OCULOPLASTICS AND ORBIT



Efficacy and safety of an artificial dermal graft for the reconstruction of exenterated sockets: a preliminary report

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Abstract

Purpose The purpose of this study is to report our experience with the use of artificial dermis grafts for orbital socket reconstruction following orbital exenteration (OE).

Method A retrospective study was conducted in our ocular oncology centre from May 2018 to June 2020 in patients undergoing OE for orbital malignancies in whom an artificial dermis device (Integra® template, 2 layers) was used for reconstruction. Data recorded included demographics, previous and adjuvant treatments, aetiologies, surgical procedure, surgical reconstruction, complications and follow-up. The main outcome measure was the time between OE and the full granulation of the cavity.

Results Ten patients (mean age, 71.3 years [43–92]) were included. Tumours originated from the conjunctiva (n = 5, 50%), eyelid (n = 3, 30%) and orbit (n = 2, 20%). Nine patients underwent total OE, and one required enlarged OE. Orbital reconstruction was performed using an artificial dermis alone (n = 9, 90%) or combined with regional flaps (n = 1, 10%). The mean granulation time was 3.3 weeks (2–4). Three (30%) patients received adjuvant radiotherapy 1 month post-surgery. The mean time to spontaneous epithelialization was 9.4 weeks (6–12). Preoperative and postoperative radiotherapy was not associated with a delayed epithelialization of the socket (p = 0.463 and p = 0.236, respectively). One (10%) and 2 (20%) patients experienced postoperative socket infection and an ethmoidal fistula, respectively. The mean follow-up was 11.6 months (6–16).

Conclusion Using artificial dermis grafts alone or with regional flaps appears to be a viable surgical procedure for orbital socket reconstruction. They reduce surgical morbidity and hospital stay. Preoperative and postoperative radiotherapy does not seem to delay socket healing.

Key messages:

- Reconstruction of the orbital socket is challenging and may involve highly disfiguring surgical procedures such as free flaps.
- Using artificial dermis for the reconstruction of orbital sockets is a viable surgical procedure.
- Advantages include: lower morbidity, reduced hospital stay, bowl-shaped cavities enabling subsequent prosthesis delivery and easy monitoring for tumor recurrence.
- Combining artificial dermis grafts with regional flaps could alleviate the need to use complex and time-consuming free flaps in case of extended orbital exenteration.

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Keywords Orbital exenteration · Socket reconstruction · Artificial dermis · Radiotherapy

Introduction

Orbital exenteration (OE) is a radical and disfiguring procedure required for the management of orbital malignancies. OE consists in the subperiosteal removal of all orbital contents [1-3]. Evelid-sparing and total and extended OE (e.g. to the adjacent bony orbit or sinuses) have been described [3, 4]. The main indications of OE are periocular malignancies originating from the conjunctiva or the eyelids, ocular malignancies with extrascleral extension, orbital malignancies or sinonasal malignancies invading the orbit [1, 3, 5-7]. Total OE is the most commonly used surgical technique. The reconstruction of the exenterated socket is challenging, and several techniques have been described: spontaneous epithelialization, split-thickness skin graft (STSG), regional flaps (temporalis or frontalis muscle flaps, temporalis aponeurosis flaps, galeal flaps, cheek flaps) and free flaps (abdominal rectus muscle, dorsalis major muscle, lateral thigh muscle). Most flaps, especially free flaps, are time-consuming, increase the perioperative morbidity and require a long hospital stay [8]. Cosmetic rehabilitation following OE is achieved through prosthesis delivery [9]. One of the aims of OE is to provide, whenever possible, a bowl-shaped orbital socket to enable subsequent prosthesis delivery [2, 10-12].

The use of artificial dermal templates has recently been reported for orbital socket reconstruction. These allografts have been widely used in the field of reconstructive and plastic surgery [13–16]. They are usually composed of two layers: the dermal layer made of bovine collagen and glycosaminoglycan and the epidermal layer made of silicone. Previous studies have reported favourable outcomes when an artificial dermis template was used after OE [17–21]. However, these studies were limited by their small sample size or the lack of data concerning irradiated sockets.

The aim of this study was to report our experience with orbital sockets reconstructed with an artificial dermal template (Integra®) with a focus on irradiated sockets.

