

A Prospective Clinical Study of the SenoRx StarchMark™ Biopsy Site Marker

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PURPOSE:

We compared two biopsy site markers' ability to control and manage bleeding at the time of biopsy, the StarchMark™ and an industry standard marker.

BACKGROUND:

Ultrasound and stereotactic breast biopsy methods have appropriately minimized the invasion portion of breast biopsies. The accuracy of these biopsies as well as pain control has been optimized. Bleeding at the time of biopsy has not been addressed until recently. Bleeding causes post operative discomfort in the patient and also represents time for the surgeon or technician when attempting to control this issue. SenoRx, Inc. (Irvine, CA) has recently developed a new marking system that deploys a PLA/PGA pellet with a surgical grade stainless steel wireform marker for future reference and short-term ultra-sound identification, and starch pellets to help control the immediate bleeding issue at the time of biopsy.

MATERIALS & METHODS:

A blinded study was performed to compare the effectiveness of two biopsy site markers in 45 women requiring a breast biopsy with a z-axis value ≥ 15 mm; the StarchMark group had 22 patients and the GMU* group had 23 patients. Both markers provide clear marking with ultrasound, as well as place a wireform marker in a PLA/PGA pellet for long term visualization of the biopsy site with mammography. In addition to the wireform marker, the StarchMark contains six bioresorbable starch pellets to control the blood flow at the time of biopsy (Figure 1). The pellets are also visible with ultrasonography following the biopsy if further surgical procedures are warranted.

Figure 1. StarchMark Breast Biopsy Marker

Marker includes 6 starch pellets and 1 PLA/PGA pellet with a stainless steel wireform marker



The patients underwent a stereotactic biopsy using an EnCor[®] 7-gauge probe following which the compression plate was released and direct pressure was applied to the local area. Blood flow was measured by timing the cessation of bleeding after marker placement at 30-second intervals following compression.

RESULTS:

The StarchMark group was able to significantly inhibit blood flow faster than the GMU group. As shown in Table 1, in the StarchMark group bleeding stopped in 55% of patients vs. 26% in the GMU group within 1 minute, 82% vs. 57% within 2 minutes, and 96% vs. 61% within 3 minutes. The StarchMark was able to control the bleeding within 1 minute in 50% more patients.

Each 30-second interval represents one bleeding count measurement. As shown in Table 2, the StarchMark mean bleeding count (3.09) can be converted to 1 minute 33 seconds (or 93 seconds) and 2 minutes 17 seconds (or 137 seconds) for the GMU group. This resulted in a 32% mean reduction in bleeding time for the StarchMark group.

All patients in the StarchMark group (N=22) and 91% (21/23) of patients in the GMU group had venous bleeding (as opposed to arterial). The two patients with arterial bleeding in the Gel Mark Ultra group had a bleeding time of 5 minutes and 1 minute 30 seconds, respectively. Type of bleeding did not appear to be a factor.

Sometimes there is no alternative but to puncture a vein during a biopsy procedure. When this occurs, it is expected that it will take longer to control the bleeding. In order to evaluate the relationship between the proximity of a vein to the biopsy site and bleeding time, we looked at all patients who took 5 minutes or longer for bleeding to stop. There were three patients that met this condition, one in the StarchMark group at 7 minutes and two in the GMU group at 5 minutes each. The highest counts in both groups were due to the close proximity of the biopsy site to a vein.

In the StarchMark group, the blood flow ceased in 95% (21/22) of the patients within 3 minutes. The close proximity to a vein accounts for the single patient in the StarchMark

Table 1. Bleeding Cessation Frequency

Bleeding Time	StarchMark (N=22)		GMU (N=23)	
	n	(n/N) %	n	(n/N) %
0:00	1	4.6	0	0
≤ 1:00	12	54.6	6	26.1
≤ 2:00	18	81.8	13	56.5
≤ 3:00	21	95.5	14	60.9
> 3:00	1	4.6	7	30.4

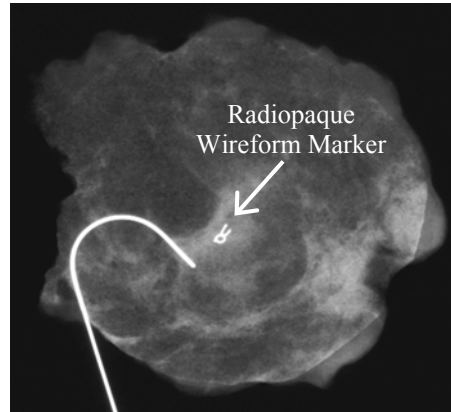
Table 2. Bleeding Count

Statistics	StarchMark	GMU
Mean ± SD	3.09 ± 2.96	4.57 ± 2.84
Min, Max	0, 14	1, 10

group whose bleeding time was greater than 3 minutes. In the GMU group, the blood flow stopped in 70% (16/22) of the patients within 3 minutes. The close proximity to a vein only accounted for 2/7 (29%) of the patients in the GMU group whose bleeding time was greater

