A comparative study on the cosmetic outcomes of ultrasound-guided versus palpation-guided conservative breast surgery in patients with early palpable breast cancer

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Background
In conservative breast surgery, a larger volume of resected breast tissue is associated with a poorer cosmetic outcomes. Therefore, the introduction of ultrasonography in the excision of palpable breast cancer aims to minimize the excision of healthy tissue ensuring oncologically safe excision, and hence, a better cosmetic outcome compared with palpation-guided surgery (PGS).
Aim
To compare ultrasound-guided surgery (UGS) for palpable breast cancer with PGS in terms of safety margin, re-excision rate, and cosmetic outcome.
Patients and methods
This is a prospective, randomized, controlled study conducted on 79 female patients with early palpable breast cancer. Patients were randomized to undergo either UGS or PGS. The mean distance between the tumor and the resection margin, re-excision rate, operative time, cosmetic outcome, and patient satisfaction were assessed.
Statistical analysis used
Data management and statistical analysis were done using SPSS, version 28. Quantitative data were assessed for normality using the Shapiro–Wilk test and direct data visualization methods. According to normality, quantitative data were summarized as means and SDs. Categorical data were summarized as numbers and percentages. Quantitative data were compared between the studied groups using independent *t* test. Categorical data were compared using the χ^2 test. Multivariate logistic regression analysis was done to predict good to excellent patient satisfaction. All statistical tests were two-sided. *P* values less than 0.05 were considered significant.
Results
The UGS group showed significantly higher excellent panel evaluation (48.7 vs. 22.5%, $P=0.028$) and patient satisfaction (61.5 vs. 30%). The UGS group demonstrated significantly longer operative time but significantly lower re-resection rate and distance from tumor to resection margin (0.62±0.16 vs. 1.72 ±0.35 cm, $P<0.001$). The predictors of the outcomes were tumor T stage (T2 stages associated with less satisfaction), tumor to resection margin distance (the more distance the less satisfaction), and ultrasound use.
Conclusion
The UGS proves to be superior to PGS as it significantly decreases re-excision rates and improves overall cosmetic outcome and patient satisfaction.

Keywords:
breast-conserving surgery, cosmetic outcomes, patient satisfaction, ultrasound-guided surgery

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Introduction

Breast-conserving surgery (BCS) with sentinel lymph node sampling has become the main procedure, whenever possible, for the management of patients with breast cancer aiming for preservation of healthy breast tissue and healthy axillary lymph nodes. Such a procedure improves the patient's quality of life through a better aesthetic appearance (compared with mastectomy) and avoids limited mobility and arm edema associated with axillary clearance through less invasive sentinel lymph node biopsy and hence improving the functional outcome [1–3].

With the application of the screening program, the incidence of diagnosing breast cancer in early stage,

when the tumor is still small or even impalpable, increases significantly [3].

In palpable tumors, palpation can easily localize the mass intraoperatively; however, oncologically safe excision with adequate negative margins together with removal of healthy tissue as minimal as possible may be achieved better with the use of intraoperative ultrasound to objectively measure the distance from the tumor margin to the resection margin, rather than using the traditional subjective palpation-guided surgery (PGS). The use of intraoperative ultrasound allows the surgeon to visualize the tumor along the course of tumor resection and measure a safe distance for oncologically safe resection [4].

The volume of the tissue excised generally affects the cosmetic outcomes after BCS; the larger volume excised, the less favorable the cosmetic outcomes [5].

Patients and methods

Study design

This is a prospective, blinded, randomized, controlled study conducted on 79 female patients with early palpable breast cancer and take place at Benha University Hospital, General Surgery Department in the period from November 2022 to November 2023.

The present study is reported in line with CONSORT criteria (Consolidated Standards of Reporting Trials) http://www.journal-surgery.net/article/S1743-9191%2811%2900565-6/fulltext.

Inclusion criteria

Female patients diagnosed with early (T1–2, N0–1) invasive breast cancer and fit for BCS.

Exclusion criteria

(1) Patients with nonpalpable breast cancer or carcinoma *in situ*.
(2) T3 andT4 breast carcinoma (locally advanced tumor).
(3) Metastatic breast cancer.
(4) Recurrent cases of breast cancer.
(5) Breast sarcomas.
(6) Benign breast lump.
(7) Patients unwilling or unfit for BCS.

