

breastlight™

- An Introduction to Breastlight

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Breast Cancer facts

- Breast cancer is the UK's most common form of cancer and 1 in 9 women will be diagnosed with breast cancer in their lifetime
- Breast cancer survival rates are improving; 5 year survival rates have increased from 5/10 women in the 1970s to 8/10 women today

BUT

- Awareness through self examination of the breasts is low
 - Only 35-40% of women regularly check their breasts for any changes or abnormalities
 - Only 40% of women feel confident regarding the correct way to examine their breasts
- Early detection is vital - 9/10 women diagnosed with Stage I cancer survive beyond 5 years compared with 1/10 women with Stage IV cancer

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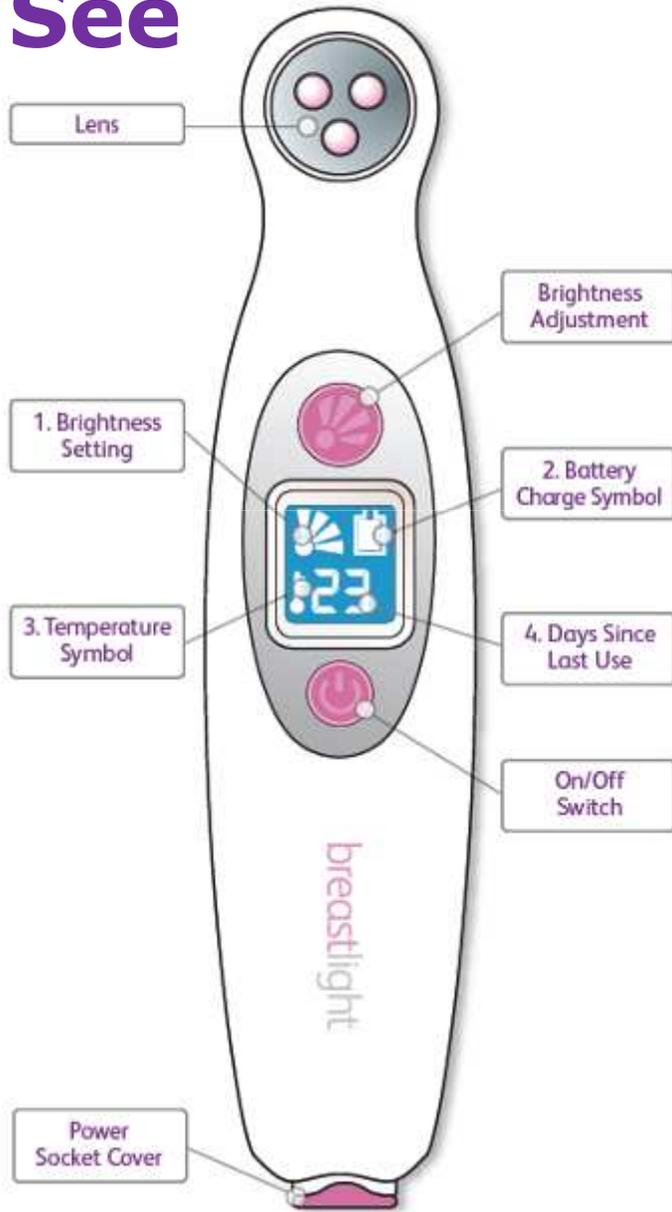
Breastlight: for earlier detection

- Breastlight is a new product that allows women to see inside their breasts
- It works by shining a powerful light through the breast tissue
- It is completely safe and easy to use
- Over 80% of women have told us they feel more confident when using Breastlight as part of their breast awareness routine
- We call this **enlightened** breast awareness