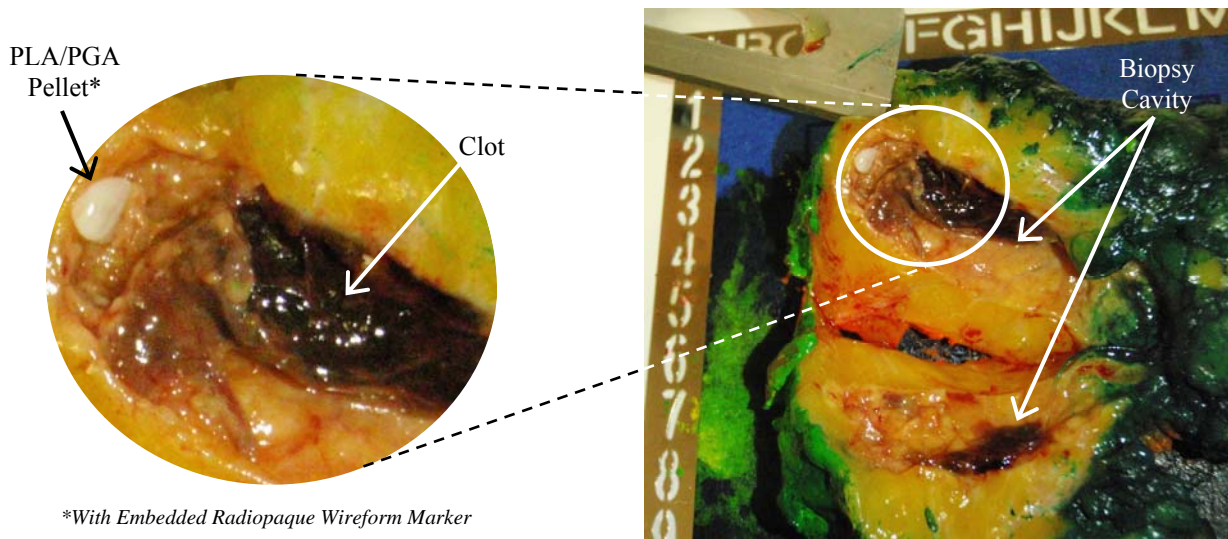
With the StarchMark deployed into the biopsy cavity, the dissolving starch quickly stabilizes the bleeding and the PLA/PGA wireform marker is contained within the cavity allowing for accurate localization of the biopsy site. As shown in Figure 2, the radiopaque wireform marker is centered within the lumpectomy specimen. The investigators observed no marker migration in any of the cases evaluated in this series, Although not addressed in this analysis, with faster clotting one would expect to find less marker movement and as a result better centration.

Figure 2. Radiograph of Lumpectomy Specimen with StarchMark and Localization Wire



A lumpectomy was performed on a patient who had undergone a biopsy utilizing the StarchMark as an identifying marker three weeks prior. This lumpectomy specimen was divided in half after inking the margin of resection. As can be seen from the photograph shown in Figure 3, there is a very small biopsy cavity. At the distal most portion of the cavity is a PLA/PGA wireform marker and in the mid portion is a well-formed clot. This clot was examined microscopically and found to contain portions of the starch pellets, which aided in the coagulation of this biopsy site. This demonstrates the effectiveness of the StarchMark.

Figure 3. Lumpectomy with StarchMark and Blood Clot in Biopsy Cavity



**With Embedded Radiopaque Wireform Marker*

Three months later, for those patients with benign pathology, X-rays were obtained of the biopsied breast and there was very little residual hematoma, if any, of the area biopsied whether it is performed with a GMU or with the StarchMark.

CONCLUSIONS:

At the time of the biopsy, the StarchMark is more effective in inhibiting the blood flow and shortening the time needed to apply pressure. The StarchMark is able to quickly address the immediate bleeding at the time of biopsy and it significantly minimizes the time for the surgeon or technician when attempting to control this outcome. The SenoRx StarchMark represents a marker capable of superior blood flow management with the added benefit of excellent marker concentration. Since bleeding is a common factor in breast biopsies and starch promotes the blood clotting cascade, additional studies are needed to confirm these encouraging early findings.