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Design and Development of Prosthetic Brassieres for Breast Cancer Patients

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Abstract: In India, breast cancer is now the most common cancer in urban and second most common cancer in the rural areas. The conventional treatment of breast cancer involves surgery (lumpectomy - removal of tumor or mastectomy removal of breast), followed by chemotherapy and / radiation depending the stage of the cancer. It is estimated that close to 45,000 women undergo mastectomy every year. Post mastectomy, women use prosthetic pads to gain better posture and body image. On the basis of availability, the market is segmented into silicon pads, cotton pads and 3D knitted prosthetic pads. These aids are characterized by low availability, high price and lack of designs. This study focused on the type of prosthetic pads used by mastectomy patients, their advantages and disadvantages. Retailers and distributors, doctors and patients were interviewed to understand the same. Findings of the study indicate, not all women use prosthetic pads. The study attempts to develop brassieres for patients with modifications. Additionally, the results of the study indicate a palpable need to develop prosthetic pads at an affordable price. Future studies can be focused on application of functional finishes like antibacterial finish, anti-fungal finish, moisture and comfort management for the same use.

Index Terms: Breast cancer, Mastectomy, Prosthetic brassieres, Prosthetic pads.

I. INTRODUCTION

Breast cancer is a type of cancer that starts in the breast. Cancer starts when cells begin to grow out of control. Noncancerous breast tumors are abnormal growths, but they do not spread outside of the breast. They are not life threatening, but some types of benign breast lumps can increase a woman's risk of getting breast cancer. Any breast lump or change needs to be checked by a health care professional to determine if it is benign or malignant (cancer) and if it might affect your future cancer risk. Breast cancers can start from different parts of the breast.

Most breast cancers begin in the ducts that carry milk to the nipple (ductal cancers) Some start in the glands that make breast milk (lobular cancers) There are also other types of breast cancer that are less common like phyllodes tumor and angiosarcoma. A small number of cancers start in other tissues in the breast. These cancers are called sarcomas and lymphomas and are not really thought of as breast cancers. A recent report published by National Cancer Registry Programme (NCRP) estimates that the number of cancer cases is likely to increase from 13.9 lakh in 2020 to 15.7 lakh by 2025, an increase of nearly 20%. Breast cancer accounts of nearly 14% of all cancers in women in India¹⁷.

Mastectomy is the medical term used for the surgical removal of one or both breasts, partially or completely. A mastectomy is usually carried out to treat breast cancer. In some cases, people believed to be at high risk of breast cancer have the operation as a preventive measure. Alternatively, some people can choose to only remove their tumour, also known as a lumpectomy, an operation in which a small volume of breast tissue containing the tumour and a surrounding margin of healthy tissue is removed to conserve the breast¹⁵.

Traditionally, in the case of breast cancer, the whole breast was removed. Currently, the decision to do the mastectomy is based on various factors, including breast size, breast density, the number of lesions, biological aggressiveness of a breast cancer, the availability of adjuvant radiation, the likelihood of cancer returning, the patient's age and overall health and the willingness of the patient, including aesthetic concerns. It is often done when a woman cannot be treated with breastconserving surgery (lumpectomy), which spares most of the breast. It can also be done if a woman chooses mastectomy over breast- conserving surgery for personal reasons. Women at very high risk of getting a second cancer sometimes have a double mastectomy, the removal of both breasts.

Mastectomy is of several types, they include:

- **Total (simple) mastectomy**: This involves the surgeon removing the entire breast but leaving the muscles under the breast and the lymph nodes in place.
- **Double mastectomy**: This involves the surgeon removing both breasts, usually as a preventive measure

— if genetic features indicate a high risk of breast cancer, for example.

- **Radical mastectomy**: This involves the surgeon removing the entire breast, the underarm lymph nodes, and the chest wall muscles.
- **Modified radical mastectomy**: This involves the surgeon removing the entire breast and underarm lymph nodes but leaving the chest wall muscles intact.
- Skin-sparing mastectomy: This involves the surgeon removing the breast tissue and nipple but leaving the skin intact. A surgeon also reconstructs the breast during the procedure.
- **Nipple-sparing mastectomy**: This relatively new procedure involves leaving the skin, nipple, and peripheral breast tissue intact¹⁶.

