ABS Conference, 16th – 18th May 2021

AGAPLESION MARKUS KRANKENHAUS FRANKFURT

Novel pulse biopsy platform incorporating adaptive open-tip sampling needle increases sampling yield and needle control

M. Thill[1], K.-U. Schässburger[2], S. Paepke[3]

[1]Agaplesion Markus Hospital, Department of Gynecology and Gynecologic Oncology, Frankfurt am Main, Germany, [2]NeoDynamics AB, Lidingö, Sweden [3]Technical University of Munich, Department of Obstetrics and Gynecology, Munich, Germany

Introduction

Certain lesions are challenging to reach and target, e.g. axillary lymph nodes. A novel biopsy platform, NeoNavia® (NeoDynamics, Sweden), incorporates a pneumatic needle insertion mechanism intended to provide better control of needle progression.

It offers a 14G automated core needle (CorePulse™), 10G vacuum biopsy needle (VacuPulse™) and newly developed adaptive 14G open-tip sampling needle (FlexiPulse™).

Sampling yield of the 14G open-tip needle was benchmarked against a currently used core needle biopsy (CNB) device (BD Achieve 14) in a tissue model and needle velocity was measured.

Conclusions

The evaluated needle significantly outperforms a standard CNB regarding sampling yield.

The maximum velocity is higher than for commonly used spring-loaded devices and is reached over a significantly shorter stroke length.

The needle advances gradually through tissue with pneumatic pulses enabling optimal needle control.

This 14G open-tip sampling needle is currently being evaluated for use in the axilla as part of the PULSE trial (NCT03975855) in Germany and the COMPULSE trial (NCT04500262) in the UK.

Methods

NeoNavia Biopsy System

NeoNavia is a newly developed precision biopsy system operating with pneumatic pulse technology to provide controlled needle insertion. The pulse technology generates a stepwise needle advancement when penetrating tissue. The biopsy system consist of a base unit, a handheld driver and three different needle options (see fig. 1 and 2.)

The 14G FlexiPulse probe features a front-loaded, open-tip sampling needle and a retractable trocar. This needle design is especially suited for challenging biopsy cases such as small lesions, lesions located near the skin and the axillary lymph nodes. See fig. 3 for sampling methodology.

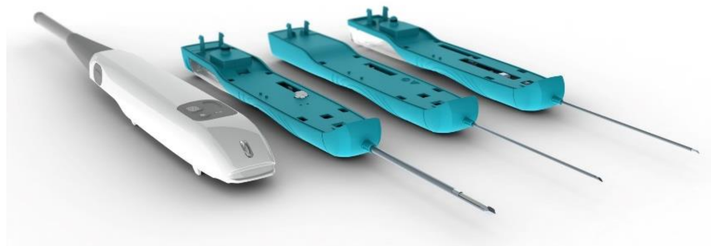
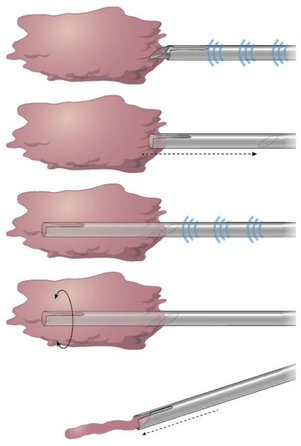


Figure 1: NeoNavia Biopsy System incorporates a handheld driver and three different needle options. A 14G automated core needle (CorePulse), a 10G vacuum biopsy needle (VacuPulse) and newly developed adaptive 14G open-tip sampling needle (FlexiPulse).

Figure 2: The base unit provides pressurized air for the pulse technology and negative gauge pressure for the vacuum function.



1. The FlexiPulse probe features an open-tip sampling needle and a retractable dissection tip. Pulses are used to advance the needle through healthy tissue towards the lesion.
2. When the needle has reached the lesion, the dissection tip is retracted and the open-tip sampling needle faces the lesion.
3. Pulses are used to advance the sampling needle into the lesion thereby filling it with tissue. Vacuum suction assists in increasing sampling yield. Insertion length can be adapted to the lesion at hand.
4. The tissue sample is cut off by a rotation of the sampling needle.
5. The biopsy needle is withdrawn. The tissue sample is ejected by extending the dissection tip into its initial position.

Figure 3: Sampling methodology for the front-loaded, open-tip sampling needle.

Measurements

To evaluate sampling yield, thirty samples were obtained with the 14G FlexiPulse open-tip needle and a commonly used side-cut CNB device (14G BD Achieve biopsy needle) respectively. The tissue model used was turkey breast. Samples were individually weighed. Student´s t-test, significance level of 5% (two-sided test) was used for analysis. To characterize needle dynamics, the velocity of the FlexiPulse needle was measured using a specially developed test bed.

Results

Sampling weight

Weight (mean ± SD) of samples was 697.5 ± 74.5 mg for FlexiPulse and 174.6 ± 26.3 mg for the comparator. (see fig.4 and fig. 5). The difference was statistically significant with a mean difference of 522.9 mg ($p < 0.0001$).

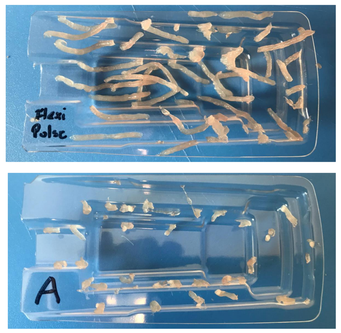


Figure 5: Comparison of 30 samples obtained with BD Achieve (bottom) and FlexiPulse (top).

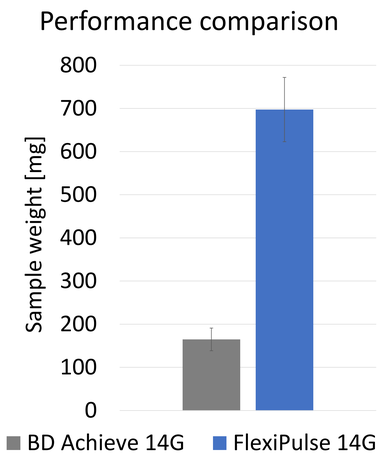


Figure 4: Histogram of sample weights.

The FlexiPulse needle outperformed the standard CNB device by 299%.

Needle velocity

Insertion of current CNB devices is based on a single-shot spring-loaded mechanism which thrusts the needle into the lesion at a predefined stroke length of usually around 20 mm. The needle reaches its maximum cutting speed at the end of the stroke length. Maximum cutting speed is reported to be 8–22 m/s (measured in air).

In contrast, NeoNavia uses pneumatic pulses to advance the needle. Each click of the designated pulse button results in a high acceleration of the needle over a short stroke length (2 mm). The measured maximum cutting speed of FlexiPulse was 18 [15–28] m/s (median [range], n=6 measurements). Maximum cutting speed was reached within the first millimeter of needle travel.

This needle movement combined with manual advancement of the biopsy device by the operator generates a stepwise needle advancement when penetrating tissue. Real-time ultrasound visualization of the stepwise needle advancement increases control.

Contact: marc.thill@fdk.info