Aesth. Plast. Surg. 27:368–375, 2003
DOI: 10.1007/s00266-003-3012-3

Aesthetic Plastic Surgery

Porcine Dermal Collagen (Permacol) for Facial Contour Augmentation: Preliminary Report

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Abstract. Soft tissue loss or damage can occur for various reasons, including trauma, surgery, and disease. Reconstruction of normal contours can be achieved by using either alloplastic implants or autogenous tissues. Permacol, a dermal replacement material derived from fibrous acellular porcine dermal collagen, has been used for restoration of soft-tissue contours in the face. Eight patients were treated with porcine collagen in an attempt to achieve a smooth contour and a natural feel. Clinically visible soft tissue defects were successfully covered and aesthetic results were satisfying. Transient swelling that subsided within a week was noted in all patients. Meticulous and aseptic technique is mandatory for Permacol use. With this limited experience, Permacol was successfully used as a filler implant in reconstruction of post-traumatic soft-tissue defects, correcting post-parotidectomy hallowing and secondary nasal surgery to cover osseocartilaginous irregularities. However, there is a potential risk of inflammation and skin contractures in thin-skinned patients when implants are placed superficially.

Key words: Permacol—Porcine collagen—Soft-tissue reconstruction—Facial deformity

Tissue contour defects resulting from the loss of dermis, subcutaneous fat or supporting structures are common problems facing the plastic surgeon. The advent of newer improvements in anaesthetic and surgical techniques has broadened the indications and goals for facial rejuvenation and contour restoration. Surgeons currently strive to replace the missing or defective soft tissue with analogous material, restoring structural integrity, volume and texture. The most acceptable material for the repair of maxillofacial soft-tissue defects is autogenous tissue of a similar consistency [8]. Various techniques have been used in facial soft tissue contouring and these include autogenous transplants (free fat, dermis, dermal-fat grafts, autocollagen, and tissue cocktail), heterogenous transplants (bovine collagen), and alloplastic implants (silicone, tentalium mesh, Gore-Tex, suture materials, and hyaluronic acid) [7–10,12,17,18,20–22]. Autogenous grafts have disadvantages, however, including a variable degree of resorption of dermal-fat grafts and simple technical difficulties in shaping bone grafts, which also may be limited in size and may resorb at a subsequent time. Inherent drawbacks of the autogenous materials have stimulated prolific research to synthesize new biomaterials, either allogeneic or xenogenic [3]. Ideal material for soft-tissue augmentation would be biocompatible, non-immunogenic, easily obtainable, inexpensive, non-resorbable and easily stored. To date, studies have not yielded such a versatile material to be used in patients.

Permacol (Tissue Science Laboratories, Aldershot, UK) is a sterile, moist, and tough but flexible sheet of acellular cross-linked porcine dermal collagen and its constituent elastin fibers. Unlike other medical collagen products in either injectable or dressing form, the collagen is maintained in its original form rather than being reconstituted. It is speculated to be non-allergenic, non-toxic, and devoid of foreign body response (unpublished data, Tissue Science Laboratories plc, 1998). It has structural similarities to the architecture of human dermis and is readily invaded by host tissue cells and blood vessels (unpublished data, Tissue Science Laboratories plc, 1998).

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Table 1. Documentation of patients

Patient	Age/Sex	Site	Etiology	Absorption	Follow-up	Complication
1	8/F	Forehead	Trauma	None	2 years	None
2	24/F	Nasal dorsum	Saddle nose	None	2 years	None
3	28/F	Ala nasi	Excessive resection	Partial	6 months	Migration and soft tissue lumps
4	30/F	Nasolabial groove	Hemifacial atrophy	Partial	1 year	Infection
5	50/M	Temporal	Resection of SCC	None	2 years	None
6	52/M	Pre-auricular	Parotidectomy	None	16 months	None
7	26/M	Malar	Trauma	None	8 months	None
8	30/M	Cheek	Atrophic scarring	None	7 months	None

F: female, M: male, SCC: squamous cell carcinoma

Advancements in biotechnology mandate continual reassessment of new implants and techniques, which may offer an improvement in outcomes. In this preliminary report, Permacol was used to correct facial soft-tissue deficits that were caused by trauma, tumor ablation, aesthetic nasal surgery and hemifacial atrophy in eight patients who refused autogenous tissue harvesting.

