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Potential Psychological Benefits of a Regenerative Graft for Nipple Reconstruction

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Abstract

Mastectomy is a frequent therapeutic treatment that many women with breast cancer undergo. Many women's self-image, femininity, and sexual well-being are intimately related to their appearance of their breasts. This type of surgery and subsequent psychological distress that is caused by the disfigurement of one's breast has been somewhat modified with improved plastic surgical techniques. Studies have shown that much of the psychological stress is related to the appearance and preservation of the nipple. A novel human-derived allogeneic acellular regenerative graft, the BioAesthetics NACgraft, has been developed to provide a better a solution for this significant psychological and aesthetic problem.

Keywords: Breast cancer; Nipple reconstruction; Mastectomy; Breast surgery

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Introduction

There were approximately 2.1 million world-wide new diagnoses of breast cancer in 2018 [1]. This common disease will strike about 1 in 8 women. Data from 2017 shows approximately 252,710 patients to have newly diagnosed invasive breast cancer with 40,610 deaths from cancer in North America [2]. The diagnosis is made by history, physical exam, mammography, MRI (in selected cases), breast ultrasound, core biopsy with histological determination of molecular markers of estrogen receptors (ER), progesterone receptors (PgR), human epidermal growth factor receptors (formerly HER2 now ERBB2), and antigen Ki67. These markers are integral to the type of therapy that is chosen. The treatment for nonmetastatic breast cancer is to remove the tumor from the breast and regional lymph nodes to prevent metastasis and reoccurrence. A combination of therapies is used for the treatment of early breast cancer. It consists of local modalities, surgery, radiotherapy, systemic anticancer treatments and supportive measures all delivered in diverse sequences. The choice of treatment strategy is based on the tumor burden/location (size and location of primary tumor, number of lesions, extent of lymph node involvement) and biology (pathology, including biomarkers and gene expression), as well as the age, menopausal status, general health status and preferences of the patient.

Psychological impact of breast cancer and mastectomy

The psychological aspects of a diagnosis of breast cancer are complex and far reaching. When a woman is diagnosed with breast cancer, a cascade of events with significant psychological impact begins. She must first cope with the diagnosis followed by treatment decisions all of which increase fear, anxiety, and depression. Since the breast is so important in the external (and frequently internal) identification of femininity, this diagnosis and treatment plan can have a devastating psychological impact. Women with breast cancer experience significantly poorer body image and greater rates of sexual dysfunction than do healthy women [3]. This may lead to feelings of self-consciousness, insecurity, inferiority, self-loathing, and sexual dysfunction, all which motivate many women to seek reconstructive surgery [4]. How each woman copes with this situation is based on a myriad of factors including overall health, state of mind, body image (especially as it relates to their breasts), femininity, sexuality, general anxiety, age, mental health, education, outlook on life, and general optimism. Treatment can take many forms but frequently involves mastectomy and/or radiation and chemotherapy, which adds to additional concerns of losing hair, recurrence of cancer, surgical complications, and losing a breast.

Mastectomy presents an unwelcome complex of psychological stress for a woman that is affected by multiple factors such as age, psychological well-being, general anxiety level, general health, medical history, extent and type of surgery planned, fear of additional cancer, fear of complications from the surgery, use of chemotherapy or radiation therapy, emotional relationships, sexual well-being, body image, and confidence in her surgical

team [5,6]. These complex physical, social, medical, and emotional factors all interact with the outcome of the surgical procedure to make an impact on a woman's quality of life. Sexual problems affect a significant number of these women and vary greatly, from 25 to 100 percent [7]. Sexual identity after breast cancer affects sexuality, body image, and frequently leads to self-loathing and relationship disturbances. Symptoms of sexual dysfunction in breast cancer patients is often exhibited by decreased libido, dyspareunia, vaginal atrophy and dryness, loss of breast sensitivity, and lowered sexual pleasure and satisfaction [8]. This is often coupled with considerable body shame and dissatisfaction, feelings of physical unattractiveness, and decreased self-esteem and femininity [9]. In order to prevent many of these sexual and psychological complications associated with breast surgery many women have been opting for reconstructive surgery [10]. This trend has increased for early stage breast cancer due to improved surgical reconstructive techniques with better cosmetic outcomes [11].

