# A clinical investigation to develop an evidence base for the use of Breastlight in examining the breast

## Results

## FINAL Version 1.0

### December 2009

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# Contents

# Executive Summary

This study analysed 300 women in the Sunderland region who were referred by their GP to secondary care for breast assessment. The average age of women referred was 46 years (SD 15). A significant proportion were premenopausal (59%).

The major findings of the study are as follows:

- In terms of usage, breast light was found to be 'fairly easy to easy' to use (84%), with users 'fairly confident to confident' in its findings (88%)
- Breast light correlates well in terms of sensitivity and specificity when compared to imaging techniques such as Ultrasound and Mammography. This was also the case when compared to histology/cytology.
- The use of breast light is applicable to women irrespective of breast size

## Summary

Breastlight compares very well to Imaging and Histology. Less so with Clinical examination. However, Clinical examination has inherent problems due to the high number of false positives

# 1.0  Introduction

## 1.1  The dataset

The dataset comprised 300 subjects who were referred to the breast clinic in Sunderland for a variety of reasons.  All subjects had both breasts examined using Breastlight.  The researchers retrospectively identified the index breast for which women had been referred by her GP.  However, a number of women were referred with problems in both breasts.  For the purposes of analysis, if a woman was referred for problems with both breasts the index breast was identified as that which was biopsied or randomly chosen in all other cases.  The results for the primary analysis refer to the index breast only.

## 1.2  Statistical Analysis

The analysis of the data is largely descriptive using summary statistics and tables as appropriate.  Inter-rater reliability was performed on duplicate readings of photo assessments in a subset of 56 patients.  Agreement between assessment, ease of assessment and confidence in assessment was assessed using a simple kappa statistic.  Agreement between direct Breastlight assessment and photo assessment was assessed on the whole group using a simple kappa statistic.  Association between Breastlight result and results of other investigations (clinical, imaging, histological/cytological) was tested using Fishers exact test.  The utility of the Breastlight assessment compared with clinical diagnosis of a lump, imaging diagnosis of a lump and histological/cytological diagnosis of a lump was expressed using sensitivity, specificity, positive predictive value and negative predictive value.

## 1.3   Note on Interpretation of Results

It should be noted that whilst sensitivity and specificity do not vary according to prevalence of lump, positive predictive value and negative predictive value are highly dependent upon prevalence and therefore are not transferable to other situations where the prevalence of a lump may be different.

# 2.0   Characteristics of the Sample

## 2.1   Reason for Referral

Up to 3 reasons were listed for referral; if lump was listed as part of the reason for referral this was always listed as the primary reason.   Thus, primary reason for referral only has been summarised.   Table 1 shows that a lump was the primary reason for referral in 207 (69%) of cases.

### Table 1.  Primary Reason for referral

| Primary reason for referral | Freq. | Percent | Cum. |
|---|---|---|---|
| Lump | 207 | 69.00 | 69.00 |
| Pain | 50 | 16.67 | 85.67 |
| Nipple Discharge | 5 | 1.67 | 87.33 |
| Other | 36 | 12.00 | 99.33 |
| Missing | 2 | 0.67 | 100.00 |
| Total | 300 | 100.00 | |

## 2.2   Age

Average age was 46 years, SD 15 with a range from 19 to 88 years

## 2.3    Menopausal Status

### Table 2.  Menopausal Status

| Menopausal | Freq. | Percent | Cum. |
|---|---|---|---|
| Premenopausal | 177 | 59.00 | 59.00 |
| Perimenopausal | 17 | 5.67 | 64.67 |
| Postmenopausal | 92 | 30.67 | 95.33 |
| Not Known | 14 | 4.67 | 100.00 |
| Total | 300 | 100.00 | |

## 2.4    Drug Therapy

### Table 3.  Use of Oral Contraceptive Pill

| Drug therapy OCP | Freq. | Percent | Cum. |
|---|---|---|---|
| Current | 38 | 12.67 | 12.67 |
| Previous | 205 | 68.33 | 81.00 |
| Never | 55 | 18.33 | 99.33 |
| . | 2 | 0.67 | 100.00 |
| Total | 300 | 100.00 | |