Patients and Methods

Between April 1998 and January 2001, 8 patients (4 male, 4 female) underwent Permacol grafting for reconstructive and aesthetic surgery. The average age was 31 years (range: 8–52 years). The operative sites, indications and follow-up are reported in Table 1.

Surgical Technique

Depending on any additional procedures that were required, local or general anesthesia is used. Three basins with 500 ml sterile saline were prepared. Use of sharp instruments and toothed forceps are avoided when handling Permacol. The Permacol is taken from the sterile inner sachet of the package and aseptically put into the first of three basins containing 500 ml of sterile saline and agitated gently for one minute. The implant is transferred from one basin to another after rinsing for one minute and is left submerged in the final basin until required for use. Extreme attention is paid to prevent the implant from drying out. Depending upon the volume and area of the soft tissue deficit in every case, Permacol is cut and shaped to suit the requirements of the tissue space. However, if a thicker block of implant is needed, it is preferable to cut the material into separate sheets, creating edges rather than to fold it, presenting the maximum number of cut surfaces to body tissue, to enhance penetration by cells and blood vessels. If needed, Permacol may be sutured in place and, being a strong material, it will take and hold sutures easily and firmly while it is incorporated into surrounding tissues. Permacol graft adheres to the recipient bed as soon as it is placed there, and usually does not require immobilization. Then the overlying is sutured and a mild pressure dressing is applied for several days, after which no fixation is required. A course of antibiotics is used peri-operatively in every patient.

Case Reports

Case 1

An 8-year-old child was admitted to the Emergency Ward with an oblique and long traumatic laceration that traversed her face from the left malar area to the midline of forehead and parietal region of scalp. Surgery was performed immediately. Avulsion and contusion of the frontalis muscle and overlying tissues from the bone was noted. Foreign materials were removed, hemostasis was done and the laceration was closed in layers. The incision healed uneventfully and the complaint of the child and her parents was the soft tissue depression on the left half of her forehead after 6 months (Fig. 1A). The alternatives of groin dermal graft or Permacol were presented to her parents, and they opted for Permacol. The patient was re-operated on and a previous laceration in the scalp was used to conceal the scar. A precise left forehead pocket was dissected through this incision and a 5×10 cm implant 1.5 mm thick was used to restore forehead contour. No immobilization was required. The entry site was closed with 4-0 Vicryl and 4-0 Prolene sutures. No problem was observed except for edema that persisted for 10 days postoperatively. Postoperatively, the feel of the forehead is normal on palpation and top and frontal views show the restoration of forehead contour (Fig. 1B). The child and her family are satisfied.

Case 2

A 24-year-old woman, the second patient in our series, presented to the office complaining of a nasal contour deformity after cosmetic septorhinoplasty surgery was performed 2 years earlier. The patient's