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Try it and See



Touch sensor technology

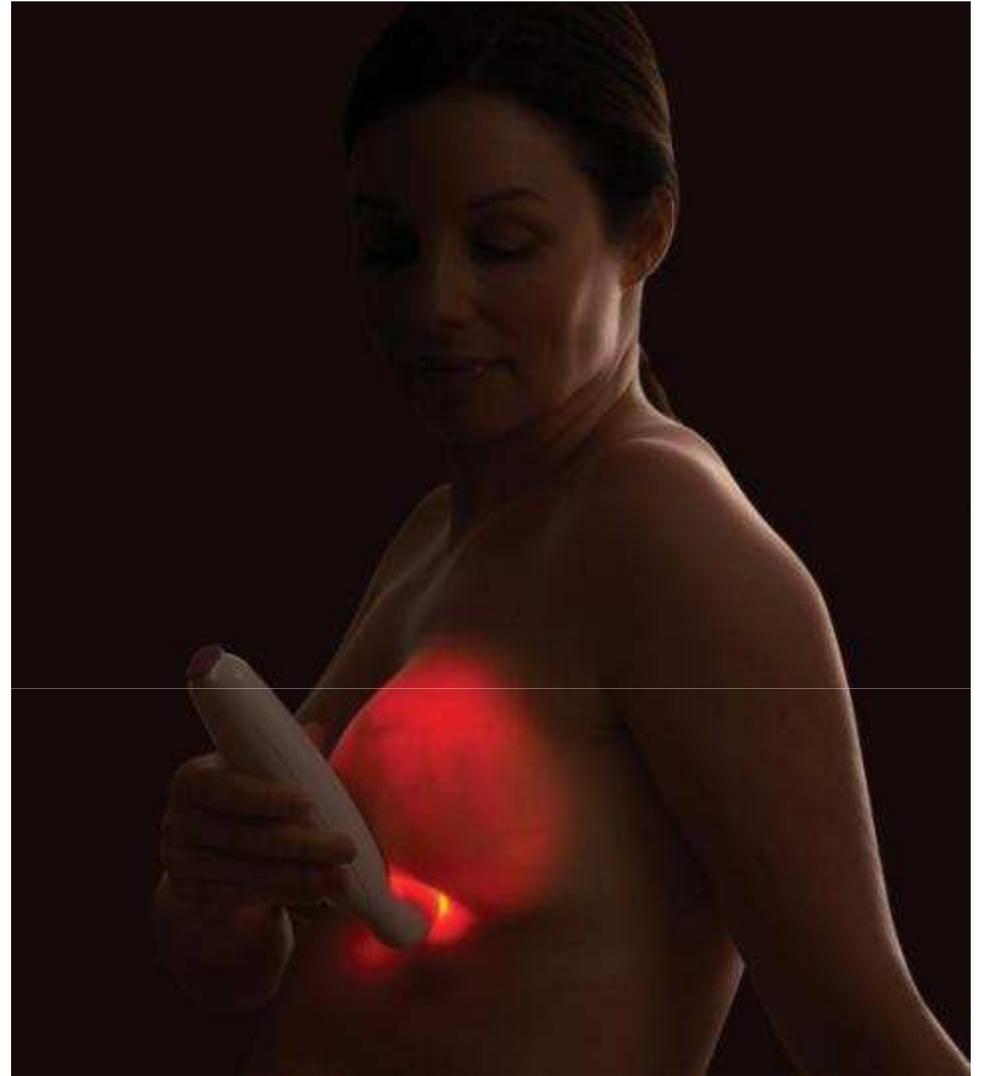
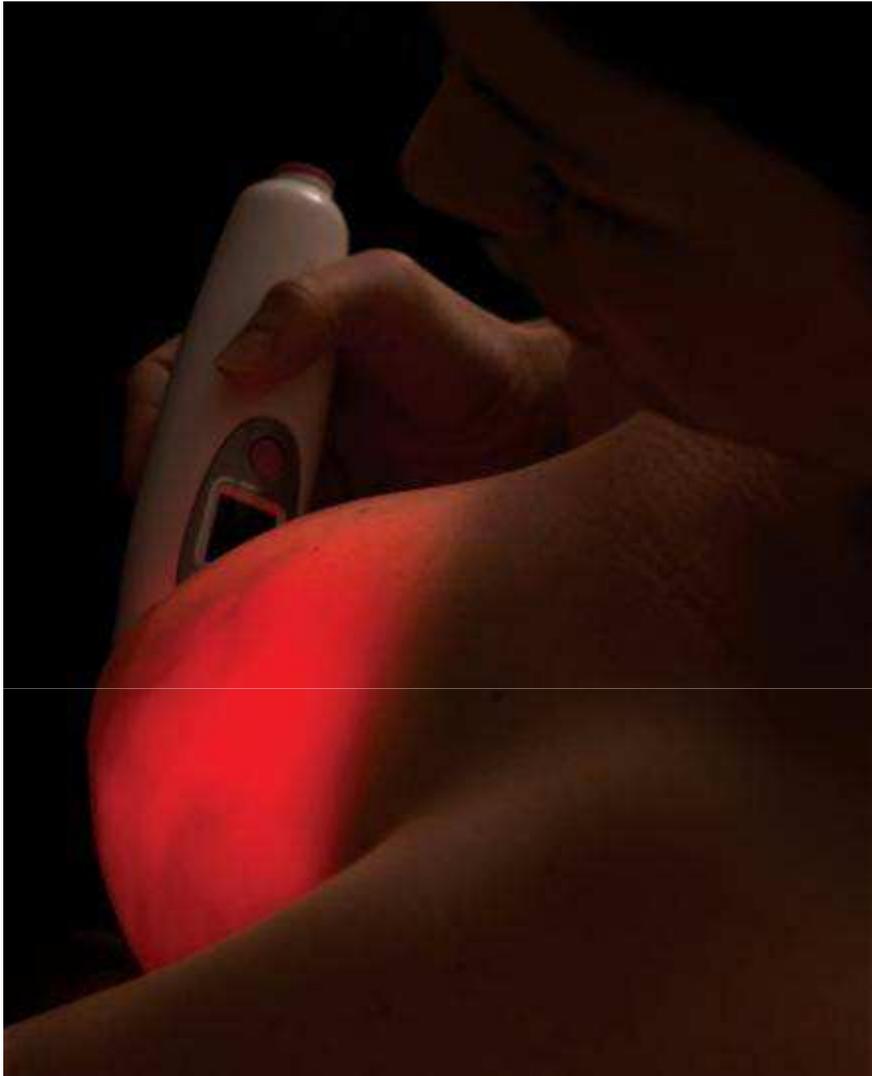
Rechargeable battery



