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This presentation provides an overview of the data supporting the use of breast conservation therapy in the treatment of early stage breast cancer.

## Breast Conservation Therapy (BCT) as an Alternative to Mastectomy

- 20+ years of data support BCT as standard of care
- Multiple studies of conservative surgery plus radiation vs. mastectomy provide comparable outcomes:
  - Local recurrence
  - Distant metastases
  - Long term survival

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During the past two decades breast conserving surgery—lumpectomy followed by radiation therapy—has become the standard of care for the treatment of early stage breast cancer. This treatment was originally investigated as an alternative to mastectomy because in addition to allowing a woman to preserve her breast it optimized local control and provided better cosmetic results.

There are now over 20 years of data supporting BCT as the standard of care. Six major trials have proven that there is no significant difference between BCT and radiation versus mastectomy, when you look at local recurrence, distant metastasis and survival.

## Prospective Randomized Trials: BCT vs. Mastectomy

Trial	Local Recurrence (%)		Survival (%)		F/U Interval
	BCT	M	BCT	M	
NSABP B-O6 <sup>1</sup>	3	10	46	47	20 years
Milan I <sup>2</sup>	9	2	59	59	20 years
NCI <sup>3</sup>	19	6	77	75	10 years
EORTC <sup>4</sup>	17	14	54	61	8 years
IGR <sup>5</sup>	9	14	73	65	15 years
DBCG <sup>6</sup>	3	4	79	82	6 years

<sup>1</sup>Fisher et al. *N Engl J Med.* 2002;347:1233-1241. <sup>2</sup>Veronesi et al. *N Engl J Med.* 2002;347:1227-1232.  
<sup>3</sup>Winchester et al. *CA Cancer J Clin.* 1998;48:83-107. <sup>4</sup>Van Dongen et al. *Natl Cancer Inst Monogr.* 1992;11:15-18.  
<sup>5</sup>Arriagada et al. *J Clin Oncol.* 1996;12:1558-1564. <sup>6</sup>Blichert-Toft et al. *J Natl Cancer Inst Monogr.* 1992;11:19-25.

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These are the key trials that showed that there is no significant difference between mastectomy and lumpectomy plus radiation therapy in terms of survival and local recurrence.

1. Fisher B, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med.* 2002;347:1233-1241.
2. Veronesi U, et al. Twenty-year follow-up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer. *N Engl J Med.* 2002;347:1227-1232.
3. Winchester D.P., et al. Standards for diagnosis and management of invasive breast carcinoma. *CA Cancer J Clin.* 1998;48:83-107
4. Van Dongen JA, Bartelink H, Fentiman IS, et al: Randomized clinical trial to assess the value of breast-conserving therapy in stage I and II breast cancer: EORTC 10801 trial. *Natl Cancer Inst Monogr.* 1992;11:15-18.
5. Arriagada R, Le MG, Rochard F, et al: Conservative treatment versus mastectomy in early breast cancer: patterns of failure with 15 years of follow-up data. Institut Gustave-Roussy Breast Cancer Group. *J Clin Oncol.* 1996;14:1558-1564.
6. Blichert-Toft M, Rose C, Andersen JA, et al. Danish randomized trial comparing breast conservation therapy with mastectomy: six years of life-table analysis. Danish Breast Cancer Cooperative Group. *J Natl Cancer Inst Monogr.* 1992:19-25.

## Is it Safe to Omit Radiation Therapy After BCS?

- Several randomized trials have been conducted to determine if radiation therapy (RT) can be omitted after breast-conserving surgery.
- No subset of patients has been identified that can conclusively be treated with surgery alone.

<sup>1</sup> Baxter et al. *J Natl Cancer Inst.* 2004;96:443-448.

<sup>2</sup> Burstein et al. *N Engl J Med.* 2004;350:1430-1441.

<sup>3</sup> Houghton et al. *Lancet.* 2003;362:95-102.

<sup>4</sup> Julien et al. *Lancet.* 2000;355:528-533.

<sup>5</sup> Fisher et al. *N Engl J Med.* 1993;328:1581-1586.