The type of mastectomy that is most suited for a patient depends on several factors, including age and general health of the patient, menopause status, tumour size, tumour stage (I, II or III), tumour grade or aggressiveness, impact of cancer on the lymph nodes and impact of any other treatment on the patient.

There are lots of physical and psychological impacts of a mastectomy on the overall health and well-being of the patient. The physical health issues are taken care of by the support of doctors and health care staff. However, the psychological impacts last much longer and affect the self-esteem and body image of an individual for a long time. To balance these issues, breast prosthesis and prosthetic brassieres are available which can help the patients in faster and better recovery.

A breast prosthesis is an artificial breast form which replaces the shape of the entire breast or a part of the breast that has been surgically removed. The prosthesis fits in a bra cup with or without a bra pocket.

Most breast prostheses are made from soft silicone gel encased in a thin film. They're moulded to resemble the natural shape of a woman's breast, or part of a breast. The outer surface feels soft and smooth, and may include a nipple outline.

Many women who undergo mastectomy and do not undergo breast reconstruction wear a breast prosthesis. For some women, wearing a prosthesis may be a temporary choice prior to reconstruction. Other women may choose not (or be unable) to have breast reconstruction and find wearing a prosthesis an effective and suitable long-term choice. Some women who do not to have a reconstruction choose not to wear a prosthesis. Various factors affect like education, age and financial background are strong factors which impact the use of prosthetic pads.

Prostheses are available in a variety of shapes, sizes and skin tones and are made from materials that are designed to move, feel and weigh as similar to a natural breast as possible. It is important for patients to choose a prosthesis that suits your lifestyle as much as possible. Sometimes people choose to just wear their temporary prosthesis instead of a permanent prosthesis.

- Full or standard prosthesis: This prosthesis has various backings designed to go straight against the chest wall where all breast tissue has been removed. It is matched in size, shape and skin tone to your other breast.
- Partial or shaped prosthesis: A partial prosthesis is for women who have had part of their breast removed. It is worn inside a bra and is shaped to fill out the breast outline. It can also be made of the same silicone material as most full prostheses.
- Shell prosthesis: This is a type of partial prosthesis that may be used if your breasts are different in size from each other. It's a soft 'shell' of silicone / cotton and foam, that fits over your smaller breast so that it matches the larger one. This type of prosthesis can also be useful for women who have had breast reconstruction surgery where symmetry has not been achieved, or if an implant is in the process of being expanded.
- Stick-on prosthesis: A stick-on prosthesis (full or partial) sticks directly onto the skin. These can suit women who are active or who want to wear a less supportive bra. Most women are advised not to wear a stick-on prosthesis for 12 months after surgery or during radiotherapy as it may damage the skin⁶.

Breast prostheses come in symmetrical, teardrop or asymmetrical shape.

- Symmetrical: A symmetrical form is usually an oval or triangular shape that can be worn on either the left or right side.
- Teardrop: The teardrop shape is often more suitable for women whose breasts are fuller in the lower and outer area and less full above the nipple. These can also be worn on either the right or left side.
- Asymmetrical: These are generally more suitable for women who have had more extensive surgery as they have extensions to fit under the arm or upper chest wall. However, they can also be used by women who have not had extensive surgery. They are specifically designed for either the left or right side.
- Made-to-measure: This technique uses a 3D scanner to produce a computerised 3D image of the chest area, which can then be used to create a customised prosthesis shape. It is made to give a good match to the chest wall, which stops the prostheses moving, and is matched to your skin tone.

Prosthesis pads can be made from one of the following materials:

- **Silicone.** This is the most expensive type of breast form. It looks and moves more naturally than other breast forms. It is also heavier than cotton or other material. Silicone breast forms can make your skin feel hot and sweaty.
- Fiber-fill or foam. These are lighter and cooler than silicone. They also cost a lot less. They don't look as natural under form-fitting tops, but they work well for lounging at home. They also work well if your breast is still healing from surgery.