Randomization method

Using an Excel spreadsheet, a randomization sequence with a 1 : 1 allocation using random block sizes of 2 and 4 was generated by an independent doctor. The allocation of treatment was determined by a researcher not included in the team of the present study using sequential opening of opaque, numbered, and sealed envelopes. After randomization, none of the patients were excluded from the study.

Sample size calculation

Calculation of the sample size was conducted using an online software (https://clincalc.com/stats/samplesize.aspx).

After obtaining approval for the present study from the Ethics Committee of the Faculty of Medicine, Benha University, 79 female patients were randomly assigned into the following two groups:

Group A underwent ultrasound-guided surgery (UGS).
Group B underwent PGS.

A written informed consent was obtained from the participants. The benefits and hazards of the different methods of surgeries were thoroughly explained. All patients were assessed through a multidisciplinary team (including specialized doctor from the general surgery, medical oncology, radiology, radiotherapy, and pathology).

All patients included in the study underwent the following:

(1) A full history documentation and clinical examination.
(2) Laboratory investigations, including full blood picture, liver and renal function tests, fasting and 2-h postprandial blood glucose measurement and tumor marker assessment (CA 15–3).
(3) Bilateral mammography and breast ultrasound.
(4) Metastatic workup investigation (plain chest radiograph, pelviabdominal ultrasound, and bone scan (when indicated).
(5) Tissue diagnosis: in the form of tru-cut biopsy from the breast mass. Tru-cut biopsy or fine needle cytology from axillary lymph nodes was performed when suspicious nodes were detected by axillary ultrasound.

Surgical technique

All cases were performed by the same surgical team under general anesthesia aiming to obtain a safety margin of up to 1 cm around the malignant mass. No oncoplastic techniques were used to close the cavity after excision of the tumor allowing seroma formation.

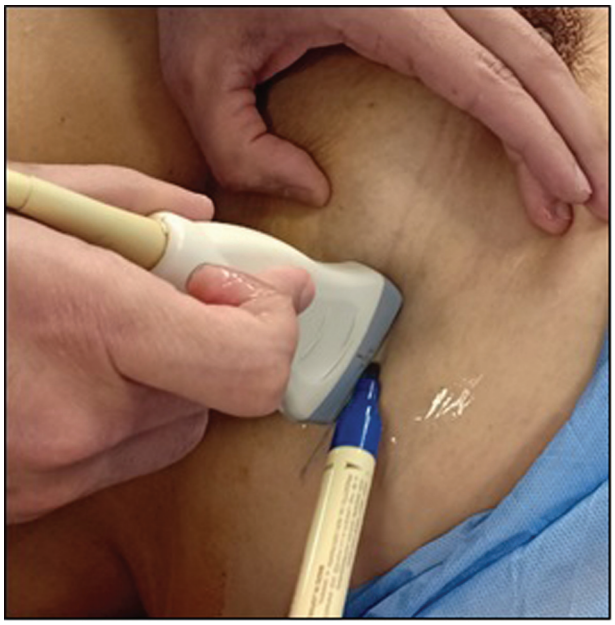
Ultrasound-guided surgery

Before skin incision, the surgeon performed an assessment to the lesion using a THI 14 MHz US probe (LOGIQ_ eportable ultrasound; Philadelphia, USA was used) under supervision of an experienced radiologist (Figs 1 and 2).

Then, the probe of the US unit was enclosed in a sterile surgical glove filled with sterile gel, allowing its application the surgical wound (Fig. 3).

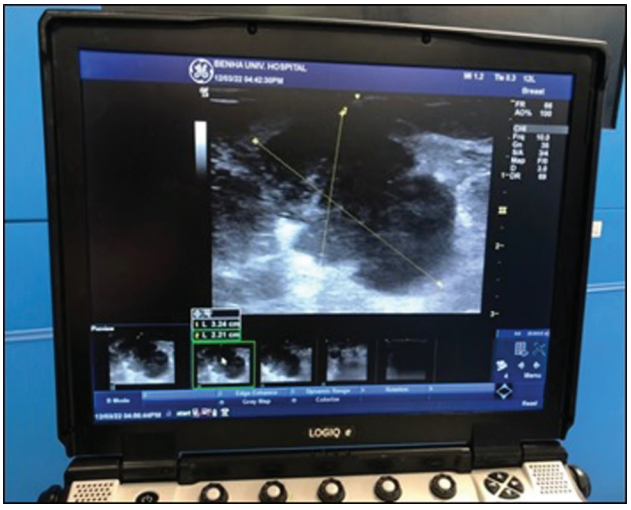
The breast was fixed by the assistant's hand in a way that brought the mass as close to the skin as possible.

