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Original Article

Long-term outcomes of surgically removed migrated polyalkylimide (bio-alcamid) filler to the periorbital area

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Abstract

Purpose: To report the long-term follow-up results after surgical excision of migrated Bio-Alcamid fillers to the Periorbita area.
Methods: A retrospective case series of all patients who underwent surgical removal of migrated Bio-Alcamid fillers to the Periorbita area with minimal follow-up of 1 year from January 2009 to January 2018 was done.
Results: 16 female patients (24–52 y) presented with an upper or lower eyelid swelling 3–7 years following a filler injection in the nasal bridge, temporal or malar area. All patients had surgical excision of a granulomatous mass ranging in size from 1–3.5 cm. The histopathology report revealed a giant cell reaction in all patients. Follow–up periods ranged from 1 to 8 years. One patient developed lid retraction and another had recurrence 3 years later; the remaining had an unremarkable course.
Conclusions: Filler migration is one of the potential complications associated with Bio-Alcamid soft tissue injection. It is important for all physicians to assess nodules/masses/swelling in the facial area to be aware that soft tissue fillers may migrate to a location away from their intended site of injection years after the injection. Patients undergoing surgical excision tend to have favorable overall long-term outcomes in terms of aesthetics and incidence of recurrence.

Keywords: Polyalkylimide, Filler, Periorbita, Permanent

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Introduction

Soft tissue augmentation (dermal fillers) has become an increasingly popular tool for restoration of facial folds, wrinkles, facial volume and contour.[1] Dermal fillers have the advantage of lower cost and minimal recovery time, in comparison to cosmetic surgery.[1] They are second to only botulinum toxin type A as a non-surgical method for facial rejuvenation.[2] This expansion in number of procedures has brought an interest in the possible reactions and/or complications accompanying such a procedure, which can be classified to immediate, early and delayed onset. Immediate reactions can include erythema, edema, pain and bruising. Early onset (within weeks)involves infection, hypersensitivity, discoloration, vascular occlusion and cosmetic irregularities. Delayed complications (weeks to years) appear in shapes of infections, granulomatous reaction, scarring and migration.[3–9]

Bio-Alcamid is a nonresorbable, biocompatible polymeric gel composed of 96% water and 4% polyalkylimide gel. When it is Injected subdermally, it resembles fatty tissue and gets encapsulated by a collagenous capsule.[9] Bio-Alcamid filler migration is an established complication reported in numerous articles.[4–8] Several methods of management were introduced in the literature, depending

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on filler material. However surgical excision remains the only effective treatment option for Bio-Alcamid fillers.[7] In this study, we reported the long-term outcome after surgical excision of migrated Bio-alcamid fillers to the periorbital area.

Materials & methods

This retrospective interventional case series study was approved by the Institutional Review Board (IRB) in King AbdulAziz University Hospital, King Saud University and it adhered to the tenets of the Declaration of Helsinki. The medical records of all consecutive patients who underwent surgical excision of migrated Bio-alcamid fillers to the periorbital area between January 2009 and January 2018 were reviewed. Detailed history was gathered from patients including filler type, site of injection, duration between injection and filler migration, facial procedure or needling and past medical history. Complete ophthalmic clinical examination and assessment of migrated filler to the periorbital area along with examination of the face to presence of the filler were noted. Pathology reports were gathered along with follow-up findings and outcomes. Only patients with minimum follow-up of 12 months after surgical excision were included.

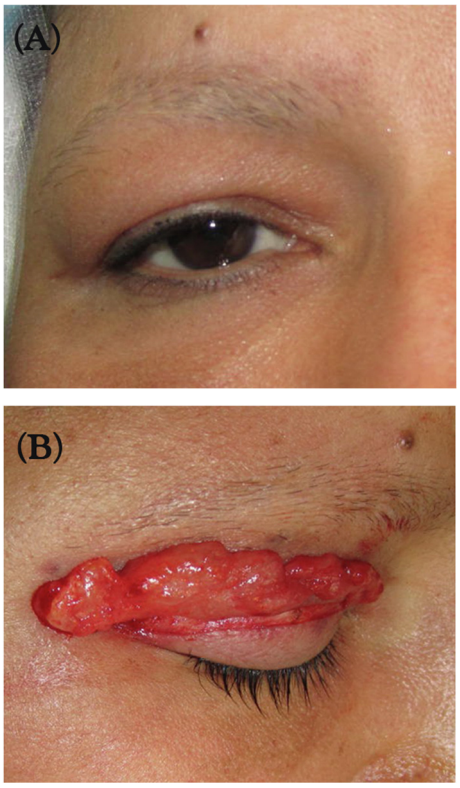

Fig. 1. (A) This patient present with right upper eyelid swelling appeared 4 years after injecting Bio-alcamid filler to both temporalis area. (B) After surgical removal through upper eyelid crease incision.