- **Homemade.** Many women use things they already have in their closet—from a shoulder pad to a wad of nylons—to fill out their bra cup. If you always wear loose-fitting tops that don't reveal your breast shape, a homemade breast form may be all you want.
- Waterproof or water resistant. You can wear most breast forms when you swim, but many of them soak up water and get quite heavy. If you swim a lot, you might think about getting a special breast form just for swimming.
- **Custom-made breast forms:** A custom-made form is made by making a mold of your chest area so that the form will fit your chest and body exactly. Because of the extra work involved, custom-made breast forms cost much more than ready-made forms¹⁹.

II. AIM & OBJECTIVES

The study aims to design and develop low-cost variations in designs of prosthetics brassieres for breast cancer patients who have undergone mastectomy.

The objectives of the study are:

- To understand availability of different kind of prosthetics and prosthesis brassieres available in the market.
- To understand the kind of issues / problems faced by the breast cancer patients with the use of prosthetics and prosthetic brassieres available in the market.
- To create designs and develop different kind of prosthetic brassieres which are currently unavailable in the market.

III. METHODOLOGY

This research has employed a multi-method (face - to - face interview, questionnaire, observation and market surveys) and multi-agent design (doctors, patients, distributors and retailers). Since the respondents involved in the study were doctors and patients, the study used methods such as observation, discussions and interviews with the respondents because of the following reasons:

- Patients were not in the best of their health and were also susceptible to infections which led to telephonic interviews and discussions rather than questionnaire method. Some patients were able to fill the questionnaire forms (Survey 1).
- Doctors at prominent Mumbai hospitals were very busy and it was difficult to take a lot of their precious time.
- Distributors / Retailers were busy during the shop hours and could not take out too much time to answer the questionnaire forms, hence observations and interviews were conducted.
- On the basis of the results of the discussions, telephonic interviews and market visits, the researcher developed nine designs of prosthetic brassieres for breast cancer patients who have undergone mastectomy. The developed designs were shown to the patients and a

survey was conducted to understand their preferences (Survey 2).

The sample size of the participants for the purpose of the research study are as follows:

- Distributors / Retailers 3
- Hospitals 4
- Doctors -2
- Patients 30

The sampling technique used was "reliance on available subjects" and all those who consented to be a part of the study were selected.

IV. RESULTS & DISCUSSION

A. Results of Survey 1 from Patients:

This survey was conducted with the patients of breast cancer to understand the products used by them and the problems they face due to the lack of / unavailability of appropriate products for them. the data was collected through the questionnaire form for some of the patients while some were asked the same questions since they were not in the best of their health. The results obtained are as follows:

1) Use of prosthesis:

The following figure (Fig No. 1) shows the distribution of patients using prosthesis. The results show that all most $3/4^{\text{th}}$ of the participants use prosthesis, while 28% of the participants do not use any prosthesis. Some of the participants mentioned high cost of the prosthetic as a reason for not using the same.



Fig. No.1 Use of prostheses

2) Color of the Prosthetic:

Figure No.2 shows the color of prosthetic used 11% of participants used to colorful prosthetic, 25% used Cream prosthesis and while the remaining 64% used white prosthetic only. This may be because of availability of white prosthetic majorly in the market as found out from the distributors / retailers.



3) Type of Prosthetic Used:

The figure below (Fig. No. 3) shows the kind of prosthetic used by the patients. The results show that 64% of the participants use silicon prosthetic while 1/4th of the patients use cotton pads. Only 11% used 3-D knitted pads. The 3-D knitted pads are one of the latest developments in the field and are expensive in comparison to the silicon and cotton pads. These are also not easily available at all the shops, hence the usage amongst patients is also very low.



4) Place of Purchase:

The results indicated in Fig No. 4 show that 11% of the patients purchase the prosthetics from the hospital itself. These patients have purchased the prosthetic for the first time and are not aware of the various places where the prosthetics maybe available. 64% of the patients purchase the prosthetics from a retail shop close to the hospital while 25% of the patients buy the same from retail outlets in shopping malls. The results indicate that the patients using 3-D knitted pads and those buying the prosthetics from the retail outlets from shopping malls are the same.



