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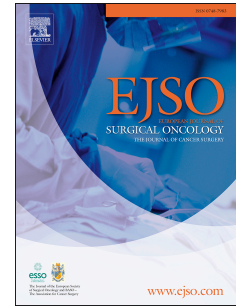
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# Accepted Manuscript

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A population-based audit of surgical practice and outcomes of oncoplastic breast conservations in Scotland – an analysis of 589 patients

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## Abstract

**Introduction:** current evidence for oncoplastic breast conservation (OBC) is based on single institutional series. Therefore, we carried out a population-based audit of OBC practice and outcomes in Scotland.

**Methods:** a predefined database of patients treated with OBC was completed retrospectively in all breast units practicing OBC in Scotland.

**Results:** 589 patients were included from 11 units. Patients were diagnosed between September 2005 and March 2017. High volume units performed a mean of 19.3 OBCs per year vs. low volume units who did 11.1 ( $p=0.012$ ). 23 different surgical techniques were used. High volume units offered a wider range of techniques (8 – 14) than low volume units (3 – 6) ( $p=0.004$ ). OBC was carried out as a joint operation involving a breast and a plastic surgeon in 389 patients. Immediate contralateral symmetrisation rate was significantly higher when OBC was performed as a joint operation (70.7% vs. not joint operations: 29.8%;  $p<0.001$ ). The incomplete excision rate was 10.4% and was significantly higher after surgery for invasive lobular carcinoma (18.9%;  $p=0.0292$ ), but was significantly lower after neoadjuvant chemotherapy (3%;  $p=0.031$ ). 9.2% of patients developed major complications requiring hospital admission. Overall the complication rate was significantly lower after neoadjuvant chemotherapy ( $p=0.035$ ). The 5 year local recurrence rate was 2.7%, which was higher after OBC for DCIS (8.3%;) than invasive ductal cancer (1.6%;  $p=0.026$ ). 5-year disease-free survival was 91.7%, overall survival was 93.8%, and cancer-specific survival was 96.1%.

**Conclusion:** this study demonstrated that measured outcomes of OBC in a population-based multi-centre setting can be comparable to the outcomes of large volume single centre series.

**Keywords:** Mastectomy, Segmental; Mammoplasty; Breast reconstruction; Breast surgery; Breast conservation therapy; Postoperative complications

## Introduction

Oncoplastic breast conserving surgery has become an integral part of breast cancer surgical treatment over the last two decades <sup>1</sup>. The evidence for oncoplastic breast conservation (OBC) is limited and prospective randomized controlled trials are unlikely ever to be undertaken given the complex ethical implications <sup>2</sup>.

Current evidence is largely based on single-institution retrospective series <sup>3-15</sup>. Systematic literature reviews, meta-analyses and reviews further strengthen the evidence base but numbers in many series are small <sup>2, 16-24</sup>. The majority of data reflect the practice of high-volume, mainly tertiary referral centres with few data outside of such units. There is only a single study underway to delineate OBC practice prospectively in a multi-unit level <sup>25</sup>. Due to the lack of robust data outside of the previously mentioned larger units, the published outcomes of OBC do not mirror the results of the majority of patients who are treated outside of these centres. OBC is a rapidly developing field in breast cancer surgery, so it is vital to gain “real-life” data.

Oncoplastic breast conserving surgery practice has been studied in each breast unit from a geographically well-defined area in order to get “real-life” experience in OBC practice and outcomes. In Scotland, all patients treated with oncoplastic breast conservation were analysed with regards to indications, oncoplastic surgical techniques, incomplete excision rate, complication rate, (neo)adjuvant treatment and recurrence rate.

## Methods

A predefined database was filled in retrospectively from all breast units who practise oncoplastic breast conservation in Scotland. The following characteristics were collected: age, date of diagnosis and surgery, presentation, oncoplastic surgical technique, immediate contralateral symmetrisation, tumour type, invasive tumour size, whole tumour size, grade, ER and HER-2 expression, lymph node status, multifocality, excision margins, neoadjuvant systemic treatment, adjuvant chemo-, radio-, hormonal, and anti-HER-2 treatment, postoperative complication, date and site of recurrence, date and cause of death, date of last follow-up, presence of plastic surgeon at the operation. Units were asked to enter patients treated with OBC consecutively. Patients who needed completion mastectomy or who had distant metastasis at presentation were excluded.