Figure 1



Precise marking of the tumor site using the ultrasound.

Figure 2

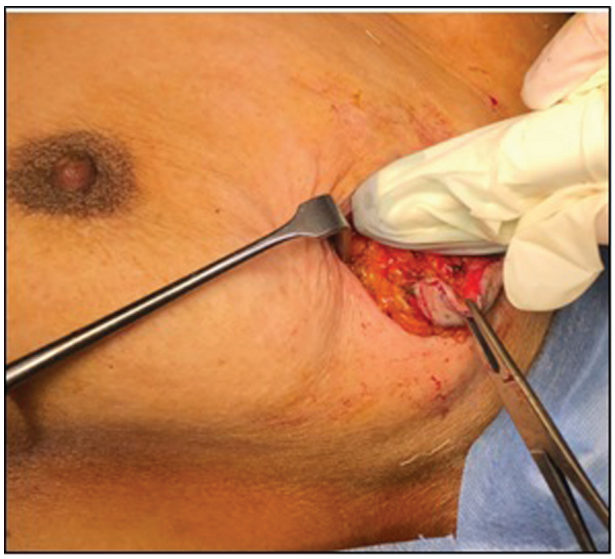


US assessment of the lesion. US, ultrasound.

Precise localization of the tumor was marked on the skin using the US and then a skin incision was made, followed by the elevation of skin flaps. The US probe was applied inside the wound by the surgeon under the supervision and guidance of the radiologist to assess the position of the tumor and guide the dissection together with palpation, ensuring an adequate safety margin.

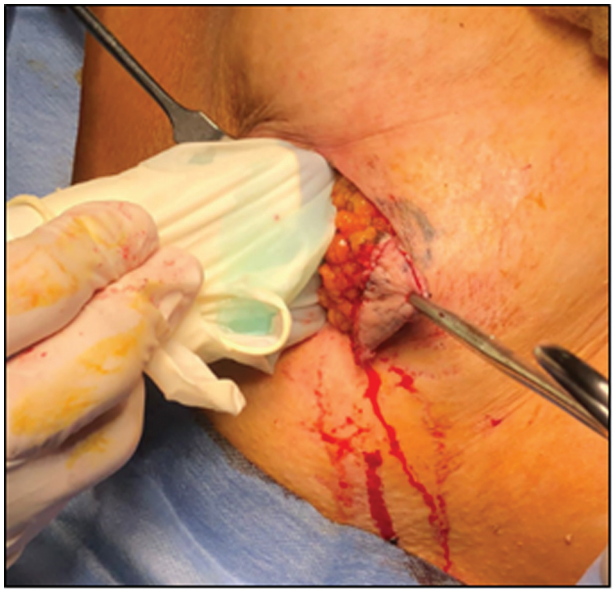
Dissection continued posteriorly between the lesion and the pectoral fascia with repeated application of the probe to assess the depth of the lesion and ensure a safety margin (Fig. 4).

Figure 3



Application of the US probe inside the wound to aid the dissection. US, ultrasound.

Figure 4



Assessment of the posterior margin using the US probe. US, ultrasound.

After complete excision of the tumor, orientation of the specimen was done using sutures and the specimen was reassessed by the US to ensure complete, safe excision of the mass and then the specimen was sent for frozen section assessment by a pathologist so that positive margins were resected.

The cavity after excision was marked using titanium clips to guide radiotherapy. Proper hemostasis was ensured and closure of the skin without drainage was achieved using 3/0 Vicryl sutures (no oncoplastic methods or tissue mobilization were used).

Palpation-guided surgery

In PGS, the excision was guided by palpation using the index finger to palpate and retract the mass and guide the dissection. The specimen was dealt with in the same manner as the UGS group, and the cavity was marked by titanium clips and the wound was closed without drain.

