Achieving clear margins is an important aspect of breast conservation therapy. For patients undergoing intra-operative radiation therapy (IORT) clear margins are even more important. Having positive margins following the lumpectomy procedure where intra-operative radiation was used, leads to another surgery follow by whole breast radiation. Therefore, for patients suitable for intra-operative radiation, the utmost attention should be given to achieve clear margins during the initial lumpectomy procedure. We present our initial experience with MarginProbe®, a real-time intra-operative margin assessment tool, used in cases where INTRABEAM® IORT was performed.

Materials and Methods

The MarginProbe® System (Figure 1) is comprised of two components; a console and a hand-held probe. The probe is a detachable, sterile, single-use, single-patient component. The system utilizes radiofrequency spectroscopy to characterize breast tissue in real-time, measuring differences in the electric properties between normal and malignant breast tissue.

MarginProbe was used in a consecutive group of patients undergoing lumpectomy and IORT. All patients meet the national criteria for IORT. Lumpectomy was performed according to routine practice. MarginProbe was used intra-operatively on all six faces of the main lumpectomy specimen, providing a positive or negative indication for each margin. The device was not used on additional shavings. Whenever indicate intraoperative imaging was performed. All specimens were sectioned and gross pathology evaluation was done. Additional shavings were taken based on the information received from all the above modalities. INTRABEAM® IORT was then undertaken.

Between February 2014 and September 2016, 79 clinical Stage I breast cancer patients were treated. Patients characteristics are presented in Table 1. MarginProbe measurements of each point took 1.5 seconds and measuring the whole specimen less than 5 minutes. Average volume of the specimen was 44cc. There were, on average, 1.5 shavings with no cancer taken per case.

In eight (10%, 8/79) cases, the main lumpectomy specimen had positive margins (tumor on ink) based on the final Pathology report Table 2.

During surgery, through a combination of MarginProbe detection and gross pathology, seven of these cases were identified and six intra-operatively corrected.

In one patient shaving of the margins continued to be positive in the final report and in another one the positive margins were not detected, leading to two re-excision procedures (2.5%, 2/79).

MarginProbe correctly detected all positive margins on the main specimen in four cases (4/8, 50%).

In one additional case, cancer was found in a MarginProbe triggered shaving even though pathological margins of the main specimen were clear.

Altogether, MarginProbe provided added clinical value in 6% (5/79) of the cases.

Discussion

Intra-operative margin assessment contributes to achieving clear margins, resulting in a very low rate of re-excision procedures. In this set of patients, the combination of MarginProbe and gross pathology reduced by 8% (6/79) the need of a second surgery. In conjunction with IORT as final local treatment it helps reducing stress and costs associated with addition of external radiation. Further studies may include the use of the device on the shavings.