**Target Study**

A radiopaque hydrogel to improve target definition for radiotherapy following breast conserving surgery

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**Introduction**

During breast conserving surgery (BCS), the surgical cavity is closed in multiple layers, which reduces seroma formation. This creates challenges for radiotherapy target definition using clips; it has a poor inter-observer agreement: median conformity index (Cx) of 0.44. This potentially leads to geographical misses with consequent risk of local recurrence or toxicity. We hypothesize that injection of a radiopaque hydrogel in the lumpectomy cavity before closure improves radiotherapy (RTx) target definition.

A prospective intervention cavity study was performed in women undergoing BCS. 3-9ml of iodined Polyethylene Glycol hydrogel (TraceIT®, Augmenix) and clips were used to mark the surgical cavity. CT images of BCS patients with standard clips only were used as control group, matched on resected specimen weight, maximum distance between clips and age. A CT-scan was made just after surgery, at 2-4 weeks, and 2-3 months. 6 radiation oncologists delineated the tumored volume and rated the cavity visualization score (CVS, 1-5 score). Primary endpoint was the Conformity Index (Cx) between observers target volumes.

**Methods**

**Figure 1:** Examples of hydrogel clearly demarcating the tumor bed (a), hydrogel behavior in case of natural seroma formation (b)

**Figure 2:** Examples of tumor bed contours of 6 observers with hydrogel+clips, Cx=0.72 (a) and 3 observers with clips only, Cx=0.46 (b)

**Results**

Twenty-one interventional patients were analyzed, 21 controls. Feasibility of the intervention was 100%. Usability of the hydrogel intervention was high, with a mean System Usability Scale score of 97. Two patients (9.5%) in the intervention group developed a surgical site infection and 3 patients (14.3%) had symptomatic seroma formation.

**Table 1:** RTx target definition outcomes, comparison between groups

<table>
<thead>
<tr>
<th></th>
<th>Hydrogel +clips n=221</th>
<th>Clips only n=150</th>
<th>p- value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cx</td>
<td>0.70 [0.58-0.77]</td>
<td>0.59 [0.47-0.70]</td>
<td>&lt;0.001</td>
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<tr>
<td>CVS</td>
<td>3 [2-4]</td>
<td>2 [2-3]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Target volume*</td>
<td>26.4cc [13.9-42.6]</td>
<td>11.7cc [5.7-24.8]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time per delineation</td>
<td>5 minutes [4-7.5]</td>
<td>4 minutes [3-5]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Median Conformity Index was higher in the intervention group (Cx=0.70; IQR[0.58-0.77]) than in the control group (Cx=0.59; IQR[0.47-0.70]), p<0.001.

Multivariate analyses of independent variables group (hydrogel+clips vs. clips only) and target volume on dependent variable Cx showed that the adjusted Beta coefficient of group (hydrogel+clips) was 0.06 (95%CI[0.03-0.09]).

**Conclusions**

- The use of a radiopaque hydrogel during breast conserving surgery is feasible, safe and easy to perform.
- Hydrogel+clips resulted in a higher interobserver agreement of radiotherapy target definition, compared to standard clips only.
- This higher accuracy potentially reduces risk of cancer recurrence and RTx toxicity.

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