Fig.No.4 Place of Purchase of Prostheses

5) *Life of Prosthesis:*

On the basis of the responses received from the patients, it can be noted that there is no defined period for which the prosthesis can be used. The quality of the product may vary on the basis of the place of purchase. However, it can be noted in Fig No. 5, that the silicon pads have a maximum life while that of 3-D knitted pads and cotton pads is lesser. Patients also added that in case of any sharp object or even a finger nail coming in contact with the silicon pad can spoil it and render it unusable. While on the other hand, cotton pads and 3-D knitted pads loose their shape relatively faster. Thus, the average life of the silicon pads is 9 years while that of cotton pads and 3-D knitted pads is 5 years.



Fig. No. 5 Life of Prosthesis

6) Cost of Prosthesis:

Figure No. 1.6 shows the cost of the prosthetics used by the patients. It can be noted that a similar variation can be observed withing each type viz., silicon, cotton and 3-D knitted pads, similar to the variation noted in the life of the prosthetics. It may be noted that the cost may depend on the place of purchase as well as the quality of the product. From the results received, it can be noted that the average cost of silicon pads is Rs. 5500, 3-D knitted pad is Rs. 1500 and the cost of cotton pads is approximately Rs. 500. It is interesting to note that even though the life of cotton pad and 3-D knitted pad is the same, however there is a variation in the cost of the prosthetic, with 3-D knitted pads costing more than the cotton pads.



Fig. No.1.6 Cost of Prosthesis

With reference to the comfort of the prosthetic pads the patients confirmed that the cotton pads were most comfortable to the skin, followed by 3-D knitted pads and silicon pads. This may be attributed to the higher air permeability of the cotton pads while retaining an overall low weight of the product. On the other hand, a silicon pad weighs the most and is least air permeable.

Some of the other issues mentioned by the patients were:

- The patients have to face a lot of emotional issues in addition to the stress of the treatment, like lose of confidence, dignity and femineity.
- Lack of availability of designs and variety in fabrics of prosthetic brassieres.
- Silicon pads give a good shape to the wearer; however, they are heavy in weight and it is difficult to use them for an extended period of time.
- The cost of silicon prosthetics is high and can be damaged easily with any sharp object.
- Silicon prosthetics cause skin rashes with use for an extended period of time.
- Because of the weight of the silicon pads, it causes posture imbalance, abnormal gait and movement and shoulder and cervical pain.
- Cotton pads are comfortable to the skin and air permeable. They do not cause any rashes on the skin.
- Cotton pads lose shape easily and are not suitable for outdoor activities.
- Cotton pads can be used only with loose fitting clothing, since they do not give a graceful look to the body in fitted clothes.
- B. Results of Discussion with Doctors (Oncologist specializing in Breast Cancer):

The researcher met two Oncologists, specializing in breast cancer at leading hospitals in Mumbai. The doctors very kindly shared some of the issues arising from mastectomy in breast cancer patients. Some of the points discussed were:

- Mastectomy impacts the patient both physically as well as psychologically. It takes a period of almost a month to heal after the surgery, while it can impact the self-esteem of the patient for a very long time.
- Mastectomy leads to long term issues ergonomically, since the removal of one or both breasts cause an imbalance in the body structure, thereby leading to shoulder slumping, backache and change in gait.
- Comfort is of prime importance and there is a dearth of options available to the patients. Some options that are available can be very expensive for the patients.
- Knitted pads as per the shape of the chest of the patient is one of the latest developments in prosthetic pads, however they cost around Rs. 8000/-.
- More research in the area of prosthetic brassieres and pads can be helpful in giving better comfort and after care to patients.

C. Results of Discussion with Distributors / Retailers:

The researcher visited several stores selling prosthetic brassieres and prosthetic pads, however only three distributors

/ retailers shared the details of products available. They showed products and shared information on the different types of products available for breast cancer patients like hand sleeves, stocking, various types of silicon pads, light weight prosthetics, water-proof prosthetic covers, prosthetic brassieres and prosthesis pocket. Some of the details shared by them were:

- Prosthetic brassieres are mostly available in two colors, white and cream. They are also available in cotton woven fabric in a simple pattern with a pocket inside for the prosthetic to be inserted.
- The price of the prosthetics vary depending on the quality and brand. The price range of different types of prosthetics is:
- Silicon prosthetics: Rs. 1500 Rs. 8000
- Cotton prosthetics: Rs. 500 Rs. 1500
- 3-D knitted prosthetics: Rs. 1000 Rs. 2000
- The weight of the prosthetics range between 500 gm to 6 kg per pair.
- The prosthetics brassieres as well as prosthetic pads are available in the size range of Small to 14XL.