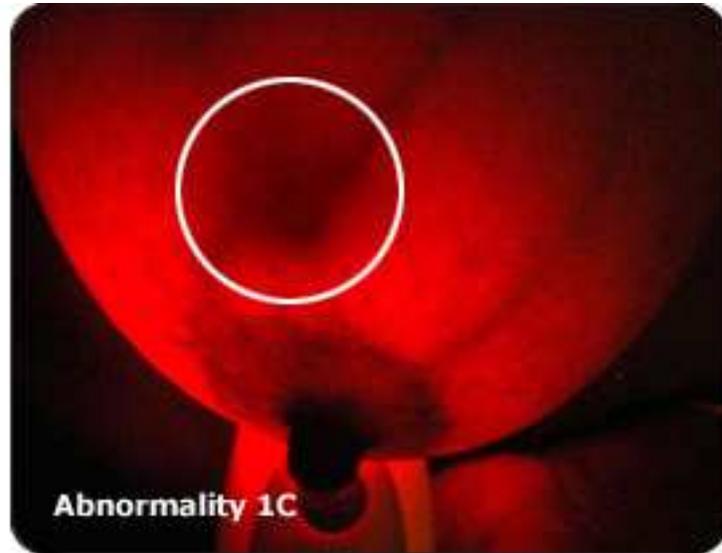
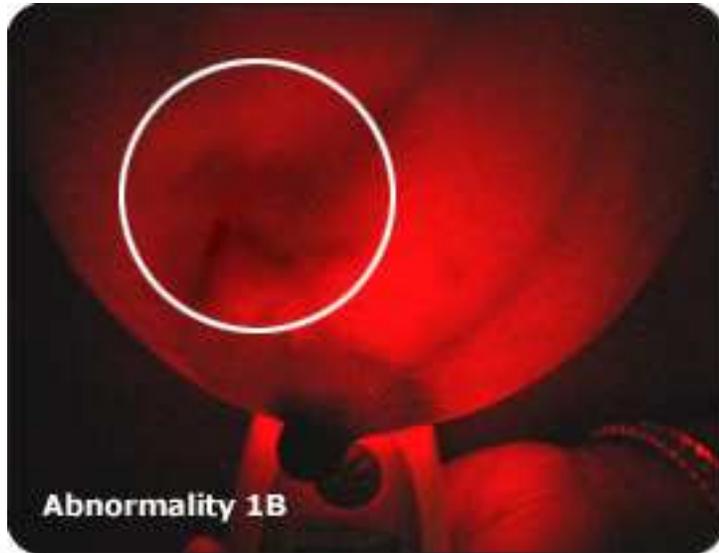
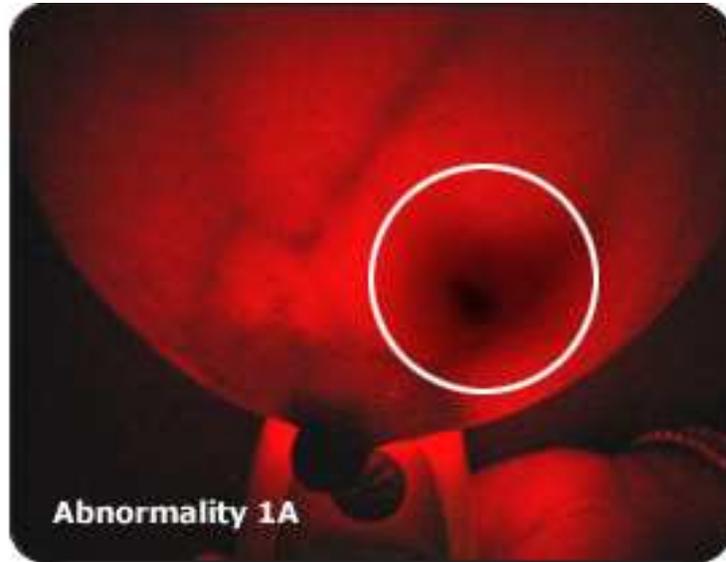
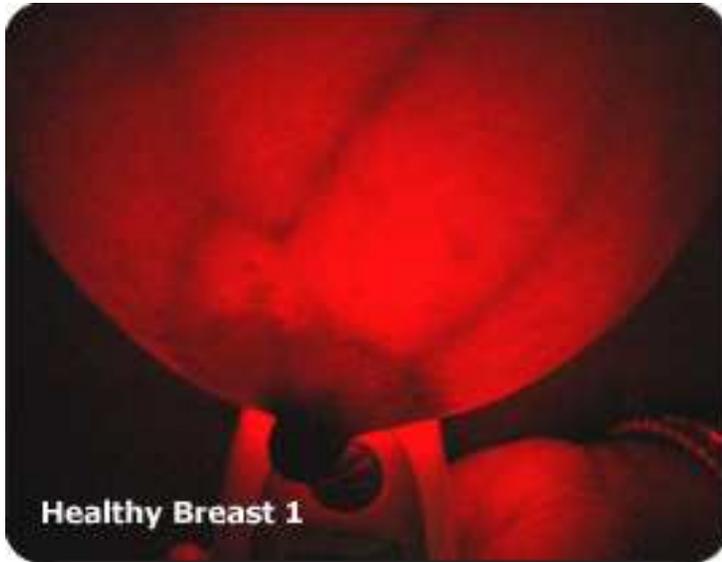
How does Breastlight work?