Oncoplastic technique was determined by the ratio of tumour size to breast size, tumour location, and patients' anatomy and preferences. This was decided subjectively by oncoplastic breast surgeons, or breast and plastic surgeons together. Only patients who underwent significant volume excision followed by volume displacement accompanied by adequate skin envelope reduction, or true volume replacement were included (level II oncoplastic techniques as defined by Clough et al.) <sup>26</sup>. Patients treated with simple reshaping such as dual plane mobilization without skin envelope reduction were not included in the study.

Units were classified as high and low volume units based on the number of OBC done per year. A high volume unit was defined as one which reported at least 100 patients having OBC over two consecutive years.

Joint operations were defined as OBC carried out by a breast (general) and a plastic surgeon together. When a breast surgeon operated together with another breast surgeon, a breast surgical trainee or an oncoplastic fellow, this did not count as a joint procedure.

Incomplete margins were determined by local guidelines of the time. Since 2016, a 1 mm clear margin was considered to be satisfactory for invasive and *in-situ* disease, while 1 or 2 mm clear margin was required previously in some of the Units in Scotland<sup>27</sup>. Overall survival was defined as the time from the date of surgery to the date of death due to any cause, while cancer specific survival is defined as death due to breast cancer. Disease-free survival (DFS) was defined as the time from the date of surgery to the date of the first relapse or the date of death due to any cause. DFS events were defined as any ipsilateral or contralateral breast recurrence (invasive or non-invasive), regional or distant metastases. Patients who were alive or diseased were censored at the time of last follow-up.

Complications were classified as major or minor. A major complication was considered when readmission or prolonged hospital admission was required for subsequent treatments, that were mainly further surgery for complications and / or intravenous antibiotic administration. All other subsequent treatment not requiring inpatient care was classified as a minor complication.

Chi-square and Mann-Whitney U tests were used for comparison of categorical variables. For comparison between case-load of units or case numbers of time periods ANOVA test was used. For correlation between the case load of units and the number of oncoplastic techniques offered Spearman's rho test was used. A P-value equal to or less than 0.05 was considered statistically significant.

## Results

589 patients were included in the analysis. The median age was 56 years [range 21-86]. Almost two-thirds of the patients were from the symptomatic service (273 (62.7%)); one third from breast screening: 159 (36.5%), and the remainder from follow-up or family history clinics between September 2005 and March 2017. The number of patients treated with OBC in a unit ranged between 4 and 145 (Table 1). 11 of 17 units practising oncoplastic breast conservation contributed to the study. The 6 remaining units are relatively small units and they do not practise OBC. Of these, high volume units performed a mean of 19.3 cases per year [17,3 – 26,5] vs. low volume units doing 11.1 cases per year [7.7–14.4] (p=0.012) (Table 2). Between 2005 and 2010 the number of patients treated with OBC in Scotland increased yearly. In 2005 - 2010 a mean of 20 patients per year [5-42] were treated with OBC. This trend plateaued after 2011 when no further increase was observed (2011 – 2016: mean of 76 patients per year [51-121] (p=0.002)).



23 different oncoplastic surgical techniques were used (Table 3). The number of oncoplastic techniques performed in a unit was associated with case-load: high volume units used a wider range of surgical techniques (8 – 14 different oncoplastic techniques per unit) compared to low volume units (3 – 6 different techniques) ( $p=0.004$ ) (Table 4). Oncoplastic reduction techniques (volume displacement) were used in 515 patients (91.3%), compared to volume replacement oncoplastic technique in 49 patients (8.7%) (Table 3). Immediate symmetrisation was carried out in 336 patients (57%). The immediate symmetrisation rate in patients treated with oncoplastic reduction mammoplasty was 61.7% (327 of 530 patients). The joint operation rate was 66.3% (389 patients). Immediate contralateral symmetrisation rate was significantly higher when the procedure was carried out as a joint operation (70.7% vs. not joint operations: 29.8%;  $p<0.001$ ).

