

Study Approach

In 2015, THEYA Healthcare commissioned an independent study into the clinical and psychosocial impact of its post surgery range on patients following breast cancer surgery as well as an analysis of the fabric used in the range to see how it performs in comparison to cotton and competing products.

The clinical study was carried out by Claire Kelly (BSc. in Nursing, R.G.N, G. Dip in Adult Cancer Nursing) in fulfillment of her Research Masters (MSc) of Science submitted to University College Dublin.

Research Questions:

- "Does the THEYA Healthcare Post Surgery Range, when compared to current competitors used during and after breast cancer treatment, affect the clinical and psychosocial well-being of patients following Breast Cancer Surgery?"
- 2. "Does THEYA Healthcare's bamboo mix fabric demonstrate a superior anti-bacterial effect, wicking ability, absorbency and breathability when compared with 100% cotton and/or a competitor's product?"

Methodology:

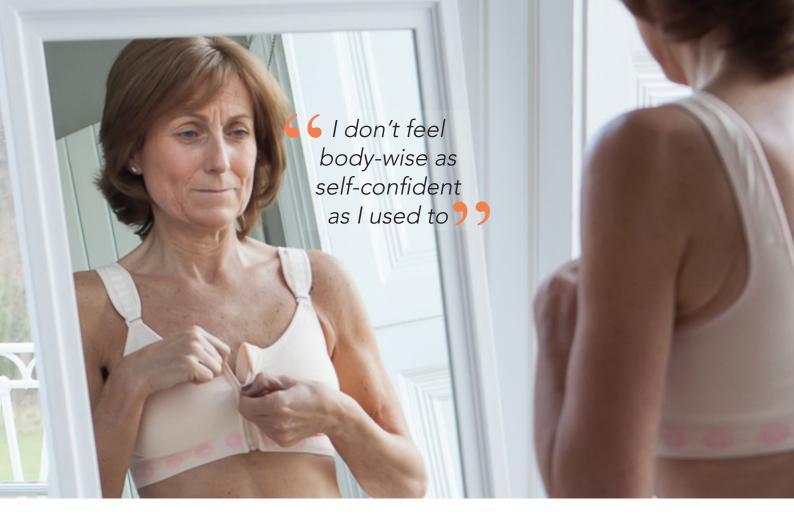
The clinical study was carried out in conjunction with four acute teaching hospitals in Dublin, Ireland. The participants consisted of 20 women aged 46-79 years, who were newly diagnosed with breast cancer and undergoing surgery. The women were randomly assigned to the intervention (THEYA Healthcare) group or the control (current practice) group to wear the allocated bras for a period of 4 weeks. Both semistructured qualitative interviews and validated quantitative patient reported questions were used to measure the impact on body image, quality of life (QOL) and health status.

The fabric testing was completed as per International standards by University College Dublin School of Engineering and BTTG, Shirley Technologies Ltd, Leeds. It included analysis of the anti-microbial, wicking ability, wettability and water vapour resistance of THEYA Healthcare's bamboo mix fabric in comparison to 100% cotton and the fabric used in Amoena's Frances bra (90% cotton, 10% elastane).

Clinical Study Results

The results of the interviews carried out to investigate the women's experience show that lingerie, and which type patients wear following breast cancer surgery, had a significant impact clinically and psychosocially on participants.

This was particularly evident in the areas of Body Image, Pain and Comfort.



Body Image:

Body image encompasses one's view of their body and is central to one's self-identity, self-esteem, confidence, femininity and interpersonal relationships (Engel et al., 2004).

Following surgery, a notable reduction in body image was experienced by all participants in our study. In particular we saw a reduction in self-confidence and their view of themselves from their altered appearance and scarring. One participant commented:

"I don't feel body-wise as self-confident as I used to"

Women commonly mentioned their scars and how they viewed and felt about the appearance of them:

"I find the scar terrible you know",

"There's a gap there where your breastbone is and it is like a hole".

In addition to the overall reduction in selfconfidence, there was a significant impact on body image dependent on the bra that was worn after surgery, with a higher number of participants randomised to the intervention (THEYA Healthcare) arm verbalising an improvement in body image.

