A Comparison of the Delivery Methods of Simulated Anesthetic in Vacuum-Assisted Breast Biopsy Systems

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BACKGROUND

Of the four commonly diagnosed cancers for women, breast cancer has the highest incidence rate with an estimated 226,870 new cases diagnosed in 2012.[1,2] Furthermore, almost two million women required a breast biopsy procedure to establish a benign or malignant diagnosis in 2012.[3] Compared to operative excisional biopsies, percutaneous needle biopsies offer a less traumatic approach for the diagnosis of breast lesions. However, even a minimally invasive breast biopsy can be an uncomfortable procedure. In addition to the initial dose of local anesthetic given directly into the breast prior to insertion of the biopsy device, administration of supplemental local anesthetic through the biopsy needle may be necessary to alleviate pain during the procedure of sample collection.

The following *in vitro* study compares fluid dynamics during bench testing of the device using simulated anesthetic.

METHODS

The penetration of simulated anesthetic into two *in vitro* models was evaluated during simulated procedures utilizing two Vacuum-Assisted Breast Biopsy systems (9G Eviva™ Breast Biopsy System, Hologic, Bedford, MA; 10G EnCor Enspire® Breast Biopsy System, Bard Biopsy Systems, Tempe, AZ). The testing was performed by Bard Biopsy Systems in Tempe, AZ.[4]

Simulated anesthesia was created by mixing blue food dye with water in a 1 drop / 100 cc concentration. The mixture had a representative viscosity similar to local anesthesia. Two *in vitro* models were used to simulate homogenous breast tissue. Raw chicken breast was used to model dense breast tissue and raw pork belly was used to simulate adipose breast tissue. The vacuum biopsy systems and probes were set up and anesthetic delivery was performed according to the instructions for use of the respective devices.[5]

The biopsy needle was inserted into the center of each model (at least 5 cm deep) and light pressure was applied to the model with a hand to simulate the compression from a stereotactic table (or ultrasound transducer) on the breast tissue and biopsy probe. The simulated anesthesia was delivered at a rate of approximately 10-15 seconds / 10 cc of fluid. The amount of anesthesia delivered was equivalent for both biopsy systems because they both “lose” similar amounts of fluid within the system tubing (1.0 cc for the Eviva™ Breast Biopsy System and 1.8 cc for the EnCor Enspire® Breast Biopsy System). The biopsy

Table 1: Simulated Anesthetic Infiltration per Sample

	Measured Diameter (cm)			
	Dense Tissue *In Vitro* Model		Adipose Tissue *In Vitro* Model	
Sample #	Hologic Eviva™	EnCor Enspire®	Hologic Eviva™	EnCor Enspire®
1	0.0	3.4	2.4	2.7
2	0.3	3.6	0.4	3.3
3	0.2	2.5	1.6	2.5
4	0.4	4.1	0.7	4.7
5	1.0	4.0	0.7	3.9

probe was closed and removed from the respective model. The model was cut in a cross section along the length of the biopsy needle track, parallel to the table. The model was visually inspected for the presence of the simulated anesthesia. Calipers were used to measure the maximum diameter of infiltration from the simulated anesthetic (perpendicular to the direction of insertion of the needle).

The procedure was repeated for a total of five samples in each model (n=10) for each Vacuum-Assisted Breast Biopsy system. Representative images of the anesthetic delivery procedure are found in Figure 3.