Patients and methods

Study design, inclusion criteria and data recorded

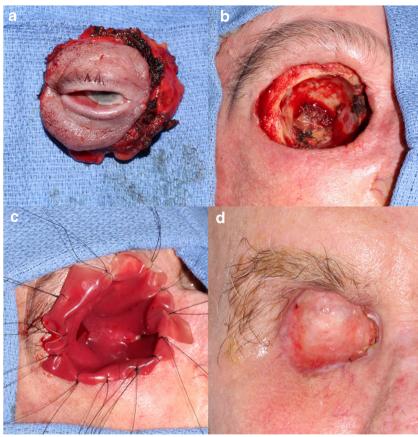
A retrospective monocentric study was conducted in our tertiary care centre specialized in ocular oncology between May 2018 and June 2020. Patients aged \geq 18 years who underwent orbital socket reconstruction with an artificial dermis used alone or in combination with other flaps or grafts were included. The following data were recorded: demographics, previous treatments (e.g. radiotherapy, surgery), surgical indication, type of surgery performed, type of reconstructive surgery performed, perioperative complications, time between OE and the granulation and then epithelialization of the cavity, adjuvant treatment including radiotherapy and follow-up duration.

All patients gave their informed consent. The study was approved by the French Ophthalmic Society (IRB number, 00008855) and met the principles outlined in the Declaration of Helsinki and its further amendments.

Surgical considerations

All surgeries consisted in total or enlarged OE and were performed under general anaesthesia. The surgeon status was divided into two categories: junior (surgical experience of less than 5 years) and senior (surgical experience of more than 5 years). Briefly, the orbital rim was marked over 360°. Additional margins were added depending on the tumour location and histology. A subcutaneous infiltration of Xylocaine and adrenaline was performed to enhance haemostasis and was followed by a cutaneous incision. Dissection was carried out through the orbicularis muscle until reaching the periosteum. The periosteum was incised and reflected. Dissection was continued subperiosteally using a periosteal elevator. Care was taken to avoid bony penetration especially in the medial and superior bony parts. The supra-orbital, supra-trochlear, zygomaticofacial, zygomaticotemporal and ethmoidal neurovascular bundles were identified and then cauterized with bipolar cautery. Monopolar cautery was avoided given the increased risk of cerebrospinal fluid leakage. The nasolacrimal duct and then the orbital apex were transected with curved scissors. Haemostasis was achieved by manual compression and/or bipolar cautery. Immediate pathological examination was performed by the pathologist. If required, OE was extended to the surrounding bony orbit and/or sinuses. For all patients, the orbital socket was reconstructed using an artificial dermis (Integra®, life sciences, Saint-Priest, France). A 10×12.5 cm template was customized to fit the orbital cavity (Fig. 1). The posterior part of the template was sutured to the remaining optic nerve stump at the orbital apex with a 4/0 Vicryl suture. The artificial dermis graft was then sutured to the adjacent skin with interrupted 5/0 silk sutures (Fig. 1). Regional flaps were raised and rotated when necessary (Fig. 2). A compressive dressing was then inserted to provide haemostasis and allow the template to be secured to the surrounding orbital bone. All but one patient received broad-spectrum prophylactic antibiotics (amoxicillin + clavulanic acid) for 10 days.

Fig. 1 Example of orbital exenteration defect reconstructed with an artificial dermis. **a**, **b** Total orbital exenteration. **c** Socket reconstruction using an artificial dermal template and 4/0 interrupted silk sutures. **d** Socket aspect 2 months after surgery. Epithelialization of the orbital socket is almost achieved



Daily home care was provided by a nurse and consisted in irrigating the dressing with sterile water and applying antibiotic ointment around the wound. Analgesics were prescribed when needed. Re-evaluation was scheduled on days 7 and 21. The silicone layer was removed about 3 weeks after surgery. The spontaneous epithelialization of the socket was then maintained without skin graft (Fig. 1).

Statistics

Data were analysed using SPSS software v22.0 (IBM, Chicago, IL, USA). Descriptive statistics are presented as counts and percentages for categorical variables and as means for continuous variables. The analyses were performed using an independent *t*-test to compare quantitative data. A value of p < 0.05 was considered statistically significant.