### Table 4.  Use of Hormone Replacement Therapy

| Drug Therapy HRT | Freq. | Percent | Cum. |
|---|---|---|---|
| Current | 6 | 2.00 | 2.00 |
| Previous | 33 | 11.00 | 13.00 |
| Never | 261 | 87.00 | 100.00 |
| Total | 300 | 100.00 | |

## 2.5    Previous Breast Cancer

### Table 5.  Previous Mastectomy

| Previous Mastectomy | Freq. | Percent | Cum. |
|---|---|---|---|
| Right | 4 | 1.33 | 1.33 |
| Left | 2 | 0.67 | 2.00 |
| None | 294 | 98.00 | 100.00 |
| Total | 300 | 100.00 | |

### Table 6.  Previous Carcinoma of the Breast

| Previous CA Breast | Freq. | Percent | Cum. |
|---|---|---|---|
| Right | 6 | 2.00 | 2.00 |
| Left | 4 | 1.33 | 3.33 |
| None | 290 | 96.67 | 100.00 |
| Total | 300 | 100.00 | |

6 women in the study sample had a previous mastectomy in the non-index breast; 10 women had a previous breast carcinoma (3 in the index breast, 7 in the non-index breast)

## 2.6  Breast size

<u>Table 7.  Cup Size</u>

| Cup size | Freq. | Percent | Cum. |
|---|---|---|---|
|  | 13 | 4.33 | 4.33 |
| A | 28 | 9.33 | 13.67 |
| B | 59 | 19.67 | 33.33 |
| C | 73 | 24.33 | 57.67 |
| D | 51 | 17.00 | 74.67 |
| DD | 42 | 14.00 | 88.67 |
| E | 14 | 4.67 | 93.33 |
| EE | 1 | 0.33 | 93.67 |
| F | 6 | 2.00 | 95.67 |
| FF | 7 | 2.33 | 98.00 |
| G | 1 | 0.33 | 98.33 |
| GG | 2 | 0.67 | 99.00 |
| H | 1 | 0.33 | 99.33 |
| HH | 2 | 0.67 | 100.00 |
| Total | 300 | 100.00 | |

**Cup size was missing for 13 women.**

# 3.0  Clinical Findings

## 3.1    Lump on Presentation

The surgeon noted that 161 (54%) women had a lump on presentation.


### Table 8.  Lump on Presentation

```
  Lump on  |
presentatio|
         n |   Freq.       Percent        Cum.
-----------+---------------------------------------
       Yes |     161        53.67        53.67
        No |     138        46.00        99.67
         . |       1         0.33       100.00
-----------+---------------------------------------
     Total |     300       100.00
```


## 3.2    Clinic Findings


### Table 9.  Clinical Findings

```
Clinical Findings|
   in Index Breast|   Freq.       Percent        Cum.
-----------------+---------------------------------------
           Normal|     40        13.33        13.33
           Benign|     49        16.33        29.67
   Probably Benign|    162        54.00        83.67
Probably Malignant|     36        12.00        95.67
        Malignant|      8         2.67        98.33
          missing|      5         1.67       100.00
-----------------+---------------------------------------
            Total|    300       100.00
```

## Table 10. Mammogram Findings

| Grade of Mammogram of Index Breast | Lump on Mammogram of Index Breast | | | | Total |
|---|---|---|---|---|---|
| | Not Done | Yes | No | missing | |
| Normal | 0 | 5 | 101 | 0 | 106 |
| Benign | 0 | 52 | 34 | 0 | 86 |
| Probably Benign | 0 | 9 | 0 | 0 | 9 |
| Probably Malignant | 0 | 9 | 0 | 0 | 9 |
| Malignant | 0 | 11 | 0 | 0 | 11 |
| missing | 72 | 3 | 3 | 1 | 79 |
| Total | 72 | 89 | 138 | 1 | 300 |

