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Delayed two stage breast reconstruction with acellular dermal matrix

M. Chotárová[1], D. Mitevová[1], F. Čaniga[1] , R. Trška[1,2], D. Palenčár[1,2]

[1] Department of Plastic Surgery, University Hospital Bratislava, Slovakia
[2] Department of Plastic Surgery, Medical Faculty, Comenius University, Bratislava, Slovakia

Summary

Introduction: The aim of this study was to assess the long-term impact and potential effectiveness of our specialized acellular dermal matrix (ADM) in a two-stage breast reconstruction process. **Objective:** Opinions regarding the use of ADMs are currently divided. While their positive contribution to reconstructive breast surgery is evident, the results of studies vary depending on specific procedures, patient selection, and techniques employed. **Material and methods:** In a retrospective study conducted between January 2015 and October 2023, it was examined a cohort of patients who underwent delayed two-stage breast reconstruction with the addition of ADM prepared by Central Tissue Bank (CTB) the Burn and Reconstructive Surgery Department University Hospital Ružinov. Our primary focus was on the occurrence of significant postoperative complications during both the initial and subsequent reconstruction periods, taking into account patients' medical history, comorbidities, and adjuvant therapy. **Results:** We examined a total of 46 patients (49 breasts) who underwent two-stage breast reconstruction. The average age of the patients was 46 and the average BMI was 23.1. The average length of outpatient follow-up for female patients was 32 months. We observed a total of 4 cases of capsular contracture, ranging from grade I to grade III, with 2 cases requiring surgical revision through capsulotomy and implant exchange. Postoperative complications, such as infection and dehiscence leading to expander/implant loss, occurred in one case. The occurrence of seroma was noted in 3 cases. Complications were more frequently observed in the group of patients with post-radiation chest changes and comorbidities such as diabetes or hypertension, and in patients with a lower BMI than the group's average (23.1). In the group of patients who were smokers, we did not observe an increased rate of complications, with the exception of wound dehiscence in cases where there was no expander exposure. **Conclusion:** In experienced hands, ADM prepared by CTB and used in delayed two-stage breast reconstruction, can be beneficial as an adjunct to prosthetic breast reconstruction while also reducing costs.

Key words

breast reconstruction – prosthetic breast reconstruction – acellular dermal matrix – breast expander

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Introduction

The initial use of matrices in breast surgery was first reported in 2001, specifically in revisional aesthetic breast surgery, and later in breast reconstruction in 2005 [1–3]. Since then, matrices have gained widespread use in breast reconstruction procedures worldwide [4]. The use of acellular dermal matrices (ADM) in two-stage reconstruction, particularly in cases of modified radical mastectomy, offers several advantages. These include the ability to create a larger implant pocket with better control over its position, a higher volume of intra-operative expander fill, and the potential to shorten the expansion period compared to submuscular placement alone [5,6]. Additionally, optimal implant positioning can be achieved without the need for serratus anterior muscle elevation, resulting in reduced postoperative pain [7]. Commercially available ADM are commonly used alongside prosthetic reconstructions due to their presumed and documented advantages [8]. However, there is a growing concern that the use of matrices in breast reconstruction may increase the risk of complications, as they are non-vascularized materials in an environment with poorly circulated mastectomy flaps [9]. Certain studies have reported a higher incidence of postoperative complications in patients with a higher BMI, such as the presence of seroma, and inflammation, particularly in soft tissues that have been fibrotized by radiotherapy or are very thin [10–12]. The pathophysiological changes resulting from radiotherapy are well-documented, and in the past, patients with these complications were considered relatively contraindicated for implant-based breast reconstruction, and reconstruction with an ex-

Tab. 1. Patient characteristics of the studied group.

Age	average 46 years (32–61)			
BMI	average 23.1 (18.9–33.3)			
Comorbidities	arterial hypertension	diabetes mellitus	hypothyreosis	psychiatric diagnosis
	6	1	3	5
Abuses	smoker	nonsmoker	alcohol	–
	5	39	0	–
Type of mastectomy	modified radical mastectomy	skin sparing mastectomy	nipple sparing mastectomy	–
	32	13	4	–
Site of mastectomy	left side	right side	–	–
	24	25	–	–
Adjuvant therapy	radiotherapy	chemotherapy	hormonal therapy	–
	16	22	22	–

pander was not recommended for these patients [13,14]. Additionally, comorbidities like diabetes mellitus, obesity, and smoking can also contribute to compromised blood circulation in dermal flaps [15,16].