Management of the axilla

Patients with clinically and radiologically negative axillary lymph nodes were subjected to sentinel lymph node sampling using patent blue dye (combined peri-tumoral and retro-areolar injection technique were done). Then, the sentinel nodes were sent to be assessed by a frozen section and if they were positive for metastasis, axillary lymph node dissection was done.

Patients with clinically or radiologically positive axillary lymph nodes as proved by preoperative fine needle aspiration cytology underwent axillary clearance immediately.

Patient follow-up

Patients were assessed at 1, 3, and 6 months postoperatively by patient self-evaluation questionnaire (to assess patient satisfaction) and standardized four-viewpoint digital photographs of the breast (one frontal, one lateral, and two oblique pictures from the neck to the waist).

End points

Mean distance between the tumor and the resection margin, rate of intraoperative reexcision, time of the operation (excluding axillary surgery time), cosmetic outcome, and patient satisfaction.

Cosmetic outcome assessment and scoring

Cosmetic outcomes were assessed through panel assessment and self-evaluation. In these methods, a comparison between the cosmetic end result of the treated breast with the healthy breast was done and scored using the four-point Likert scale, classifying the results into 'excellent,' 'good,' 'fair,' or 'poor' results. The term 'excellent' refers to results comparable to those of the healthy breast, while 'poor' results indicate marked distortion or differences between the treated and healthy breast.

Panel evaluation

The photographs were evaluated by a three-member panel (consisting of a breast surgeon and two laymen). The breast surgeon did not perform the surgery. The study arm and the patient's information were hidden to the panel members. Four-viewpoint photographs of each case at the specific follow-up time point were reviewed. Points to be reviewed include breast contour, volume, degree of deformity, position of the nipple, scar, and overall cosmetic end-result.

Patient cosmetic self-evaluation

A composite questionnaire was used which include questions on the degree of similarity between the treated and the healthy breast on different parameters as firmness, position of the nipple, breast contour and size, surgical scar appearance, final cosmetic outcome, and the degree of satisfaction with the final appearance of the breast.

Results

General characteristics

As shown in Table 1, the two groups were comparable regarding age (P=0.652), BMI (P=0.695), tumor type (P=0.379), and tumor stage (P=0.184).

The UGS group demonstrated significantly higher operative time (28±4 vs. 17±3 min, P<0.001) but significantly lower re-resection rate (7.7 vs. 35%, P=0.003) and distance from tumor to resection margin (0.62±0.16 vs. 1.72±0.35 cm, P<0.001) (Table 1, Fig. 5).

Regarding satisfaction, the UGS group showed significantly higher excellent panel evaluation (48.7 vs. 22.5%, P=0.028) and patient satisfaction (61.5 vs. 30%, P=0.006) (Table 1, Fig. 6).

Agreement between the panel and patient evaluation

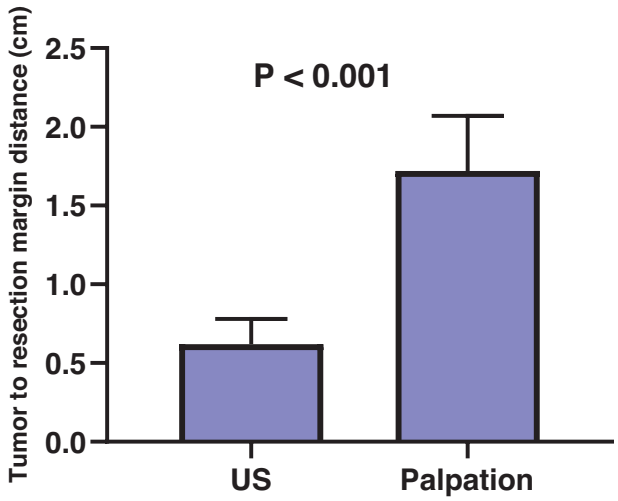
In the UGS group, there was a moderate agreement between panel evaluation and patient self-evaluation (Kappa=0.539, P<0.001). In addition, in the palpation group, a good agreement was observed (Kappa=0.7, P<0.001), with an obvious tendency in patients for a higher evaluation in both groups (Table 2).

