



Intraoperative radiological margin assessment in breast-conserving surgery

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Abstract

A prospective study was lead in order to analyze the accuracy of an X-ray device settled in the operating room for margin assessment, when performing breast-conserving surgery.

Patients and methods: One hundred and seventy patients were included. All lesions were visible on the preoperative mammograms. An intraoperative X-ray of the lumpectomy specimen was systematically performed for margins assessment. Final histological data were collected and the accuracy of intraoperative specimen radiography (IOSR) for margin assessment was analyzed.

Results: IOSR allowed an evaluation of margins status in 155 cases (91.2%). After final histological examination, the positive margins rate would have been 6.5% if margin assessment had relied only on IOSR.

Conclusion: Margin assessment with a two-dimensional X-ray device would have allowed the achievement of negative margins in 93.5% of the cases. Moreover, this procedure allows important time-saving and could have a substantial economical impact.

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In breast-conserving surgery (BCS), the main objective is to obtain negative histological margins which are known to be a major prognostic factor for tumor recurrence.^{1,2} Until now, the intra-operative evaluation of margin status (MS) for palpable cancers has relied on histological examination (HE) by the pathologist. For non-palpable, radio-opaque lesions, the intra-operative MS was assessed using conventional specimen radiography (CSR). However, these two procedures need a specific organization of the breast surgery department (pathologist in the operating room or transport of the lumpectomy specimen to the pathology or radiology unit) and are time consuming. In order to propose an alternative to these intra-operative procedures for lesions visible on mammograms, a prospective study was lead in order to analyze the concordance between margin

evaluation with intra-operative HE or CSR and margin assessment using a dedicated X-ray imaging device settled in the operating room (Faxitron MX20, Faxitron Bioptics, Illinois). The potential economical and organizational benefits of this procedure were studied.

Patients and methods

Between 2010 and 2012, one hundred and seventy consecutive, non-selected patients (median age: 61 years-old, range: 32–91) treated with BCS for palpable or non-palpable breast cancers were included.

All lesions were visible on the preoperative mammograms.

Surgical procedures were performed under general anesthesia. For invasive lesions, the operation started with sentinel lymph node biopsy. For non-palpable lesions, tumor resection relied on wire-guided localization. For tumor removal, the surgical procedure was as follows:

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Once the skin incision performed, subcutaneous undermining was achieved. The gland was cut, down to the pectoralis muscle fascia one centimeter far from tumor location. The gland was then separated from the pectoralis fascia all around the tumor and the lumpectomy was achieved by cutting the gland all around the tumor. Each lumpectomy specimen was orientated using metallic clips and settled on a radio-opaque grid (Fig. 1, picture 1a). For each patient, intraoperative specimen radiography was performed with a two-dimensional X-ray device settled in the operating room of the lumpectomy [Faxitron (FX).] The margins surrounding the tumor were then measured (Fig. 1, picture 1b) by the surgeons. The device used was a Faxitron MX-20 equipped with a large camera,