It is crucial to consider known patient-related risk factors, as well as those related to prosthetics and acellular dermal matrices, during patient selection and surgical planning [17,18]. It is important for patients to have knowledge about the risks of complications to make informed decisions regarding allogenic breast reconstruction [7].

Nonetheless, Hallberg et al. have noted that no patient has had ADM *in situ* for more than 16 years, and few more than 5 years. Today, almost 6 years after the publication, there is a little more data available, but there is still limited information on the long-term effects of ADM in larger patient groups [17,19,20]. Therefore, further research is needed to better understand these effects [21].

Methods

In this study, a retrospective analysis was conducted on medical records of patients who underwent delayed two-stage breast reconstruction using ADM from January 2015 to October 2023. It is important to note that in our country, Slovakia, and at our clinic, we exclusively utilized ADM prepared by the Central Tissue Bank (CTB) of Burn and Reconstructive Surgery Department University Hospital Ružinov, specifically through the special decellularization method known as Dragúňová [22]. This ADM is human derived, cryopreserved and prepared using a non-cytotoxic decellularization method, as stated by the manufacturer. Additionally, it is worth mentioning that the ADM from CTB of Burn and Reconstructive Surgery Department University Hospital Bratislava is significantly more cost-effective compared to commercially produced equivalents, priced at 1 euro per cm^2, whereas other commercially prepared ADMs, such as AlloDerm RTM, are priced around 30 euros per cm^2 [23,24].

All patients included in the study underwent a thorough evaluation by their oncologists and received approval to undergo breast reconstruction at the time of their initial surgery.

The analysis included a total of 46 patients with 49 breasts (24 left breasts and 25 right breasts), three of which underwent bilateral breast reconstruction. Patients included in the study had undergone mastectomy alone or breast-conserving surgery in the past, followed by modified radical mastectomy, skin-sparing mastectomy, or nipple-sparing mastectomy (Tab. 1), with or without adjuvant radiotherapy, chemotherapy, or hormonal therapy. Radiotherapy in each patient was explicitly adjuvant, and no patient underwent radiation with an implanted breast expander or implant.

The primary focus of the study was to evaluate the impact of ADM as an adjunct to two-stage delayed breast reconstruction, specifically regarding the incidence of major postoperative complications, such as infection, capsular contracture requiring revision surgery, and the number of failed reconstructions. The study received approval from the University Hospital Bratislava Ethics Committee in November 2022 (No. EC/157/2022).

Surgical technique

Breast reconstruction surgeries were performed at the Department of Plastic Surgery, University Hospital Bratislava, Ružinov. A consistent surgical technique was employed for all patients. The procedure involved two stages – the use of breast expanders in the first stage, which were later replaced with

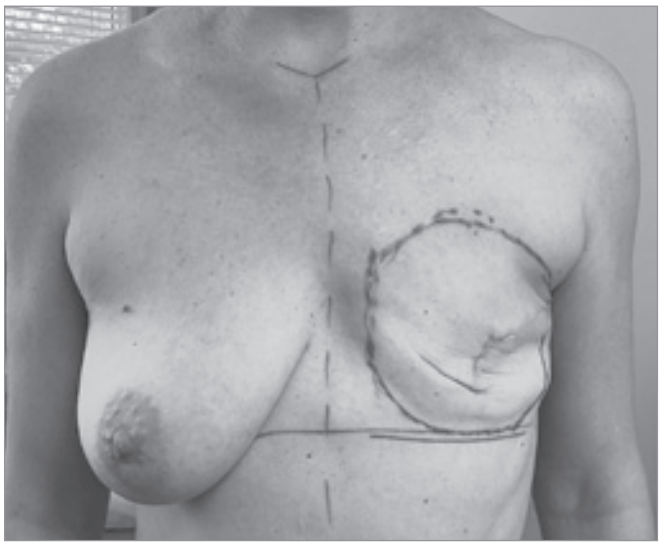

Fig. 1. Preoperative markings.