## Table 11. Ultrasound Findings

| Grade of Ultrasound of Index Breast | Lump on Ultrasound of Index Breast | | | | Total |
|---|---|---|---|---|---|
| | Not Done | Yes | No | missing | |
| Normal | 0 | 13 | 107 | 0 | 120 |
| Benign | 0 | 78 | 36 | 0 | 114 |
| Probably Benign | 0 | 12 | 0 | 0 | 12 |
| Probably Malignant | 0 | 8 | 0 | 0 | 8 |
| Malignant | 0 | 13 | 0 | 0 | 13 |
| missing | 23 | 4 | 5 | 1 | 33 |
| Total | 23 | 128 | 148 | 1 | 300 |

## Table 12. Aspirations/Biopsies

| Aspiration/Biopsy | Result of Aspiration/Biopsy | | | | Total |
|---|---|---|---|---|---|
| | Benign | Malignant | No Biopsy | missing | |
| Not Done | 0 | 0 | 241 | 0 | 241 |
| Cytology | 24 | 1 | 0 | 0 | 25 |
| Histology | 13 | 16 | 0 | 0 | 29 |
| Cytology and Histolog | 3 | 1 | 0 | 0 | 4 |
| Missing | 0 | 0 | 0 | 1 | 1 |
| Total | 40 | 18 | 241 | 1 | 300 |

The surgeon considered that 44 women had a lump that was probably malignant or malignant. 227 women had a mammogram of which 89 revealed a lump; of those 89, 20 were scored as being probably malignant or malignant. 276 women had an ultrasound of which 128 revealed a lump; of those 128 lumps 21 were scored as probably malignant or malignant.

Those 20 women with a lump scored as being probably malignant or malignant on mammogram were also scored as being probably malignant or malignant on ultrasound; the 21st probably malignant or malignant lump on ultrasound had a missing mammogram finding. 58 aspiration or biopsy investigations were performed; 18 cancers were diagnosed. Of these, 17 were graded as probably malignant or malignant on ultrasound and 16 were graded as probably malignant or malignant on mammogram.

# 4.0 Analysis of Breastlight Assessment – Index Breast

## 4.1 Intra-Rater Reliability of Overall Assessment of Photos

Duplicate assessments of the photos were available for 56 subjects.

Table 13.  Agreement on Assessment of Breastlight Photos

```
                       Photos
                     positive?
Photos               2nd Read
positive?
1st Read             Yes     No
─────────────────────────────────
         Yes          6       5
          No          1      44
```

Table 14.  Kappa for Agreement on Assessment of Breastlight Photos

| Agreement | Expected Agreement | Kappa | Std. Err. | Z | Prob>Z |
|-----------|--------------------|-------|-----------|---|--------|
| 89.29% | 72.77% | 0.6066 | 0.1290 | 4.70 | 0.0000 |

There was substantial agreement overall for whether photos were classified as positive or negative; 50 of the 56 photos (89%) were classified the same for both reads yielding a kappa of 0.61

## 4.2 Intra-Rater Reliability of Confidence in Assessment of Photos

### Table 15.  Agreement on Confidence of Assessment of Breastlight Photos

| Confidence 1st Read | Confidence 2nd Read | | | Total |
|---|---|---|---|---|
| | Confident | Fairly Co | Fairly Un | |
| Confident | 24 | 5 | 1 | 30 |
| Fairly Confident | 10 | 7 | 2 | 19 |
| Fairly Unsure | 3 | 1 | 0 | 4 |
| Unsure | 0 | 1 | 2 | 3 |
| Total | 37 | 14 | 5 | 56 |

### Table 16.  Kappa for Agreement on Confidence of Assessment of Breastlight Photos

| Agreement | Expected Agreement | Kappa | Std. Err. | Z | Prob>Z |
|---|---|---|---|---|---|
| 55.36% | 44.52% | 0.1954 | 0.0990 | 1.97 | 0.0242 |

There was slight agreement overall for the confidence with which photos were classified as positive or negative;  agreement was reached for 31 of 56 photos which were rated twice (55%) yielding a kappa of 0.20.

