Purpose: Many published reports have demonstrated that early stage breast cancer patients need a radiotherapy boost on tumor bed after breast conserving surgery (BCS) and whole breast irradiation. Linac-based IORT boost with electrons was implemented to prevent the contamination with subclinical tumor cells in the vicinity of tumor site, followed by external beam radiotherapy. A IORT boost may allow to reduce the incidence of local recurrence, obtaining good esthetical results compared to external beam boost, due to skin sparing. In addition to whole breast irradiation (WBI), it has yielded excellent long-term results. The aim of this study is to present the long term follow up results on local control, esthetic evaluation and toxicity of a randomized prospective study on early stage breast cancer patients treated with IORT boost of 10 Gy versus the same external beam dose.

Material and Methods: A randomized prospective study on IORT versus external beam boost in early breast cancer patients was carried on in our Institution. Primary endpoints of the study were the evaluation of local recurrence (LR), toxicity and cosmetic result.

From April 1999 to April 2004, 244 patients were enrolled: 126 in IORT arm (131 treatments for 5 bilateral) and 118 in no IORT arm. The average age was 49.2 and 50.7 respectively.

Toxicity valuation was assessed using EORTC/RTOG scale. The cosmetic result was detected on five parameters: hyper-pigmentation, telangiectasias, hypertrophic scar, profile asymmetry and difference in consistency.

Results: The median follow-up was 130.6 months (range 96-156 months). Ten patients were lost at the follow up. Sixty women (24.6%) were younger than 45 years, 33 in IORT and 27 in no IORT arm. Two and five true local recurrences were observed in IORT and no IORT arm respectively. Both of the IORT arm recurrences were observed at more than 100 months follow up: one of them (in field) was a 62 years old woman, with pT1bN0M0 G2 infiltrating ductal carcinoma (IDC), after 100 months and the other (marginal) was a 56 years old pT1cN0M0 G3 IDC, after 112 months follow up. A third patient presented an ipsilateral out of field recurrence: she was a 72 years old with a pT1cN0M0 G3 IDC, after 120 months follow up. The mean time to recurrence in no IORT group was earlier (55.2 months). One patient was a 46 years old, pre-menopausal, with a pT2N2M0 G3 IDC, after 50 months; one was a 51, pre-menopausal, pT1cN0M0 G3 medulary carcinoma, after 40 months; one patient was 69 pT1cN0M0 G2 IDC after 45 months; one was 67, pT1cN0M0 G3 IDC, after 56 months; the last was a 71 years old woman, pT1cN0M0 G2 infiltrating lobular carcinoma, after 90 months.

No local failures were observed in the group of IORT pre-menopausal women.

As acute toxicity 12 patients developed post-surgical seromas and 7 wound healing problems (7.8%). No late complications associated with IORT were observed, but three cases of liponecrosis in the treatment area. In 5 patients, a secondary mastectomy was performed for tumour multi centricity or excessive intraductal component. Cosmetic result was very good (objective valuation 92.8% good or excellent, subjective valuation 90.2%) and comparable to patients treated with external boost (87.4% good or excellent). The DFS was 89.1% and 86.4% in IORT and no IORT arm, 22 patients developed distant metastasis and 19 died (fourteen of them for disease).

Conclusion: Our data suggest that IORT as anticipated boost after breast-conserving surgery can be performed without significant morbidity and it’s a reliable alternative to conventional postoperative external beam boost, particularly in younger women, for whom published studies indicate higher risk of local recurrence. The incidence of recurrence with the IORT boost, for any age, including young women, is quite low. Further research is required to clarify several issues such as identification of the most appropriate subgroups of patients for IORT as boost or complete replacement of postoperative radiotherapy.