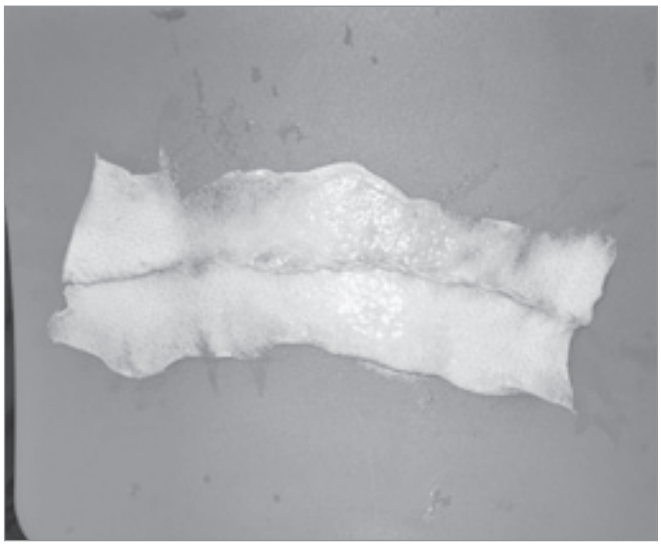

Fig. 2. ADM two pieces sutured togeather, ready to be sutured to the patient body.

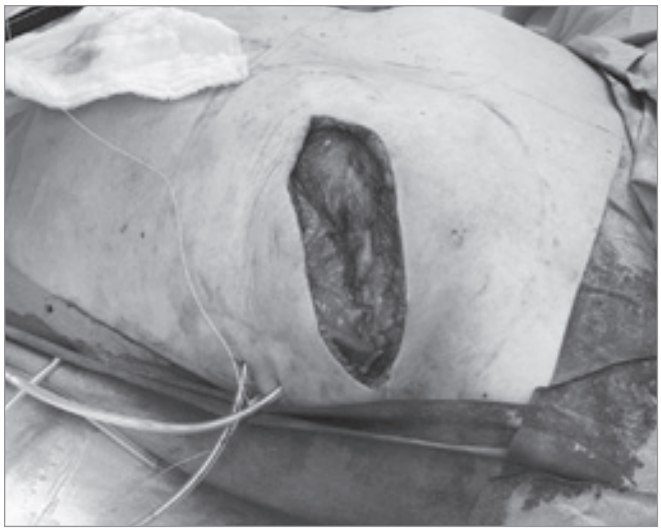

Fig. 3. ADM sutured to the lower border of the pectoralis muscle, tissue expander is already inserted under the ADM.

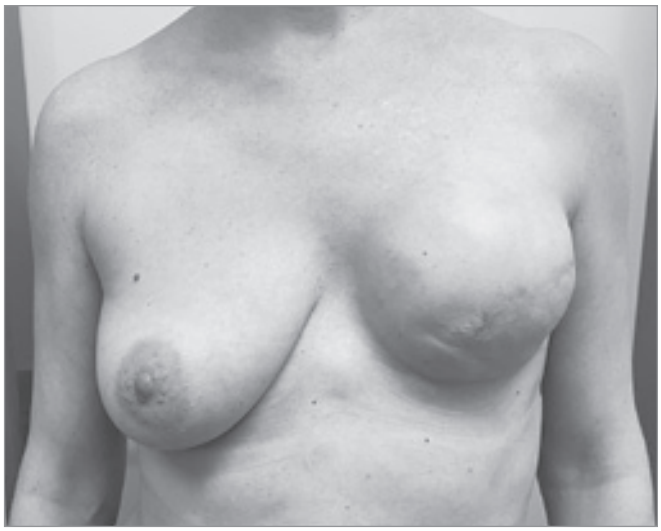

Fig. 4. The patient after the consolidation (first stage of reconstruction is finished).

permanent implants in the second stage.

Before surgery, patients received preoperative antibiotic prophylaxis, followed by necessary surgical markings (Fig. 1). The excision of the postmastectomy scar was performed initially, followed by the preparation and identification of the inferior margin of the pectoralis major muscle. The pectoralis major muscle was then elevated along with the rectus abdominis fascia to create space for the expander. After preparation, the ADM was sutured to the inferior border of the mobilized pectoralis muscle, and its inferior border was sutured to the newly planned inframammary fold (Fig. 2, 3).