## 4.3 Intra-Rater Reliability of Ease of Assessment of Photos

### Table 17. Agreement on Ease of Assessment of Breastlight Photos

| Ease 1st read | Ease 2nd read | | | Total |
|---|---|---|---|---|
| | Easy | Fairly Ea | Fairly Di | |
| Easy | 26 | 4 | 3 | 33 |
| Fairly Easy | 7 | 6 | 0 | 13 |
| Fairly Difficult | 2 | 4 | 2 | 8 |
| Difficult | 0 | 1 | 1 | 2 |
| Total | 35 | 15 | 6 | 56 |

### Table 18. Kappa for Agreement on Ease of Assessment of Breastlight Photos

| Agreement | Expected Agreement | Kappa | Std. Err. | Z | Prob>Z |
|---|---|---|---|---|---|
| 60.71% | 44.58% | 0.2911 | 0.0972 | 3.00 | 0.0014 |

There was fair agreement overall for the ease with which the photos were classified as positive or negative; agreement was reached for 34 of 56 photos (61%) yielding a kappa of 0.29.

Although assessments were made of each breast, the confidence and ease ratings were made for a woman overall rather than for each breast. Thus, interpretation of these results is difficult although the overall assessment is likely to reflect the confidence/ease of the hardest assessment. In addition, rating the confidence in assessment and ease of assessment yield unacceptable levels of disagreement within one rater and therefore do not appear to be useful.

## 4.4 Breastlight Results

### Table 19. Overall Breastlight Results (Index Breast)

| Breastlight + in Index Breast | Freq. | Percent | Cum. |
|---|---|---|---|
| Yes | 54 | 18.00 | 18.00 |
| No | 246 | 82.00 | 100.00 |
| Total | 300 | 100.00 | |

### Table 20. Confidence in Breastlight Assessment (Overall)

| Confidence | Freq. | Percent | Cum. |
|---|---|---|---|
| Confident | 33 | 11.00 | 11.00 |
| Fairly Confident | 230 | 76.67 | 87.67 |
| Fairly Unsure | 37 | 12.33 | 100.00 |
| Total | 300 | 100.00 | |

### Table 21. Ease of Breastlight Assessment (Overall)

| Ease | Freq. | Percent | Cum. |
|---|---|---|---|
| Easy | 39 | 13.00 | 13.00 |
| Fairly Easy | 213 | 71.00 | 84.00 |
| Fairly Difficult | 45 | 15.00 | 99.00 |
| Difficult | 3 | 1.00 | 100.00 |

54 (18%) index breasts were rated as positive by Breastlight. Assessments of confidence and ease were made overall rather than by index breast so will be summarised only. 266 (88%) of assessments were rated as fairly confident or confident; 252 (84%) of assessments were rated as easy or fairly easy.

## 4.5    Comparison of Breastlight Assessment with Photo Assessment

**Table 22.    Agreement between Breastlight Assessment and Photo Assessment**

<mark>Results to Follow</mark>

**Table 23.    Kappa for agreement between Breastlight Assessment and Photo Assessment**

Results to Follow

## 4.6 Comparison of Breastlight Assessment with Clinical Assessment

Table 24. Comparison of Clinical Findings and Breastlight Findings

| Clinical Findings in Index Breast | Breastlight + in Index Breast | | Total |
| --- | --- | --- | --- |
| | Yes | No | |
| Normal | 4 | 36 | 40 |
| | 10.00 | 90.00 | 100.00 |
| Benign | 3 | 46 | 49 |
| | 6.12 | 93.88 | 100.00 |
| Probably Benign | 24 | 138 | 162 |
| | 14.81 | 85.19 | 100.00 |
| Probably Malignant | 15 | 21 | 36 |
| | 41.67 | 58.33 | 100.00 |
| Malignant | 7 | 1 | 8 |
| | 87.50 | 12.50 | 100.00 |
| missing | 1 | 4 | 5 |
| | 20.00 | 80.00 | 100.00 |
| Total | 54 | 246 | 300 |
| | 18.00 | 82.00 | 100.00 |

Of the 44 lumps that are coded as 'probably malignant or malignant', Breastlight is positive in 22 (50%); in the remaining 256 lumps, Breastlight is negative in 224 (88%).