D. Designs of Prosthesis Brassieres

Some of the common problems associated with breast cancer and mastectomy of patients include:

- Imbalance in the body structure because of removal of breast tissue
- Back ache because of the unbalanced load
- Shoulder slumping on one or both sides because of uneven distribution of weight
- Difficulty in using back opening brassieres because of pain in underarm, back and shoulder.

Thus, keeping the above in mind the brassieres have been designed to aid the patients to lead a relatively better and painfree life. Additionally, the prosthetic brassieres are available in only one pattern with limited/no options in colour, fabric and pattern. This also impacts the patients psychologically. Variations in fabric have been tried to boost the morale of the patients.

1) Design 1:

Fig. No. 7 shows the following design characteristics for use by breast cancer patients:

- Front button opening with front pocket its make designing simple
- Use of knitted fabric to offer better comfort and support
- Perfect for sleep, and Make Leisure comfy



Fig. No. 7 Design for Prosthetic Brassiere

2) Design 2:

Fig. No. 8 shows the following design characteristics for use by breast cancer patients:

- Front Pocket bra wireless Zipper, front Lace cotton on hem with cotton lining.
- It is soft and comfortable.
- Designed for superior shaping with comfortable straps and gives a smooth look under cloth.



Fig. No. 8 Design for Prosthetic Brassiere

3) Design 3:

Fig. No. 9 shows the following design characteristics for use by breast cancer patients:

- Front pocket brassieres with zip opening.
- Designed with Cotton lace and mesh cloth, high elastin but band for plus size, front zipper closure and wire free to get comfortable feelings



Fig. No. 9 Design for Prosthetic Brassiere

4) Design 4:

Fig. No. 10 shows the following design characteristics for use by breast cancer patients:

• Pocketed plunge mastectomy brassieres.

• A stunning floral lace bra exudes style and femininity whilst giving support and comfort.



Fig. No. 10 Design for Prosthetic Brassiere

5) Design 5:

Fig. No. 11 shows the following design characteristics for use by breast cancer patients:

- Side pocket with specially designed secure
- Velcro closure is scratch-free and snag-free.
- Straps are wide and comfortable giving adequate support to the shoulders



Fig. No. 11 Design for Prosthetic Brassiere

6) Design 6:

Fig. No. 12 shows the following design characteristics for use by breast cancer patients:

- Side pocket plunge style brassieres with front opening.
- Shoulder side easy opening.
- Get the support and comfort have been looking for with this stylish mastectomy Brassieres.
- Elastic Gives support and shape.



Fig. No. 12 Design for Prosthetic Brassiere

7) Design7:

Fig. No. 13 shows the following design characteristics for use by breast cancer patients:

- Side pocket V neckline.
- Lace fabric on front hemline easy operation bra.
- Get the support and comfort have been looking for with this stylish mastectomy brassiere.



Fig. No. 13 Design for Prosthetic Brassiere

8) Design 8:

Fig. No. 14 shows the following design characteristics for use by breast cancer patients:

- Front open zipper side pocket brassier.
- It gave look like sports brassier, its very comfortable to touch and wear.
- Designed to make a woman look younger and ravishing.



Fig. No. 14 Design for Prosthetic Brassiere

9) Design 9:

Fig. No. 15 shows the following design characteristics for use by breast cancer patients:

- Broad cross straps on back, it provides enough support to keep your back from hurting.
- Helps to support the imbalance due to mastectomy



Fig. No. 15 Design for Prosthetic Brassiere

E. Results of Survey 2 from Patients:

The above designs were created for prosthetic brassieres and the same were shown to the patients using prosthetic brassieres. They were asked to review the designs and rate the various aspects of a brassiere on a rating scale of 10. The responses received from the participants are as follows:

1) Fabric Preference for Brassieres:

Figure No. 16 shows the preferences of fabric for brassieres, on a scale of 10. It can be noted that the highest rating has been given to woven cotton fabrics, keeping comfort in mind, followed by knitted fabrics which has a rating of 6. Lace and woven lace fabrics are not as preferred for prosthetic brassieres.



