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The role of oxidized regenerate cellulose to prevent cosmetic defects in oncoplastic breast surgery

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ABSTRACT. – BACKGROUND, Breast conserving surgery (BCS) combined with postoperative radiotherapy has become the gold standard of locoregional treatment for the majority of patients with early-stage breast cancer, offering equivalent survival and improved body image and lifestyle scores as compared to mastectomy. In an attempt to optimize the oncologic safety and cosmetic results of BCS, oncoplastic procedures (OPP) have been introduced in recent years combining the best principles of surgical oncology with those of plastic surgery. However, even with the use of OPP, cosmetic outcomes may result unsatisfying when a large volume of parenchyma has to be removed, particularly in small-medium size breasts.

AIM, The aim of this article is to report our preliminary results with the use of oxidized regenerate cellulose (ORC) (Tabotamp fibrillar®, Johnson & Johnson; Ethicon, USA) as an agent to prevent cosmetic defects in patients undergoing OPP for breast cancer and to analyze the technical refinements that can enhance its efficacy in optimizing cosmetic defects.

METHODS, Different OPP are selected based on the location and size of the tumor as well as volume and shape of the breast. After excision of the tumor, glandular flaps are created by dissection of the residual parenchyma from the pectoralis and serratus muscles and from the skin. After careful haemostasis, five layers of ORC are positioned on the pectoralis major in the residual cavity and covered by advancement of the glandular flaps. Two additional layers of ORC are positioned above the flaps and covered by cutaneous-subcutaenous flaps.

RESULTS, The use of ORC after OPP has shown promising preliminary results, indicating a good tolerability and positive effects on cosmesis.

CONCLUSIONS, This simple and reliable surgical technique may allow not only to reduce the rate of post-operative bleeding and infection at the surgical site but also to improve cosmetic results.

Key Words:

Breast cancer, Oncoplastic surgery, Cosmetic results, Oxidized regenerate cellulose.

Introduction

Breast conserving surgery (BCS) combined with postoperative radiotherapy has become the gold standard of locoregional treatment for the majority of patients with early-stage breast cancer, offering equivalent survival and improved body image and lifestyle scores as compared to mastectomy[1-2]. In the era of early diagnosis and effective neoadjuvant therapies, BCS can be offered to over two-thirds of breast cancer patients. The goals of BCS are to ensure a complete removal of the tumor with adequate surgical margins while preserving the natural shape and appearance of the breast. In some cases, achieving both goals may be quite challenging and as the need to secure an oncologically safe resection is the first priority, BCS may lead to unsatisfying cosmetic results[3-7].

In the effort to overcome this difficulty and expand the use and efficacy of BCS, oncoplastic procedures (OPP) have been introduced in recent years gaining widespread attention both among surgeons and patients[8-12]. These procedures associate the best principles of surgical oncology with the best principles of reconstructive surgery to optimize oncologic safety and cosmetic outcomes.

OPP are characterized by more aesthetic skin incisions, use of enlarged resection patterns, careful reshaping of the gland, eventually by repositioning of the nipple-areola complex (NAC) to the center of the breast mound, and symmetrization procedures on the controlateral breast to improve cosmesis.

In our Department the adoption of OPP since 1998 has allowed to expand the use of BCS to over 80% of our breast cancer patients

Over the last 5 years in performing OPP, we have started to use oxidized regenerate cellulose (ORC) (Tabotamp fibrillar®, Johnson & Johnson; Ethicon, New Brunswick, NJ, USA) as a possible aid to reduce the risk of postoperative haematoma and in-