## 4.7    Comparison of Breastlight Assessment with US Assessment

### Table 25.  Comparison of Ultrasound Findings and Breastlight Findings

| Grade of Ultrasound of Index Breast | Breastlight + in Index Breast Yes | No | Total |
|---|---|---|---|
| Normal | 12 10.00 | 108 90.00 | 120 100.00 |
| Benign | 21 18.42 | 93 81.58 | 114 100.00 |
| Probably Benign | 3 25.00 | 9 75.00 | 12 100.00 |
| Probably Malignant | 5 62.50 | 3 37.50 | 8 100.00 |
| Malignant | 7 53.85 | 6 46.15 | 13 100.00 |
| missing | 6 18.18 | 27 81.82 | 33 100.00 |
| Total | 54 18.00 | 246 82.00 | 300 100.00 |

There was a significant association between ultrasound grade and Breastlight result (P<0.001, Fisher's exact test)

## 4.8 Comparison of Breastlight Assessment with Mammogram Assessment

Table 26. Comparison of Mammogram Findings and Breastlight Findings

| Grade of Mammogram of Index Breast | Breastlight + in Index Breast | | |
|---|---|---|---|
| | Yes | No | Total |
| Normal | 11<br>10.38 | 95<br>89.62 | 106<br>100.00 |
| Benign | 16<br>18.60 | 70<br>81.40 | 86<br>100.00 |
| Probably Benign | 4<br>44.44 | 5<br>55.56 | 9<br>100.00 |
| Probably Malignant | 6<br>66.67 | 3<br>33.33 | 9<br>100.00 |
| Malignant | 5<br>45.45 | 6<br>54.55 | 11<br>100.00 |
| missing | 12<br>15.19 | 67<br>84.81 | 79<br>100.00 |
| Total | 54<br>18.00 | 246<br>82.00 | 300<br>100.00 |

**There was a significant association between mammogram grade and Breastlight result (P<0.001, Fisher's exact test)**

## 4.9    Comparison of Breastlight with Imaging Results

21 lumps were indicated as being probably malignant or malignant by both ultrasound and mammography; of these Breastlight was positive in 12 giving an estimated sensitivity of 57% (95% CI 34% to 78%).  Of the remaining 279 lumps, 237 were negative on Breastlight giving a specificity of 85% (95% CI 80% to 89%).  The positive predictive value is estimated as 22% (95% CI 12 to 36%) and the negative predictive value is estimated as 96% (95% CI 93 to 98%)

## 4.10 Comparison of Breastlight Assessment with Cytology/Histology Result

<u>Table 27. Comparison of Cytology/Histology Test performed and Breastlight Findings</u>

```
Aspiration      Breastlight + in
 or biopsy       Index Breast
performed?        Yes        No        Total
───────────────────────────────────────────
        No         35       206          241
                14.52     85.48       100.00
───────────────────────────────────────────
       Yes         19        39           58
                32.76     67.24       100.00
───────────────────────────────────────────
   missing          0         1            1
                 0.00    100.00       100.00
───────────────────────────────────────────
     Total         54       246          300
                18.00     82.00       100.00
```

Of the 58 breasts that underwent aspiration/biopsy, 19 were positive on Breastlight (33%)

## Table 28. Comparison of Cytology/Histology Test Results and Breastlight Findings

| Result of Aspiration /Biopsy | Breastlight + in Index Breast | | Total |
|---|---|---|---|
| | Yes | No | |
| Benign | 7 | 33 | 40 |
| | 17.50 | 82.50 | 100.00 |
| Malignant | 12 | 6 | 18 |
| | 66.67 | 33.33 | 100.00 |
| No Biopsy | 35 | 206 | 241 |
| | 14.52 | 85.48 | 100.00 |
| missing | 0 | 1 | 1 |
| | 0.00 | 100.00 | 100.00 |
| Total | 54 | 246 | 300 |
| | 18.00 | 82.00 | 100.00 |

There was a significant association between cytological/histological findings and Breastlight result (P<0.001, Fisher's exact test)

