

One size fits all? Novel pulse biopsy platform offers improved needle control, high tissue yield and multiple needle options – pre-clinical results

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Background

Lesions indicated for breast biopsies are increasingly challenging to reach and target with current biopsy devices. Accordingly, there is a need for improved tissue sampling quantity and quality in precision medicine.

A new biopsy platform has been developed, NeoNavia[®] (NeoDynamics, Sweden; Fig. 1), which incorporates pneumatic pulse technology supporting:

- controlled needle insertion
- accurate lesion targeting
- three different single-use needle options:
 - 14G open-tip sampling needle (FlexiPulse[™])
 - 14G automated core needle (CorePulse[™])
 - 10G vacuum biopsy needle (VacuPulse[™])

Aim

To benchmark sampling yield of NeoNavia against currently used devices.

Materials and Methods

- 30 samples with 14G CorePulse and 14G FlexiPulse
Benchmark device: 14G BD Achieve[®]
- 25 samples (5 per incision × 5 incisions) with 10G VacuPulse
Benchmark device: 10G Mammotome elite[®]
- Tissue model: turkey breast
- Analysis: Student's t-test, significance level of 5% (two-sided)

Results

All devices obtained a sample in 100% of attempts. Mean sample weights (Table 1) of NeoNavia devices were significantly higher than those of respective benchmark devices [FlexiPulse by 299% (Fig. 2), CorePulse by 37%, VacuPulse by 12%; all $p < 0.0001$]. NeoNavia devices also achieved higher minimum and maximum sampling weights.

Device	N	Needle diameter	Sample weight [mg]		
			Mean ± SD	Min	Max
NeoNavia FlexiPulse	30	14G	697.5 ± 74.5	520	840
NeoNavia CorePulse	30	14G	239.9 ± 30.7	190	283
BD Achieve	30	14G	174.6 ± 26.3	107	225
NeoNavia VacuPulse	5	10G	8734.2 ± 760.0	7578	9615
Mammotome elite	5	10G	7811.7 ± 486.9	7206	8452

Table 1: Sample weights of NeoNavia and benchmark devices.



Fig. 2: Comparison of 30 samples taken with FlexiPulse (top) and Achieve (bottom).



Fig. 1: NeoNavia base unit, driver and probe options.

Conclusions

- NeoNavia devices significantly outperformed all benchmark devices regarding sampling yield (i.e., obtained larger samples utilizing an identical needle diameter) in bench tests.
- The FlexiPulse needle design used for sampling axillary lymph nodes is currently evaluated in the PULSE (NCT03975855) and COMPULSE trial (NCT04500262). Further post-market clinical follow-up studies will evaluate the performance of all three needle types in the breast and axilla.
- NeoNavia could potentially replace all current methods for ultrasound-guided biopsies.