Utilization of BioZorb implantable device in breast-conserving surgery

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Introduction

The BioZorb® (BZ) surgical marker is used to identify the tumor excision site after breast conserving surgery (BCS). The device itself is a three-dimensional, bioabsorbable coil that resorbs over time, with six titanium clips that serve as targets for radiation therapy planning. The device also acts as a scaffold for the tissue healing process after BCS.

Objective: To assess early and late complications associated with the BioZorb device.

Methods

All patients who underwent lumpectomy with planned radiotherapy and BZ placement were enrolled in a retrospective, single-center study at Cedars-Sinai Medical Center. Early and late infectious complications from BZ placement were the primary outcome of interest. Noninfectious complications including device migration, reoperation to remove BZ, and development of hematoma or seroma were assessed as secondary outcomes. Patients were implanted with conventional and low-profile device configurations.

Results

Eighty-nine patients were implanted with the BZ in 91 surgeries (79 in the setting of BCS, 12 during re-excision for margins) from April 2016 to June 2018. Median tumor size was 1.95 cm; 27.5% had multifocal tumors. Most tumors were invasive ductal carcinoma (61.5%). BZ placement was most commonly in the upper outer quadrant (40.7%). A single BZ was implanted in most operations (92.3%), with 2 BZs implanted in 7.7%. Multiple devices were used for multifocal tumors (two separate lumpectomy cavities); when cosmetic outcome was improved with two smaller adjacent devices compared to a single larger device (same lumpectomy cavity); or due to reoperation for margins. Of 98 BZs placed, 81 (82.7%) were conventional device sizes and 17 (17.3%) were low-profile devices.

- Early infectious complications (< 30 days) occurred after 5.5% of procedures (superficial cellulitis, 3.3%; abscess, 2.2%). None required device removal. Symptomatic seroma occurred in one patient, requiring conservative treatment. No hematoma or wound dehiscence was observed.
- Through a median follow-up of 1.6 years, 1 patient exhibited device migration to the axilla, resulting in surgical explant. This may have been due to nonabsorbable sutures potentially dislodged during post-BCS mastopexy.
- Twenty-two patients (24.7%) required reoperation for margins (90.9% repeat BCS, 9.1% mastectomy). In 86.5% of reoperations, the BZ was retained.
- One patient (1.1%) had device removal due to discomfort and palpability, with device removal performed 18 days after implant during reoperation for margins; two patients (9.1%) had device removal during subsequent mastectomy.
- During clinical breast examination (CBE) performed at a median 1.1 years post implant, 63.6% of patients had a palpable BZ. The latest CBE with a palpable BZ occurred at 2.8 years post implant.

Conclusion

BZ implantation is feasible and safe in all breast quadrants during breast conserving surgery, and is associated with limited early and late complications through a median follow-up of 1.6 years. Communication with patients regarding the possibility of long-term palpability is important, as time to resorption is variable and often occurs more than 1 year after implantation.