During the surgical procedure, a deflated breast expander was inserted through a lateral opening in the newly formed pocket, located approximately in the anterior axillary line. Two Redon drains were placed – one in the pocket and another in the subcutaneous layer to minimize dead space. The pocket was then sutured, followed by the closure of the wound in anatomical layers. Using magnetic navigation, saline solution was either instilled or not instilled into the breast expander, and the wound was covered with Steristrip and bandaged. The decision to fill the expander intraoperatively was based on the elasticity of the pectoralis major muscle and postmastectomy skin flaps. The dressing was exchanged for an elastic bra on the first day after surgery. Drains were removed once the production decreased below 20 mL per 24 hrs.

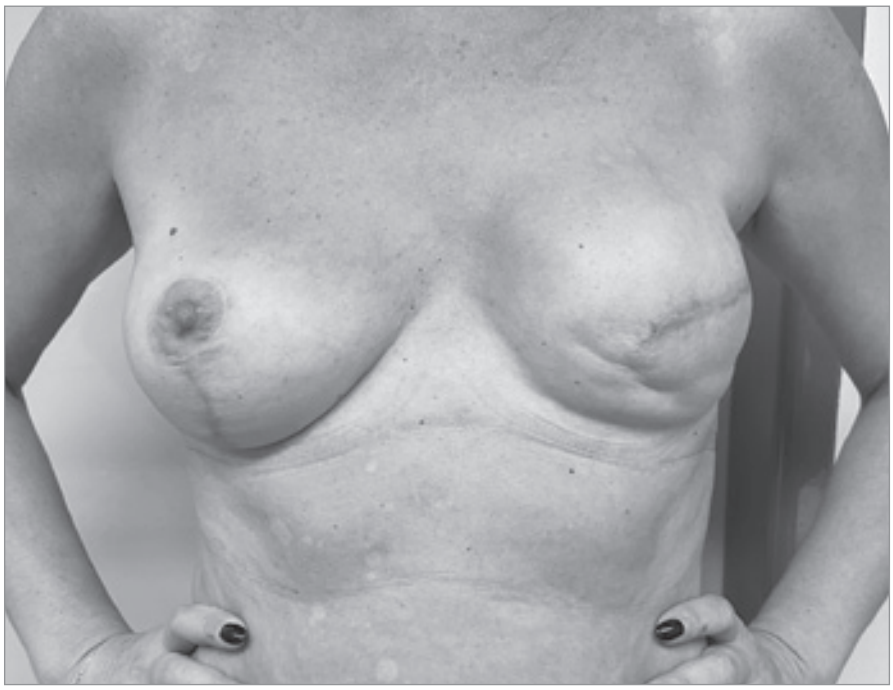

Fig. 5. The patient three months after expander/implant exchange and contralateralvertical mammaplasty modelation.

Tab. 2. Operation statistics of the study.

Stage	Item	Value
1. stage of the reconstruction	operation time	106.11 min (60–180 min)
	peroperation expansion volume	135.43 mL (0–500 mL)
	final expansion volume	470 mL (230–1,120 mL)
2. stage of the reconstruction	operation time	78 min (36–180 min)
	final implant volume	424.2 mL
post-operation	average follow-up time	32 months
	minimum follow-up time	6 months
	maximum follow-up time	89 months

The additional filling of the expander was performed as an outpatient procedure, but only after ensuring that the wound had healed without any complications, typically after a minimum of 14 days following expander insertion. During this period, the expander was gradually filled with 50–100 mL of saline every 14 days, taking into consideration tissue tolerance. Once the desired size was achieved, a consolidation period of 3 months followed before proceeding with the second stage of breast reconstruction (Fig. 4).

The incision for the second stage was made using the same postmastectomy scar as in the initial stage. The tissue expander was removed, and the ADM was found to be fully incorporated. The capsule formed around the expander was modified with capsulotomy if needed, and after changing surgical gloves and dressing, the implant was inserted. A Redon drain was placed in the implant pocket. The closure process followed the same steps as mentioned during the first stage. After the surgical wound healing, patients were instructed to begin massaging and moisturizing the scar and the entire neobreast. A compressive bra was recommended to be worn for an additional 6 weeks (Fig. 5) – the final result of the reconstruction with contralateral mastopexy symmetrization.

