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EDITORIAL – BREAST ONCOLOGY

The Search Continues for the Ideal Method to Localize Nonpalpable Breast Lesions

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In this issue of *Annals of Surgical Oncology,* an alternative method of surgical localization for nonpalpable breast lesions is described.[1] The technique uses a small implantable device placed through a needle via ultrasound or stereotactic guidance, similar to current radiologic localization techniques. Once implanted, the device is activated by infrared light from the handpiece, and an electromagnetic wave is reflected back to the console. Similar to radioactive seed-localized (RSL) breast surgery, a handpiece and console are utilized with continuous audible feedback.

In this feasibility study, the authors retrieved the seed and the targeted lesion in 100 % of cases and thought that this was subjectively easier than a wire localized approach. This was a single-arm pilot study with specific inclusion/exclusion criteria, performed by two highly experienced breast surgical teams, and some issues were identified during the pilot that led to refinements in the delivery system.

Although all targeted lesions were recovered, in six cases (12 %), the reflector placed in the breast for localization was not able to be identified by the surgeon in the operating room before incision. In five cases it was detected after skin incision. In one case the reflector malfunctioned and could not be localized, and in another case the reflector was deactivated by contact with electrocautery. No other localization devices were used in any cases. The ability to remove the lesion in all cases, despite the technology's shortcomings and failure, speaks to the surgeon's skill and experience, as 2-view postlocalization mammograms and preoperative ultrasounds were adequate for incision planning in their hands.

On the basis of these and other issues uncovered during the pilot study, a number of technologic modifications were made to the system, including addressing a reflector malfunction that prevented detection, incorporating an additional component into the reflector to minimize the likelihood of cautery deactivation, incorporating a display screen on the console, and designing shorter, more lightweight localization needles for ease of radiologic placement.

It is worth noting the inclusion criteria required that the implantable device be placed a maximum of 3 cm deep into the breast parenchyma. Two of the reflectors that were not detected before skin incision were outside this depth range, placed 4.5 and 6 cm deep. It is not clear, but it would appear that this limitation is related to a combination of breast density and the distance between the reflector and probe. This will, I hope, be further defined in the ongoing prospective multiinstitutional single-arm validation study that is actively accruing.

In terms of margin status, the findings are purely descriptive, with 41 patients having ductal carcinoma-in-situ or invasive disease. Two of the 41 cases had positive margins, and six were within 1 mm (20 % margin $\leq$1 mm). One issue that was not reported in this pilot system was the cost of the device. Unlike a wire or RSL in which no new capital budget is required, incorporation of the Savi Scout will require the purchase of new equipment. Wire localization does not require any additional operating room equipment, and for RSL surgery the probes are already present in most operative theatres, as they are required when performing radiocolloid-guided sentinel lymph node (SLN) biopsy.

Radioactive seed localization was developed and pioneered by one of the coauthors (CEC), and thus it is probably not surprising that the Savi Scout has many of the

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same advantages, most important of which is it that its use appears to be intuitive to the operating surgeon. Not having to deal with a radioactive source is an obvious advantage of the Savi Scout, and this would be a major incentive to many institutions. It appears instinctively similar to RSL but without the obstacles of tracking, handling, and transporting radioactive material, which has been prohibitive for some centers wanting to adopt this approach. If proven reliable, the downside of the Savi Scout would be the need for two localization systems (two probes and two consoles) for all lumpectomy cases requiring a SLN biopsy, creating a more crowded operative field and needing to switch from one device to the other during the procedure.

The surgeons in this trial draw from a wealth of clinical practice and are clearly highly experienced and innovative. This pilot study of new technology for an alternative approach to nonpalpable breast lesions is certainly welcome and has the potential to provide an additional means of replacing wire-localized procedures. Targeting nonpalpable breast lesions is becoming a crowded field, with many different approaches jockeying for position, and it is not clear which technology will become the standard in the operating room of the future. Will surgeons of the future become so facile in ultrasound that localization devices beyond the biopsy clip will become passé? Will the nuclear regulations be relaxed such that radioactive seeds below a certain threshold will not require stringent oversight? Or will alternative injectable source such as nonradioactive magnetic iron oxide particles or nanoparticles be able to localize both the primary lesion and migrate to the SLN, potentially only localizing to a SLN if it is involved with disease?[2,3]

Overall, this prospective study is a positive addition to the literature by forward-thinking surgeons. I look forward to continued surgeon-led innovation, along with the results of larger ongoing trials and cost data to help shape this evolving landscape. The search for the holy grail of localization techniques continues.

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