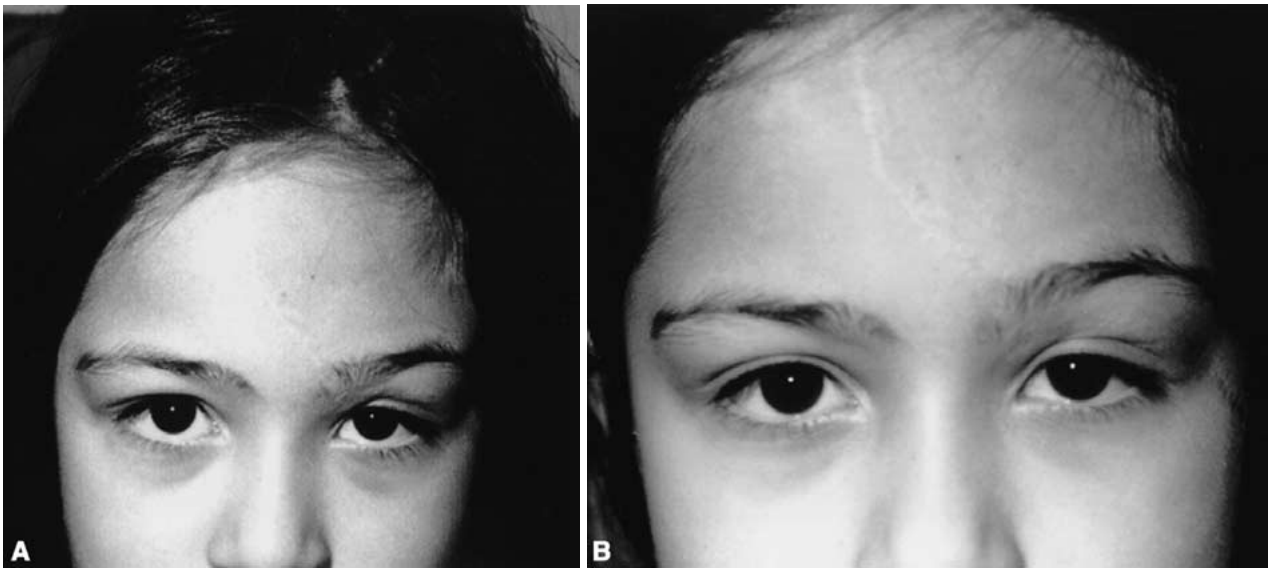

Fig. 1. A. An 8-year-old girl with left-sided depression of the forehead contour resulting from traumatic partial avulsion (Case 1). **B.** Permacol implant has completely levelled with the right half of the forehead and depressed contour of the left half forehead has disappeared in a later view of the patient.

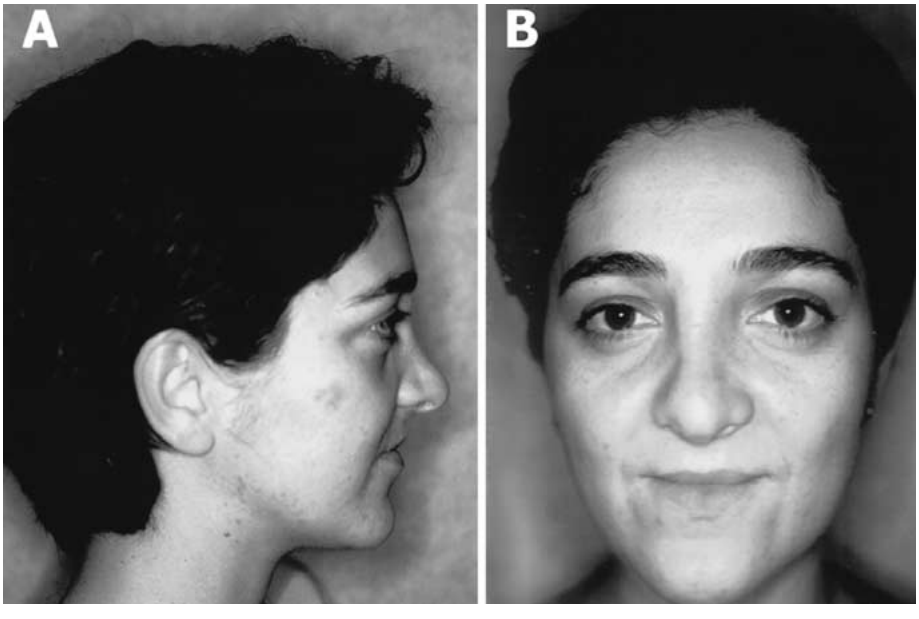

Fig. 2. A, B. Evidence of previous nasal surgery that resulted in visible dorsal irregularities and ''saddle nose'' deformity (Case 2). Preoperatively (**A**) lateral view, (**B**) frontal view.

