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A Possible Technique for the Complex Reconstruction of Exposed Breast Implant: Applicability and Microcirculation of the Capsule Flap

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ABSTRACT

Aim of the Study: Immediate breast reconstruction is often applied after mastectomy. However, inappropriate surgical technique, postoperative radiotherapy and infection may lead to tissue necrosis and implant protrusion. Traditional therapies frequently fail. However, previous data suggested that capsule flaps may be appropriate for the salvage of implants. Our goal was to investigate the usefulness of capsuloplasty in patients with exposed breast implant and to monitor the blood supply of capsule flaps during the operation. *Materials and Methods*: Capsuloplasty was performed in 19 patients with exposed implant. After removal of necrotic tissue, capsulotomy was performed, the planned flap was dissected free, the implant was covered with the flap and the wound was then closed. During operation, the blood flow of the flap was determined by means of laser Doppler flowmetry. Moreover, tissue samples were taken for histology and immunostaining for CD34. *Results*: The postoperative follow-up showed that capsule flaps survived in each case: no complications were found. The blood flow of the flaps did not change significantly during the intervention as compared with the baseline values. The histology and the immunohistochemistry revealed considerable vascularization and angiogenesis in the flap. *Conclusions*: Capsule flaps seem to be appropriate for the salvage of exposed implants and for enhancement of implant cover in the case of thin and injured tissue.

Keywords: breast reconstruction; capsule flap; exposed implant; microcirculation; laser Doppler; angiogenesis

INTRODUCTION

Immediate one-stage breast reconstruction is becoming a widely-accepted and preferred method. Implants should be covered with tissue of appropriate thick-

- 5 ness and viability especially if patients receive postmastectomy radiation therapy. It is known that radiotherapy may be accompanied by a number of complications¹ including impaired wound healing, wound separation, infection and fistula.²⁻⁴ These fac-
- 10 tors may lead to a considerable contraction of the capsule around the implant. This shrinking makes the surface of the implant irregular which therefore exerts uneven pressure on the overlying skin.

According to a hypothesis, the increased pressure affecting such areas may impair the microcirculation 15 of the covering tissue layer potentially resulting in necrosis and exposure of the implant.⁴ Inappropriate surgical technique may also cause insufficient local blood supply leading to necrosis and implant protrusion. Accompanying infection may contribute to this 20 process. Although exposed implants are traditionally treated by insertion of a new one, many authors have reported successful salvage of implant¹⁻³ or alternative therapeutic strategies.⁴⁻⁸ However, these interventions may fail in cases of previous radiotherapy or 25 where tissue is injured or thin, necessitating implant removal.

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For such cases, capsuloplasty seems to be an appropriate technique. The capsule appearing around the

- 30 implant is a reaction to foreign material.^{7,9} It consists of fibroblasts and collagen fibers, has own blood supply and previous radiotherapy contributes to its development.¹ Bengston and coworkers described the application of capsule flap decades ago. According
- 35 to their animal experiments, capsule flaps are viable and their vascular system is sufficient for the nutrition of the overlying skin graft.¹⁰ In human, several areas of use of capsule flap were reported e.g., prevention of implant wrinkling,^{7,11} pharyngeal reconstruction,¹²
- 40 shaping of inframammary fold¹³ and cover for exposed implants.⁵⁻⁸ However, the blood flow in capsule flaps has not yet been quantitatively determined *in vivo*.
- Thus, the goal of our present study was to investi-
- 45 gate the usefulness of capsuloplasty in patients with exposed breast implant and to monitor the blood supply of the capsule flaps during the operation.

MATERIALS AND METHODS

Patients

- 50 Capsuloplasty was performed in 19 females between January 2016 and November 2017. These patients underwent earlier mastectomy and immediate breast reconstruction. Their average age was 47.6 years (range: 33–72 years). The right side was affected in
- 55 10 cases and the left side in 9 cases. 4 patients underwent bilateral mastectomy. Bilateral capsuloplasty was performed in 3 of these 4 patients, the remaining 1 female underwent unilateral capsuloplasty (right side). Table 1 demonstrates the local60 ization of the defects indicating the operation. None
- of these patients received radiotherapy except 1 patient who underwent irradiation 1 year before mastectomy.