Results

A total of 46 patients, with an average age of 46 years (ranging from 32 to 61), and an average BMI of 23.1 (ranging from 18.9 to 33.3), were included in this study of two-stage delayed breast reconstruction. The study encompassed 49 breasts, with 24 on the left side and 25 on the right side. Prior to surgery, 34.7% of patients received adjuvant radiotherapy, 47.8% received chemotherapy, 10.8% underwent both chemotherapy and radiation, and hormonal therapy was given to 10.8% of patients. Additionally, 17.3% of patients received only chemotherapy, 8.7% received chemotherapy and hormonal therapy, and 4.3% were treated with only radiation and hormonal therapy.

Arterial hypertension was recorded in 13% of patients (6 individuals), 10.8% had psychiatric comorbidities such as anxious depressive syndrome (5 patients), 6.5% had psychiatric comorbidities (3 patients), and 2.2% had diabetes mellitus (1 patient), which could potentially have an adverse effect on the reconstruction outcome. Additionally, 10.86% of patients were smokers. An overview of patients' characteristics can be found in Tab. 1.

The average maximal expansion volume was 470 mL, and the average size of the exchanged implant was 424.5 mL. The average surgical time for the first stage was 106 min, and for the second stage, it was 78 min. Operation statistics are summarized in Tab. 2.

During the first stage of reconstruction, one hematoma, two seromas (of which one patient also had an infection requiring treatment with orally administered antibiotics), one expander

rupture with exchange, and two instances of secondary wound healing without expander exposure were recorded.

During the second stage of reconstruction, major complications were recorded, such as capsular contracture (CC) Backer II–III grade which was observed in 4 patients (2 patients with CC grade II had a history of adjuvant radiotherapy, and 1 was diabetic with a BMI [31.25 – above the group average]). Two of the patients had to undergo capsulotomy and implant exchange. The two seroma patients had a history of radiation. One patient underwent implant capsule revision and IMF lowering procedure due to superior migration of the implant. Complications related to the reconstruction led to one implant loss after a previous seroma and infection formation in a patient with hypertension, post-radiation changes, and a BMI above the average. Overall, three patients with complications that needed additional surgical intervention also had a history of radiation. No major complications were recorded in the smoker group. Mild complications are described in Tab. 3.

Tab. 3. Complication statistics of the study.

Stage	Complication	No. of patients affected
1. stage of the reconstruction	infection	1
	hematoma	1
	seroma	2
	expander rupture	1
	minor skin necrosis	2
2. stage of the reconstruction	infection	1
	seroma	3
	capsular contracture	4
	nonspecific inflamation	1
	minor skin necrosis	1
	failed reconstruction	1

The average follow-up was 32 months, ranging from 6 to 89 months. No cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) or breast implant illness (BII) complications were documented during the follow-up period.

Discussion

Despite undergoing breast conserving therapy, mastectomy remains a crucial surgical procedure for a significant number of breast cancer patients, approximately 20–40% worldwide, as part of their oncology treatment and this number is further increased by prophylactic mastectomies [25,26]. In Slovakia, it is estimated that around 1/3 of newly diagnosed patients undergo mastectomy, which amounts to approximately 3,500 cases per year [27]. During prosthetic breast reconstruction, our primary objective is to provide most effective breast reconstruction algorithm for these patients also considering the aesthetic part. Two-stage delayed breast reconstruction with prosthetic material after mastectomy continues to be a reliable option in the plastic surgeon's repertoire for breast reconstruction [28].

We believe that the use of ADM can greatly facilitate the expansion process and enhance lower pole projection [7]. This is because ADM serves as an additional protective layer for the prosthesis [12,29–31]. Once inserted into the patient's body, ADM acts as a biological scaffold that is revascularized and repopulated by host cells, such as endothelial cells and fibroblasts [32]. This revascularization process typically takes around 2 to 8 weeks [30,33]. Histological confirmation of blood vessel growth was observed in the specific type of ADM prepared by CTB during the time of expander exchange [34]. Additionally, the growth of lymphatic vessels was also observed in an animal model, and in one patient [35].