- It is used in a darkened room and held tightly to the skin
- The transmission of the red light illuminates the breast and allows the woman to see some detail inside the breast
- The red light is absorbed by any blood present:
 - in the normal blood supply vessels
 - where an abnormality has caused a concentration of vessels or an aggregation of blood
(e.g. a blood filled cyst, abscess or haematoma)
- The red light passes through normal tissue, non blood filled cysts and breast implants

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Features

- Handheld unit
- Intuitive to use
- 2 buttons-on/off & brightness
- Varying brightness, rechargeable battery
- Class 1 medical device
- C.E. Marked



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Breastlight clinical support

There have been 3 clinical trials – Edinburgh 1986, Aberdeen 1995, Sunderland 2009

These trials consistently show Breastlight can detect malignant tumours

- Breastlight detection rate of malignant tumours is between 67%² & 73%¹
(Mammography screening detection rates vary from 60% – 90%³ depending on age/breast density)
- Tumour sizes as small as 0.7cm were detected²
- 29% of non palpable tumours were detected¹
(Generally accepted that clinicians can palpate tumours from 1cm, women at home can palpate from 2cm.⁵)
- Age, menopausal status, breast size and density do not effect Breastlight performance²
(Mammography is less effective in women with denser breast tissue⁴. Its not used on women under 35 in the UK)
- Benign lesions (e.g. fibrous cysts) generally do not show up as positive with Breastlight
(Fibrous cysts, which are benign & often recurrent, can be felt by women self palpating)
- Breastlight is comparable to mammography in correctly confirming no presence of cancer (specificity of Breastlight 82%¹ – 85%² vs 75% – 95%³ for mammography)

Note: Breastlight is for women to use at home & is not a substitute for mammography

¹ Brittenden J Watmough D.J. Heys S.D. and Eremin O. [1995] Preliminary clinical evaluation of a combined optical Doppler ultrasound instrument for the detection of breast cancer. Brit. J. Radiol. 68, 1344 – 1348.

² “A Clinical Investigation to Develop an Evidence Base for the use of Breastlight in examining the Breast” City Hospitals Sunderland awaiting publication

³ Kavanagh et al (2000) The sensitivity, specificity, and positive predictive value of screening mammography and symptomatic status, Journal of medical screening

⁴ Kavanagh et al (2008) Using mammographic density to improve breast cancer screening outcomes, Cancer Epidemiology, Biomarkers & Prevention Canadian Cancer society

⁵ Canadian Cancer society

Sunderland Trial photography



Patient 85 - 2.2 cm tumour



Patient 85 - contra lateral



Patient 99 - 3.6 cm tumour

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Comparable results for the target group of 35-50 year old women

Breastlight is aimed for women to use at home & is primarily aimed at women who are currently not part of the national screening programme (35-50)

Using published data on positive & negative predictive values on breast self examination, mammography & Breastlight the following can be estimated:

For every cancer correctly identified:

- There will be 333 false positive results of breast self-examinations
- There will be 53 false positive results of Breastlight examinations
- There will be 14 false positive results of mammography examinations

For every 1000 examinations with a negative result:

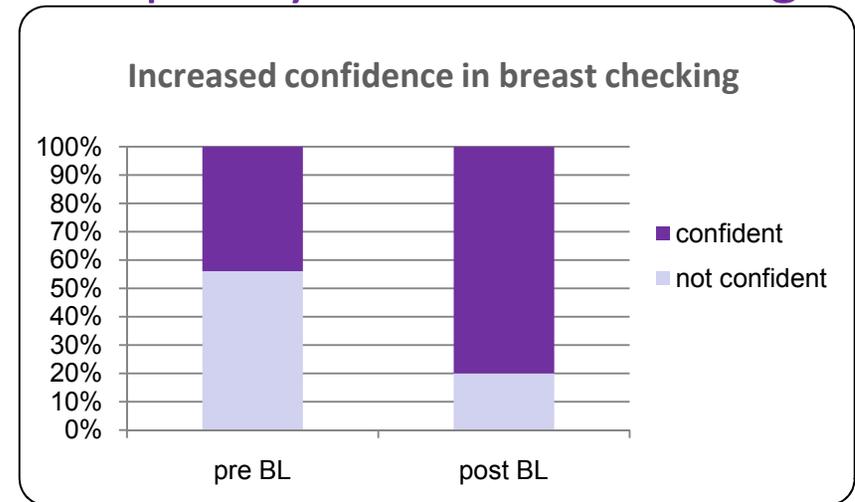
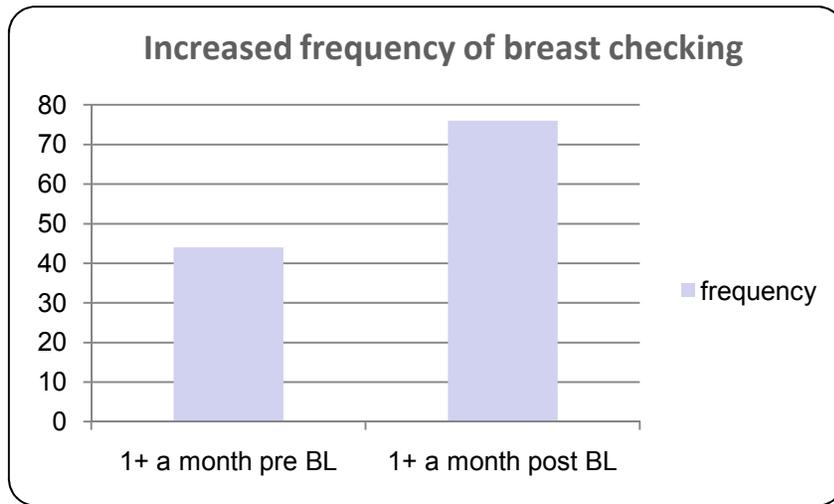
- There will be 6 cancers missed by breast self examination
- There will be 2 cancers missed by Breastlight examination
- There will be 1 cancer missed by mammography examination

Therefore, although Breastlight examination cannot be seen as a substitute for mammography screening, it can be expected to perform substantially better than breast self-examination, resulting in fewer missed cancers and substantially fewer false alarms.⁶

⁶ Analysis of published & unpublished data, JB Medical Ltd Feb 2010

Breastlight UK user study 2008

The use of Breastlight increases the frequency of breast checking



User study⁷ with over 1000 women showed:

- Women significantly more likely to regularly check their breasts after using Breastlight (at least once a month). 60% of women do not routinely check their breasts⁸
- Women are nearly twice as confident conducting breast awareness with Breastlight
- Breastlight does not cause increased anxiety (only 1.3% users visited a GP)
- Breastlight does not alter behaviour with regard to seeking GP advice or attending screening
- One user (Dorothy) saw a shadow and was subsequently diagnosed with early stage breast cancer
- Breastlight was particularly useful for women aged 35-49 (pre screening) & those who have difficulty in palpation (those with large/lumpy breasts)

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⁷ Feedback Consumer Research for PWB Health 2008, study in asymptomatic women. Reviewed by Mr Jayant Vaidya and Dr Mangesh Thorat at the 2nd International Meeting Innovations & Progress in Healthcare for Women 9th – 11th November 2009 RCOG London

⁸ Breakthrough Breast cancer survey 2008

Professional Feedback

It appears that this device does not cause unnecessary anxiety, nor is it likely to result in a number of false positives. It could prove useful for younger women who do not benefit from routine mammogram testing and often have more aggressive cancers.

Jayant Vaidya, Consultant Breast Surgeon, UCLH

It's about knowing your body well and Breastlight enables you to see that one stage further.

Lieva Nation, Specialist Breast Nurse

Using Breastlight may increase confidence in women's own breast assessment and their ability to communicate with their own doctors.