Fig. No. 16 Fabric Preferences for Prosthetic Brassieres

2) Color Preference for brassieres:

Figure No. 17 shows the color preference for the prosthetic brassieres. It is evident from the results that the participants prefer light / nude colors which have received a rating of 9 and 7 respectively.



Fig. No. 17 Color Preference for Prosthetic Brassieres

3) Preference for Designs of Prosthetic Brassieres:

Figure No. 18 indicates the preference for Designs for prosthetic brassieres. Nine designs were created on the basis of the feedback received from the patients. Of all the designs created, maximum ratings were given to Design 1 and Design 9 followed by Design 4. The design characteristics show a front opening, which offers more comfort while wearing and removing, Cross back design is also preferred since it offers more support, thus helping in balancing the imbalance due to the mastectomy. Design 4 has been rated 7 on 10 by the patients, which has a plunge neck, enhancing the body image and selfesteem of the wearer.



Fig. No.18 Preference for Designs for Prosthetic Brassieres Design

CONCLUSION

The results of the study indicate that the patients of breast cancer who have undergone mastectomy prefer comfortable and stylish yet low-cost options in prosthetic brassieres. Market research shows the availability of only cotton woven prosthetic brassieres in white and skin colors. These brassieres are created in the same way as a regular brassiere, only with the addition of a pocket to insert the prosthetic pad. It is important to understand the ergonomic as well as the psychological issues associated with mastectomy. It is essential to introduce a sizing chart specially created for mastectomy patients. This also highlights the need of a trained and experienced mastectomy fitter who can understand the issues and customize prosthetic brassieres. Studies can also be done to enhance the performance of the brassieres through application of comfort management and anti-microbial finishes thereby giving more comfort to the wearer and avoid rashes caused by long-term use of prosthetic pads.

REFERENCES:

- https://www.cancer.org/cancer/breast-cancer/about/what-isbreast-cancer.html
- https://www.mayoclinic.org/diseases-conditions/breastcancer/symptoms-causes/syc- 20352470
- https://www.breastcancer.org/treatment/surgery/reconstructio n/prosthetics#:~:text=Breast% 20prostheses% 20come% 20 in% 20many,specially% 20designed% 20bra% 20or% 20cam isole.
- https://breastcancernow.org/information-support/facingbreast-cancer/living-beyond-breast-cancer/yourbody/breast-prosthesis/types-breast-prosthesis
- https://www.hortonsoandp.com/category/mastectomy/ http://lacenlingerie.com/mastectomy-bra-an-aid-for-thesurvivors/
- https://www.hopkinsmedicine.org/health/treatment-tests-and-

therapies/postmastectomy-prosthesis

- https://www.amoena.com/global/about-us/breast-formbasics/ https://contourmed.com/how-to-care-for-yourcustom-breast-form/
- https://breastcancernow.org/information-support/facingbreast-cancer/living-beyond-breastbody/breast-prosthesis
- https://www.businesswire.com/news/home/20190206005385/ en/Global-Breast-Prosthesis-Market-Report-2019-Breakdown
- https://pubmed.ncbi.nlm.nih.gov/9676177/
- https://pubmed.ncbi.nlm.nih.gov/9128231/
- https://www.archivesofpathology.org/doi/full/10.1043/0003-9985%282003%29127%3Ce115%3AALCLAI%3E2.0.C O%3B2
- https://breastcancernow.org/information-support/facingbreast-cancer/living-beyond-breast- cancer/suppliers-brasprostheses-clothes-swimwear
- https://www.cancercouncil.com.au/cancerinformation/managing-cancer-side-effects/breastprostheses-and-reconstruction/breast-prostheses/wearingone/
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5473097/
- https://www.researchgate.net/publication/8126076_Women's _Satisfaction_with_Their_Breast_Prosthesis_What_Deter mines_a_Quality_Prosthesis
- https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/postmastectomy-prosthesis
- https://breastcancernow.org/information-support/facingbreast-cancer/living-beyond-breast-cancer/yourbody/breast-prosthesis/types-breast-prosthesis