Results

Ten patients (8 men, 2 women) with a mean age of 71.3 years (43-92)(SD = 14.9) were included during the study period. Patients' characteristics are summarized in Table 1. The tumours originated from the conjunctiva (n = 5, 50%), the eyelid (n = 3, 30%) and the orbit (n = 2, 20%). Squamous cell

carcinoma (SCC) was the most common histological type identified (n = 5, 50%). The visual acuity (VA) ranged from no light perception to 20/25. One (10%) patient was treated with antiplatelets during surgery and did not experience any intraoperative haemorrhage. Five (50%) patients had received previous radiotherapy; among them, 4 (40%) had been treated with proton beam therapy and 1 (10%) with radiosurgery.

The surgical details and follow-up are presented in Table 2. Nine (90%) patients underwent total OE, and one (10%; patient 8) underwent enlarged OE. Socket reconstruction was performed using an artificial dermal template alone in all patients except in the patient who underwent enlarged OE for whom two regional flaps (frontalis + cervicofacial) were used in combination with the artificial dermal template (Fig. 2). The mean operative time was $145 \min (65-240)(SD = 56.7)$. No intraoperative complications were found. The mean hospital stay was 2.5 days (1-4)(SD = 0.9). The silicone layer was removed between the second and the fourth postoperative week. The mean time between ablative surgery and the granulation of the cavity was 3.3 weeks (3, 4)(SD = 0.5). All the sockets were left to epithelialize spontaneously. The mean time to socket epithe liabilization was 9.4 weeks (6-12)(SD = 2.5). One (10%)patient, who did not receive prophylactic antibiotics after surgery, experienced postoperative infection requiring early

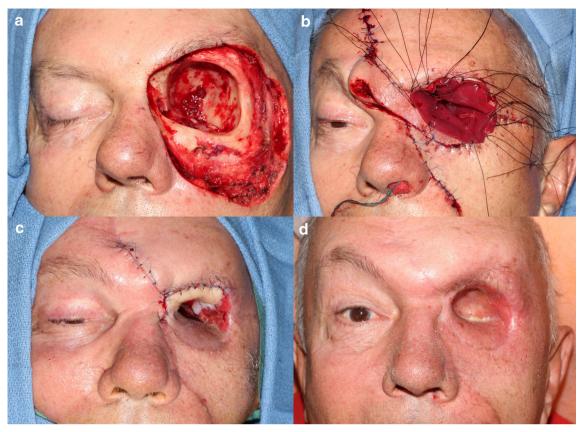


Fig.2 Example of enlarged orbital exenteration defect reconstructed with a combination of regional flaps and artificial dermis in order to avoid a free flap. **a** Orbital exenteration extended to the maxillary and ethmoid sinuses to treat an orbital adenocarcinoma. **b** The socket was reconstructed using a combination of frontalis flap, cervicofacial flap

and artificial dermal template. **c** Intraoperative aspect when dividing the frontalis flap (second surgical time) at 1 month. Full granulation of the cavity was already obtained. **d** Socket aspect 3 months after surgery. Complete epithelialization of the orbital socket despite receiving adjuvant radiotherapy

silicone layer removal as well as local and systemic antibiotics (Fig. 3). The outcome was favourable without significant delay in granulation and epithelialization of the cavity (Fig. 3). Two (20%) patients experienced postoperatively an ethmoidal fistula. Three (30%) patients received uneventful radiation beam therapy (60 Gy) 1 month after surgery without delayed socket epithelialization. Preoperative and postoperative radiotherapy was not associated with a delayed

Patients	Age	Sex	Tumour origin	Histology	Preoperative radiotherapy
1	73	F	Orbit	Mucoepidermoid carcinoma	No
2	81	М	Conjunctiva	Melanoma	Yes (proton)
3	43	М	Conjunctiva	Melanoma	Yes (proton)
4	51	F	Conjunctiva	SCC	Yes (proton)
5	92	М	Eyelid	BCC	No
6	77	М	Eyelid	SCC	No
7	74	М	Eyelid	SCC	No
8	67	М	Orbit	Adenocarcinoma	Yes (radiosurgery)
9	86	М	Conjunctiva	SCC	No
10	69	М	Conjunctiva	SCC	Yes (proton and conventional radiotherapy)

SCC, squamous cell carcinoma; BCC, basal cell carcinoma

Table 1 Preoperative patients' characteristics Preoperative patients'