Dr Sarah Burnett, Consultant Radiologist and former breast cancer patient

Everyone has been affected by this disease. We know that the earlier it's detected the better. Something like Breastlight that will help identify a problem earlier, is just wonderful.

Fawn Leith, Family Nurse

It appears that Breastlight is effective in the detection of malignant tumours and in some cases can differentiate between malignant and benign disease. This device will prove to be of particular value to women who experience difficulty in self examination – for example those with a history of recurrent cysts.

Mr Obi Iwuchukwu Consultant Breast Surgeon – Sunderland City Hospital

Case studies

Feedback from women who have used Breastlight & shared their experiences with PWB Health

UK User study - Dorothy

- Aged 50 Oct 2008
- Saw shadow when using Breastlight, unable to feel any lump
- Went to GP, also unable to palpate anything
- Referred to symptomatic clinic
- After biopsy, diagnosed with early stage breast cancer
- Had mastectomy (due to other health issues)
- **Breast cancer survivor**

UK User study - Jeanette

- Aged 45, Sept 2008
- Detected lump after self palpation. Checked with her breastlight, saw shadow
- GP referred to consultant
- After mammogram & ultrasound no biopsy required. Confirmed as not cancerous
- Uses Breastlight regularly to monitor and can see shadow shrinking.
- **Decreased anxiety** as can see improvement

India Gynaecologist patient - Agra

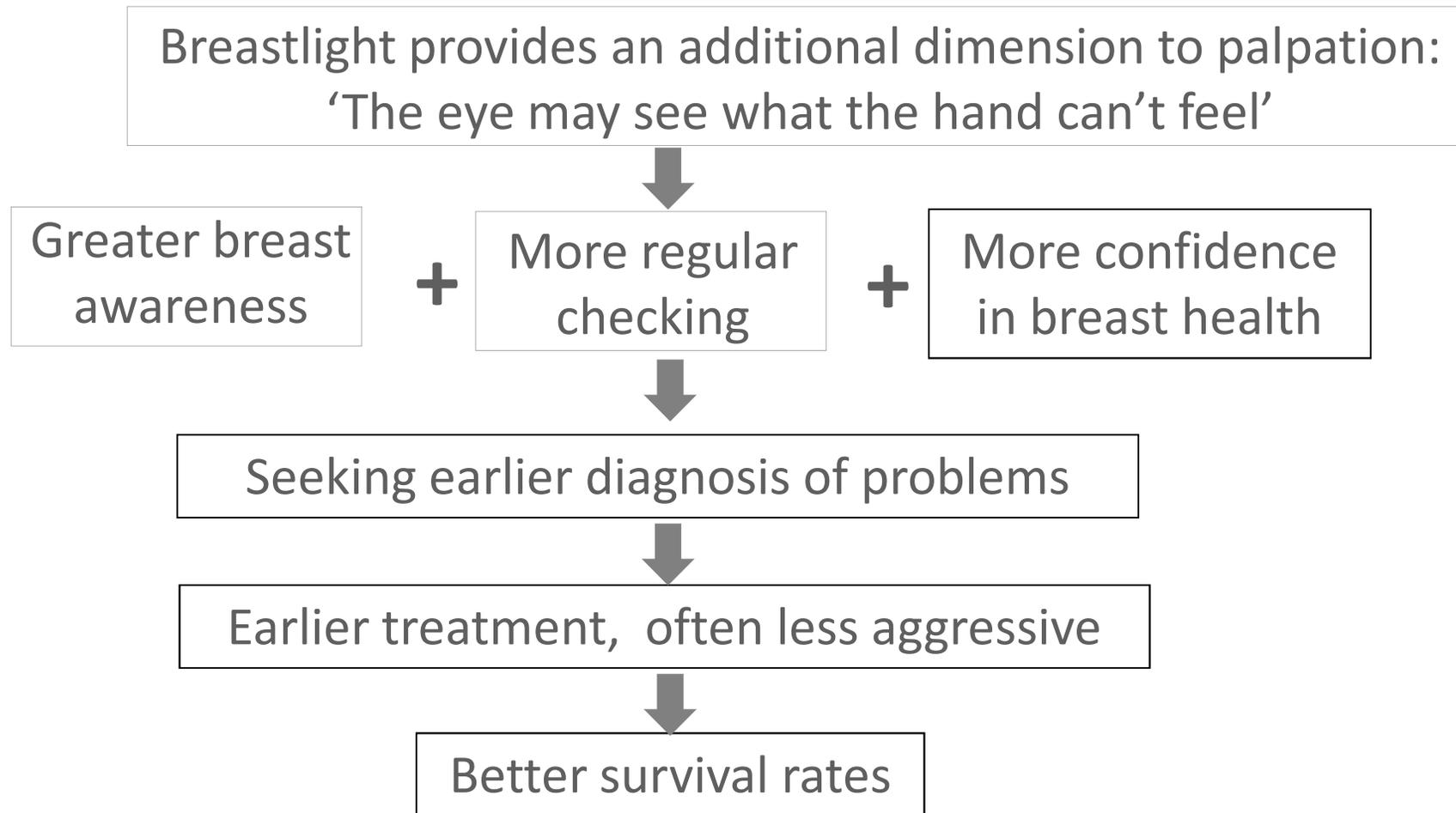
- Aged 47, Jan 2010
- Previous fibrous tissue
- Visited Gynaecologist for routine check-up. No abnormalities on initial clinical breast exam
- Breastlight used as additional tool. Shadow seen & subsequent deep palpation on area detected lump
- After biopsy, diagnosed with early stage breast cancer
- Treatment ongoing
- **Earlier detection**