One participant highlighted that she liked that the THEYA Healthcare bra covered her scar:

"THEYA comes up high and covers my scar and it hides all that". - Intervention

In contrast to this, a participant randomised to the control group stated:

" I would have preferred if it covered the scar you know. If I was wearing anything with a "V" you can if you're looking down you would see the scar and I would prefer better coverage of it"- Control.

Participants specifically spoke about the fact they were concerned and felt self-conscious

about how others viewed them and how they looked externally in public. One mentioned she had the negative experience of: "some people looking at you,"

bras on it's great, it makes such a difference you feel great 🤰

(THEYA Healthcare)

6 6 Once you've the right

- Intervention Group

myself.... I would feel awful without a bra"-Control

"Once you've the right bras on it's great, it makes such a difference you feel great" -Intervention

> The positive impact on body image of the THEYA Healthcare bra is supported by the quantitative results of the Body Image Scale (BIS) which showed that those participants randomised to THEYA Healthcare had an improvement of 8.5% in

their body image whereas those randomised to the control group had a decrease in their body image by 9.5% (Fig 1.1)

increase any feeling of self-consciousness.

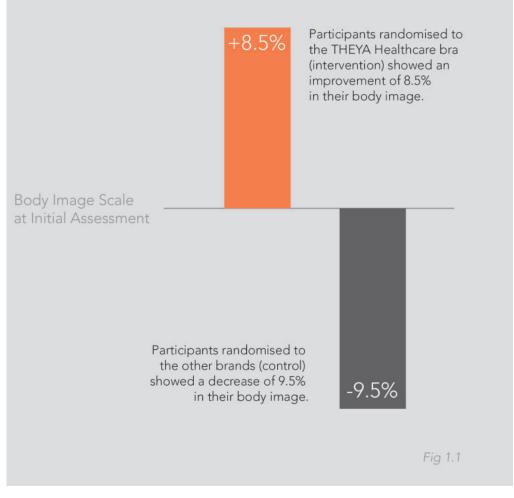
and this would potentially cause upset and

Feeling self-conscious caused one woman to change her normal style to feel better about herself in public:

"I'd be quite conscious and have actually changed the way I have dressed since, the type of clothes I wear, to something with a pocket or something over the left breast so it will distract from that"

Interestingly, participants experienced a positive and improved body image when wearing a bra after surgery.

"I feel a lot better with the bra on of course, I felt good enough about



Pain:

Post-operative pain has been found to be a significant clinical problem post breast cancer surgery (Gartner et al., 2009), with a reported incidence of between 58% to 79% experienced by women **6** The first week (Eversely et al., 2005; Vitug and Newman, 2007). especially after wearing

a bra is very painful 🤊 🤊 Most participants discussed pain at numerous stages during their interviews and in particular remember the pain they experienced in the immediate recovery period:

"Everything is unbelievably painful just after surgery",

"The most painful was underneath my arm, where I felt it the most"

The impact that their bra had on patients in the immediate post-operative period and throughout the initial recovery phase was **6** The bra was interfering clear. with the drains and

Participants in the control group commented:

"The bra was interfering with the drains and pressing on the wounds initially"-Control.

"The first week especially after wearing a bra was very painful" – Control.

This participant then commented on how she

needed analgesia because of the discomfort experienced from the bra:

"I mean when and if that's what you are taking painkillers for your poor old kidney and liver are working hard for, that could be

> sorted another way." -Control.

- Control Group (other brands)

In addition, when asked about how the bra felt on their wound and scar participants in the control group stated:

"It's sore as it is tight because there is no band on it; it does ride up and hurt the scar and I'd have to take it off,"- Control.

"The other bras I tried on the day of discharge too, there were five or six bras they were just dreadful, chafing and they felt wrong" - Control.

Whereas, those randomised to the intervention and received the THEYA

> Healthcare bamboo mix fabric bra found that:

- Control Group (other brands)

"It was nice to get a bra with nothing on the back, so nice to not have that, made a big difference" -Intervention.

"They [other bras] sort of dig into the side where the THEYA Healthcare one just sat nice, less lumps and bumps with it"- Intervention.