The median invasive tumour size was 21 mm [0-120] and the median whole tumour size was 26 mm [1-200]. Although there was a trend that the median whole tumour size was larger in patients who were operated on in high volume units (28 mm [1-180]) when compared to patients treated in low volume units (25 mm [7-200]), this difference was not significant ( $p=0.164$ ). Details of tumour characteristics are summarized in Table 5.

The neoadjuvant systemic treatment rate was 28.6% (142 of 496 patients with invasive carcinoma). Of those, 68 patients received neoadjuvant chemotherapy (13.7%) and 74 patients had neoadjuvant hormonal treatment (14.9%). 208 patients received adjuvant chemotherapy, 419 patients received (neo)adjuvant hormonal treatment including 10 patients with DCIS, and anti-HER-2 treatment was given to 71 patients. Adjuvant radiotherapy was given to all patients when clinically indicated except eight patients with invasive ductal, four patients with DCIS, one patient with invasive lobular and one patient with Paget's disease.

The incomplete excision rate was 10.4% (60 of 578) and was significantly higher in invasive lobular carcinoma (18.86%; 10 of 53) when compared to invasive ductal carcinoma (9.2%; 38 of 413;  $p=0.029$ ). Incomplete excision rate after DCIS was similar to invasive ductal carcinoma (8.97%; 7 of 78). After neoadjuvant chemotherapy incomplete excision rate was significantly lower (2.94%; 2 of 68 vs. no neoadjuvant treatment: 9.89%; 35 of 354;  $p=0.031$ ) than when no neoadjuvant treatment was used. When the whole tumour size was larger than the invasive component, incomplete excision rate was higher compared to those cases when whole tumour size was the same as the invasive tumour size, but this difference was not significant (14.96%; 19 of 127 vs. 10.33%; 28 of 271;  $p=0.092$ ). Case load did not influence incomplete excision rate (high volume: 9.77%; 39 of 399 vs. low volume: 10.65%; 18 of 169). Similarly, incomplete excision rate was almost identical when OBC was performed as a joint case with a plastic surgeon (10.05%; 39 of 388 vs. 10.66%; 21 of 197).

145 of 510 patients developed complications, giving an overall complication rate of 28.4%. 47 patients had major complications (9.2%) and 98 patients had minor complications (19.2%) (Table 6). Overall complication rate was significantly lower after neoadjuvant chemotherapy (15.9%; 11 of 69) compared to patients who did not receive neoadjuvant chemotherapy (27.9%; 127 of 455 patients) ( $p=0.035$ ). Case load had no influence on complication rates

(high volume units: 24.2%; 98 of 401 vs. low volume units: 24.7%; 42 of 170). When complication rate was analysed by date of surgery, it was significantly higher in the third of the patients who were operated earlier, between July 2005 and July 2012 (37.2%; 73 of 196) compared to the third of patients operated on between July 2012 and February 2015 (23.9%; 40 of 167;  $p=0.006$ ) or the third of patients operated on most recently, between February 2015 and April 2017 (21.8%; 32 of 147;  $p=0.002$ ).

Median follow-up time for all patients was 30 months [1-129]. Of those, 259 patients diagnosed with (non)invasive carcinoma had a median follow-up time of 5 years [35-124]. Of these 7 patients (2.7%) developed isolated local recurrence. 5-year local recurrence rate after DCIS was higher than after pure invasive ductal carcinoma (DCIS: 8.3%; 3 of 36 vs. ductal: 1.6%; 3 of 181;  $p=0.026$ ). 5-year disease-free survival was 91.7%, overall survival was 93.8%, and cancer-specific survival was 96.1%. 5-year DFS was somewhat lower in patients who had major postoperative complication compared to patients with minor or no complication, but this was not significant (86.11%; 5 of 36 vs. 92.1%; 16 of 204;  $p=0.236$ ).

