Original Article

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

Ziyad A. AlHarbia, Hind M. Alkatan, Adel H. Alsuhaibani

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

Introduction

Soft tissue augmentation (dermal fillers) has become an increasingly popular tool for restoration of facial folds, wrinkles, facial volume and contour. Dermal fillers have the advantage of lower cost and minimal recovery time, in comparison to cosmetic surgery. They are second to only botulinum toxin type A as a non-surgical method for facial rejuvenation. 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.

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. Bio-Alcamid filler migration is an established complication reported in numerous articles. Several methods of management were introduced in the literature, depending...
on filler material. However surgical excision remains the only effective treatment option for Bio-Alcamid fillers.\textsuperscript{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.

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 lower eyelid. The excised tissue had the gross appearance of a defined yellowish mass, two with a liquefied core and all corresponding

![Fig. 1](https://via.placeholder.com/150)

(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.

| 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   | LUL            | 5                                             | None           | 3               | None          |
| 14       | 35         | Nasal bridge   | LUL            | 1                                             | None           | 1               | None          |
| 15       | 50         | Right temple   | LUL            | 4                                             | None           | 1               | None          |
| 16       | 34         | Left cheek     | LUL            | 8                                             | Needling       | 1               | None          |

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

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

252 Z.A. AlHarbi et al.
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 ophthalmic 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. 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). 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. 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.
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-inflamatory 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.7 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-biogradable nature of Bio-Alcamid material, surgical excision is the therapeutic method of choice.5,11,21 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.

References

1. Funt D, Pavicic T. Dermal fillers in aesthetics: an overview of adverse events and treatment approaches. Clin Cosmet Investig Dermatol 2013;12:295–316.
2. American Society of Plastic Surgeons. 2017 Plastic surgery statistics report Available at: https://www.plasticsurgery.org.
3. Junkins-Hopkins JM. Filler complications. J Am Acad Dermatol 2010;63(4):703–5. https://doi.org/10.1016/j.jaad.2010.07.045.
4. Requena L, Requena C, Christensen L, Zimmermann US, Kutzner H, Cerroni L. Adverse reactions to injectable soft tissue fillers. J Am Acad Dermatol 2011;64(1):1–34. https://doi.org/10.1016/j.jaad.2010.02.064.
5. Duffy DM. Complications of fillers: overview. Dermatol Surg 2005;31 (11 Pt 2):1626–33.
6. Alsuhaibani AH, Alfawaz N. Lower eyelid swelling as a late complication of Bio-Alcamid filler into the malar area. Saudi J Ophthalmol 2011;25(1):75–9.
7. Jordan DR, Stoica B. Filler migration: a number of mechanisms to consider. Ophthal Plast Reconstr Surg 2015;31(4):257–62. https://doi.org/10.1097/IOP.0000000000000368.
8. Schelke LW, Van Den Elzen HJ, Canninga M, Neumann MHA. Complications after treatment with polyalkylimide. Dermatol Surg 2009,35(s2):1625–8.
9. Ramires PA, Miccoli MA, Panzarini E, Dini L, Protopapa C. In vitro and in vivo biocompatibility evaluation of a polyalkylimide hydrogel for soft tissue augmentation. J Biomed Mater Res – Part B Appl Biomater 2005;72(2):230–9.
10. Protopapa C, Sito G, Caporale D, Cammarota N. Bio-AlcamidTM in drug-induced lipodystrophy. J Cosmetic Laser Therapy 2003;5(3–4):226–30.
11. Nelson L, Stewart KJ. Early and late complications of polyalkylimide gel (Bio-Alcamid)J Plast Reconstr Aesthetic Surg 2011;64(3):401–4. https://doi.org/10.1016/j.bjps.2010.04.039.
12. Ross AH, Malthotra R. Long-term orbitofacial complications of polyalkylimide 4% (Bio-Alcamid). Ophthal Plast Reconstr Surg 2009;25(5):394–7.
13. Nathoo NA, Rasmussen S, Dolman PJ, Rossman DW. Periocular mass lesions secondary to dermatogetic fillers: report of 3 cases. Can J Ophthool 2014;49(5):468–72.
14. Eun YS, Cho SH, Lee JD, Kim HS. Periorbital lipogranuloma related to filler migration: a rare complication of facial fillers. J Cosmet Laser Ther 2014;16(3):149–50.
15. Malik S, Mehta P, Adesanya O, Ahuwalia HS. Migrated periocular filler masquerading as arteriovenous malformation: a diagnostic and therapeutic dilemma. Ophthal Plast Reconstr Surg 2013;29(1):e18–20.
16. Mustacchio V, Cabbdi D, Minervini MI, Barresi E, Amato S. A diagnostic trap for the dermatopathologist: granulomatous reactions from cutaneous microimplants for cosmetic purposes. J Cutan Pathol 2007;34(3):281–3.
17. Kadouch JA, Kadouch DJ, Fortuin S, van Rozelaar L, Karim RB, Hoekzema R. Delayed-onset complications of facial soft tissue augmentation with permanent fillers in 85 patients. Dermatologic Surg 2013;39:1474–85.
18. George DA, Erel E, Waters R. Patient satisfaction following Bio-Alcamid injection for facial contour defects. J Plast Reconstr Aesthetic Surg 2012;65:1622–6. https://doi.org/10.1016/j.bjs.2012.06.017.
19. Schelke LW, Velkhis PJ, van Dijk MR. Polyalkylimide: a nonstable filler over time. Dermatol Surg 2018;44:563–7.
20. Kim H, Cho SH, Lee JD, Kim HS. Delayed onset filler complication: two case reports and literature review. Dermatol Ther 2017;30:2–5.
21. Chiang YZ, Pierone G, Al-Niaimi F. Dermal fillers: pathophysiology, prevention and treatment of complications. J Eur Acad Dermatol Venereol 2017;31:405–13.