Conclusions

- Breastlight is proven to detect breast abnormalities that a clinician and women at home may not be able to feel.¹ Detecting tumours when they are smaller means detecting tumours earlier.
- Breastlight is shown to encourage a more regular breast awareness routine.² Women more familiar with their breast health will spot changes more easily and find abnormalities earlier.
- Earlier detection is the key to better patient outcomes.

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Summary



Breastlight is a tool that in conjunction with other breast awareness techniques such as palpation and alongside screening can help in the battle to beat breast cancer

Breastlight is now available worldwide

- Breastlight is available in retail pharmacy in UK
- Distributors with local specialist knowledge have been used to launch across Europe where Breast awareness is developed
- Model in markets with low breast awareness is different. Trials taking place in India & Africa to determine Breastlight's effectiveness as a breast screening tool in rural areas & as a device to be used & sold by gynaecologists for the emerging middle classes.

Retail distribution -



- Launched October 2009 in 140 stores initially.
- Supported with a free standing display unit that generated awareness for a new category
- Rolled out to 600 stores across the UK, on shelf with blood pressure monitors.
- Also available online at www.boots.com. Breastlight featured on breast cancer section of WebMD, new information service available through Boots.



Developing Markets – working with charities

- Mammocare, Ghana – due to its portable nature, Breastlight is used by local health care workers conducting breast screening in rural areas to determine the women who may require further investigation. Over 6000 women tested & the results were presented at the African Breast Cancer conference 2009.
- India – Trial underway to determine Breastlight's effectiveness as a screening device. 60,000 women in the trial, 1/3 to be screened using Breastlight. Part of the WHO Cancer research programme.
- Angels for Africa Campaign - UK Association of Spouses of African High Commissioners, representing 34 African countries. Evaluating using Breastlight as they undertake a breast screening campaign using cutting edge technologies that are cost effective

How effective is Breastlight?

Important points to consider:

- Breastlight should be used in conjunction with regular examination as part of a woman's normal breast awareness routine
- The device is not a substitute for routine breast screening/examination and if a woman notices any changes she should consult her doctor
- If a woman finds 'something' upon examination of her breasts or during use of the Breastlight device it does not necessarily mean she has breast cancer. In this instance the woman should consult their doctor for advise/reassurance

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