## Discussion

Evidence for OBC is largely based on single centre retrospective series<sup>16</sup>. Breast centres that publish their experience on OBC are usually high-volume units, tertiary referral centres, which are the most experienced units in complex breast surgery<sup>3-6, 10, 15, 28, 29</sup>. It is well established that the outcomes of surgical breast cancer treatment in centres with significantly higher hospital volume are superior<sup>30-32</sup>. However, only a minority of patients are treated in such units overall. It is conceivable that the outcome results in the published meta-analyses on OBC are skewed, as those are predominantly based on data from centres of excellence<sup>2, 16-18</sup>. As the majority of patients are treated outside of these units, it is important to acquire outcome results reflecting the “real-life” scenario. Hence, we carried out a population-based audit of practice and outcomes of OBC involving all breast units in Scotland.

Individual breast units in Scotland were carrying out between 8 – 26 OBC operations per year, with an average between 11 cases (low volume units) to 19 cases (high volume units) yearly. This is comparable to data published by Clough et al., who found that 13.9% of breast conserving surgeries were OBC in France, based on a representative survey including 33 nationally renowned breast surgeons<sup>33</sup>. However the numbers of OBC procedures performed yearly were much higher in the previously mentioned leading units worldwide in comparison to breast units in Scotland. It ranged from 32 to 147 cases per year, and it was particularly high in the European Institute of Oncology, MD Anderson Cancer Center and the Division of Surgical Oncology, Emory University<sup>4, 10, 15, 28, 29</sup>.

A variety of oncoplastic techniques were used in the Scottish units for OBC. The vast majority of patients were treated with oncoplastic reduction techniques (91.3%), while only a small number had volume replacement surgery (8.7%). Others published similarly low rates of volume replacement amongst all OBC. *Rezai* et al. applied volume replacement in 5.1% of 1035 patients treated with OBC<sup>28</sup>. *De La Cruz* et al. reported on 6011 patients in a meta-analysis and



found that 9.5% of patients were treated with volume replacement<sup>16</sup>. *De Lorenzi et al.* applied volume replacement in 10.3% of 454 OBC patients<sup>10</sup>. Amongst oncoplastic reduction techniques Wise pattern reduction was the most frequently applied technique (66.5%) followed by round block excision (6.1%) in Scotland. This trend was similar to other published series, although the dominance of Wise pattern reduction ranged from 35.4% to 87%<sup>5, 16, 34</sup>. Similarly, immediate symmetrisation rate, which was 61.7% in Scotland, varied significantly in the published literature. *Rietjens et al.* performed contralateral symmetrisation in all cases in a series of 148 patients, while *Fitoussi et al.* reported only 46.1% immediate symmetrisation rate in a series of 540 patients<sup>3, 35</sup>.

Median whole tumour size of 26 mm and invasive tumour size of 21 mm in the Scottish series was comparable to results of others. *Clough et al.* published exactly the same tumour size in a series of 350 OBC patients, while *Fitoussi et al.* published 29.1 mm median tumour size in their series<sup>3, 4</sup>. *McIntosh et al.* reported a mean tumour size ranging between 15 and 32.5 mm in a meta-analysis containing 1702 patients<sup>19</sup>. *De La Cruz et al.* reported 23 mm, while *Losken et al.* reported 27 mm in two meta-analyses, respectively<sup>16, 18</sup>. However, many of the above studies report on invasive tumour size only<sup>3, 16, 18, 19</sup>.

Overall incomplete excision rate of 10.4% in the Scottish series was similar to the figures published elsewhere<sup>3, 4, 16, 18, 28</sup>. However, our study did not include patients who required completion mastectomy after failed OBC. Previous studies from our unit indicated a completion mastectomy rate between 0 - 13.2% of patients treated with OBC indicating a relatively high completion mastectomy rate after initially failed OBC<sup>8, 9, 14, 36, 37</sup>. Although these figures cannot be projected to the practice of the whole country, it is conceivable that true incomplete margin rate after OBC is somewhat higher in Scotland. Interestingly, many of the large retrospective series do not report on completion mastectomy rates either<sup>4, 10, 11, 15</sup>. Others report a completion mastectomy rate between 1 - 9.4% of patients treated with OBC<sup>3, 5, 28, 35, 38</sup>. We found a higher incomplete excision rate after OBC for invasive lobular carcinoma compared to ductal (18.86% vs. 9.2%:  $p=0.029$ ), which is similar to findings published elsewhere<sup>4</sup>.