One participant who had trialled other bras herself found a big difference in discomfort in comparison with the THEYA Healthcare bra:

pressing on the wounds

initially 🤊 🤊

"I don't feel the need to take it off whereas I needed to get those other bras off me, it was like having a rope tied around you, you know?" - Intervention.

A few participants randomised to THEYA Healthcare specifically associated a bra with the alleviation or reduction of pain;

"Definitely the white one yeah, it's like a form of bandage for me over my dressing it keeps it snug it's definitely good and feels good when it is on", "Yes, because of the way it opened" and "Yes, it was good support".

Similar sentiments were expressed across most participants who discussed and highlighted the importance of comfort in a bra and saw this as helping in reducing pain and discomfort.

Comfort

Participants placed great emphasis on the necessity of a comfortable bra and the impact it has, not only on discomfort,

but also sleep, mood, body image, ability to cope and thereby quality of life (QOL).

One participant mentioned that:

"You want that sense of comfort.... because of the nerve pain all around the side."

Participants randomised to the control group, had tried an array of different bras. They highlighted their feelings about these bras:

"Uncomfortable. Marks and Spencer's, it was

difficult to find one without a wire in it to be honest" - Control.

"It gets more uncomfortable as the day goes on, it feels tight and it feels.... it's just not very comfortable and I tend to take it off as the day goes on." - Control.

"I found it very tight and I had to take it off".
- Control.

When questioned on the fabric and how it felt against their skin respondents in the control group said:

"The fabric wasn't great, like an old-fashioned Playtex bra, not enough cotton, too em... synthetic, not comfortable" - Control.

"The cotton ones had a lot of stitching and the synthetic ones whilst softer, I don't know they just, nothing felt particularly good". -Control.

6 6 Lovely, like you had nothing on 🤰 🤊

- Intervention Group (THEYA Healthcare)

In contrast, those randomised to the intervention group who received the THEYA Healthcare bamboo mix bra seemed unanimously

pleased with the comfort of the bra.

"You can't buy that kind of comfort" Intervention

"Because they're comfortable I don't feel the need to take it off"... "Actually you're uncomfortable taking it off". - Intervention

"Lovely, like you had nothing on"..."Thank God I have them." - Intervention Regarding the THEYA Healthcare fabric, respondents stated:



"I have to say I loved the THEYA one, loved the feel of it on my skin". - Intervention

"Very comfortable, would have bought them had I seen them in the shop" - Intervention

In addition to comfort some of the participants discussed how they wanted to feel secured, protected and cosy after their surgery giving them that sense of not only comfort but safety and improving their QOL.

"You are a bit delicate so you did kind of feel like you need the support there. Because it is good support, you feel protected in it"-Intervention

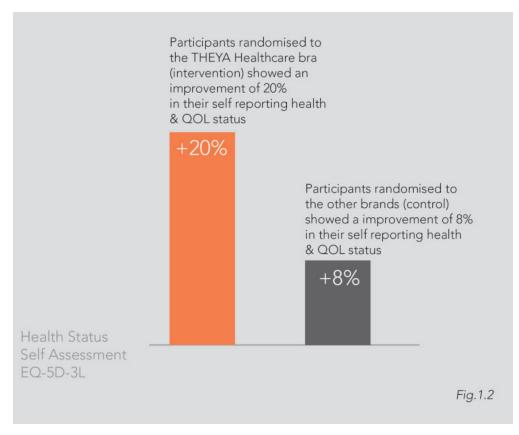
The results from QOL assessment (EQ-5D-3L) underline the positive impact the THEYA Healthcare bra has on QOL.

