Annals of Medicine and Surgery 5 (2016) 57–66

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.annalsjournal.com

Observed outcomes on the use of oxidized and regenerated cellulose polymer for breast conserving surgery – A case series

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HIGHLIGHTS

- The oncoplastic breast surgery (OBS) joins tumor excision with reconstruction techniques.
- The oxidized regenerated cellulose polymer is a filler to support volume and shape.
- 18 patients with T1-T2 breast cancer and proliferative benign lesion were selected.
- Complications occurred within 36-month after OBS in elderly patients with fatty breasts.
- Aesthetic outcomes improved with lower age, higher dense breasts and lower BMI.

ARTICLE INFO

Article history:
Received 10 October 2015
Received in revised form
1 December 2015
Accepted 19 December 2015

Keywords:
Breast cancer
Breast-conserving surgery
Oncoplastic breast surgery
Oxidized regenerated cellulose polymer

ABSTRACT

Background: Oxidized regenerated cellulose polymer (ORCP) may be used for reshaping and filling lack of volume in breast-conserving surgery (BCS). The study aimed to observe both the aesthetic and diagnostic outcomes in patients with different age, BMI, breast volume, and breast tissue composition over 36 months after BCS with ORCP.

Patients and methods: 18 patients with early breast cancer and with proliferative benign lesions underwent BCS with ORCP that was layered in three-dimensional wafer, and placed into the Chassaignac space between the mammary gland and the fascia of *pectoralis major* with no fixation. After surgery, patients started a clinical and instrumental 36-month follow-up with mammography, ultrasonography, magnetic resonance imaging (MRI) and cytological examination with fine needle aspiration when seroma occurred.

Results: Below the median age of 66 years old no complications were observed even in case both of overweight, and large breasts with low density. Over the median age seromas occurred with either small or large skin retraction, with the exception of 1 patient having quite dense breasts and low BMI, which had no complications. In elderly patients, 1 case with quite dense breasts and high BMI showed severe seroma and skin retraction, while 1 case with low BMI and less dense breasts highlighted milder complications.

Conclusion: During 36 months after BCS with ORCP, a significant correlation between positive diagnostic and aesthetic outcomes and low age, dense breasts, and low BMI of patient was observed. Despite of the few number of cases, either low BMI, or high breast density improved the aesthetic outcomes and reduced the entity of complications even in the elderly patients.

1. Introduction

In the last few years, breast surgeons have learned a new discipline for breast cancer treatment: oncoplastic breast surgery (OBS) [1]. Breast and plastic surgeons often work together to ensure a radical surgery and achieve the best possible cosmetic result, including acceptable breast symmetry [2]. Breast-conserving surgery (BCS) could provide better aesthetic results when compared to

Abbreviations: BCS, breast-conserving surgery; OBS, oncoplastic breast surgery; ORCP, oxidized regenerated cellulose polymer.

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http://dx.doi.org/10.1016/j.amsu.2015.12.050

mastectomy. It has become the mainstream surgery for early breast cancer [1,2]. If less than 20% of the breast volume is excised, a level I procedure is adequate and a breast surgeon who lacks specific training in plastic surgery can carry it out; excisions that exceed 20–50% of the breast volume require a level II procedure that is based on mammoplasty techniques and specific training [3]. OBS requires preoperative planning according to the volume of the breast and location of the tumour for proper reduction, displacement, and replacement technique to fill the breast deformation. Breast reshaping absorbs the volume loss and decreases the risk of localized defects, although some zones have a high risk of deformity and cosmetic failure [4]. There is a wide spectrum of reconstructive options, allowing patients and surgeons to choose the best reconstruction technique [5]. Usually, reconstruction after oncological resection can be performed with expanders and implants or autologous grafts (fat or muscle) to correct volume and shape defects [6].

The oxidized regenerated cellulose polymer (ORCP) has been used in recent years to fill resection defects, to adjust the shape, the volume and the symmetry of the breast and to prevent the skin retraction. The ORCP is a haemostatic agent with bactericidal effects against aerobic and anaerobic bacteria due to its acidic pH, and it acts as a scaffold for fibrin deposition, creating a three-dimensional structure as a permanent filler [7]. This haemostatic agent may be peeled off in the desired amount, facilitating placement of the customized pieces under both the gland and skin.