The nipple's importance to the psyche

More in-depth research reveals that a woman's body image, femininity, sexual libido and functioning, as well as psychological adjustment to her mastectomy are intimately linked to the preservation of the appearance and sensation of the nipples. Several studies have shown that preserving or reconstructing the nipple-areolar complex (NAC) creates a positive impact on body image and psychological adjustment in women with breast cancer. Body image is known to be a multidimensional concept that not only involves expectations with one's appearance [12], but also body image disturbances and investment in appearance (which is the importance of body image in defining self-worth) [13]. Those women who have shown high appearance investment and low self-body image also show close association not only with self-esteem, but of general psychosocial functioning. It is widely agreed that body image is a prominent issue in a woman's experience with mastectomy.

Although the treatment of breast cancer has significantly improved from the primary use of disfiguring radical mastectomy, with its potential of significant psychological scarring, to more conservative surgeries such as skin-sparing mastectomy (SSM) or nipple-sparing mastectomy (NSM), there is still a significant fear of treatment failure, with mortality, morbidity, and disfigurement as a possibility. As surgical techniques continue to evolve, SSM, which preserves the breast skin envelope, and NSM, which preserves the nipple, have been developed [14]. Following treatment, in an effort to feel like themselves again, patients often elect breast and nipple reconstruction. Breast reconstruction can take many forms (tissue expander, autologous flaps, SSM) and has been shown to have a positive psychological impact for patients. NSM has been the next advancement in this type of surgical oncology treatment. NSM is a derivative of SSM but uses thinner skin flaps and creates a 2-3 mm nipple-areolar flap [15]. NSM is only applicable to a small percentage of patients. The best candidates for NSM and direct-to-implant breast reconstruction are those women who want to keep their current breast size and have a defined breast ptosis (when the nipple is at or up to 1 cm below the crease {Grade I} or ptosis with the nipple at a level 1 to 3 cm below the crease {Grade II}) [16,17]. A woman's psychological perception of her breasts as symbols of her femininity and attractiveness plays a big part in her decision to have reconstructive breast surgery [18]. The goal of NSM is to remove all the cancer, have limited surgical complications, and establish a more natural contour of the breast. It was also hoped to provide better projection and sensation, but frequently does not provide the wanted sensation or the optimum projection, so not fulfilling the cosmetic and subsequent psychological outcome, which would lead to the development of a better body image, feeling of self-worth, sexuality, and quality of life. This procedure is not even possible in many patients who have nipple involvement with induration, retraction, fixation, ulceration, pathologic nipple discharge, or Paget's disease. This type of surgery is avoided if the tumor is close to the NAC, or if they have had prior breast surgery with periareolar incisions [19].

More recent research has shown that prophylactic NSM may actually provide a better long-term body image and sexual well-being for women compared with SSM. Those who chose the NSM procedure also did not experience higher distress over future breast cancer risk or other psychosocial functioning than the women who chose the SSM procedure [20]. In several studies with those patients who were eligible, NSM followed by post mastectomy reconstructive surgery has been found to provide a greater sexual and psychosocial-sparing well-being effect than those with SSM and reconstructive nipple surgery [21]. Zong has shown that there is a big difference in psychological outcomes if the NAC is spared during mastectomy rather than reconstructed at a later date under local anesthesia [22]. He found that patients exhibited lower satisfaction with a reconstructed nipple. In addition, Wei reported that psychosocial well-being and sexual well-being are lower in SSM compared to NSM [23]. The re-creation, by surgery and/or tattooing, of the nipple has a high correlation with overall patient satisfaction and acceptance of body image. Unfortunately, the long-term patient total satisfaction has been reported to be only 16% [24].