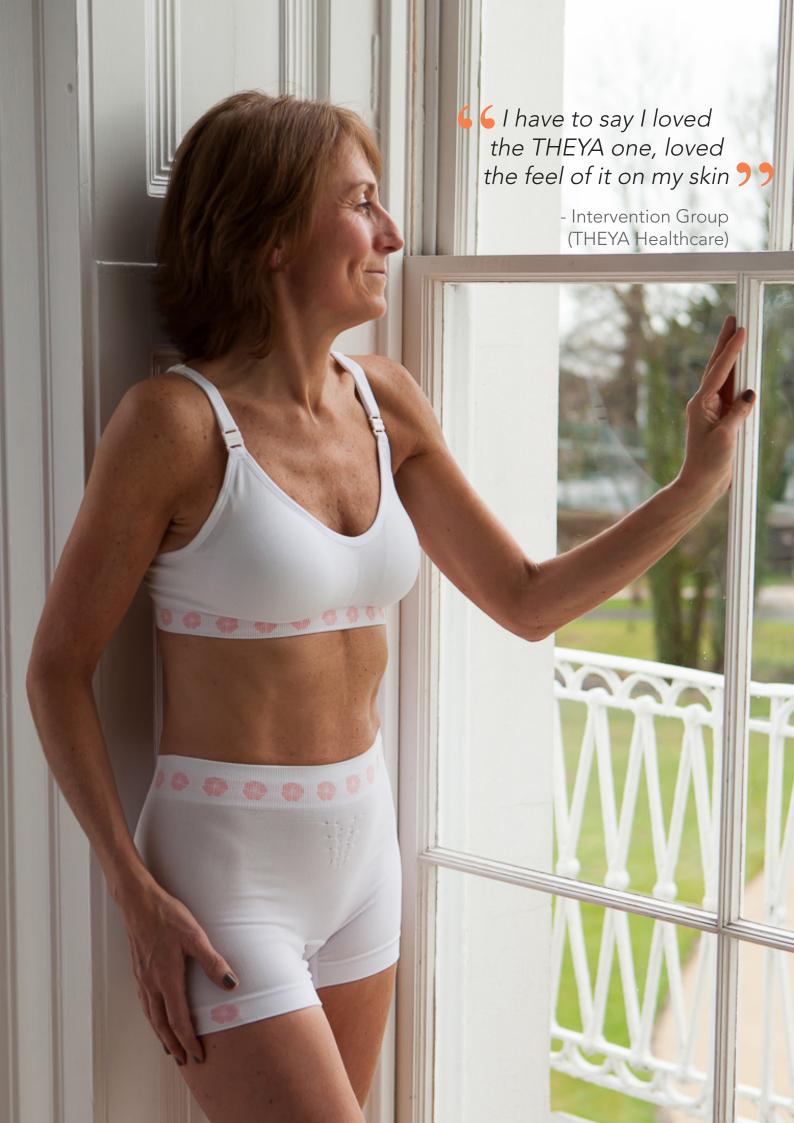
The EQ-5D-3L uses a Visual Analogue Scale (VAS) to allow participants self-report and self-assess their health status on a given day.

The scale ranges from 0 representing the "worst possible imaginable health status" to 100 showing the "best possible health status imaginable" (Van Reenan and Oppe, 2015).

Participants randomised to the THEYA Healthcare (intervention) arm had an overall improvement of 20% in their self-reporting health and QOL status from an initial preassessment of 53% to 73%.

Whereas those randomised to the current practice (control) has only 8% improvement, (60.8% compared to 68.8%). (see Fig 1.2).





Fabric Testing Results

THEYA Healthcare's Post Surgery Range is made from a unique bamboo mix fabric. Bamboo fabric has been increasingly sought by consumers and retailers due its extremely soft nature as a fabric and being a renewable resource deemed more eco-friendly than cotton. Many companies market bamboo fabric as being antibacterial, absorbent, breathable and with a high wicking ability but with little evidence to support these claims. We sought to investigate these claims, while adhering to the textile industry's standards and obtained the following results for THEYA Healthcare's bamboo mix fabric.

The fabric testing was completed in the laboratory of University College Dublin Biomedical Engineering at the School of Mechanical and Materials Engineering and by BTTG, Shirley Technologies Limited, Leeds. The fabrics tested were the THEYA Healthcare's bamboo mix fabric compared to 100% cotton and the fabric used in the Amoena Frances bra (90% cotton, 10% elastane).

