the preferred guidance modality is ultrasound (US) as it offers real time visualization, ready access to all parts of the breast including the axilla and, compared to modalities such as mammography and magnetic resonance imaging (MRI), a shorter procedure time, increased patient comfort and no exposure to ionizing radiation or intravenous contrast media [6].

Core needle biopsy devices currently used in breast diagnostics were conceived in the late 80's and are based on a tissue cutting or punching mechanism. The insertion of the CNB needle into the tumor is usually powered by a spring-loaded mechanism which thrusts the needle into the tumor. The outer diameter of a CNB needle is in the range of 18–14 G (1.3–2.1 mm). Vacuum assisted biopsy devices were first presented in the mid-90's. These devices are based on CNB technique, but additionally employ a vacuum to prolapse the tissue into the aperture while also incorporating larger needle diameters in the range of 7–14 G (4.6–2.1 mm). Illustrations of CNB and VAB mechanisms are given in Fig. 1. Both CNB and VAB incorporate needle placement mechanisms with predetermined stroke lengths, can incorporate large and sharp needle tips as well as needle designs that only use a fraction of the biopsy needle volume for actual sample acquisition. Challenging cases of ultrasound-guided breast biopsies described in the literature include

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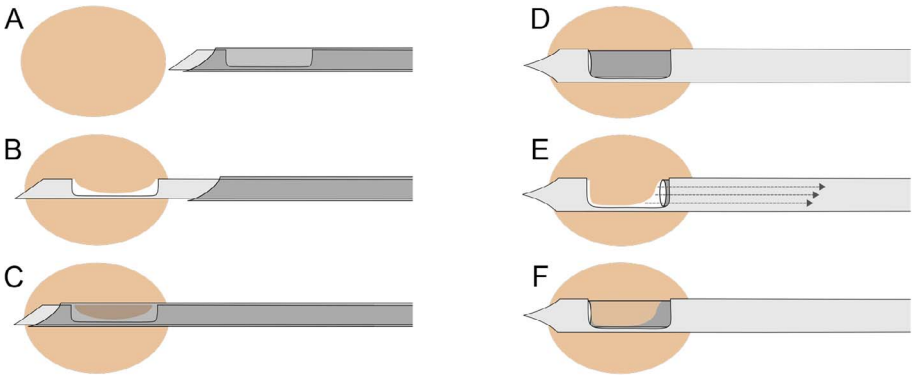

Fig. 1. Illustration of insertion and sampling technique of CNB and VAB in the left and right column, respectively. (A) The inner and outer cannula of the CNB are aligned as the needle is inserted through healthy tissue towards the suspicious lesion. The aperture is closed. (B) The inner needle incorporating a needle tip of around 5 mm is fired into the lesion over a distance of approximately 20 mm. (C) The firing of the inner needle automatically triggers a system for immediate advancement of the outer cannula to cut the sampled tissue trapped inside the aperture. The biopsy needle is subsequently withdrawn from the patient and the outer cannula is retracted to expose the sample inside the notch. (D) The VAB needle is inserted to the area of interest with the aperture closed by the inner cutting cannula. Placement is achieved either by manually pushing the needle forward or via a placement mechanism. VAB needles incorporate needle tips of around 10 mm (E) Once at the area if interest, the inner cannula is retracted and vacuum activated. Surrounding tissue prolapses into the aperture. (F) The rotating inner cutting cannula advances, thereby cutting the tissue trapped inside the aperture. Samples are either transported into a sampling chamber or the needle is retracted from the patient and the sample removed after opening the aperture.

small breast lesions, tumors near the skin surface, deep lesions, lesions adjacent to silicon implants and those near the chest wall, calcified lesions and mobile lesions such as small fibroadenoma [7]. Biopsies in the axilla, with its specific topography, i.e. the closeness of the lymph nodes to blood vessels and nerves, also poses specific challenges, limiting the practicability of current biopsy devices [8]. It is reported that needle insertion towards the lesion may be cumbersome in patients with dense breasts or fibrosis [7]. Challenging cases are generally those that present with a lesion that is hard to reach or target, cases where the lesion gets pushed aside by the biopsy needle tip resulting in the collection of non-representative samples and lesions in the vicinity of delicate anatomical structures.