Complications are generally poorly defined in the majority of publications, with no definitions or classification provided in the methods<sup>3, 15, 16, 19, 28, 29</sup>. We classified complications as major or minor complications based on the necessity of hospital admission. In our series 9.2% of the patients had major complication, although there was a significant decrease in complication rates noted as units gained experience in OBC techniques. The overall complication rate of 28.4% is higher compared to large series of single institutions or complication rates reported in meta-analyses<sup>2-4, 10, 15, 16, 28</sup>. This can be explained by the multi-centre nature of our series with initially less experience in OBC techniques. Interestingly, we found a significantly lower overall complication rate after neo-adjuvant chemotherapy (15.9%) despite others reporting no difference in complication rates after neo-adjuvant chemotherapy followed by OBC or mastectomy<sup>4, 39</sup>.

The 2.7% 5-year local recurrence rate and 91.7% DFS in this study is at the lower end of single institutional studies or meta-analyses reporting on recurrence rates after OBC<sup>2-4, 10, 15-19, 28</sup>. Interestingly, we found a trend towards a lower DFS in patients with major complications compared to patients who had

no complication (86.1% vs. 92.1%). It has been suggested previously that postoperative complications after postmastectomy breast reconstruction worsen prognosis although this has not been demonstrated after OBC as yet<sup>40, 41</sup>.

Our study has a few limitations. We did not determine whether the relatively higher complication rate delayed adjuvant therapy or not, although the low recurrence rates suggest that it had no significant effect overall. Similarly, complications may have had an impact on cosmetic outcome, which was not evaluated either. The time period of patients treated with OBC were not identical in the various units in this study, which more or less reflects the different learning curve for oncoplastic techniques and practices across the country.

In conclusion, we demonstrated that outcomes of OBC in Scotland are comparable to outcomes of those in the leading high volume breast centres. Although this study demonstrated that measured outcomes of OBC in a population-based multi-centre setting are not inferior to large volume single centre series, we recommend that prospective multi-centre national audits of OBC outcomes should be carried out for quality insurance in OBC practice.

#### Legends:

Table 1. Number of patients treated with oncoplastic breast conservation in each unit with time periods over which they were carried out.

Table 2. Case load of oncoplastic breast conservation in high and low volume units in Scotland with mean cases per year.

Table 3. Oncoplastic surgical techniques used, with frequencies.

Table 4. Relationship between the number of different oncoplastic techniques used in each unit and total OBC case-load.

Table 5. Tumour characteristics of all patients who underwent OBC surgery on Scotland with breakdown of those who had at least 5 years follow-up. <sup>1</sup> with (non)invasive breast carcinoma; CPR = complete pathological response, [ ] = number of patients received neo-adjuvant systemic treatment, <sup>2</sup> invasive cancers only, <sup>3</sup> hormone receptor expression was determined for 30 and 19 patients with DCIS, respectively; n/a = not applicable

Table 6. Rates of major and minor complications in 510 patients who underwent OBC surgery (79 patients had incomplete data).

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Units	Number of patients	Time period
Western General Hospital Edinburgh	145	April 2005 – August 2015
Victoria Infirmary Glasgow	144	September 2005 – March 2017
Ninewells Hospital Dundee	111	January 2013 – October 2016
Western Infirmary Glasgow	78	July 2005 – October 2016
University Hospital Crosshouse	36	June 2005 – December 2015
Aberdeen Royal Infirmary	31	January 2014 – May 2016
Forth Valley Royal Hospital	13	September 2014 – November 2015
Stobhill Hospital Glasgow	12	March 2006 – March 2014
Glasgow Royal Infirmary	9	July 2005 – April 2010
Wishaw General Hospital	6	August 2015 – December 2015
Royal Alexandra Hospital Paisley	4	August 2015 – October 2015