Anti-bacterial effect

In the clinical setting, surgical site infections (SSIs) can occur following breast surgery and can deteriorate not only a woman's physical condition, but also her psychological condition, potentially increasing pain, length of hospital stays, length of recovery process and delaying adjuvant treatments. Therefore, a bra that elicited a bacteriostatic effect would be beneficial to these patients. A study completed in the National Health

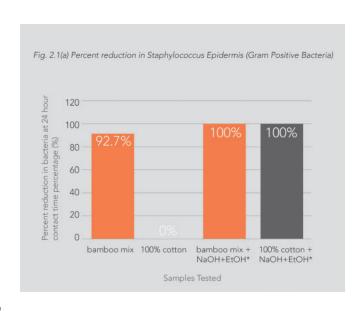
Service (NHS) in the UK, studied patients for a period of thirty days post breast surgery and found there to be a 10.1% rate of infection present (Tanner et al., 2011).

As per the international standard test method "AATCC TM 100: 2004 Antibacterial Finishes on Textiles" (AATCC, 2004), THEYA Healthcare's bamboo mix fabric was tested in comparison to 100% cotton, using two bacteria that mimic those most commonly found in SSIs, one Gram-positive (Staphylococcus Epidermis) and one Gramnegative (Pseudomonas Fluorescens).

NaOH + EtOH is used as a positive control, to ensure a clear anti-microbial effect for the bacteria. As expected positive controls reduced all bacteria by 100%.

Gram-Positive Bacteria

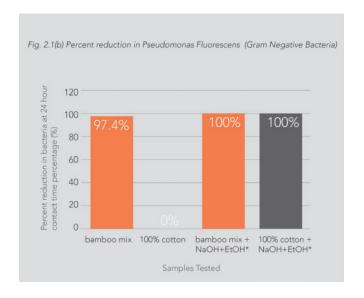
THEYA Healthcare's bamboo mix fabric demonstrated an anti-microbial effect on Gram-positive Staphylococcus Epidermis when compared to 100% cotton. Specifically, the results show a reduction of 92.7% of Staphylococcus Epidermidis in the bamboo mix sample, compared to 0% reduction for 100% cotton. (Figure 2.1(a)).



Gram-negative Bacteria

The bamboo mix demonstrated a clear anti-microbial effect on the Gram-negative Pseudomonas Fluorescens bacterium compared to 100% cotton.

The results show that the bamboo mix gives a reduction of 97.4% of Pseudomonas Fluorescens compared to 0% reduction for 100% cotton. (Figure 2.1(b)).

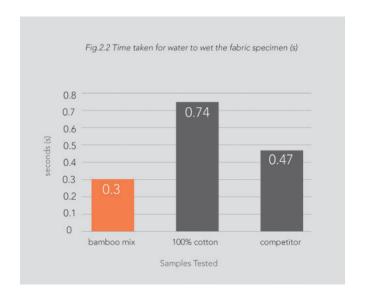


Absorbency/Wettability

The ability of an undergarment fabric to absorb large amounts of perspiration is vital for patients undergoing treatment for breast cancer, who may be experiencing hot flushes from chemotherapy or endocrine therapy or may have hot, inflamed, irritated or broken skin secondary to radiotherapy treatment.

Using the Laboratory protocol derived as per the "British Standard Method of Test for Wettability of Textile Fabrics, BS4554:1970", THEYA Healthcare's bamboo mix fabric demonstrated a superior absorbency/wettability rate compared to both the 100% cotton and the Amoena Frances (90% cotton, 100% elastane).

Specifically, results show that the bamboo mix has the greatest absorbency at 0.3 seconds, compared to 0.74 seconds for 100% cotton and 0.47 seconds for the Amoena Frances (90% cotton, 100% elastane). The bamboo mix has the highest wettability of the samples tested compared to 100% cotton fabric and the competitor garment (Figure 2.2).



Wicking Ability

The horizontal wicking rate is responsible for sweat evaporation during activity (Raja et al, 2012). It quantitatively measures the horizontal movement of water by capillary action laterally throughout a textile material. In short, the faster a fabric can draw moisture away from the skin, the more comfortable the wearer.

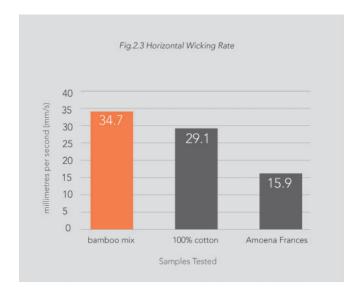
The test conducted used the international standard test method "AATCC TM 198:2012 – Horizontal Wicking of Textiles" (AATCC, 2012).