Breastlight performs well against cytological/histological findings; 12 of 18 malignant tumours were detected using Breastlight giving a sensitivity of 67% (95% confidence interval 41% to 87%). 240 of 282 breasts with no malignancy found were correctly identified as negative giving a specificity of 85% (95% confidence interval 80% to 89%). Of the 54 positive results given by Breastlight, 12 turned out to be malignant tumours giving a positive predictive value of 22% (95% confidence interval 12% to 36%). Of the 246 negative results given by Breastlight only 6 turned out to be malignant tumours giving a negative predictive value of 98% (95% confidence interval 95% to 99%)

## 4.11 Influence of Cup-Size

<u>Table 29. Relationship between Breastlight Result and cupsize (all index Breasts)</u>

| cupsize1 | Breastlight + in Index Breast | | |
|---|---|---|---|
| | No | Yes | Total |
| A | 23<br>82.14 | 5<br>17.86 | 28<br>100.00 |
| B | 50<br>84.75 | 9<br>15.25 | 59<br>100.00 |
| C | 62<br>84.93 | 11<br>15.07 | 73<br>100.00 |
| D | 40<br>78.43 | 11<br>21.57 | 51<br>100.00 |
| DD | 32<br>76.19 | 10<br>23.81 | 42<br>100.00 |
| E or larger | 28<br>82.35 | 6<br>17.65 | 34<br>100.00 |
| Total | 235<br>81.88 | 52<br>18.12 | 287<br>100.00 |

> Percentage of positive Breastlight results does not appear to be related to cup size in all breasts (malignant and non-malignant).

## Table 30. Relationship between Breastlight Result and cupsize (all malignant lumps

| cupsize1 | Breastlight + in Index Breast | | |
| --- | --- | --- | --- |
| | No | Yes | Total |
| A | 0<br>0.00 | 2<br>100.00 | 2<br>100.00 |
| B | 2<br>33.33 | 4<br>66.67 | 6<br>100.00 |
| C | 1<br>25.00 | 3<br>75.00 | 4<br>100.00 |
| D | 2<br>50.00 | 2<br>50.00 | 4<br>100.00 |
| DD | 1<br>100.00 | 0<br>0.00 | 1<br>100.00 |
| Total | 6<br>35.29 | 11<br>64.71 | 17<br>100.00 |

There are too few malignant breastlumps in order to make a sensible assessment as to whether cupsize is associated with Breastlight result in malignant lumps

## 4.12  Influence of Lump Size

### Table 31. Clinical Estimate of Size tablulated by Clinical findings

| Clinical Findings in Index Breast | Clinical Size Categories | | | | | |
|---|---|---|---|---|---|---|
| | 0 to 0.9 | 1 to 1.9 | 2 to 2.9 | 3 to 3.9 | 4 to 4.9 | Tota |
| Benign | 1<br>33.33 | 0<br>0.00 | 2<br>66.67 | 0<br>0.00 | 0<br>0.00 | 100.00 |
| Probably Benign | 7<br>25.00 | 9<br>32.14 | 9<br>32.14 | 3<br>10.71 | 0<br>0.00 | 2<br>100.00 |
| Probably Malignant | 0<br>0.00 | 1<br>20.00 | 1<br>20.00 | 2<br>40.00 | 1<br>20.00 | 100.00 |
| Malignant | 0<br>0.00 | 0<br>0.00 | 3<br>100.00 | 0<br>0.00 | 0<br>0.00 | 100.00 |
| Total | 8<br>20.51 | 10<br>25.64 | 15<br>38.46 | 5<br>12.82 | 1<br>2.56 | 3<br>100.00 |

A clinical estimate of size of lump was provided in only 39 cases and it was not specified to which breast the size pertained.

### Table 32  Summary of Imaging Size by Clinical Size Category

| Clinical Size Categories | med(size) | min(size) | max(size) | Freq. |
|---|---|---|---|---|
| 0 to 0.9 cm | 2.5 | 0 | 11 | 8 |
| 1 to 1.9 cm | 7 | 0 | 35 | 10 |
| 2 to 2.9 cm | 11 | 0 | 35 | 15 |
| 3 to 3.9 cm | 0 | 0 | 55 | 5 |
| 4 to 4.9 cm | 0 | 0 | 0 | 1 |

An imaging size was estimated (either ultrasound or mammogram) for 115 lumps.  Table 32 shows median, minimum and maximum size estimated by imaging tabulated by clinical size category.  The results indicate poor agreement between clinical size and imaging size for the 39 breasts in which a clinical size was estimated.  Imaging size was generally much larger than that estimated by the surgeon.  Clinical estimate of size appears to be of little value and no further analysis of clinical size is presented.