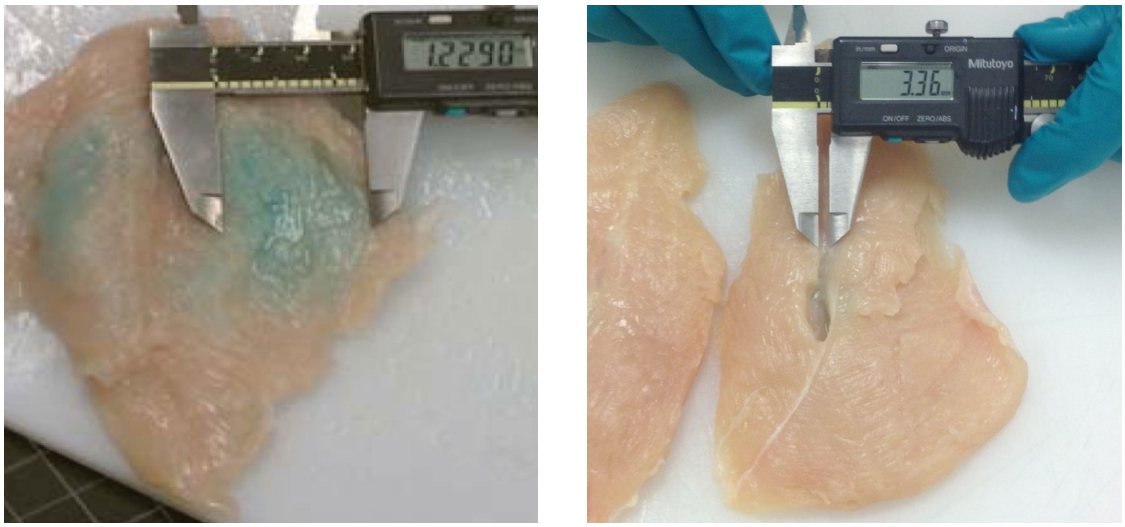
RESULTS

The results of the simulated anesthetic infiltration per sample in the *in vitro* models are summarized in Table 1.

In the dense tissue model (Figure 1), there was minimal presence of simulated anesthetic in the samples that used the Eviva™ Breast Biopsy System. The average infiltration of simulated anesthetic for the Eviva™ Breast Biopsy System was 0.4 +/- 0.4 cm (range 0.0 cm - 1.0 cm). The average infiltration of simulated anesthetic for the EnCor Enspire® Breast Biopsy System was 3.5 +/- 0.6 cm (range 2.5 cm – 4.1 cm). Therefore, the simulated anesthetic penetration

Figure 1: Dense Tissue Model – Cross Section

EnCor Enspire®, left; Hologic Eviva™, right



Bench test results may not be indicative of clinical performance.

diameter in simulated dense breast tissue was superior for the EnCor Enspire® samples compared to the Eviva™ samples (3.5 cm vs. 0.4 cm, p = 0.05, paired T-test).

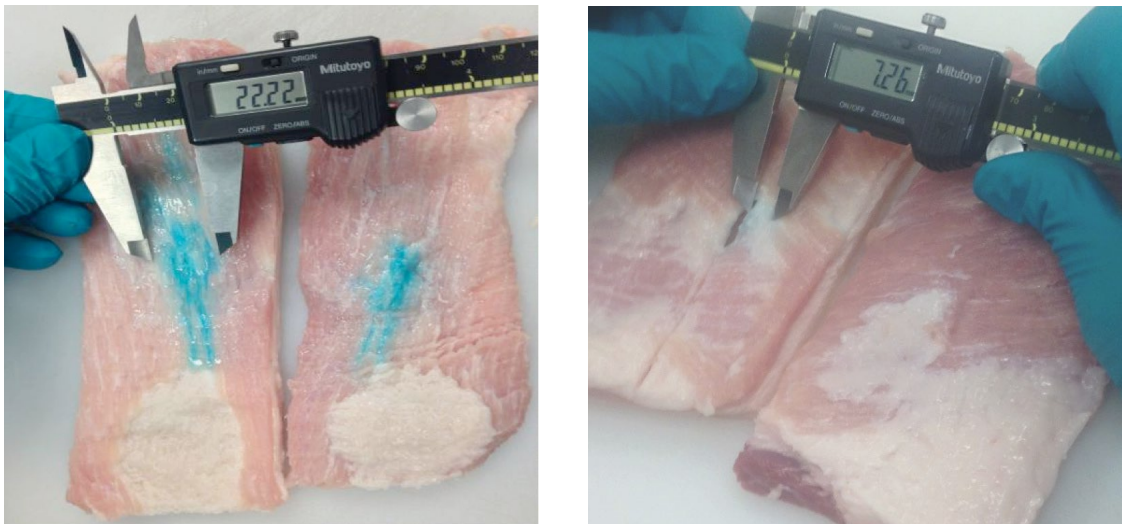
In the adipose tissue model (Figure 2), the average infiltration of simulated anesthetic in five of the Eviva™ Breast Biopsy System samples was 1.2 +/- 0.8 cm (range 0.4 cm to 2.4 cm). The average infiltration of simulated anesthetic for the EnCor Enspire® Breast Biopsy System was 3.4 +/- 0.9 cm (range 2.5 cm - 4.7 cm). Therefore, the simulated anesthetic infiltration diameter in simulated adipose breast tissue was superior for the EnCor Enspire® samples compared to the Eviva™ samples (3.4 cm vs. 1.2 cm, p = 0.05, paired T-test).