However, despite the tremendous increase in NSM, there is still controversy over the appropriate patient, the risk of surgery, preferred type of reconstructive surgery, and patient safety and satisfaction [25]. NSM has been found to have an incidence of less than 1% cancer in the retained nipple after risk-reducing mastectomy, but the rate of nipple necrosis varies from 8% for total necrosis to 16% for partial necrosis [26]. Reported rates of NAC and mastectomy flap necrosis range from 4.4% to 37.5% and 2% to 12.7% in the literature, respectively [27]. Established risk factors for NAC and mastectomy flap necrosis include elevated body mass index (BMI), smoking, preoperative radiation, incision placement, and mastectomy specimen weight, among others [28]. But many times after NSM the nipple will flatten. Before the nipple stabilizes, during the first 3 months as much as 30% of the nipple flattens [29].

In order to improve surgical outcomes, new regenerative medical technology has been developed to address many of these problems with reconstruction of the NAC. Nipple reconstruction is the crowning achievement of a successful

breast reconstruction. However, diverse surgical techniques have been attempted to reconstruct the NAC with a decrease over time of nipple projection still being a problem. This causes a poor aesthetic result with a subsequent psychological impact of overall patient disappointment. Many surgeons have tried the insertion of alloplastic materials, such as calcium hydroxyapatite, polytetrafluoroethylene, or autologous tissue grafts, to prevent flattening with added support [30]. However, this can lead to increased operative times, pain, infection, and greater patient morbidity. Unfortunately, many of these are non-permanent, non-living nipples that do not have adequate depth or projection. Conventional techniques (autografts, CV flaps, etc.) and newer product techniques (Cook Biodesign Nipple Reconstruction Cylinder [NRC] and NSM) still do not provide adequate solutions for most patients. Conventional flaps lose 70% of projection in 1 year and NRC maintenance of nipple projection was only 37.3% at 1 year and only 30% of women studied had satisfactory sensation in their nipples [31].

Allogeneic acellular graft for NAC reconstruction

The next stage in the improvement of surgical techniques for breast reconstructive surgery is the development of the human-derived allogeneic acellular graft (AAC) for NAC reconstruction (Bio-Aesthetics NAC graft) **(Figure 1).**

The use of an AAC graft would allow these patients a living and permanent tissue engineering solution to nipple reconstruction [32]. The clinical application would be to replace nipples during reconstructive surgery and to enhance the aesthetic results.

Figure 1 Allogeneic acellular graft for NAC reconstruction.

This clinical application should help enhance mastectomy and the procedure may obviate the fear associated with cancer reoccurrence when the NAC is spared for cosmetic purposes. The use of nipple regeneration may also provide a more natural, safer alternative with better cosmetic and psychological results contributing to improvement in a patient's quality of life. The idea that a woman's own cells are helping to restore her breasts with a more "natural" nipple may be very appealing to some women and help provide a better image of them. The AAC graft is the first decellularized NAC for NAC reconstruction, and it preserves the extracellular matrix including insoluble protein and proteoglycan components [33]. Since it is acellular, it obviates the rejection risk and does not require an immediate blood supply to sustain the graft. These nipples regenerated by (AAC) graft should be able to maintain nipple projection and provide a better cosmetic result. This new product is in end stage development and could be the ultimate solution, by being available to more women and providing a safe, long-lasting nipple, without the increased potential of significant complications such as necrosis and the need for additional surgery. Thus far, promising preclinical data have been obtained and we look forward to observing its clinical performance. This regenerative graft has the potential to relieve some of the anxiety and psychological and sexual stress associated with mastectomies and their complications, and helps these patients obtain a better quality of life.

Discussion and Conclusion

The diagnosis of breast cancer with the need for surgery has major psychological implications since the breast is closely tied to a woman's body image, femininity, and sexual well-being. In order to keep the breast as intact as possible, NSM with reconstructive surgery has been the most preferred surgical treatment. However, this is not possible in all women, and it may present risk of cancer recurrence in others. The cosmetic results are frequently not ideal, with the potential for flattening nipples, necrotic tissue, and the need for additional surgery. New technological breakthroughs are being developed to address this problem. A regenerative AAC graft has the potential to solve many of these problems and prevent much of the psychological stress that many women who undergo mastectomy endure.

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