## Table 33.  Summary of Imaging Size by Breastlight Result

| Breastlight + in Index Breast | med(size) | min(size) | max(size) | Freq. |
|---|---|---|---|---|
| No | 11 | 0 | 45 | 84 |
| Yes | 18 | 0 | 55 | 31 |

Note:  Imaging size was not available for 2 Breastlight positive breasts thus summary statistics relate only to 29 Breastlight positive breasts

An imaging size was provided for 115 breasts;  of these 84 (73%) were Breastlight negative and 31 (27%) were Breastlight positive.  Breastlight positive lumps were significantly larger than Breastlight negative lumps (P=0.02, Kruskal Wallis Test); Breastlight positive lumps were on average 18mm compared with Breastlight negative lumps which were 11mm on average.

## Table 33. Summary of Imaging Size by Breastlight Result – Malignant lumps only

| Breastlight + in Index Breast | med(size) | min(size) | max(size) | Freq. |
|---|---|---|---|---|
| No | 23.5 | 16 | 36 | 6 |
| Yes | 26.5 | 7 | 38 | 12 |

In the subgroup of 18 malignant lumps, there was no significant different between the size of lump picked up by Breastlight (median 26.5mm) and the size of lump not picked up by Breastlight (median 23.5mm) (P=0.9, Kruskal-Wallis Test)

## 4.13  Influence of Type of Tumour

**Table 34.  Type of Tumour by Breastlight Result – Malignant lumps only**

| Type of Cancer | Breastlight + in Index Breast No | Yes | Total |
|---|---|---|---|
| Ductal | 4 36.36 | 7 63.64 | 11 100.00 |
| Lobular | 1 25.00 | 3 75.00 | 4 100.00 |
| Mixed | 1 100.00 | 0 0.00 | 1 100.00 |
| Non-Hodgkins Lymphoma | 0 0.00 | 1 100.00 | 1 100.00 |
| Papillary | 0 0.00 | 1 100.00 | 1 100.00 |
| Total | 6 33.33 | 12 66.67 | 18 100.00 |

> With so few malignant lumps in the sample it is impossible to identify any association between type of cancer and Breastlight result;  the results do not suggest any obvious patterns.

## 4.14 Influence of Menopausal Status

### Table 35.  Relationship between Menopausal Status and Breastlight Result

| Menopausal | Breastlight + in Index Breast | | Total |
| | No | Yes | |
| --- | --- | --- | --- |
| Premenopausal | 153<br>86.44 | 24<br>13.56 | 177<br>100.00 |
| Perimenopausal | 15<br>88.24 | 2<br>11.76 | 17<br>100.00 |
| Postmenopausal | 66<br>71.74 | 26<br>28.26 | 92<br>100.00 |
| Not Known | 12<br>85.71 | 2<br>14.29 | 14<br>100.00 |
| Total | 246<br>82.00 | 54<br>18.00 | 300<br>100.00 |

Fisher's exact =                     0.027

Breastlight was significantly more likely to give a positive result in postmenopausal women (P=0.03, Fisher's exact test).  However, since 15 of the 18 malignant tumours were in postmenopausal women so this may be expected.

## Table 36.  Relationship between Menopausal Status and Breastlight Result – Malignant tumours only

| Menopausal | Breastlight + in Index Breast | | Total |
| --- | --- | --- | --- |
| | No | Yes | |
| Premenopausal | 1 | 2 | 3 |
| | 33.33 | 66.67 | 100.00 |
| Postmenopausal | 5 | 10 | 15 |
| | 33.33 | 66.67 | 100.00 |
| Total | 6 | 12 | 18 |
| | 33.33 | 66.67 | 100.00 |

