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New biopsy system with three different needle options delivers higher tissue yield compared to standard biopsy devices

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Background

Ultrasound-guided needle biopsies are today the standard-of-care due to high diagnostic precision, low cost and high patient comfort. New treatment paradigms and the emerging era of precision medicine are likely to result in expanding indications for image-guided biopsies and more challenging procedures, as well as increasing demand on both tissue quantity and quality.

A high tissue yield is imperative for high diagnostic accuracy.

NeoNavia biopsy system (NeoDynamics, Sweden), incorporates a pneumatic needle insertion mechanism intended to provide better control of needle progression. The system incorporates three different needle options: A 14G open-tip sampling needle (FlexiPulse), a 14G automated core needle (CorePulse) and a 10G vacuum-assisted biopsy needle (VacuPulse).

Sampling performance of the three needle types were benchmarked against standard biopsy needles in a commonly used breast tissue model.

Methods

Sampling tests were performed in the most commonly used tissue model (turkey breast) in a test box arrangement. Thirty samples were obtained with the 14G CorePulse, 14G FlexiPulse and comparison 14G standard core needle biopsy needle (BD Achieve), respectively. Twenty-five samples (five samples per incision, five incisions) were obtained with the 10G VacuPulse and comparator 10G vacuum-assisted biopsy needle (Mammotome elite), respectively. Student´s t-test, significance level of 5% (two-sided test), was used for analysis.

The sampling methodology of the the three probes are described below.

Driver with attached needle.

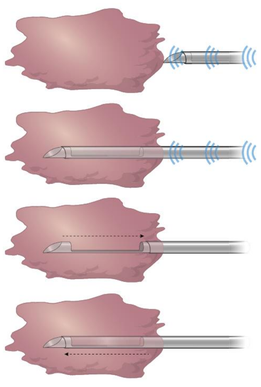
NeoNavia base unit.

Turkey breast in the test box arrangement. A weight was applied to simulate pressure from the ultrasound transducer. For all pairwise benchmarks the needle were introduced the same distance into the turbey breast.

NeoNavia CorePulse single-use probe.

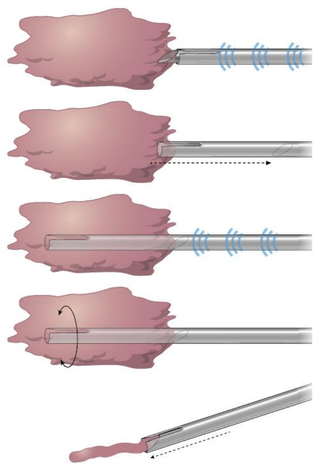
NeoNavia FlexiPulse single-use probe.

NeoNavia VacuPulse single-use probe.



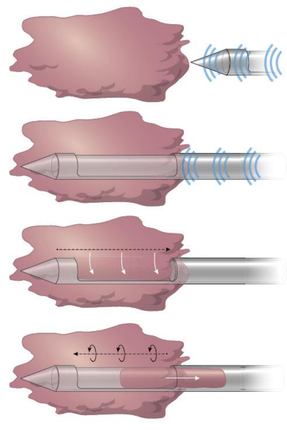
1. Pulses are used to advance the needle through healthy tissue towards the lesion with the side-notch closed.
2. Pulses are used to advance the needle to the exact desired location inside the lesion.
3. The outer cannula is retracted. Tissue enters the open side-notch of the inner needle.
4. The outer cannula is fired and the sample is separated from surrounding tissue. The biopsy needle is withdrawn and the tissue sample can be extracted.

Illustration of CorePulse sampling procedure.



1. 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. 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.

Illustration of FlexiPulse sampling procedure.