Table 1.  
Number of patients treated with oncoplastic breast conservation during the indicated time periods in the various units



Units	Number of patients	Time period reported	Mean number of OBC cases per year
<b>HIGH VOLUME UNITS</b>			
Ninewells Hospital Dundee	106	4 years	26.5 cases / year
Western General Hospital Edinburgh	142	8 years	17.7 cases / year
Victoria Infirmary Glasgow	138	8 years	17.2 cases / year
<b>TOTAL</b>	<b>386</b>	<b>20 years</b>	<b>19.3 cases / year</b>
<b>LOW VOLUME UNITS</b>			
Aberdeen Royal Infirmary	29	2 years	1.4.5 cases / year
Western Infirmary Glasgow	76	6 years	12.7 cases / year
University Hospital Crosshouse	31	4 years	7.7 cases / year
Forth Valley Royal Hospital	13	1 year and 3 months	10.4 cases / year
Stobhill Hospital Glasgow	12	1 year and 3 months	9.6 cases / year
<b>TOTAL</b>	<b>161</b>	<b>14 years and 6 months</b>	<b>11.1 cases / year</b>

Table 2.  
Case-load of oncoplastic breast conservation in high and low volume units in Scotland with mean number of cases per year.

Oncoplastic technique	Number of patients	Percentage
Wise pattern reduction	375	66.5%
Round block	34	6.1%
LICAP / TDAP / LTAP	28	5%
Regnault B-plasty	25	4.4%
Grisotti flap	24	4.3%
Vertical Lejour mammoplasty	23	4.1%
Matrix rotation / J mammoplasty	15	2.7%
Thoraco-epigastric flap	14	2.5%
Lateral / medial mammoplasty	11	2%
Tennis racquet-type excision	8	1.4%
Melon slice reduction	5	0.9%
Crescent flap	3	0.5%
Batwing mammoplasty	3	0.5%
VY lateral advancement	2	0.4%
V - mammoplasty	1	0.2%
Skin pouch mammoplasty	1	0.2%
S - mammoplasty	1	0.2%
Rotational advancement flap	1	0.2%
Local flap (other)	1	0.2%
Unknown	25	-

Table 3.  
Oncoplastic surgical techniques used.

Units	Number of oncoplastic techniques	Number of patients
<b>HIGH VOLUME UNITS</b>		
Ninewells Hospital Dundee	12	111
Western General Hospital Edinburgh	8	145
Victoria Infirmary Glasgow	14	144
<b>LOW VOLUME UNITS</b>		
Aberdeen Royal Infirmary	5	31
Western Infirmary Glasgow	5	78
University Hospital Crosshouse	6	36
Forth Valley Royal Hospital	3	13
Stobhill Hospital Glasgow	3	12

Table 4.  
Association between the number of different oncoplastic techniques used in a unit and case-loads