Surgical Procedures

65 Each intervention was preceded by careful consideration of the following parameter: quality and thickness and fistula, previous radiotherapy, localization of tissue damage, patient requirements and the extension of necrosis and wound separation. The patients were 70 carefully observed in order to detect visible signs of inflammation (erythema, edema). Moreover, leukocyte number, C-reactive protein and procalcitonin levels were also measured in each patient and samples were taken for microbiological examination. Signs of serious 75 inflammation and large tissue defect were considered exclusion criteria. However, in case of the involved patients the mentioned parameters did not display elevation and pathogenic bacteria were not found. (If capsule flap is not feasible, the implant is to be removed 80 and delayed reconstruction with a flap e.g., latissimus flap or abdominal TRAM shall be performed.) Figure 1A demonstrates a patient chosen for capsuloplasty. A pivotal point was the timing: the intervention should not be performed sooner than an appropriate 85 capsule is formed around the implant. The tissue defect in our patients appeared 8-13 weeks after the mastectomy (median interval: 9 weeks). By this time, the capsule around the implant was well-developed therefore it was appropriate to be used for reconstruction. 90 When the complication was recognized, the patients started to be prepared for the reconstruction which was performed within 3-5 days. During this period, the defect was covered with sterile dressing. Perioperative antibiotic therapy was launched that involved 95 daily 1000 mg cefuroxime (2×500 mg) administered orally. This therapy lasted 10-14 days. Another important issue was the determination of the area from which capsule can be gained for reconstruction. In 3 cases, an attempt was made to close the wound pri- 100 marily after removal of the necrotic tissue. The operation involved the following steps: after opening the wound the necrotic parts were excised, the implant was removed and capsulotomy was performed, the base of the flap remained intact, the planned flap was then dis- 105 sected free (Figure 1B). After that, the implant was positioned and covered with the capsule flap (Figure 1C). Mentor's Cohesive III implant with anatomical shape and textured surface was applied. In most cases, new implants were used. In a minority of the cases, when 110 the risk of infection and inflammation seemed to be low, the same old implants were applied. If the wound

of the breast skin, presence of inflammation, discharge

TABLE 1.	Localization	of the d	efects i	indicating	the o	operation.
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	Side		
Localization of the tissue defect	Left	Right	
Wound separation in the scar of mastectomy	3	3	
In the borderline of the inferior quadrants	2	4	
In the inferior lateral quadrant	0	2	
In the inferior medial quadrant	2	2	
In the superior lateral quadrant	1	0	



FIGURE 1. Photo documentation of the surgical intervention. A: A patient selected for capsuloplasty. B: The dissected capsule flap. C: The implant after positioning and covering with the capsule flap. D: The closed wound. E: The healed wound 3 month after the operation.

was able to be closed tension free after application of the capsule flap, the implant size was not reduced. If the tension free wound closure seemed to have diffi-

- culties, a smaller implant was chosen. The wound was closed with sutures (Figure 1D). Drainage was applied when necessary. Various capsule flaps were applied: anterior-superior medial, anterior-superior-lateral, in
- 120 1 case divided flap, and also posterior flaps from the chest wall. In 3 cases, thoraco-epigastrial fasciocutaneous flaps were used together with capsule flap in order to complete the reconstruction due to a large defect.
- 125 Patients were discharged on 3rd-5th postoperative day. An examination was performed 1 week after the surgery. The second examination and removal of the stitches were 1 week later. Following this, the patients were examined monthly once (inspection and palpa-
- 130 tion of the operated site and the above mentioned laboratory examinations were performed, too). Ultrasound imaging was performed in every 3 months (presence of capsular contracture and peri-implant fluid).

Laser Doppler Flowmetry

- Microcirculation of the flaps was monitored by means 135 of the PeriFlux System 5000 (Perimed, Järfälla, Sweden). This equipment transmits low power laser light (780 nm) to the tissue via a fiber optic probe. The returning light is processed and the relative number and 140 velocity of the blood cells in the tissue are calculated and presented as blood perfusion. The sensor was fixed to the tissue with a sterile adhesive strip provided by the manufacturer. Measurements were performed at 4 different time points: before the incision of the intact
- 145

115

of the capsule flap and after fixation of the flap. At each time point, recordings were made for 5 minutes. Perisoft for Windows software was used for data collection, storage and analysis. The data are presented as perfusion unit (P.U.). 150