Fisher's exact =            1.000

Of the 18 women with malignant tumours, 15 were postmenopausal.  Thus no sensible assessment of Breastlight result and menopause can be done in the subgroup;  the data suggest no obvious association (Fisher's exact test P=1.0)

## 4.15  Influence of Drug Therapy

**Table 37.  Relationship between Oral Contraceptive Pill and Breastlight Result**

| Drug therapy OCP | Breastlight + in Index Breast | | Total |
|---|---|---|---|
| | No | Yes | |
| Current | 33 | 5 | 38 |
| | 86.84 | 13.16 | 100.00 |
| Previous | 170 | 35 | 205 |
| | 82.93 | 17.07 | 100.00 |
| Never | 41 | 14 | 55 |
| | 74.55 | 25.45 | 100.00 |
| Total | 244 | 54 | 298 |
| | 81.88 | 18.12 | 100.00 |

Fisher's exact =                          0.258

There is no obvious relationship between use of the oral contraceptive pill and Breastlight result.

## Table 38.  Relationship between Oral Contraceptive Pill and Breastlight Result – Malignant tumours only

| Drug therapy OCP | Breastlight + in Index Breast No | Yes | Total |
|---|---|---|---|
| Previous | 4 40.00 | 6 60.00 | 10 100.00 |
| Never | 2 25.00 | 6 75.00 | 8 100.00 |
| Total | 6 33.33 | 12 66.67 | 18 100.00 |

Fisher's exact =                0.638

There is no association between use of the oral contraceptive pill and Breastlight result in the subgroup of malignant tumours (P=0.64, Fisher's exact test).

## Table 39.   Relationship between Hormone Replacement Therapy and Breastlight Result

```
      Drug  |  Breastlight + in
   Therapy  |    Index Breast
       HRT  |     No       Yes  |      Total
-----------+--------------------+-----------
   Current  |      5        1   |         6
           |  83.33     16.67   |    100.00
-----------+--------------------+-----------
  Previous  |     23       10   |        33
           |  69.70     30.30   |    100.00
-----------+--------------------+-----------
     Never  |    218       43   |       261
           |  83.52     16.48   |    100.00
-----------+--------------------+-----------
     Total  |    246       54   |       300
           |  82.00     18.00   |    100.00

          Fisher's exact =                0.156
```

There is no association between use of hormone replacement therapy and Breastlight result (P=0.16, Fisher's exact test).

## Table 40.  Relationship between Hormone Replacement Therapy and Breastlight Result – Malignant Tumours

| Drug Therapy HRT | Breastlight + in Index Breast | | Total |
|---|---|---|---|
| | No | Yes | |
| Previous | 1 | 3 | 4 |
| | 25.00 | 75.00 | 100.00 |
| Never | 5 | 9 | 14 |
| | 35.71 | 64.29 | 100.00 |
| Total | 6 | 12 | 18 |
| | 33.33 | 66.67 | 100.00 |

Fisher's exact =                    1.000

There is no association between use of hormone replacement therapy and Breastlight result in malignant tumours (P=1.0, Fisher's exact test).

# 5.0 Analysis of Breastlight Assessment – Non-Index Breast

220 non-index breasts were examined with Breastlight; of these 7 (3.2%) were positive (presumed false positive). Of the 7, 2 were also positive for the index breast.

## 6.0 Conclusions

Breastlight assessment appears to provide some useful information. Assessment of confidence in result or ease of decision making were not reproducible and therefore appear to be of little value. Data were not available at the time of analysis to assess the agreement between the direct Breastlight assessment and the photo assessment.

Breastlight results did not correlate well with clinical assessment but the value of the clinical assessment (in the absence of further imaging or diagnostic testing) is questionable and thus one might not expect a strong relationship. Estimates of sensitivity and specificity compared with the imaging results were good, as were estimates of sensitivity and specificity compared with histology/cytology.

Breastlight assessments did not appear to be dependent upon bra cupsize, use of hormone replacement therapy or the oral contraceptive pill. Postmenopausal women were significantly more likely to have a positive Breastlight result overall, as were women with larger sized lumps. It is impossible to say whether menopausal status or lump size influence the results of Breastlight in the subgroup of malignant lumps because the sample of malignant lumps is so small.

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