Table 1 General and clinical characteristics of the studied groups

	US (*N*=39)	Palpation (*N*=40)	*P* value
Age (years)	50±8	49±8	0.652
BMI	30±6	29±6	0.695
Tumor type			
IDC	28 (71.8)	25 (62.5)	0.379
ILC	11 (28.2)	15 (37.5)	
Tumor T stage			
T1	11 (28.2)	17 (42.5)	0.184
T2	28 (71.8)	23 (57.5)	
Operation time (min)	28±4	17±3	<**0.001**
Re-resection	3 (7.7)	14 (35)	**0.003**
Tumor to resection margin distance (cm)	0.62±0.16	1.72±0.35	<**0.001**
Panel evaluation			
Poor	2 (5.1)	10 (25)	**0.028**
Fair	8 (20.5)	9 (22.5)	
Good	10 (25.6)	12 (30)	
Excellent	19 (48.7)	9 (22.5)	
Patient cosmetic self-evaluation			
Poor	1 (2.6)	9 (22.5)	**0.006**
Fair	4 (10.3)	9 (22.5)	
Good	10 (25.6)	10 (25)	
Excellent	24 (61.5)	12 (30)	

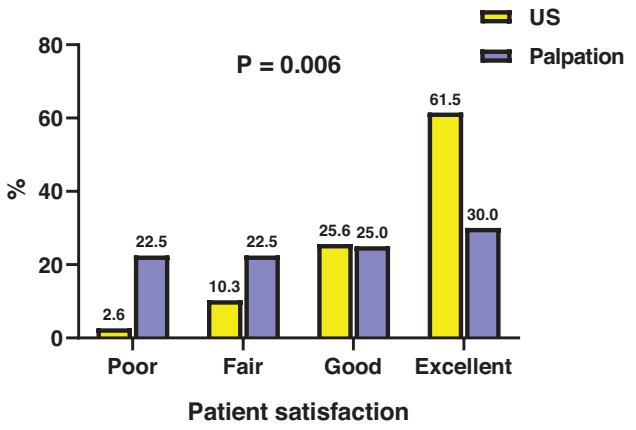
Data are presented as mean±SD or *n* (%). IDC, infiltrating duct carcinoma; ILC, infiltrating lobular carcinoma. Significant *P* values are marked in bold.

Figure 5



Tumor to resection margin distance in the studied groups.

Figure 6



Patient satisfaction in the studied groups.

Prediction of good to excellent patients' satisfaction

Multivariate logistic regression analysis was performed to predict good to excellent patient satisfaction rated as good to excellent. The predictors included T2 stage (associated with lower satisfaction [odds ratio (OR)= 0.099, 95% confidence interval (CI)=0.02–0.483, *P*=0.044], tumor-to-resection margin distance (the more distance the less satisfaction; OR=0.104, 95% CI=0.035–0.310, *P*<0.001), and the use of ultrasound, associated with better satisfaction (OR=5.547, 95% CI=1.773–17.358, *P*=0.003), controlling for age and BMI (Table 3).

Statistical analysis

Data management and statistical analysis were done using SPSS, version 28 (IBM, Armonk, New York, USA). Quantitative data were assessed for normality using the Shapiro–Wilk test and direct data visualization methods. According to normality, quantitative data were summarized as means and SDs. Categorical data were summarized as numbers and percentages. Quantitative data were compared

Table 2 Agreement between the panel and patient evaluation in each studied group

		Patient cosmetic self-evaluation					
Panel evaluation	Total	Poor	Fair	Good	Excellent	Kappa	*P* value
Ultrasound							
Poor	2	1 (50)	1 (50)	0	0	0.539	<**0.001**
Fair	8	0	3 (37.5)	5 (62.5)	0		
Good	10	0	0	5 (50)	5 (50)		
Excellent	19	0	0	0	19 (100)		
Palpation							
Poor	10	8 (80)	2 (20)	0	0	0.7	<**0.001**
Fair	9	1 (11.1)	6 (66.7)	2 (22.2)	0		
Good	12	0	1 (8.3)	8 (66.7)	3 (25)		
Excellent	9	0	0	0	9 (100)		

Data are presented as *n* (%). Significant *P* values are marked in bold.