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Patients	Patients Reconstruction Surgical time (mi	Surgical time (min)	Hospital stay (days)	Hospital stay Weeks until Weeks (days) silicone layer until ablation granula	Weeks until granulation	Weeks until epithelialization	Postoperative complications	Postoperative radiotherapy	Second surgery for implant placement	Prosthesis Follow-up delivery (months)	Follow-up (months)
	AD	210	2	3	3	10	None	Yes	Yes	No	14
2	AD	120	2	3	3	8	Ethmoidal fistula	No	No	No (died)	12
3	AD	150	1	3	3	12	None	No	Yes	No	10
4	AD	200	2	3	3	12	None	No	Yes	No	16
5	AD	65	4	3	3	12	None	No	No	Yes	12
9	AD	95	2	4	4	8	None	No	No	Yes	12
Г	AD	92	4	2	4	6	Socket infection Ethmoidal fistula	Yes	No	No	12
~	AD + regional flaps	240	Э	4	4	8	None	Yes	No	No	10
6	AD	126	3	Э	3	6	None	No	No	Yes	12
10	AD	150	2	3	3	12	None	No	No	No	9
AD, arti	AD, artificial dermis template	plate									

Surgical and postoperative outcomes

Table 2

epithelialization of the cavity (p = 0.463 and p = 0.236, respectively). The mean follow-up duration was 11.6 months (6–14)(SD = 2.6). One (10%) patient died from a metastatic spread of his conjunctival melanoma despite targeted therapy. At the time this article was written, 3 (30%) patients wore an adhesive-retained prosthesis, 3 (30%) other patients received orbital implants for subsequent prosthesis delivery, and 1 (10%) patient died from a metastatic spread before wearing his prosthesis.

Discussion

In this study, we reported favourable outcomes with the use of an artificial dermis graft for orbital socket reconstruction. The mean hospital stay was only 2.5 days (SD = 0.9). The mean time to spontaneous granulation and epithelialization of the cavity was 3.3 weeks and 9.4 weeks, respectively. Combining artificial dermis grafts with regional flaps could alleviate the need to use complex and time-consuming free flaps. Artificial dermal templates can be used in previously irradiated orbits or when postoperative radiotherapy is scheduled.

Reconstructing the orbital socket following OE is challenging. Several techniques have been described such as spontaneous granulation, STSG, regional flaps and free flaps [9, 10, 22]. Surgeons should keep in mind the benefits and disadvantages of each technique summarized in Table 3. Spontaneous granulation is associated with a longer epithelialization time (usually 4-5 months), a prolonged daily use of wound care dressings and an increased rate of ethmoidal fistulas [1, 3, 4, 22]. STSG is widely used for socket reconstruction with an epithelialization time of 6-8 weeks but requires a second surgical site which increases the operative time as well as postoperative wound care [10]. The reconstruction of the orbital cavity with regional or free flaps allows covering the sinuses and cranial cavity defects. However, these flaps are time-consuming, increase the hospital stay [9] and the perioperative morbidity and often lead to fullness of the orbital socket [8, 9, 17]. Whenever possible, a bowl-shaped socket is recommended to enable subsequent prosthesis delivery [22]. In our study, one of our patients (patient 8) underwent OE extended to the ethmoidal and maxillary sinuses. For such defects, a free flap is usually mandatory. We chose to perform a reconstruction using two regional flaps (frontalis + cervicofacial flaps) to cover the ethmoidal and maxillary defects, respectively, in combination with an artificial dermis graft to cover the orbital roof and apex (Fig. 2).

Cosmetic rehabilitation is better achieved through prosthesis delivery. Several studies have shown the superiority of bone-anchored orbital implants over adhesive- or spectacleretained prostheses [9, 10, 23, 24]. Obtaining a bowl-shaped cavity at the end of surgery is mandatory for prosthesis



Fig. 3 Example of artificial dermis template infection with favourable outcome. **a** Total exenteration for treating an upper eyelid squamous cell carcinoma. **b** Reconstruction using an artificial dermal template. **c**

Postoperative socket infection (day 7) requiring silicone layer removal and systemic antibiotics. **d** Favourable outcomes 2 months after surgery. Full granulation of the cavity was obtained

retention and was easily obtained with the artificial dermis templates in our study.

