Patient-Reported and Toxicity Results from the FABREC Study: A Multicenter Randomized Trial of Hypofractionated vs. Conventionally-Fractionated Postmastectomy Radiation Therapy after Implant-Based Reconstruction

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Disclosure & Study Team

• I have no conflicts of interest to disclose
• This study was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CER-1609-36063)

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Background

• Postmastectomy RT indicated for ~30% of mastectomy patients
• Immediate reconstruction at time of mastectomy has benefits
• Implant-based reconstruction with tissue expander or implant
• Radiation (5-6 weeks) increases risk of reconstruction complications
• Hypofractionation (3-4 weeks) has been widely adopted after breast-conserving surgery
  • Equivalent long-term oncologic and improved 6-month quality of life (QOL) outcomes
  • Improved cosmetic results
## Patient experiences with CF

<table>
<thead>
<tr>
<th>Patient</th>
<th>Experience</th>
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<tbody>
<tr>
<td>Patient 1</td>
<td>The <strong>hardest thing about radiation was the time it took to do it</strong> and scheduling.</td>
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<tr>
<td>Patient 2</td>
<td>I live far so coming in for daily radiation for over 5 weeks meant missing significant life events. I missed my kids’ first day of school. I had to get a friend to do my daughter’s hair because I missed picture day. I would have definitely wanted short-course radiation had it been an option. It’s time you don’t get back.</td>
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<tr>
<td>Patient 3</td>
<td>I stayed in Boston every other night so that I was just driving two hours a day instead of four. This meant that I was away from the kids every other day. I couldn’t afford a hotel. Five weeks of treatment was a huge strain on me and my family. I would be thrilled if there were new methods created where future working mothers like me wouldn’t have to miss over a month of their family’s lives. I was lucky to find free places to stay, but it was a financial strain on us to have me traveling, paying for gas, and eating out when I was away. If I hadn’t found free housing, I wouldn’t have been able to stay in Boston and then all that driving would have impacted my job, which would have major life implications. By week three of treatment, I started to feel very down. I was alone, the novelty had worn off, I was sad and felt like it would never end. <strong>With so many treatments, by the last two weeks I do think I was developing some level of anxiety and (radiation) machine phobia.</strong></td>
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<tr>
<td>Patient 4</td>
<td>I like the idea of taking the radiation down to 3 weeks...anything to reduce the time is great.</td>
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<tr>
<td>Patient 5</td>
<td>My mother had breast cancer at the same time as me and was able to have a radiation regimen that lasted only 3 weeks...but for me (because of the mastectomy and reconstruction) it wasn’t possible.</td>
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Methods

• 400 patients with Stage 0-III breast cancer treated with mastectomy and immediate implant-based reconstruction

• Enrolled between 3/2018 and 11/2021 across 16 institutions

• Randomized 1:1
  • Conventional Fractionation (CF):
    • 25 fractions (M-F, 5 weeks) of 200 cGy
  • Hypofractionation (HF):
    • 16 fractions (M-F, ~3 weeks) of 266 cGy

• Primary study endpoint was improvement in the Physical Well-Being (ΔPWB) domain of FACT-B at 6 months controlling for age
Study cohort

• Randomization: 201 CF and 199 HF arm
• Median age 47.0 years (range, 23-79)
• Median time from surgery to PMRT was 2.6 months
• Treatment break
  • 7.7% in CF (average 3.3 days)
  • 2.7% in HF (average 2.8 days)
  • p=0.03
Results – HF versus CF

• 385 patients analyzed with median f/u of 40.4 months
• No difference in any of the oncologic outcomes
  • Distant recurrence, Death, Local Recurrence
• No difference in toxicity outcomes
  • Chest wall toxicity (p=0.80)
    • 39 patients (19 CF; 20 HF)
• Change in Physical Well Being (ΔPWB) score at 6-months controlling for age group (<45 versus ≥45 years)
  • ΔPWB = 0.20 (95% CI:-0.80,1.18) with HF (p=0.70)
Results - Physical Well-Being

![Graph showing PWB scores across different age groups and time points.](image)

- **PWB Score**
  - BL: Baseline
  - 6-mo: 6-month follow-up
  - < 45: younger than 45 years
  - ≥ 45: 45 years or older

- **Groups**: CF (control) and HF (intervention)

- **Statistical Significance**: p = 0.049

- **Legend**:
  - CF: Dark blue bars
  - HF: Light blue bars with diagonal lines

- **Note**: The graph indicates a significant difference in PWB scores between the control and intervention groups, particularly for those younger than 45 years.
Results – Less bothered by side effects
Results – Financial toxicity

• Mean number of hours of unpaid time off from work for treatment among those patients who took such time (n=51)
  • 125.8 hours for CF
  • 73.7 hours for HF
  • p=0.046
Conclusions

• First study to report randomized phase III results of HF vs. CF in patients with mastectomy and implant-based reconstruction
• Primary outcome and toxicity profile of HF comparable to CF
• Improvement in specific QOL domains with HF, especially among younger patients
• Fewer treatment breaks with HF
• Less financial toxicity with HF
• Our results support the use of HF PMRT for patients with implant-based reconstruction