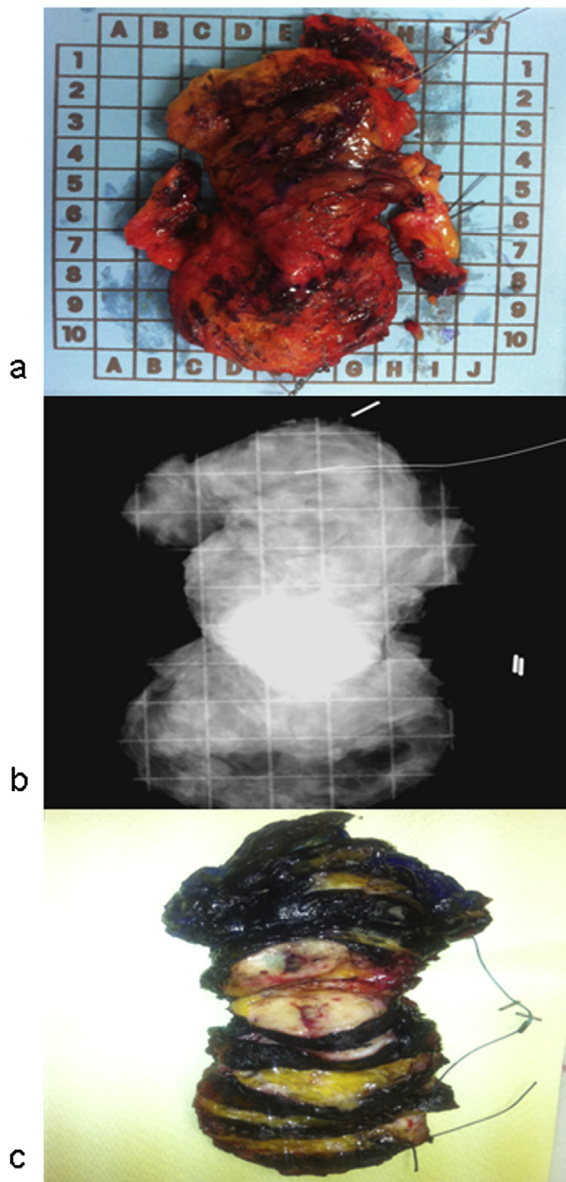


Figure 1. The Faxitron procedure for a three centimeters invasive ductal carcinoma. Picture 1a: Specimen on a radio-opaque grid. Picture 1b: Image analysis and achievement of lateral re-excisions. Picture 1c: Histological examination: no re-excision required.

which provides 10 line pairs per millimeter (lp/mm) spatial resolution in contact mode and up to 50 lp/mm at full $5 \times$ magnification. When margins were inferior to 10 mm, complementary resections were systematically performed. For non-palpable lesions, the lumpectomy was sent for conventional specimen radiography. For palpable lesions, the specimen was systematically sent for intra-operative HE (Fig. 1, picture 1c): the surgical fresh specimen was inked according to the surgeon's orientation marks and macroscopical serial sections were performed in order to assess the distance between the tumor and the surgical margins. In rare cases, mainly if preoperative histological diagnosis was doubtful, frozen section of the tumor was performed. Complementary glandular excisions were performed when required by the radiologist or the pathologist.

For each patient the final histological data, provided by the pathology unit 10 days after the operation, were collected. Margins were considered free when tumor cells did not touch ink on final pathology. When margins were inferior or equal to 2 mm, each case was discussed during multidisciplinary team meetings. Re-excision was proposed when the patient had several risk factors of local recurrence.

The primary objective of this study was to analyze the accuracy of FX for the evaluation of margin status. Hence, it was possible to compare the results of the FX procedure with the results of intra-operative HE or CSR.

In order to evaluate the time-saving induced by FX, the time needed to obtain the results of CSR and/or HE was calculated for each patient. Thus, the secondary objective of this study was to evaluate the impact of the FX procedure in a surgical department from an organizational point of view.

Statistical analysis was performed using Student's and Fisher's tests.

Results

The treated lesions were ductal carcinoma in situ DCIS in 16 cases (9.4%), invasive ductal carcinomas IDC in 127 cases (74.7%), invasive lobular carcinomas ILC in 20 cases (11.8%) and a combination of histological subtypes (ductal and lobular carcinomas in the same sample) in 7 cases (4.1%). Breast lesions were palpable in 48.2% of the cases. Median tumor size was 12 mm [2–80].

FX provided an X-ray image of the lumpectomy specimen in 90 s. The surgeons by themselves evaluated the specimen obtained by FX in less than 2 min thanks to the radio-opaque grid. The FX allowed an evaluation of the margins status (MS) in 155 cases (91.2%). In the 15 remaining cases, the image provided by FX did not allow an accurate evaluation of the margins. These patients were excluded from the analysis of FX's accuracy for the evaluation of margin status. Nevertheless, these 15 patients had high breast density (type 3 or 4) and a smaller median tumor size (8 mm vs. 12 mm) ($p = 0.035$).

After intraoperative HE and/or CSR, complementary excisions were required in 16 cases (10.3%) (14 after HE and

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