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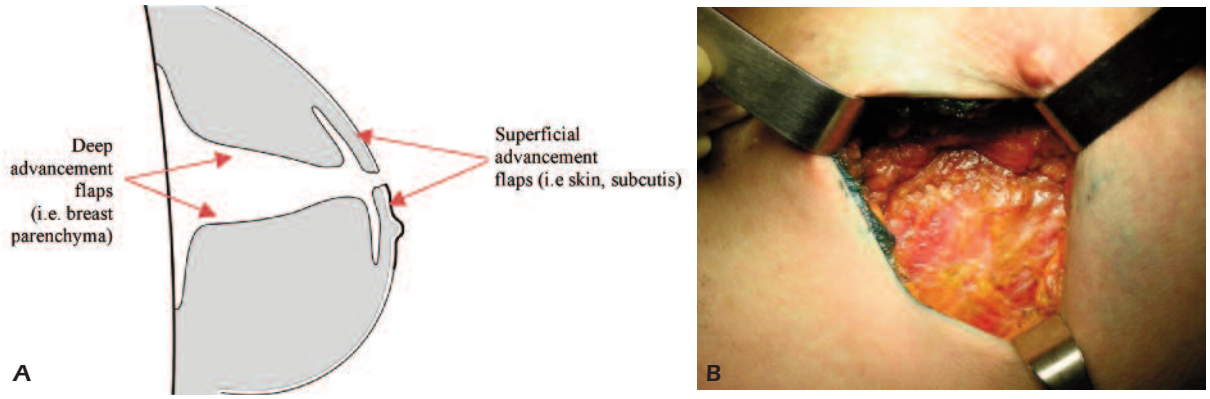

Figure 1. ***A,*** After complete tumor excision, adequate reshaping of the gland is performed by dissecting the residual breast parenchyma from the pectoralis major fascia and then from the superficial subcutaneous tissue for approximatively 2 cm. With this dissection, two opponent superficial advancement flaps (i.e. skin, subcutis) and two opponent deep advancement flaps (i.e. breast parenchyma) are obtained. ***B,*** Residual cavity after quadrantectomy and adeguate reshaping of gland.

fections. In the follow-up of these patients, the haemostatic and bactericidal value of ORC was confirmed and an improvement of the cosmetic outcomes was also empirically observed. As consequence, we have hypothesized a possible role for ORC as a reconstructive biomaterial that could facilitate the healing of the residual cavity and adopted its use in OPP also for cosmetic purposes.

The aim of this paper is to describe this new surgical technique and analyze the preliminary results.

Patients and Methods

From February 2007 to April 2012, in 1004 patients undergoing an OPP for breast cancer at our Center, ORC has been used after quadrantectomy to reduce the risk of unfavorable cosmetic results.

Depending in the size and location of the tumor and the volume and shape of the breast as previously reported[8,9], different OPP have been used including glandular reshaping procedures, "round block" procedures, mammoplasty reduction procedures, central quadrantectomy procedures, inframammary fold procedures and batwing mastopexy procedures. The technique that we have used for ORC placement follows a standard pattern.

After complete tumor excision, adequate reshaping of the gland is performed by dissecting the residual breast parenchyma from the pectoralis major fascia and then from the superficial subcutaneous tissue for approximatively 2 cm. With this dissection, two opponent superficial advancement flaps (i.e. skin, subcutis) and two opponent deep advancement flaps (i.e. breast parenchyma) are obtained (Figure 1 A,B). Major