	<i>All patients</i>		<i>Patients<sup>1</sup> with 5-year follow-up</i>	
<b>HISTOLOGICAL TYPE</b>	<b>n=</b>	<b>(%)</b>	<b>n=</b>	<b>(%)</b>
Ductal	413	(70.2%)	182	(70.3%)
Lobular	53	(9%)	25	(9.6%)
Mixed ductal and lobular	6	(1%)	2	(0.8%)
Mixed ductal and papillary	1	(0.2%)	-	
Tubular	7	(1.2%)	4	(1.5%)
Mucinous	6	(1%)	4	(1.5%)
Metaplastic	2	(0.3%)	1	(0.4%)
Not determined (CPR)	5	(0.8%)	1	(0.4%)
DCIS	78	(13.2%)	36	(13.9%)
Paget's disease	2	(0.3%)	2	(0.8%)
Papillary carcinoma	1	(0.2%)	1	(0.4%)
LCIS	3	(0.5%)	1	(0.4%)
Hamartoma	1	(0.2%)	n/a	
Phylloides	8	(1.3%)	n/a	
Diabetic mastopathy	1	(0.2%)	n/a	
Basal cell carcinoma	1	(0.2%)	n/a	
Osteosarcoma	1	(0.2%)	n/a	
<b>TOTAL</b>	<b>589</b>	<b>(100%)</b>	<b>259</b>	<b>(100%)</b>
<b>PATHOLOGICAL T STAGE</b>				
T <sub>is</sub>	83	(14.4%)	39	(15%)
- [ypT0]	13	(2.2%) [13]	5	(1.9%) [5]
T1a [ypT1a]	18	(3.2%) [6]	17	(6.6%) [4]
T1b [ypT1b]	47	(8.1%) [10]	28	(10.9%) [4]
T1c [ypT1c]	142	(24.6%) [30]	33	(12.7%) [11]
T2 [ypT2]	225	(39%) [66]	110	(42.5%) [33]
T3 [ypT3]	27	(4.7%) [10]	14	(5.4%) [10]
Incomplete data	22	(3.8%) [17]	13	(5%) [5]
<b>TOTAL</b>	<b>577</b>	<b>(100%) [152]</b>	<b>259</b>	<b>(100%) [72]</b>
<b>TUMOUR GRADE<sup>2</sup></b>				
Grade 1	50	(10.1%)	26	(11.9%)
Grade 2	243	(49.2%)	105	(48.2%)
Grade 3	197	(39.9%)	83	(38.1%)
Incomplete/ not determined	4	(0.8%)	4	(1.8%)
<b>TOTAL</b>	<b>494</b>	<b>(100%)</b>	<b>218</b>	<b>(100%)</b>
<b>HORMONE EXPRESSION<sup>3</sup></b>				
ER positive	437	(83.4%)	200	(84.4%)
ER negative	83	(15.8%)	37	(15.6%)
Incomplete data	4	(0.8%)	-	
<b>TOTAL</b>	<b>524</b>	<b>(100%)</b>	<b>237</b>	<b>(100%)</b>
<b>HER-2 EXPRESSION<sup>2</sup></b>				
HER-2 positive	85	(17.2%)	32	(14.7%)
HER-2 negative	401	(81.2%)	181	(83%)
Incomplete/ not determined	8	(1.6%)	5	(2.3%)
<b>TOTAL</b>	<b>494</b>	<b>(100%)</b>	<b>218</b>	<b>(100%)</b>

<b>NODAL METASTASIS<sup>2</sup></b>			
Node positive	136 (27.5%)	58 (26.6%)	
Node negative	353 (71.4%)	157 (72%)	
Incomplete	5 (1%)	3 (1.4%)	
<b>TOTAL</b>	<b>494 (100%)</b>	<b>218 (100%)</b>	
<b>FOCALITY</b>			
Multifocal	117 (20.3%)	46 (17.8%)	
Unifocal	440 (76.2%)	208 (80.3%)	
Incomplete / not determined	20 (3.5%)	5 (1.9%)	
<b>TOTAL</b>	<b>577 (100%)</b>	<b>259 (100%)</b>	

Table 5. Tumour characteristics

<sup>1</sup> with (non)invasive breast carcinoma; CPR = complete pathological response, [ ] = number of patients received neo-adjuvant systemic treatment, <sup>2</sup> invasive cancers only, <sup>3</sup> hormone receptor expression was determined for 30 and 19 patients with DCIS, respectively; n/a = not applicable

	Number of patients	Percentage of patients
All complications	145	28.4%
<b>MAJOR COMPLICATIONS</b>		
Infection	16	3.1%
Haematoma	10	2%
Delayed wound healing	7	1.3%
Skin necrosis	5	1%
Fat necrosis	5	1%
Nipple necrosis	2	0.4%
Flap insertion delayed	1	0.2%
Pulmonary embolism	1	0.2%
TOTAL	47	9.2%
<b>MINOR COMPLICATIONS</b>		
Infection	27	5.3%
Delayed wound healing	21	4.1%
Haematoma	18	3.5%
Skin necrosis	16	3.2%
Fat necrosis	11	2.1%
Nipple necrosis	5	1%
TOTAL	98	19.2%

Table 6. Major and minor complications in 510 patients. 79 patients had incomplete data.