main complaint was the apparent concavity of the nasal dorsum (Fig. 2). The lateral view reveals the saddle nose deformity. Use of autogenous cartilage harvested from the ear or rib was suggested alongside the Permacol implant. The patient negated the possibility of additional morbidity and accepted the use of porcine dermal collagen. Through unilateral intercartilaginous incision, the nasal dorsal skin was undermined and the nasal pyramid was skeletonized. Any obvious bony or cartilaginous prominences were rasped to reduce irregularities. Two layers of Permacol were cut, shaped and sutured to each other as a two-layered graft. The bilayered implant was soaked in rifampin-saline solution, placed into the dorsal pocket and spread over the area to be covered. The edges were examined for any unwanted folds, and the position was confirmed visually and by palpation. A 4-0 Prolene suture was placed in the superior pole of the Permacol and threaded through a straight needle; the other was pulled towards the glabellar skin using an Aufricht retractor and the suture was knotted over fusidic acid-coated gauze. The suture was removed after 5 days. The intranasal incisions were closed with 5-0 catgut sutures. Nasal skin was covered with horizontally applied skin tapes. An antibiotic was administered for 10 days postop-

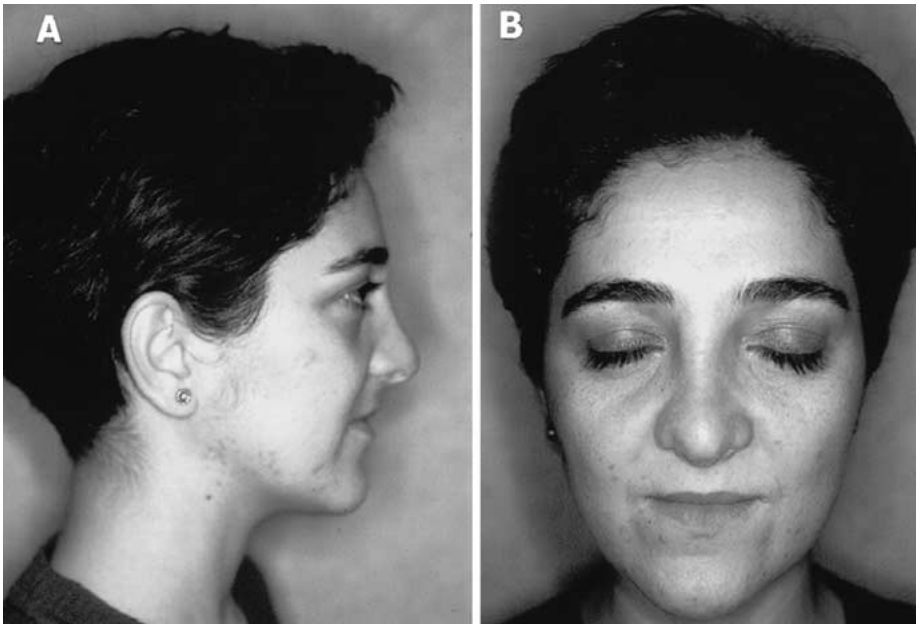

Fig. 3. A, B. Postoperative view: imperfect result after Permacol grafting for correction of the deformity: (**A**) lateral view, (**B**) frontal view.