DISCUSSION

In order to interpret the results, the mode of action for anesthetic delivery of each biopsy system must be clearly understood. Hologic's Eviva™ breast biopsy probe delivers anesthetic through the saline line that runs between the needle and the coaxial cannula. When the anesthetic reached the sample notch of the biopsy probe, the simulated anesthetic fluid was observed to fill the notch and follow the path of least resistance, flowing in a retrograde direction back through the probe towards the collection canister instead of traveling in an antegrade direction into the biopsy cavity. Figure 3 (arrow) demonstrates the simulated anesthesia flowing through the collection tubing with the saline. This reversal of flow offers an explanation for the demonstrated lack of simulated anesthetic in the *in vitro* models.

In contrast, the EnCor Enspire® Breast Biopsy System design creates a one-way path of antegrade travel of anesthetic to the sample notch (without saline) because there is no communication with the vacuum tubing. Due to the positive pressure created by the one-way path, the full dose of anesthetic can be reliably delivered into the biopsy cavity (Figure 3). As demonstrated in the models, a large amount of simulated anesthetic is delivered. In these simulated *in vitro* tests, there was a statistically significant improvement in tissue penetration of simulated anesthetic with the EnCor Enspire® Breast Biopsy System over the Eviva™ Breast Biopsy System. Another feature of the EnCor Enspire® Breast Biopsy System is the Anesthetic 360 feature. When the Anesthetic 360 feature is activated on the EnCor Enspire® Breast Biopsy System, the probe is designed to circumferentially deliver anesthetic on all sides throughout the cavity. This feature was not tested in this study.

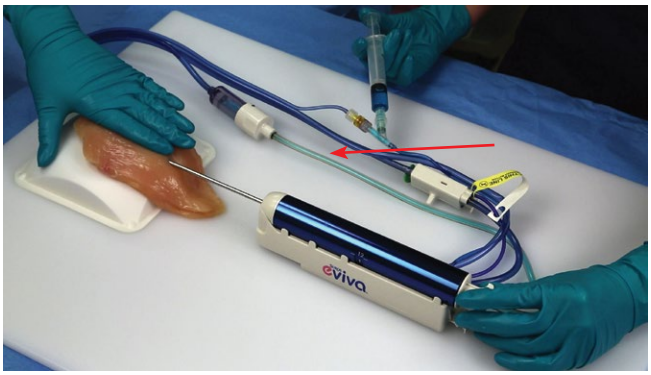
Figure 2: Adipose Tissue Model – Cross Section
EnCor Enspire®, left; Hologic Eviva™, right



Bench test results may not be indicative of clinical performance.

Figure 3: Simulated Anesthetic Delivery In-Process

Simulated Anesthetic (blue dye) delivered directly through the EnCor Enspire® system, left; Simulated Anesthetic flows back into the collection tubing of the Hologic Eviva™ system, right



CONCLUSION

As demonstrated by this *in vitro* study, the simulated anesthetic penetration diameter was superior for the EnCor Enspire® Breast Biopsy System compared to the Eviva™ Breast Biopsy System. The design of the EnCor Enspire® Breast Biopsy System probe was observed to allow for the more effective delivery of simulated anesthetic throughout the use of the device.

* Linda B. Griska, MD and S. Chace Lottich, MD are currently consultants for Bard Biopsy Systems.

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