The sensitivity and specificity of high resolution ultrasound and associated technologies, such as elastography and optoacoustic imaging, are continually improving with the result of increasing diagnostic potential. The combination of increasingly sensitive imaging techniques and expanding breast cancer screening programs, early detection in high risk patient groups and increased use of breast sonography in daily care has seen an increase in the reporting of small and unclear findings, where histological clarification is indicated but current biopsy methods reach their limits [7,9]. As with imaging technology, the management of breast cancer is constantly evolving and with these changes come new challenges to existing biopsy methodologies. The need for axillary lymph node biopsies has increased with the growing number of patients receiving neoadjuvant chemotherapy. Current developments include the analysis of phenotypic and genetic intratumoral heterogeneity [10], an emerging systematic approach to biopsies of distant metastasis for improved individualization of therapy [11] and the use of image-guided biopsies to diagnose a pathological complete response in the breast after neoadjuvant chemotherapy.

Some of the current challenges faced by existing biopsy techniques could be overcome by finer needle control during insertion and improved tissue sampling efficiency. Characteristics of needle insertion are determined by the mechanics of tissue-cutting during needle penetration. Applying the framework of fracture mechanics, it has previously been proposed and validated that the tissue-cutting process during needle insertion can be split into two distinct phases [12]. In the first phase, tissue deflects progressively as the needle force builds up to the amount required to initiate cutting. The second phase occurs once the tissue has fractured and is characterized by the force subsequently stabilizing or decreasing. Increased needle acceleration minimizes tissue deflection in the first phase by creating a high force leading to instant tissue fracture. Increased needle velocity minimizes the cutting force needed for tissue fracture and minimizes tissue displacement during the second phase. As proposed in earlier work by Wiksell et al. [13], high needle acceleration and velocity can be achieved by applying pneumatic pulses to the biopsy needle. In combination with a short stroke length, in the order of millimeters, and the ability to apply multiple consecutive pulses it might be expected to enable the physician to deploy the biopsy needle into the breast in a stepwise and controlled manner without noticeable deformation or displacement of surrounding tissue on the ultrasound image. The sampling needle should further use a needle design where the complete needle volume can be used for tissue acquisition.

We report here on the development and preclinical validation of a high velocity pulsed-insertion biopsy device that incorporates a pneumatic insertion mechanism and novel sampling needle design. We describe needle dynamics using a specially designed needle trajectory test bed, compared its sampling performance with a routinely used CNB device on representative bench models and assessed the histological quality of samples collected in an *ex-vivo* setting.

2. Materials and methods

2.1. NeoNavia biopsy system

2.1.1. Pneumatic needle insertion mechanism

Building on previous institutional work reported by Wiksell et al. [13], the developed insertion mechanism reported here is based on a pneumatically driven reciprocating stainless steel weight that transfers energy via a piston to the biopsy needle (see Fig. 2). The design incorporates a 7 cm stainless steel tube containing a loose steel projectile that weighs 12 g. Magnets hold the projectile in place at the proximal end of the steel tube. A polyvinyl chloride (PVC) tube is attached to the proximal end that is connected to a regulator and compressor generating pressurized air at 4.5 bar gauge pressure. As a high-speed response solenoid valve is opened for 50 ms, pressure behind the projectile builds up until it overcomes the magnetic force holding it back.

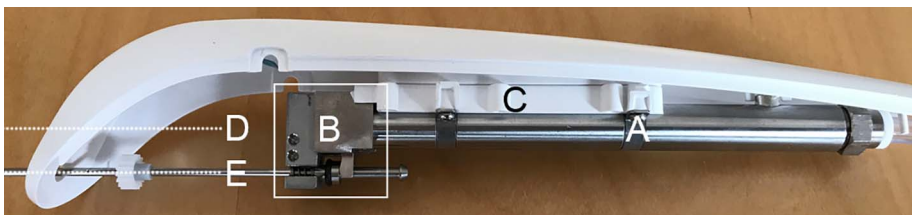

Fig. 2. Needle insertion mechanism. The steel tube incorporating the projectile is shown (A) as well as the piston arrangement (B). (C) The chamber that contains the pressure which will return the projectile to its initial position. The offset axis of the projectile trajectory and the biopsy needle are depicted with dashed lines (D) and (E), respectively.