Results

All our 16 patients were females aged from 24 to 52 years. The mean onset of complications was 5.2 years (3–7 y). All patients gave history of polyalkamide filler material injected in their faces. They presented with an appearance of a periorbital mass/masses ranging in size between 1 cm and 3.5 cm. Of these lesions, 10 patients were found to have the mass in the lower lid with bilateral lower eyelid involvement in 2 of them. The remaining 6 patients had upper lid involvement with bilateral upper eyelid involvement in 1 of them (Fig. 1). 10 patients declared a history of injection in the cheek area, 4 in the temple and 2 in the nasal bridge (cheek & temple on the same side of face as the lesion). All patients had evidence of presence of filler at the site of the primary injection. 10 had a trial of removal of the filler material from the original site of injection by needling 8–14 months (average 10 months) before the development of periorbital migration (Table 1). No imaging studies were performed due to high yield of clinical suspicion.

All patients underwent surgical excision of the migrated filler through eyelid crease incision for the upper eyelid and subciliary incision for the upper eyelid under local anesthesia. The excised tissue had the gross appearance of a defined yellowish mass, two with a liquefied core and all corresponding

Table 1. Summary of all patients included in the series.

Patients	Age (yrs.)	Injection site	Migration site	Time between primary injection and migration (yrs.)	Prior treatment	Follow-up (yrs.)	Complication
1	41	Right cheek	RLL	5	Needling	3	None
2	24	Right cheek	RLL	3	Needling	1	Sterile pus, recurrence
3	34	Left cheek	LLL	4	Needling	5	None
4	40	Left cheek	LLL	5	Needling	5	None
5	35	Right cheek	RLL	6	Needling	3	None
6	45	Left temple	LUL	7	None	3	None
7	40	Right cheek	RLL	4	Needling	2	None
8	35	Right cheek	RLL	5	Needling	3	None
9	50	Right cheek	RLL	6	Needling	7	None
10	35	Left cheek	LLL	7	Needling	8	Lid retraction
11	50	Right temple	RUL	4	None	5	None
12	52	Left temple	LUL	5	None	3	None
13	45	Nasal bridge		6	None	1	None
14	35	Nasal bridge		7	None	1	None
15	50	Right temple		4	None	1	None
16	34	Left cheek		8	Needling	1	None

LUL = left upper lid.
RUL = right upper lid.
LLL = left lower lid.
RLL = right lower lid.

to the pre-operative palpable size. The histopathology of excised tissue in these cases show pooling of the filler material with surrounding collection of epithelioid cells representing a granulomatous reaction towards the material often associated with some foreign body-type giant cells. The filler material exhibits variable prominent staining with Alcian blue stain and the granulomatous reaction might be seen extending to the surrounding soft tissue and fat (with rare cases of resulting fat necrosis) depending on the extent of the migration of that material (Fig. 2).

All patients had oral prednisolone of 0.5 mg/kg once daily for 5 days after surgery along with tobramycin and dexamethasone opthalmic ointment (tobradex®: manufactured by Alcon, Fort Worth, Texas, USA) twice daily for 1 week. Average follow-up period was 3.4 years (ranging from 1 year to 8 years with a median of 3 years). One patient developed 2 mm of lower eyelid retraction following surgery due to a middle lamella scaring which was managed by releasing the scar. One patient, with a history of needling prior to presentation, had a lower eyelid swelling 3 years after the removal of the migrated filler due to a recurrence of filler migration to the same area that was successfully removed. The rest of the patients had an uneventful course.

Discussion

Soft tissue fillers are an ever-growing method of wrinkle and fold reduction, facial volume restoration and contour enhancement. The high effectivity of this office procedure commonly performed by physicians and other providers has led to an increase in demand.[2] The nature of the procedure (blind injection) and the material being used (foreign body) have inevitably led to a wide range of complications reported in the literature. These complications have been grouped based on the type of material being used (Bio-degradable vs. permanent) and onset (immediate vs. late onset).[1] This article focuses on a special complication, faced by the authors, associated with polyalkylimide filler injection (Bio-Alcamid; Polymekon, Brindisi, Italy), a migration to the periorbita. Migration is simply defined as the presence of a material in a location distant from the one in which it was originally injected.

Bio-Alcamid is considered to be a permanent filler because of the stability of its chemical properties and resistance to hydrolysis.[9] Once injected, the material gets encapsulated by a thin collagen capsule, and theoretically stabilizing the material within 6 weeks of injection and decreasing the rate of migration.[10]