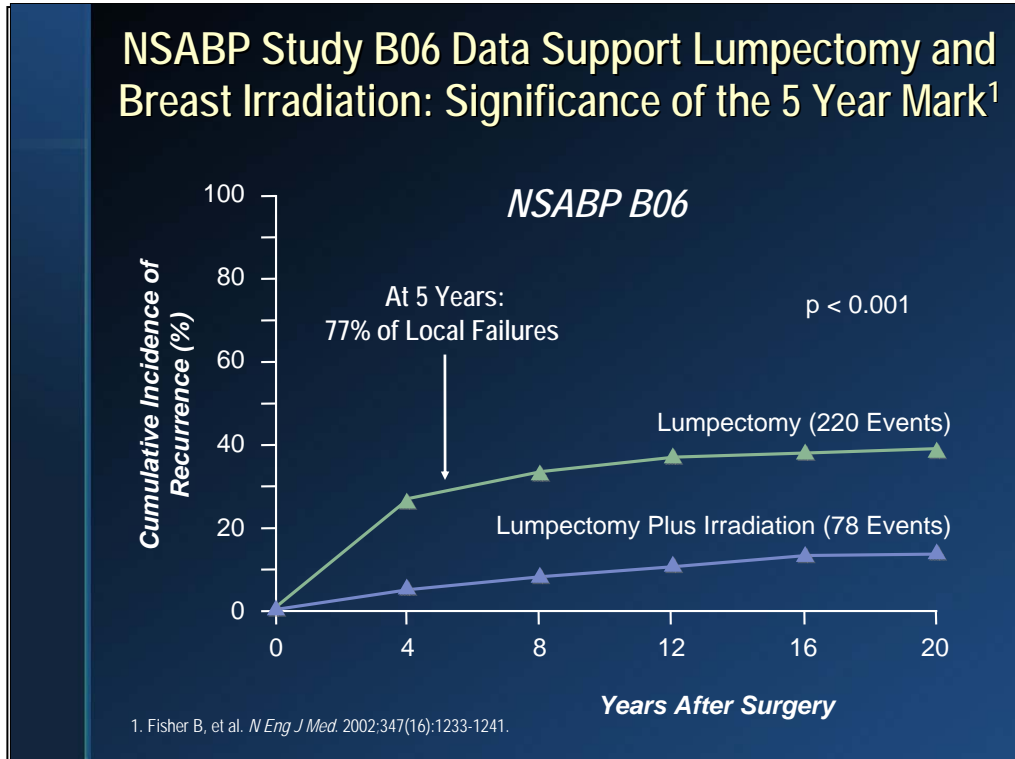
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More recent efforts have investigated whether or not some patients could skip the radiation therapy and be treated with lumpectomy only, but the answer is no. Several studies have looked at this question, but no subset of patients that can safely skip radiation therapy has been identified.

1. Baxter NN, Virnig BA, Durham SB, Tuttle TM. Trends in the treatment of ductal carcinoma in situ of the breast. *J Natl Cancer Inst.* 2004;96:443-448.
2. Burstein HJ, Polyak K, Wong JS, et al. Ductal carcinoma in situ of the breast. *N Engl J Med.* 2004;350:1430-1441.
3. Houghton J, George WD, Cuzick J, et al. Radiotherapy and tamoxifen in women with completely excised ductal carcinoma in situ of the breast in the UK, Australia, and New Zealand: randomised controlled trial. *Lancet.* 2003;362:95-102.
4. Julien JP, Bijker N, Fentiman IS, et al. Radiotherapy in breast-conserving treatment for ductal carcinoma in situ: first results of the EORTC randomised phase III trial 10853. EORTC Breast Cancer Cooperative Group and EORTC Radiotherapy Group. *Lancet.* 2000;355:528-533.
5. Fisher B, Costantino J, Redmond C, et al. Lumpectomy compared with lumpectomy and radiation therapy for the treatment of intraductal breast cancer. *N Engl J Med.* 1993;328:1581-1586.

## NSABP Study B06 Data Support Lumpectomy and Breast Irradiation: Significance of the 5 Year Mark<sup>1</sup>



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The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a clinical trials cooperative group supported by the National Cancer Institute. The results of its clinical trials have changed the way breast cancer is treated.

The graph represents the cumulative incidence of a first recurrence of cancer in the ipsilateral breast during 20 years of follow-up among 570 women treated with lumpectomy alone and 567 treated with lumpectomy and breast irradiation.

As you can see, the incidence of recurrence is greater in the lumpectomy alone group and this also demonstrates that most local failures—77%—occur within the first five years.

At 20 years the findings still show that lumpectomy and breast irradiation, as compared with lumpectomy alone, significantly decrease the incidence of a recurrence in the ipsilateral breast.

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1. Fisher B, Anderson S, Bryant J, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Eng J Med.* 2002;347(16):1233-1241.

## Studies Demonstrate Breast Conservation Alone Leads to Higher Rates of Recurrence

Trial	# Pts	Tumor Size (cm)	Surgery	% of Patients with Recurrence		% Reduction in Recurrence
				CS Alone	CS + RT	CS vs. CS+RT
NSABP B-06 <sup>1</sup>	1265	< 4.0	WE	36	12	67
Milan <sup>2</sup>	601	< 2.5	Q	24	6	75
Scottish <sup>3</sup>	584	< 4.0	WE	25	6	76
Swedish <sup>4</sup>	381	< 2.0	Q	24	9	63
Ontario <sup>5</sup>	837	< 4.0	WE	35	11	69
British <sup>6</sup>	399	< 5.0	WE	35	13	63

WE = Wide Excision; Q = Quadrantectomy; CS = Conservative Surgery; RT = Radiation Therapy

1. Fisher ER, et al. *Cancer*. 2001; 91:1679-1687.

2. Veronesi U, et al. *Ann Oncol*. 2001;12:997-1003.

3. Forrest AP, et al. *Lancet*. 1996;348:708-713.

4. Liljegren G, et al. *J Clin Oncol*. 1999;17:2326-2333.

5. Clark RM, et al. *J Natl Cancer Inst*. 1996;88:1659-1664.

6. Renton SC, et al. *Eur J Surg Oncol*. 1996;22:17-22.

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This table is a collection of data from various trials that looked at conservative surgery alone versus conservative surgery plus the addition of whole breast radiotherapy. The magnitude of the reduction in local recurrences varies from 63 to 76%. In the NSABP B-06 trial, 36% of the 1265 patients had a recurrence when just conservation surgery was used whereas only 12% of the patients had a recurrence when conservation therapy plus radiotherapy was used. The Milan, Scottish, Swedish, Ontario, and British trials all concluded that fewer patients experienced a recurrence when both conservation therapy plus radiotherapy was used to treat the cancer. You can see in the far right column how much the addition of radiation therapy reduced recurrence rates.