Artificial dermal templates were first introduced in 1981 by Yanna and Burke [25] and have been extensively used for the treatment of burn victims [26] and chronic ulcers [27]. Recently, some studies have investigated its use for orbital socket reconstruction [17–21]. The Integra® dermal regeneration template is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibres of cross-linked bovine tendon collagen and

Reconstruction	Indications	Additional operative time for socket reconstruction	Hospital stay	Difficulty in postoperative care	Postoperative socket aspect	Delay for socket epithelialization	Difficulty for diagnosing tumour recurrence
Spontaneous granulation	Lid-sparing OE Total OE	None	Reduced	Elevated	Bowl-shaped	Prolonged	Reduced
STSG	Lid-sparing OE Total OE	< 1 h	Reduced	Variable	Bowl-shaped	Variable	Reduced
Artificial dermis	Lid-sparing OE Total OE	< 30 min	Reduced	Reduced	Bowl-shaped	Variable	Reduced
Regional flaps	Total OE Extended OE	1–2h	Reduced	Variable	Bowl-shaped (*)	Reduced	Variable
Free flap	Extended OE	> 2 h	Prolonged	Elevated	Bulky shaped	Reduced	Elevated

 Table 3
 Advantages and disadvantages of each surgical reconstruction technique

OE, orbital exenteration; (*) except with the temporalis muscle flap

Table 4	Summary	y of prev	vious studies asso	essing the use	e of artificia	al dermis template	Summary of previous studies assessing the use of artificial dermis templates for orbital socket reconstruction	st reconstruction					
Study (years)	No. of Mean patients age (years	Mean age I (years)	No. of Mean Type of surgery Type of patients age performed (%) artificial (years) dermal template	Type of artificial dermal template	Mean hospital stay (days)	Mean time until Mean time to socket socket granulation epithelializati (weeks) (weeks)	Mean time to socket epithelialization (weeks)	Surgical technique for socket epithelialization	Preoperative radiotherapy: number (%)	Postoperative complication: number (%)	Postoperative radiation therapy: number (%)	Postoperative No. of patients with Mean radiation prosthesis at last follow therapy: follow-up (%) up du number (%) (mont	n Mean follow- up dura- tion (months)
Current study (2021)	10	71.3 7	Total: 90 Extended: 10	Integra	2.4	3.3	9.4	Spontaneous	5 (50%)	Fistula: 2 (20%) Infection: 1 (10%)	3 (30%)	3 (30%)	11.6
Young (2020)	14	69	Total: 93 Eyelid-sparing: 7	AlloDerm meshed SureDerm meshed	NR	NR	NR	Spontaneous	None	Fistula: 1 (7%) 1 (7.4%) Wound healing delay: 3 (21.4%) Cerebrospinal leakage: 1 (7%)		NR	12.1
Rafailov 7 (2019)		73.5 1 1	Extended: 57 Eyelid-sparing: 43	Integra	NR	NR	12	Spontaneous	None	NR	1 (14%)	4 (57%)	10.5
Ameloot (2019)	1	42	100	Integra	2	4	7	STSG	None	None	1 (100%)	1 (100%)	NR
Patel (2018)	1	63	Total: 100	Integra	NR	3	5	STSG	None	None	1 (100%)	1 (100%)	12
Ozgonul (2017)	5	74	Total :100	Integra	1	3.8	×	Spontaneous	None	None	0	NR	19.8
NR, not re	sported; S'	TSG, spl	NR, not reported; STSG, split-thickness skin graft	graft									

glycosaminoglycan (chondroitin-6-sulphate). The epidermal substitute layer is made of a thin polysiloxane (silicone) layer for water and gas exchange.

The previous studies in which artificial dermal templates have been used for orbital socket reconstruction are presented in Table 4. In accordance with our study, Rafailov et al. [17] have reported favourable results when combining artificial dermis templates with regional flaps. In our study, the mean time to granulation and epithelialization of the socket was 3.3 and 9.4 weeks, respectively. These results are in accordance with previous reports (Table 4).

In our study, spontaneous epithelialization was preferred over STSG. Ameloot et al. and Patel et al. have reported a faster epithelialization using a STSG [20, 21]. However, our patients were significantly older (Table 4), and we think that avoiding a second surgery reduces the perioperative morbidity.