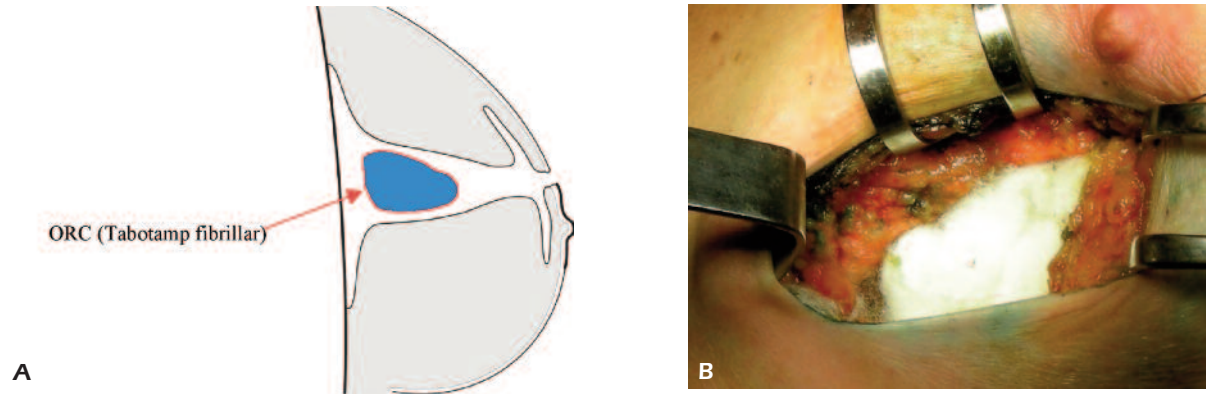

Figure 2. ***A,*** Five separate layers of ORC (Tabotamp fibrillar) are placed in the residual cavity, topping the pectoralis major muscle. ***B,*** ORC placed on the pectoralis major muscle to fill the cavity.

vascular perforators between the pectoralis muscle and residual parenchyma are preserved to minimize the risk of ischemic injury to the latter.

After careful control of the haemostasis, five separate layers of ORC (Tabotamp fibrillar) are placed in the residual cavity, topping the pectoralis major muscle (Figure 2 A,B). ORC is completely covered by advancement of the two deep glandular flaps, sutured with absorbable 2-0 sutures (Figure 3 A,B,C). Two additional separate layers of ORC (Tabotamp fibrillar) are then placed on the surface of the approximated glandular flaps (Figure 4 A,B) and covered by advancement of the superficial skin-subcutis flaps closed with a continuous absorbable 3-0 suture (Figure 5 A,B). Skin is then closed using intradermal non-absorbable 3-0 suture (Figure 5 C).

Results

The preliminary results with the use of this technique are promising, indicating a good tolerability and positive effects on cosmesis. An improvement of the cosmetic outcomes was empirically observed. The breast shape and contour were preserved and good symmetry was achieved with the contralateral breast. The patients were satisfied of the cosmetic results. We did not observe contour defect susceptible of ancillary treatments. No major complications were experienced in the follow-up of these patients. However, ORC always determines a post-operative seroma that may require repeated aspirations and were always managed with medical therapy. More demanding inflammatory reactions were observed only occasionally confirming haemostatic and bactericidal value of ORC. Two cases of allergic reactions with irritation, redness, itching, swelling, rash and hives in the mammary region was highlighted and solved after ten days with the use of steroids and antihistamine medications. Six months postoperatively, the patients undergo postoperative breast ultrasound examination as part of regular postoperative follow-up. In all cases breast ultrasound showed the presence of small round hyperechoic components within free fluid anaechoic accumulation. These typical small round images that are linked to the presence of fibrillar material always appeared hy-