Histology and Immunohistochemistry

During operation, biopsies were taken from the capsule. Tissue samples were fixed in a buffered solution of formaldehyde (4%), embedded in paraffin and $4-\mu m$ thick sections were taken. In addition to 155 routine haematoxylin-eosin staining, sections were processed for immunohistochemical localization to highlight CD34 positive vessel density. Primary antibody to CD34 (clone QBEN/10 M7165; DAKO Glostrup, Denmark) was used at 1:200 (20 min). Anti- 160 gen retrieval was performed by Bond Epitope Retrieval solution 2 at pH = 9 by BOND MAX Autostainer (Leica Biosystems, Newcastle Ltd., UK). Immunosections were counterstained with conventional haematoxylin. 165

Statistical Analysis

Data analysis was performed with SigmaStat for Windows (Jandel Scientific, Erkrath, Germany). Since the normality test (Shapiro-Wilk) failed in few cases, nonparametric test was chosen. Friedman repeated- 170 measures analysis of variance on ranks was applied. In the Figure and Results, median values (M) with 25th and 75th percentiles (25p and 75p, respectively) are given, p < 0.05 was considered statistically significant. 175 4 J. Varga et al.

RESULTS

Attempts at the primary closure of wounds after removal of necrotic tissue failed in the above mentioned 3 cases: the implants were exposed again. How-

- 180 ever, application of capsule flaps led to the healing of these patients without complication. Postoperative follow-up (ranging from 2 months to 19 months) showed that capsule flaps survived in each case. No signs of inflammation, infection, hematoma, wound
- 185 separation and implant protrusion were found. Slight erythema was detected in 2 cases. In few cases, uneven surface and wrinkling were detected. However, our examinations excluded the capsular contracture and all of these signs ceased within 3 months. Figure 1E
 190 shows a patient in the 3rd postoperative month, a
- complete healing can be seen.

As concerns microcirculation of the flaps, the baseline median value in capsule flaps was 98.97 P.U. (25p = 73.56, 75p = 124.09). The perfusion in the

- 195 capsule did not change after the capsulotomy (M = 106.96%, 25p = 62.82, 75p = 157.07) as referred to the baseline values. Although a slight decrease was measured after preparation of the capsule (M = 64.08%, 25p = 33.36, 75p = 135.99) and fixation of the flap (M =
- 200 51.41%, 25p = 32.7, 75p = 96.99), this change was not statistically significant (Figure 2A).

The baseline values of the thoraco-epigastrial fasciocutaneous flaps: M = 14.87 P.U., 25p = 10.37, 75p = 32.15. No decrease was found in their blood after cap-

205 sulotomy (M = 95.56%, 25p = 48.14, 75p = 127.44), after preparation of the capsule (M = 120.27%, 25p = 45.32, 75p = 173.77) or after fixation of the flap (M = 62.52%, 25p = 31.58, 75p = 108.59) (Figure 2B).

Histological analysis revealed that capsules were well-vascularized and several vessels were present in

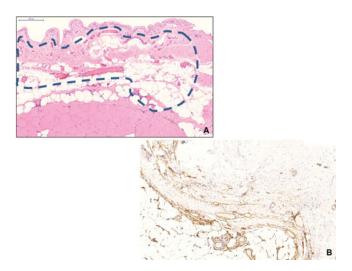


FIGURE 3. A: Low power micrograph of the capsule (haemat oxylin-eosin staining, slide scanning, scale bar: $200 \,\mu$ m). Perforating vessels in the connecting tissue between striated muscle and capsule (dashed line). B: CD34-positive structures in the capsule (immunohistochemistry for CD34, counterstaining with haematoxylin, CD34-positive parts appear brown).

the connective tissue which may provide sufficient blood supply for the capsule (Figure 3A). Immunohistochemistry confirmed this finding: the CD34-positive structures demonstrated angiogenesis in the capsule (Figure 3B).

DISCUSSION

Salvage of exposed implants is a great challenge in reconstructive surgery. Different factors may lead to implant protrusion e.g., errors in planning, thermal and mechanic injuries as surgical complications, smoking 220

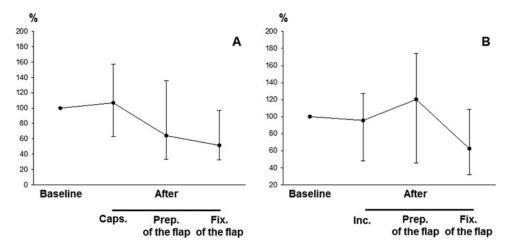


FIGURE 2. The blood flow of capsule flaps and thoraco-epigastrial fasciocutaneous flaps. Caps.: capsulotomy, Inc.: incision, Prep. of the flap: preparation of the flap, Fix. of the flap: fixation of the flap. Values are referred to the baseline and are given as percentage. Median values with 25th and 75th percentiles are demonstrated. A: blood flow of the capsule flaps in different stages of the operation. B: perfusion of the thoraco-epigastrial fasciocutaneous flaps during different steps of the intervention.