Table 3 Multivariate logistic regression analysis to predict good to excellent patient satisfaction

	OR (95% CI)†	*P* value
Tumor type	1.714 (0.563–5.222)	0.343
T2 stage	0.099 (0.02–0.483)	0.044
Tumor to resection margin distance	0.104 (0.035–0.310)	<**0.001**
Ultrasound use	5.547 (1.773–17.358)	**0.003**

†Adjusted for age and BMI. 95% CI, 95% confidence interval; OR, odds ratio; Significant *P* values are marked in bold.

between the studied groups using independent *t* test. Categorical data were compared using the χ^2 test. Multivariate logistic regression analysis was done to predict good to excellent patient satisfaction. All statistical tests were two-sided. *P* values less than 0.05 were considered significant.

Discussion

The main goal of the BCS is to achieve the best oncological outcome together with good cosmetic results; however, the aim to achieve the best attainable cosmetic outcome gain more and more attention recently. Several studies have shown the benefit of using the US in BCS as it minimizes the amount of healthy breast tissue resection and reduces the incidence of margin involvement, thereby reducing the need for additional treatments together with healthcare costs [4,6].

The present study shows a significantly lower re-resection rate (7.7 vs. 35%, *P*=0.003) and distance from tumor to resection margin (0.62±0.16 vs. 1.72 ±0.35 cm, *P*<0.001) in the UGS group compared with the PGS one. In studies by Rahusen and colleagues and Snider and colleagues, the comparison between UGS and wire-guided surgery showed the superiority of UGS in minimizing preoperative stress and discomfort, excising smaller breast volume and improving safety margins (hence avoiding the need for higher boost dose of radiotherapy, re-excision, or even mastectomy) [7,8].

In the present study, the UGS group, despite having significantly longer operative time (28±4 vs. 17±3 min, *P*<0.001), revealed significantly higher excellent panel evaluation (48.7 vs. 22.5%, *P*=0.028) and patient satisfaction (61.5 vs. 30%, *P*=0.006). Moreover, 85% of patients reported either good to excellent cosmetic outcomes in the UGS group, which is comparable to the results reported by Losken *et al.* [9] (83%) and Eichler *et al.* [10] (87%) after BCS.

The frequently used subjective methods to analyze cosmetic outcomes were panel evaluation and the patient self-evaluation methods. Patient self-evaluation and assessment of the surgical cosmetic outcome is of great value, although patients mostly report better results than that by professionals. However, panel evaluation was considered to be the most reliable subjective method for the evaluation of outcomes [11,12]. The present study shows a moderate agreement between panel evaluation and patient self-evaluation (Kappa=0.539, *P*<0.001) in the UGS group and a good agreement (Kappa=0.7, *P*<0.001) in the PGS group, with an obvious tendency in patients for a better evaluation in both groups.

In this study, factors that predict 'poor' to 'fair' cosmetic outcomes included T2 stage and larger safety margin; however, several studies revealed other factors including tumor site [13,14], wound complications [12], and the amount of radiotherapy (including radiotherapy boost) [12,15,16].

In studies by Barnett and colleagues and Immink and colleagues, the incidence of breast shrinkage or

induration increased in patients who had 'fair' or 'poor' cosmetic results few months after surgery. This highlights the importance of minimizing the amount of breast tissue resected whenever possible [5,17].

Patient's quality of life is dramatically affected when the cosmetic outcome is poor [18,19]. EORTC QLQ-C30 questionnaire was used by Hau *et al.* [20], which reported that patients with 'fair' or 'poor' cosmetic outcomes (at 5-year and 10-year follow-up) showed a significantly worse quality of life scores. Hence, we can conclude that the use of US in the resection of palpable breast mass will improve patient's quality of life compared with PGS.

Conclusion

UGS for early palpable breast cancer proves to be superior to the PGS as it significantly reduces re-excision rates and improves overall cosmetic outcome and patient satisfaction, which were attributable to reductions in total excision volumes and the need for additional therapy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Fisher B, Anderson S, Bryant J, Margolese RG, Deutsch M, Fisher ER, *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 Gotzsche PC, Nielsen M. Screening for breast cancer with mammography. Cochrane Database Syst Rev 2009; 4:CD001877.

3 Veronesi U, Banfi A, Salvadori B, Luini A, Saccozzi R, Zucali R, *et al.* Breast conservation is the treatment of choice in small breast cancer: long-term results of a randomized trial. Eur J Cancer 1990; 26:668–670.

4 Krekel NM, Haloua MH, Lopes Cardozo AM, de Wit RH, Bosch AM, de Widt-Levert LM, *et al.* Intraoperative ultrasound guidance for palpable breast cancer excision (COBALT trial): a multicentre, randomised controlled trial. Lancet Oncol 2013; 14:48–54.