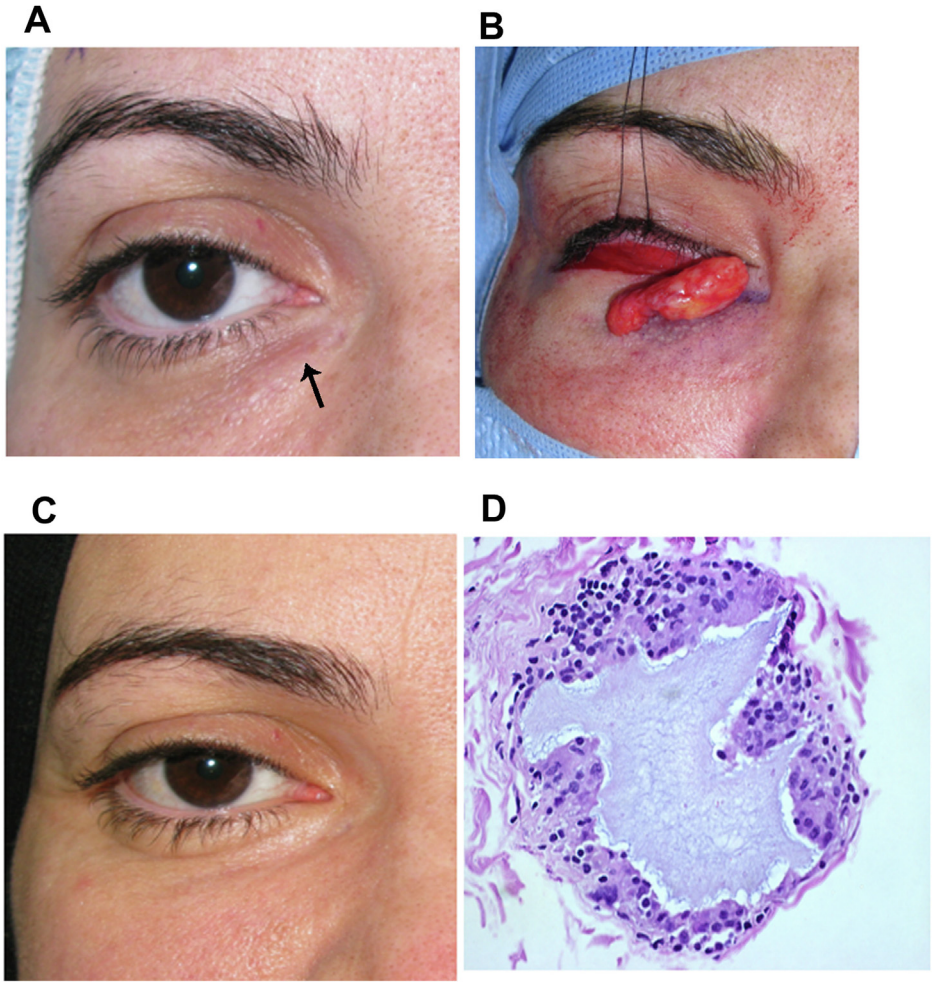

Fig. 2. (A) Preoperative photo showing the migrated filler in the tear trough. (B) Intraoperative finding following excision of the migrated trough subciliary incision. (C) 3 years postoperative photo of the same patient showing no sign of recurrence and good cosmetic appearance. (D) The histopathology of the excised tissue shows pooling of the filler material with surrounding collection of epithelioid cells representing a granulomatous reaction towards the material with associated foreign body-type giant cells (Original magnification x 400 Hematoxylin and eosin).

Most cases of filler migration present themselves as nodules which may be inflammatory or not.[6–21] Often the patient presents few years after the injection without volunteering the incidence of injection to the physician, masquerading as a multitude of alternative pathologies leading to diagnostic and therapeutic dilemma.[13,15,16] Among 85 patients presented with complications attributed to permanent filler injection, kadouch et al. reported filler migration and non-inflammatory nodules accounting for 40% of total complications to be the main late complication.[17] George et al. reported 25% filler migration rate among the 69 patients that responded to their questionnaire.[18] In 2009, Schelke et al. calculated an overall filler complication rate of 4.8% among a population of 3196 patients.[8] The same authors in 2017 estimated the rate to be ''much higher'' based on the influx of more patients.[19] The most common sites of migration are forehead, glabella, nose and eyelid.[20]

The mechanism of filler migration has been postulated to be related to several factors such as poor technique, higher volume of filler material injected, filler being injected under tissue with high pressure, gravity and muscle activity around the material.[7] Due to the non-biagradable nature of Bio-Alcamid material, surgical excision is the therapeutic method of choice.[6,11,21] Surgical pathology reports often show a chronic granuloma or in some cases active inflammatory response even years after the injection.[6,20]

Often in the presentation of such complication, a history of filler injection is either overlooked or considered irrelevant by the patient or physician because of the delayed presentation (years after the injection) and the remote site of injection. Our data are in line with the majority of the available literature in regards to historical, clinical and pathological presentation of filler migration attributed to bio-alcamid.

In conclusion, physicians injecting fillers ought to be aware of safe injection techniques as well as they should be able to recognize possible complications. Permanent filler injection in the face should be stopped because of the devastating complications.[21] Direct surgical excision of the migrated bio-alcamid filler in the periorbital area seems to be a reasonable approach, and patients tend to have a favorable long-term outcome in terms of aesthetics and incidence of recurrence. Patients need to understand that complete removal of this material is impossible and a recurrence of migration to the periorbital area is still a possibility.

Conflict of interest

The authors declared that there is no conflict of interest.

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