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in the patient's history or previous radiotherapy. In our Institution, the ratio of immediate breast reconstruction with implant comes to 41% while local complications accompany 11.6% of these cases. Traditional therapeu-

- 225 tic approaches involve antibiotics, drainage, rinsing, capsulotomy, change of the device and primary closing of the wound after excision of the necrotic tissue.⁵⁻⁷ However, they may also fail in cases of decreased tissue viability and irradiation. Implant protrusion is a
- 230 gradual process and its later stages require a more invasive surgical intervention.¹⁴ Several techniques are used for the covering of implants e.g., deepithelialized skin,^{15,16} abdominal fascial flaps,¹⁷ acellular dermal matrix (ADM),¹⁸⁻²¹ autologous dermal graft²²
- 235 and polyglycol mesh.²³ If signs of inflammation are not detected, *latissimus dorsi* flaps or local perforator flap can be applied.^{24,25} In cases of inflammation, the implant should be removed and later reconstruction or implantation of autologous fat can be chosen.⁸ How-
- ever, these procedures may have disadvantages. ADM is expensive²⁶ and its application can be accompanied by seroma and infection.^{7,27} Furthermore, patients often refuse more radical surgical therapies (e.g., different flap techniques) due to the esthetic and functional damage to the donor site, and they prefer less radical
- methods.

Capsule flaps provide a less invasive and costeffective solution. In animal experiments, capsules were used to support the survival of transplanted der-

- 250 mal grafts²⁸ as random¹⁰ or axial flaps.^{29,30} It has also been shown that capsule flaps are suitable for the correction of postimplant breast rippling³¹ and contour deformities of the breast.⁷ Capsule flap can be obtained from the anterior surface and also from the tissue layer
- 255 adjacent to the chest wall. Subject to localization of the defect and the viability of the tissue, superior, inferior, medial or lateral flaps can be applied.^{10,28-30}

Since sufficient blood supply is a cornerstone of tissue survival, several investigations have focused on the vascularity of capsule flaps. Some evidence has already indicated the appropriate blood supply of the

capsule flap. According to clinical observation, bleeding of the edges when tailoring the flap indicates a good vascularization.⁷ Moreover, a histological exami-

- 265 nation found angiogenesis in non-expanded capsules from the 4th postoperative week on, and the peak of this process was achieved by the 8th week.³² It is a further question whether expansion of the flap influences the vascularization and perfusion of the tis-
- 270 sue. In expanded flaps, vessels of higher volume were found as compared to primer flaps, but no statistically significant difference was detected in terms of vessel density.¹⁰ In another study, the radioactive microsphere technique did not reveal difference between
 275 the blood flow of expanded and non-expanded
 - flaps.³³ Our results, in accordance with findings in literature, show that capsule flaps provide a well-vascularized

layer which prevents protrusion of the implant and decreases tension, thereby promoting wound heal-280 ing and reduced risk of inflammation and superinfection. An important novel aspect of our study is the *in vivo* determination of microcirculatory status during the operation. Laser Doppler flowmetry was chosen for these measurements since it is an accu-285 rate and reliable method for assessing microcirculatory function.³⁴ Our *in vivo* finding has confirmed that surgical stress does not decrease the blood supply of flaps which then provided an optimal ground for the healing process. 290

In conclusion, the capsule flap seems to be appropriate for salvage of exposed implants and for enhancement of implant cover in case of thin and injured tissue. Capsule flaps are reliable, not difficult to prepare, have good circulation and may therefore play an important 295 role in reconstructive surgery of the breast. On the other hand, capsule flaps shall not be applied in case of serious inflammation and large tissue defect. Moreover, the number of published cases of breast reconstruction with capsule flaps is relatively low.⁷ Hence, more 300 experience with the technique may be needed before widespread adaptation.

DECLARATION OF INTEREST

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the 305 paper.

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