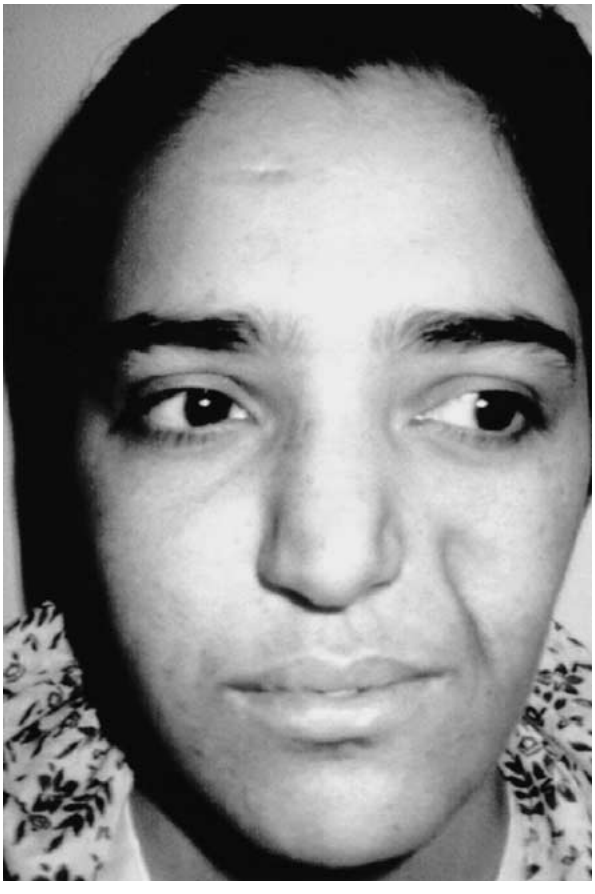

Fig. 4. Front view of a 35-year-old woman (Case 3) with left-sided hemifacial atrophy with marked soft tissue loss in the nasolabial groove.

eratively. The patient remains well without problems related to the shape of the nose or implant after 6 months (Fig. 3).

Case 3

A 35-year-old woman presented to the hospital complaining of a one-sided facial deformity (Fig. 4). She described the left side of her face as ''shrinking gradually.'' She said that the deformity on the left half side of her face had begun at 10 years of age and gradually progressed. The patient was diagnosed with progressive hemifacial atrophy and computerized tomography revealed atrophy of fat and soft tissue on the left half of the face. The possible course of the disease were explained in detail to the patient and choices of tissues available for reconstruction were suggested to her. She refused harvesting of autogenous tissues due to religious purposes and accepted the use of Permacol for correction of soft tissue loss in the left nasolabial groove.

Through a left lower eyelid blepharoplasty incision, anterior cheek skin was undermined to reach the left nasolabial fold. There was substantial loss of soft-tissue and the overlying skin was found to have thinned. A tunnel was dissected to the nasolabial fold and a pocket was developed for insertion of the Permacol implant. The area and depth of the soft-tissue deficit were analyzed by using a bone wax mold. The Permacol implant was cut, reshaped and layered to provide the amount of tissue required to correct the defect. The implant was rinsed in rifampin-saline solution and placed into the pocket through the lower eyelid incision. Additionally, a small piece of implant was inserted through another tunnel to be placed at the left alar region of the nose. Hemostasis was checked and the lower eyelid incision was closed in two layers without placing any drain.

The implants were not stabilized and no immobilization was observed in the follow-up. An oral cephalosporin was started and continued for 10 days