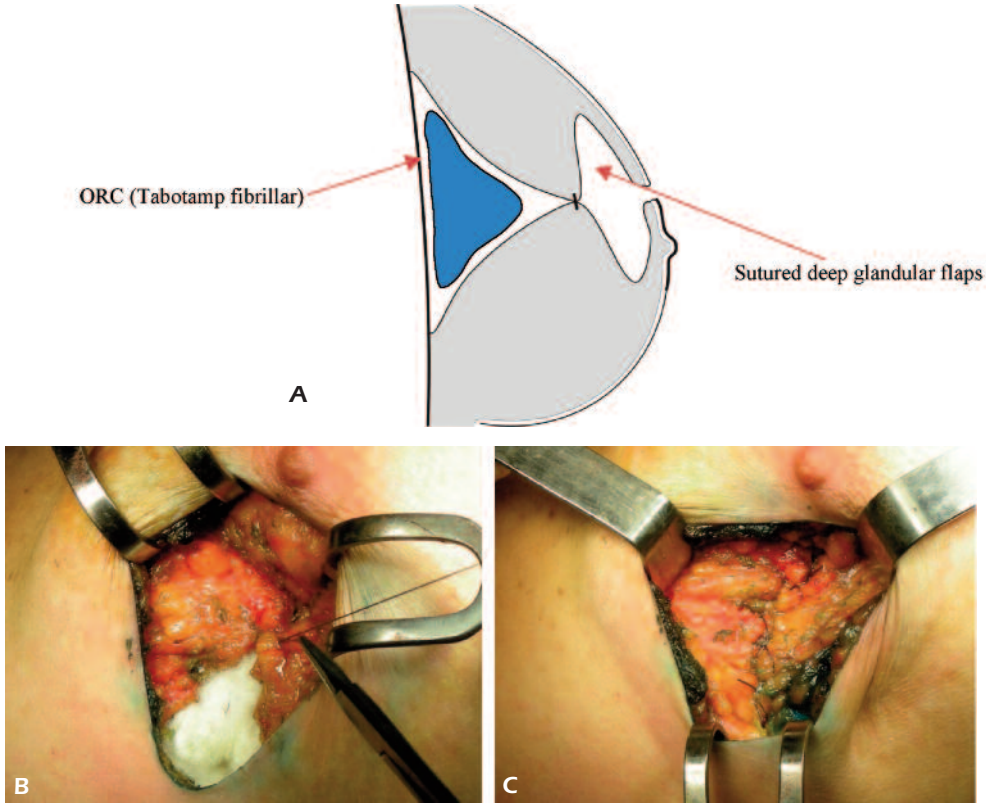

Figure 3. ***A,*** ORC is completely covered by advancement of the two deep glandular flaps, sutured with absorbable 2-0 sutures. ***B,*** The two deep glandular flaps advanced and sutured to cover ORC. ***C,*** The two deep glandular flaps completely cover the ORC.

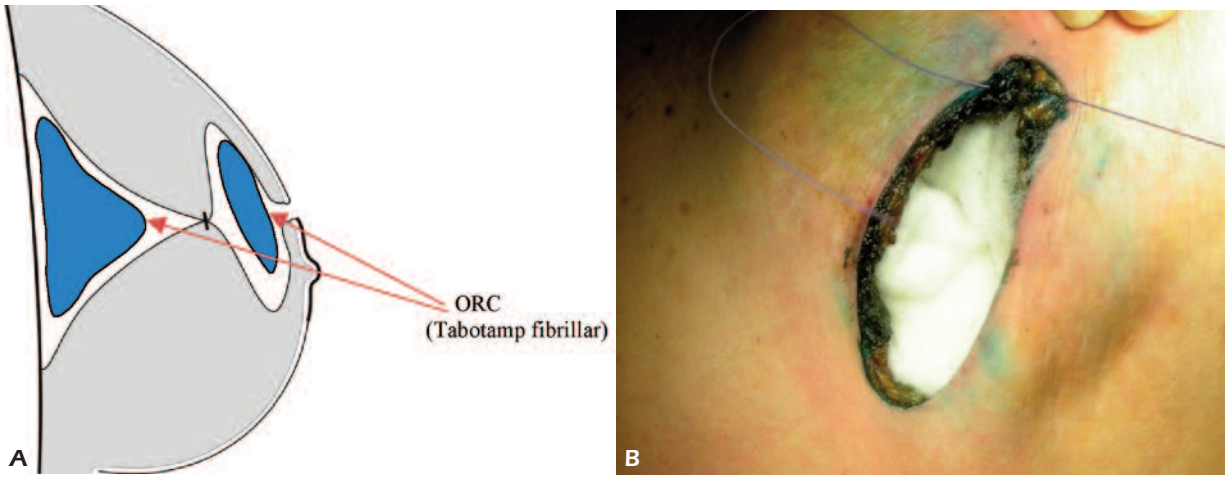

Figure 4. ***A,*** Two additional separate layers of ORC (Tabotamp fibrillar) are then placed on the surface of the approximated glandular flaps. ***B,*** ORC placed on the surface of the approximated glandular flaps.

perechoic, non-mobile, avascular, and adherent to the parenchymal tissue planes.