5 Barnett GC, Wilkinson JS, Moody AM, Wilson CB, Twyman N, Wishart GC, *et al.* Randomized controlled trial of forward planned intensity modulated radiotherapy for early breast cancer: interim results at 2 years. Int J Radiat Oncol Biol Phys 2012; 82:715–723.

6 Haloua MH, Krekel NM, Coupe VM, Bosmans JE, Lopes Cardozo AM, Meijer S, *et al.* Ultrasound-guided surgery for palpable breast cancer is cost-saving: results of a cost-benefit analysis. Breast 2013; 22: 238–243.

7 Rahusen FD, Bremers AJA, Fabry HFJ, van Amerongen AHMT, Boom RPA, Meijer S. Ultrasound-guided lumpectomy of nonpalpable breast cancer versus wire-guided resection: a randomized clinical trial. Ann Surg Oncol 2002; 9:994–998.

8 Snider HCJ, Morrison DG. Intraoperative ultrasound localization of nonpalpable breast lesions. Ann Surg Oncol 1999, 6:308–314.

9 Losken A, Dugal CS, Styblo TM, Carlson GW. A meta-analysis comparing breast conservation therapy alone to the oncoplastic technique. Ann Plast Surg 2014; 72:145–149.

10 Eichler C, Kolsch M, Sauerwald A, Bach A, Gluz O, Warm M. Lumpectomy versus mastopexy: a post-surgery patient survey. Anticancer Res 2013; 33:731–736.

11 Sneeuw KC, Aaronson NK, Yarnold JR, Broderick M, Regan J, Ross G, *et al.* Cosmetic and functional outcomes of breast conserving treatment for early stage breast cancer. 2. Relationship with psychosocial functioning. Radiother Oncol 1992; 25:160–166.

12 Sneeuw KC, Aaronson NK, Yarnold JR, Broderick M, Regan J, Ross G, *et al.* Cosmetic and functional outcomes of breast conserving treatment for early stage breast cancer. 1. Comparison of patients' ratings, observers' ratings, and objective assessments. Radiother Oncol 1992; 25:153–159.

13 Al-Ghazal SK, Blamey RW, Stewart J, Morgan AA. The cosmetic outcome in early breast cancer treated with breast conservation. Eur J Surg Oncol 1999; 25:566–570.

14 Van Limbergen E, Rijnders A, Van der Schueren E, Lerut T, Christiaens R. Cosmetic evaluation of breast conserving treatment for mammary cancer. Radiother Oncol 1989; 16:253–267.

15 Olivotto IA, Rose MA, Osteen RT, Love S, Cady B, Silver B, *et al.* Late cosmetic outcome after conservative surgery and radiotherapy: analysis of causes of cosmetic failure. Int J Radiat Oncol Biol Phys 1989; 17:747–753.

16 Vrieling C, Collette L, Fourquet A, Hoogenraad WJ, Horiot JH, Jager JJ, *et al.* The influence of patient, tumor and treatment factors on the cosmetic results after breast-conserving therapy in the EORTC 'boost vs. no boost' trial. Radiother Oncol 2000; 55:219–232.

17 Immink JM, Putter H, Bartelink H, Cardoso JS, Cardoso MJ, van der Hulst-Vijgen MH, *et al.* Long-term cosmetic changes after breast-conserving treatment of patients with stage I-II breast cancer and included in the EORTC 'boost versus no boost' trial. Ann Oncol 2012; 23:2591–2598.

18 Al-Ghazal SK, Fallowfield L, Blamey RW. Does cosmetic outcome from treatment of primary breast cancer influence psychosocial morbidity? Eur J Surg Oncol 1999; 25:571–573.

19 Waljee JF, Hu ES, Ubel PA, Smith DM, Newman LA, Alderman AK. Effect of esthetic outcome after breast-conserving surgery on psychosocial functioning and quality of life. J Clin Oncol 2008; 26:3331–3337.

20 Hau E, Browne L, Capp A, Delaney GP, Fox C, Kearsley JH, *et al.* The impact of breast cosmetic and functional outcomes on quality of life: long-term results from the St. George and Wollongong randomized breast boost trial. Breast Cancer Res Treat 2013; 139:115–123.