THEYA Healthcare's bamboo mix demonstrated an increased horizontal wicking rate compared to 100% cotton and



compared to the Amoena Frances (90% cotton, 100% elastane).

Specifically, the bamboo mix horizontal wicking rate was 34.7mm/s, compared to 29.1 mm/s for 100% cotton, with the lowest rate of 15.9mm/s horizontal wicking rate for the Amoena Frances (90% cotton, 100% elastane) Figure 2.3).



Water Vapour Resistance.

In order to assess the breathability of THEYA Healthcare's bamboo mix in comparison to 100% cotton, the fabrics were evaluated using a test that simulates the heat and moisture transfer of the human skin, ISO 11092: 1993, "Textiles – Determination of physiological properties – Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)".

The fabrics were tested in a two layer assembly as post surgery bras generally have two layers of fabric given the inclusion of a breast form pocket.

Water vapour resistance (Ret) is expressed in

m².Pa/W and is a measure for breathability. The lower the score the more breathable the fabric.

The bamboo mix double layer yielded a mean result of 10 m².Pa/W and the 100% cotton double layer a mean of 11.5 m².Pa/W. These results mean that both fabrics are highly breathable.

This excellent breathability, combined with the superior horizontal wicking rate of the bamboo mix results in an improved level of comfort for patients, in particular those suffering excessive sweating as a result of their treatments.

The pH test

The pH test confirmed that the pH value of THEYA Healthcare's bamboo mix was 7 compared to a pH of 7.5 for 100% cotton. The pH of a fabric used for apparel should be between 4-7.5 (UKAS, 2016), this aids in reducing any possible kind of irritation the fabric may have on the skin (UKAS, 2016).

Study Conclusions

Does the THEYA Healthcare Post Surgery Range, when compared to current competitors used during and after breast cancer treatment, affect the clinical and psychosocial well-being of patients following Breast Cancer Surgery?

This study has shown that compared to current practices the THEYA Healthcare Post Surgery bra has a beneficial impact on women following breast cancer surgery both clinically, with regards to pain and comfort, and psychosocially with a positive impact on body image and quality of life.

Regarding pain and discomfort and the impact of post surgical bras, respondents in the control group spoke more about discomfort associated with the bra "digging in", "strangling" or rubbing. Whereas in the intervention group, participants consistently praised the comfort of the THEYA Healthcare bra "you can't buy that kind of comfort".

In qualitative and quantitative results, respondents randomised to the THEYA Healthcare arm of the study verbalised an 8.5% improvement in body image. Whereas those randomised to the current practice arm reported a notable 9.5% decrease in body image over the course of the study.

The quantitative results of the Quality of Life (QOL) questionnaire on health status revealed that those respondents wearing the THEYA Healthcare bra reported more than twice the improvement in their health and QOL (20%) than those in the control group (8%).

Does THEYA Healthcare's bamboo mix fabric demonstrate a superior anti-bacterial effect, wicking ability, absorbency and breathability when compared with 100% cotton and/or a competitor's product?

Testing showed that the THEYA Healthcare bamboo mix fabric used in the Post Surgery Range is ideal for use in post surgery undergarments. Results supported the claimed properties of bamboo fabric being anti-bacterial, having good breathability, wicking ability and enhanced absorbency. These characteristics can only add and benefit to a wearer and in this case, be of benefit in a bra for those women post breast cancer surgery.

The bamboo mix proved to have an antibacterial effect on both Gram-positive and Gram-negative bacteria which could help to reduce surgical site infections.

The bamboo mix fabric has superior horizontal wicking ability and absorbency when compared with 100% cotton and the Amoena Frances bra; it was also shown to be highly breathable and comparable to 100% cotton.

These traits would benefit the wearer clinically and in relation to comfort especially in the context of breast cancer treatment where patients may be experiencing hot flushes from chemotherapy or endocrine therapy or may have hot, inflamed, irritated or broken skin secondary to radiotherapy treatment.



Pictured above study author Claire Kelly BSc. In Nursing, R.G.N, G. Dip in Adult Cancer Nursing MSc in Science

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