Despite of its role in promoting dermal fibroblast proliferation and cell migration [8–10], it is not yet established whether the use of ORCP can be extended to all types of breast [11]. To address this gap in knowledge, a 36-month follow-up was set up in order to evaluate which factors related to patients (age, BMI, breast volume and breast density) could either improve or worsen the diagnostic and aesthetic outcomes from the use of the ORCP in BCS.

2. Materials and methods

2.1. Study design and setting

From January 2012 to May 2013, 18 women underwent BCS with ORCP at the Department of General Surgery of the “San Giacomo” Hospital in Novi Ligure (Italy) with hospitalization in day hospital and hospital discharge after 24 h from BCS.

All the 18 patients started a clinical and instrumental 36-month follow-up with mammography, ultrasonography, magnetic resonance imaging (MRI) and cytological examination with fine needle aspiration when seroma occurred. Postoperative adjuvant therapy and follow-up were carried out according to the Breast Cancer Follow-Up and Management Guidelines [12].

2.2. Eligibility criteria of the patients

The social and physical criteria of patient selection were as follows: a) sufficient hygiene and the ability to match pre and postoperative prescriptions; b) possessing a telephone and having the support of a responsible caretaker at home; c) age under 90.

2.3. Exclusion criteria of the patients

The exclusion criteria for patient selection were as follows: a) absence of morbid obesity i.e., BMI >40, or pathologic thinness i.e., BMI <18.7; b) absence of a history of addiction to alcohol, drug or tobacco; c) absence of suffering from skin disease, rheumatic disease or metabolic disease, such as diabetes.

Table 1
Demographics, BMI, breast volume[a], and BiRADS breast tissue composition class [13] for patients who underwent BCS with ORCP.

Patient	Age	Provenience	BMI	Breast volume (cm^3)	BiRADS class
1	33	North Italy	20	200	4
2	37	North Italy	22	300	3
3	38	North Italy	20	250	3
4	39	Romania	21	300	3
5	44	North Italy	20	250	3
6	44	China	19	300	4
7	45	North Italy	22	200	3
8	60	North Italy	29	350	2
9	63	North Italy	29	400	2
10	69	North Italy	25	300	2
11	70	North Italy	29	350	2
12	71	North Italy	32	500	1
13	73	North Italy	33	500	1
14	75	North Italy	31	500	1
15	76	South Italy	21	300	3
16	76	South Italy	30	300	3
17	87	North Italy	20	200	1
18	88	North Italy	26	300	1

[a] Cup size was used for breast volume measurement.

2.4. Oncological criteria of the patients

Oncological criteria were evaluated by mammography, ultrasonography, core biopsy, and histological diagnosis and were as follows: proliferative benign breast lesions and T1-T2 breast cancer with low-medium probability of a positive lymph-node.

2.5. Patient characteristics

The 18 patients who met the inclusion criteria were female with

Table 2
Distribution of breast volume and breast density, histology and location of lesions, and of amount of ORCP among the 18 patients who underwent BCS with ORCP.

Breast volume[a]	
Small	27.7%
Medium	38.9%
Large	33.3%
Breast density (BiRADS class) [13]	
1	27.7%
2	22.2%
3	38.9%
4	11.1%
Lesion histology	
Benign	22.2%
Malignant	77.7%
Location of lesions[b]	
Q1	44.4%
Q1 – Q2	22.2%
Q2	11.1%
Q3	11.1%
Q5	5.55%
Q3-Q4	5.55%
ORCP used for BCS	
Half of 1 piece	5.55%
Single piece	83.3%
Two pieces	11.1%

[a] Breast size classification was done using cup size as follows: large breasts (>350 cm^3); medium breasts (250–300 cm^3), small breasts (<250 cm^3).

[b] Quadrant per quadrant Atlas (orientation for left breast) has been intended as follows [14]: Q1 = upper outer quadrant 1–2 o'clock; Q2 = upper inner quadrant 9–11 o'clock; Q3 = lower outer quadrant 4–5 o'clock; Q4 = lower inner quadrant 7–8 o'clock; Q5 = central subareolar with NAC resection; Q1–Q2 = upper pole 12 o'clock; Q3–Q4 = lower pole 5–7 o'clock.