Radiotherapy is known to delay the orbital socket healing. In our study, 5 (50%) patients received previous radiotherapy; among them, 4(40%) had been treated with proton beam therapy and 1 (10%) with radiosurgery. The mean epithelialization time did not differ between patients treated with preoperative radiotherapy versus those who did not (p = 0.463). Similarly, 3 (30%) patients received postoperative radiotherapy without delayed epithelialization of the cavity (p = 0.236). This finding is in line with previous studies conducted by Young et al. and Rafailov et al. [17, 18]. Other authors have reported favourable results using Integra® templates in other surgical fields in a context of preoperative and postoperative radiotherapy [13, 28]. In our study, half of our patients experienced previous radiotherapy. Of them, 3 underwent localized low-energy proton beam therapy for treating conjunctival tumours. Studies investigating the impact of localized low-energy proton beam therapy in socket healing are lacking. However, the authors believe that localized and targeted proton beam therapy is less likely to compromise the orbital and periorbital vascularization compared to whole orbital conventional radiotherapy. This could explain the surprisingly high rate of epithelialization found in our previously irradiated sockets.

In our study, the mean hospital stay was 2.5 days (SD = 0.9) which is in accordance with previous studies [20, 21]. In the study by Ozgonul et al., the patients were discharged the day of ablative surgery [19]. For psychological insights and transportation considerations (our patients lived far from our tertiary care centre), we preferred to keep our patients hospitalized one to two nights after surgery.

In our study, one patient was treated with antiplatelets (Kardegic 75 mg) at the time of surgery and did not experience any intra- and postoperative haemorrhage. The compressive dressing applied over the artificial dermis device at the end of surgery allowed achieving adequate haemostasis. Such a compressive dressing is usually not allowed with traditional flaps and grafts for vascular compromise considerations.

Reconstructing the orbital socket with an artificial dermis is easier to perform than with more traditional regional and free flaps. In the present study, 6~(60%) surgeries were performed by a junior surgeon without experiencing intraoperative difficulties.

At the time this article was written, only 3 (30%) patients wore their prosthesis, and 3 (30%) additional patients had their orbital implants placed. This result is lower than that reported by Rafailov et al. [17]. However, they have not specified in their study whether the prostheses were retained by orbital implants or by adhesive or spectacles. Several studies have shown that implant-retained prostheses are the most suitable for prosthesis retention [9, 10, 23, 24].

In line with previous studies, we did not find any postoperative complication such as haematoma, collection or necrosis. One (10%) patient, who did not receive postoperative prophylactic antibiotics, experienced postoperative infection (7 days after surgery) requiring early silicone layer removal as well as local and systemic antibiotics with favourable outcomes (Fig. 3). In accordance with other studies, we recommend the use of postoperative antibiotics for at least 7 days. The duration of postoperative systemic antibiotics is not consensual and varies from 7 days to 1 month [18, 20, 21]. Two (20%) patients experienced a postoperative fistula without requiring surgical fistula closure. These results are in line with those reported in the literature [3].

To date, no study has investigated the cost-effectiveness of these artificial dermis devices for orbital socket reconstruction. The price of the device (about 800 euros in France for a 10×12.5 cm template) should take into account the decreased costs relating to the shorter operative time and hospital stay. Further studies on this subject are needed.

This study has some limitations. First, our study is a retrospective study with a small sample size. However, OE is a rare surgical procedure. In a recent nationwide study, we have found that the mean annual incidence of OE was 0.1/100,000 inhabitants in France (mean annual number of OE procedures = 88) over the 2006–2017 period [29]. Second, our study suffers from its non-comparative design, and further studies comparing the use of artificial dermal devices to spontaneous granulation or temporalis fascia flaps in terms of efficacy (granulation, epithelialization), safety, hospital stay and cost-effectiveness would be of great relevance.

Conclusion

In our preliminary experience, the use of artificial dermal devices is an effective and safe procedure for reconstructing the orbital socket after OE. These devices reduce the perioperative morbidity and the hospital stay, may be used in combination with regional flaps to avoid free flaps in selected cases, provide a bowl-shaped cavity to enable subsequent prosthesis delivery and allow the early detection of tumour recurrence. Preoperative and postoperative radiotherapy does not seem to be associated with a significant dermal template granulation or epithelialization delay. Further prospective and comparative studies are needed to confirm our findings.

Declarations

Ethical approval The study was approved by the French Ophthalmic Society (IRB number 00008855) and was performed in accordance with the ethical standards outlined by the 1964 Declaration of Helsinki and its latter amendments.

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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