The insertion of a prosthesis during breast reconstruction triggers a physiological response in the body, resulting in the formation of a capsule around the expander/implant.

Furthermore, there is evidence from several authors suggesting that ADM may potentially reduce the formation of capsular contracture in the long term even in the presence of post-irradiation changes in the surrounding tissues [8,30,36–38]. This reaction is expected to be more pronounced in cases where the tissue has been altered by radiation, although the extent of the reaction can vary significantly between individuals, depending on other factors like the type of the implant surface, presence of biofilm, etc. [39,40]. Borrelli et al. demonstrated that capsular formation around an implant in irradiated tissue is thicker, firmer, and clinically associated with a higher incidence of capsular contracture compared to non-irradiated reconstructed breasts (implant-based reconstruction) [41].

Pannucci et al. found that a high body mass index, smoking, and diabetes, obesity and hypertension were independent risk factors for expander/implant loss, even with the assistance of ADM in breast reconstruction [42]. The analyzed sample group of patients almost does not have these comorbidities, which is beneficial. Another important risk factor to consider is radiotherapy. While radiotherapy is an integral component of the multimodal approach to

locally advanced breast cancer treatment, it is known to increase the risk of fibrosis formation and decrease vascular supply in the surrounding soft tissues. This can result in less elastic properties of the skin and subcutaneous layer, ultimately affecting tissue expansion and healing [43]. Kornowitz stated that tissue expansion is contraindicated in the presence of previous radiotherapy, as it can lead to expander extrusion or loss [9,44]. We observe an increase in prosthetic reconstructions despite the risks associated with undergoing radiotherapy [45,46]. According to Lam, when carefully selected (non-smokers), this can be a reconstruction option with success rate over 90% [47]. The use of ADM in the context of radiation therapy has conflicting recommendations, or it is recommended to use it very cautiously due to the presumed prolonged incorporation into the patient's body [48–50]. This implies an increased risk of postoperative complications such as infection and seroma, but it does not increase overall occurrence of postoperative complications [51,52]. When comparing the group with ADM and the group without ADM after radiation therapy by Stein in his study, no statistically significant difference was observed, but both groups still had a relatively high percentage of complications (42% non-ADM and 38% ADM group) [52].

Conclusion

When appropriately indicated, two-stage delayed breast reconstruction with ADM offers the advantage of not requiring the mobilization of the serratus anterior fascia or other locally available muscles for coverage of the lower expander/implant pole. The method outlined in this paper has shown to be suitable for achieving satisfactory outcomes and improving the quality of life of patients who have undergone breast loss, even in those who have received radiation therapy in the past and with larger expansion volume (over 300 cm^3). Careful patient selection and precise surgical techniques, preferably performed by experienced surgeons, are crucial.

However, our findings in this paper do not align with the findings of other authors who suggest a higher incidence of seroma, reconstruction failure when using ADM, even in patients with post-irradiation changes and smokers [9,28,52,53]. Additionally, we did not observe a higher incidence of capsular contracture or any other complication. However, this study is limited by the number of patients.

The findings suggest that the two-stage delayed reconstruction technique utilizing ADM prepared by CTB is considered a safe, repeatable, cost-effective, and easily accessible method. This technique offers the potential for reconstruction with an expander implant, even in patients who have undergone radiotherapy treatment. By incorporating ADM, we aim to provide all the benefits associated with its use while minimizing the risk of postoperative complications.

There is little scientific work done that review delayed two stage breast reconstruction with ADM and postmastectomy radiotherapy [28,52].

The study will continue with a comparative study between two groups of patients – one group who underwent adjuvant radiotherapy and two-stage reconstruction with ADM as an internal bra and another group who underwent reconstruction without the use of ADM.

Roles of the authors

Chotárová, MD, and Mitevová, MD, collaborated on the content development of the article, as well as on the retrospective processing of input data for evaluating the cohort of reconstructed patients. Mitevová, MD, and Čaniga, MD, were responsible for language editing, overseen by Trška, MD, PhD, and Palenčár, MD, PhD, throughout the entire process.

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Martina Chotárová, MD
Department of Plastic Surgery
University Hospital Bratislava
Ružinovská 6
826 06 Bratislava
Slovakia
mchotarova@yahoo.com

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