1. Fisher ER, Anderson, S, Tan-Chiu, E, et al. Fifteen-year prognostic discriminants for invasive breast carcinoma. *Cancer*. 2001;91:1679-1687.
2. Veronesi U, Marubini, E, Mariani, L, et al. Radiotherapy after breast-conserving surgery in small breast carcinoma: long-term results of a randomized trial. *Ann Oncol*. 2001;12:997-1003.
3. Forrest AP, Stewart, HJ, Everington, D, et al. Randomised controlled trial of conservation therapy for breast cancer: 6-year analysis of the Scottish trial. Scottish Cancer Trials Breast Group. *Lancet*. 1996;348:708-713.
4. Liljegren G, Holmberg L, Bergh, J, et al. 10-year results after sector resection with or without postoperative radiotherapy for stage I breast cancer: a randomized trial. *J Clin Oncol*. 1999;17:2326-2333.
5. Clark RM, Whelan T, Levine M, et al. Randomized clinical trial of breast irradiation following lumpectomy and axillary dissection for node-negative breast cancer: an update. Ontario Clinical Oncology Group. *J Natl Cancer Inst*. 1996;88:1659-1664.
6. Renton SC, Gazet JC, Ford HT, et al. The importance of the resection margin in conservative surgery for breast cancer. *Eur J Surg Oncol*. 1996;22:17-22.

## Publications Continue to Support BCS + Radiation<sup>1</sup>

- *Lancet* meta-analysis: 42,000 pts, 78 trials radiation vs. no radiation treatment
- Local recurrence after BCT can affect survival
  - 20% decrease in 5-year local recurrence risk with RT
  - 5.2% decrease in 15-year cancer mortality with RT
  - 75% of the IBF-risk occurred in first 5 years

1. Clarke M, et al. *Lancet*. 2005;366:2087-2106.

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Published studies continue to support that surgery plus radiation therapy optimizes outcomes. A recent meta-analysis from 78 trials found that local recurrence after breast conserving therapy affects survival. Overall, radiation therapy appeared to decrease the risk of local recurrences by 20% and lowered mortality rates by 5.2%. Seventy-five percent of all failures were reported within five years.

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1. Clarke M, Collins R, Darby S, et al. Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: an overview of the randomised trials. *Lancet*. 2005;366:2087-2106.

# Lumpectomy Without Radiation Increases Local Recurrence Rates

## Harvard Data

- Invasive Cancer (n=87)<sup>1</sup>
  - Unicentric T1N, infiltrating ductal carcinoma with > 1 cm negative margins
  - 19 patients (23%) with local recurrence
  - 4 patients (5%) with distant recurrences
- DCIS (n=158)<sup>2</sup>
  - Grade I/II DCIS with  $\geq 1$  cm negative margin
    - Local recurrence rate 12% at 5 years (median follow-up 40 months)

1. Lim M, et al. *Int J Radiat Oncol Biol Phys* 2006; 65(4):1149-1154.

2. Wong et al. *J Clin Oncol* 2006, Mar 1;24 (7):1031-1036.

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This recent, prospective, single-arm study from Harvard investigators attempted to identify women who did not need radiation and would do well with breast conserving surgery alone. These data demonstrated a much higher recurrence rate among women with just lumpectomy alone, versus established rates for lumpectomy plus radiation.

A local recurrence rate of 23% was reported among women diagnosed with invasive cancer and a 12% recurrence rate was found among the group of women diagnosed with DCIS.

The study was terminated after the initial analysis revealed these high rates of recurrence.

Both the *Lancet* publication and the Harvard data reinforce that radiation therapy may be required after lumpectomy for optimal results and it can potentially affect survival.

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1. Lim M, Bellon JR, Gelman R, et al. A prospective study of conservative surgery without radiation therapy in select patients with stage I breast cancer. *Int J Radiat Oncol Bio Physics* 2006;65(4):1149-1154.
  2. Wong et al. Prospective study of wide excision alone for ductal carcinoma in situ of the breast. *J Clin Oncol* 2006, Mar 1;24 (7):1031-1036.

## Summary

- Several multiyear trials show that there is no significant difference between mastectomy and lumpectomy plus radiation therapy.
- Compared to lumpectomy alone, lumpectomy and breast irradiation are associated with significantly less local recurrence.
- Breast conservation therapy is an effective alternative to mastectomy in the treatment of early stage breast cancer.

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