Discussion

ORC is a well-known haemostatic biomaterial with antimicrobial properties. It is a sterile absorbable fibrous material prepared by the controlled oxidation of regenerated cellulose. After ORC has been saturated with blood, it swells into a brownish or black gelatinous mass which aids in the formation of a clot, thereby serving as a haemostatic adjunct in the control of local haemorrhage[13-17]. In addition to its local haemostatic properties, ORC exhibits *in vitro* bactericidal properties against a wide range of Gram positive and Gram negative organisms including aerobes and anaerobes[18,19]. Due to its morphology it can be used at any surgical site as it can easily and rapidly adapt to any surface.

A possible role for ORC as a reconstructive biomaterial has also been hypothesized in cosmetic surgery of the nose. A few papers in the plastic surgery literature report the use of ORC as a wrap for the diced cartilage to obtain a moldable cartilage graft and create continuity with the surrounding tissues[20,21]. Erol[20] reported a small number of complications (less than 2%) with the use of ORC as a reconstructive scaffold in a total of 2365 patients undergoing primary rhynoplasty or treatment of post-surgical or traumatic nasal deformities with a follow-up ranging from 1 to 10 years. According to this Author ORC-related fibrosis represented the main responsible for nasal shaping.

Furthermore, other clinical applications of ORC with reparative and reconstructive purposes have been described[22-25].

To our knowledge, this is the first report on the use of ORC with reconstructive aims in breast surgery. Our preliminary results in a large series of more than 1000 patients indicate a positive role for ORC in preventing post-surgical breast deformities. This role could be explaned through a triple action:

- A mechanical action: ORC acts as a filler material that limits the volume defect created by the surgical resection and at the same time it interposes itself between the pectoralis major fascia and the skin avoiding skin-to-fascia adhesion.
- A riparative action: ORC seems to stimulate fibrogenesis in the first postoperative weeks and to favour riparative processes by inhibition of metallo-proteasis, absorption of free oxygen radicals and metallic ions as well as stabilize some growth factors[26-32].
- A fibrogenesis action: ORC idrolytic products seems to have chemocinetic stimuli on human fibroblasts favouring their migration and fibroblastic activity[27,30,33]. These actions culminate in the creation of a three-dimensional structure that acts as a permanent filler, thus allowing a definitive reconstruction of the defect and avoiding unpleasant cosmetic outcomes.

Thanks to this triple action, ORC could be considered as a reconstructive aid to better preserve the shape and volume of the mammary gland and optimize the aesthetic results of OPP. Further studies are needed to better assess these preliminary results.

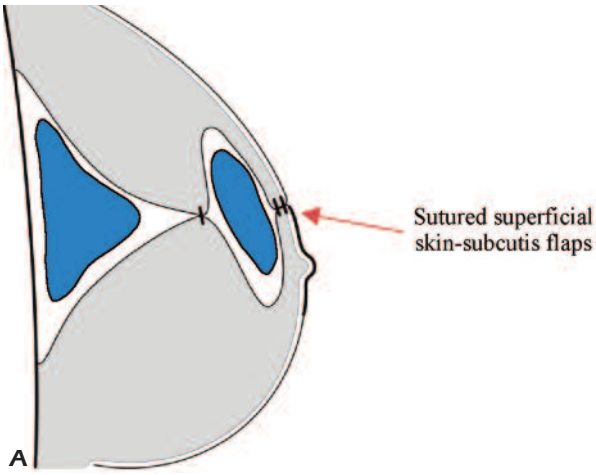

Figure 5. ***A,*** Two additional layers of ORC are covered by advancement of the superficial skin-subcutis flaps closed with a continuous absorbable 3-0 suture. ***B,*** ORC covered by sutured skin-subcutis flaps. ***C,*** Cosmetic result after six months.

Conclusions

The preliminary results show that our new surgical technique using ORC in OPP appears reliable, can ensure a good control of haemostasis, low rate of infection of the surgical site and favorable cosmetic results. Therefore, we believe that this method will further contribute to the oncoplastic surgical spectrum of breast-conservation therapy.

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