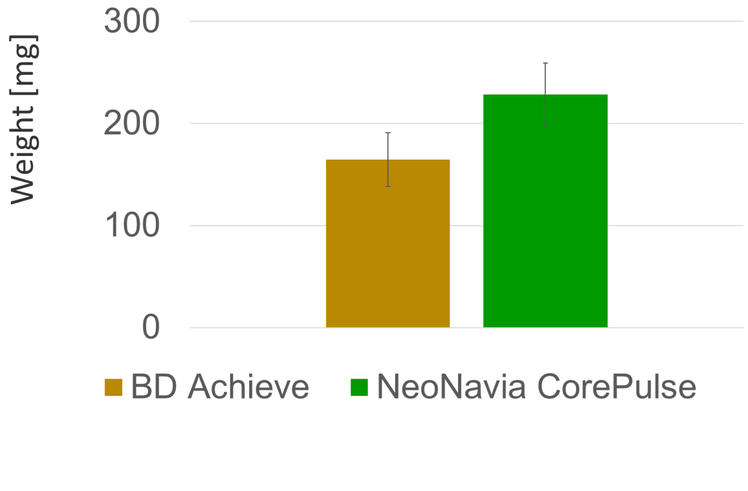


1. Pulses are used to advance the needle through healthy tissue towards the lesion.
2. Pulses are used to advance the needle to the exact desired location inside the lesion.
3. The inner cutting cannula is retracted and vacuum suction is applied. Tissue enters the side-notch.
4. The inner cutting cannula moves forward and separates the sample from surrounding tissue. The sample is transported to the back of the probe into a collection chamber.

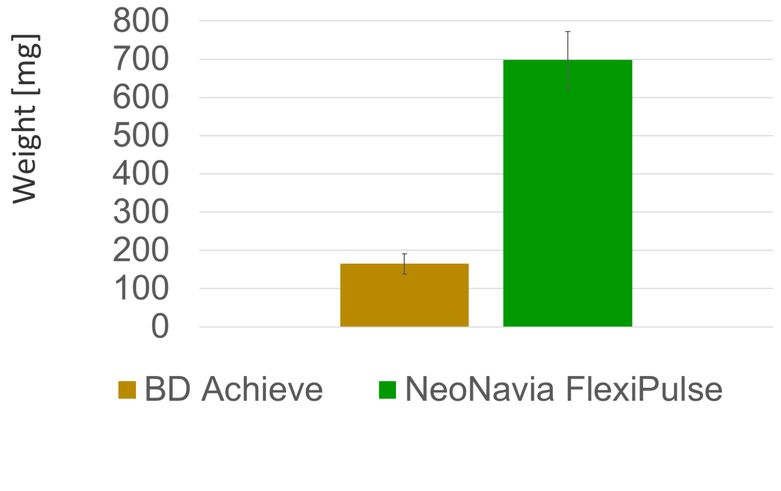
Illustration of VacuPulse sampling procedure.

Results

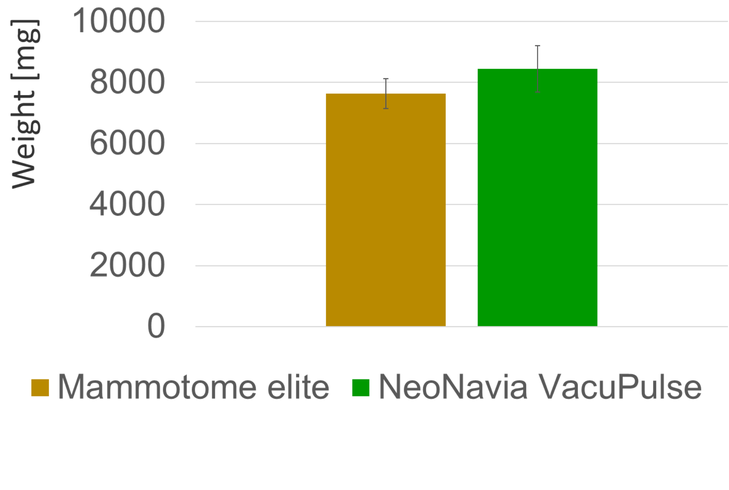
Sampling performance 14G standard CNB vs. NeoNavia CorePulse



Sampling performance 14G standard CNB vs. NeoNavia FlexiPulse



Sampling performance 10G standard VAB vs. NeoNavia VacuPulse



Weight (mean ± SD) of obtained samples was 239.9 ± 30.7 mg for 14G CorePulse; 697.5 ± 74.5 mg for 14G FlexiPulse; and 174.6 ± 26.3 mg for the comparison 14G CNB device. Total weight of the samples obtained per incision (i.e. five samples) was 8734.2 ± 760.0 mg for 10G VacuPulse and 7811.7 ± 486.9 mg for the comparator standard 10G vacuum-assisted biopsy needle. Differences were significant in all cases ($p < 0.0001$).

Conclusion

The three newly developed needles delivered significantly more tissue than standard biopsy devices using the same needle diameter in a commonly used tissue model.

Higher tissue yield could translate into clinical benefits such as higher diagnostic accuracy.

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