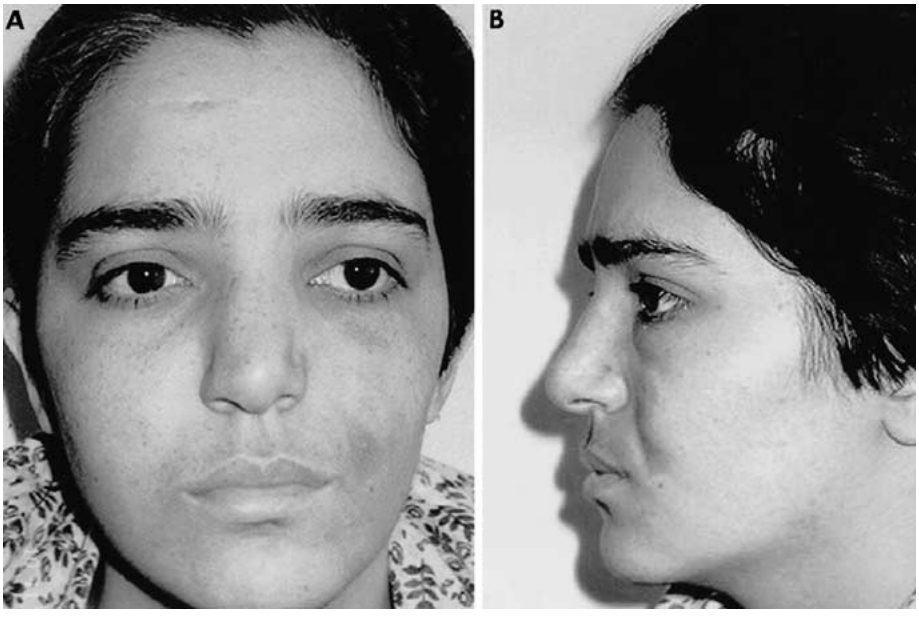

Fig. 5. Postoperative view of the patient at 5 months: (**A**) Front view, note satisfactory correction of the left nasolabial hallowing, (**B**) lateral view.

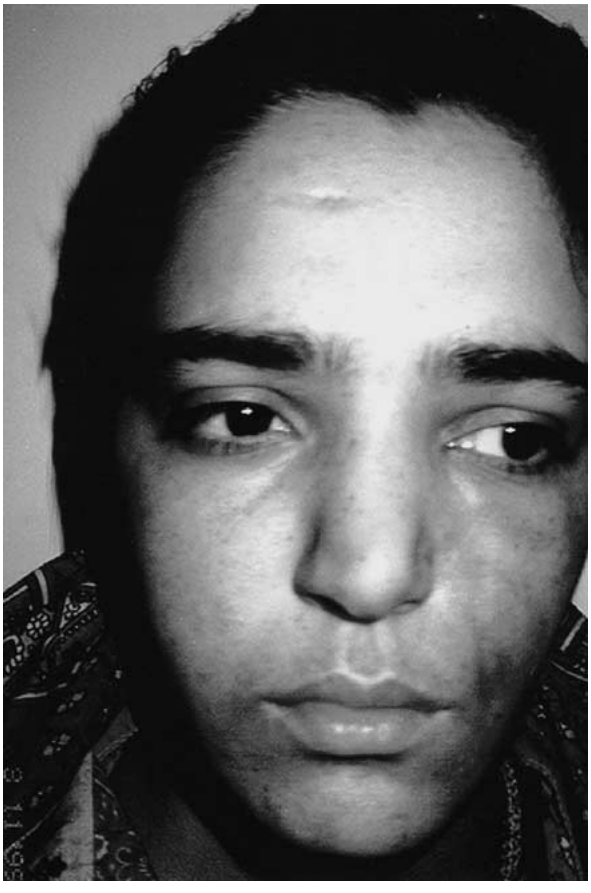

Fig. 6. (Case 3) Development of abscess formation with purulent discharge and swelling in the left cheek and nasolabial groove after Permacol implantation.

postoperatively. Follow-up was uneventful and the patient was satisfied with the result (Fig. 5). However, 5 months after surgery, she presented with erythema and pain over the left nasolabial region. She was treated with antibiotics but was irresponsive to the treatment. Signs of abscess formation with purulent discharge appeared (Fig. 6). Implants were removed through the same lower eyelid incision. The incision was left open to drain and the signs of infection subsided gradually. The implants removed from the cheek pocket were submitted for histopathological evaluation. Massive lymphocytohistiocytic cell infiltration surrounding the Permacol implant was observed. Remnants of the implant were surrounded by numerous multinucleated giant cells (Fig. 7). Infiltrates of giant cells were intermingled with elastic and collagen fibers. One area demonstrated acellular, foamy, and basophilic staining surrounded by inflammatory cells.

Results

Porcine dermal implant was used in eight cases with various indications. Implant usage for volume augmentation was limited for the facial region. Volume deficits were considered mild in 25% (n = 2), moderate in 50% (n = 4), and severe in 25% (n = 2) of the patients enrolled into the 3-year study period. Complications occurred in two patients in the late postoperative period and excellent cosmetic results were achieved in 75% (n = 6). Patients were satisfied with the final result. The postoperative follow-up duration after surgery ranged from 6 months to 2 years; there was no infection, no implant exposure, no allergic reaction and there was residual deformity in all cases but cases 3 and 4 (Table 1). Follow-up consisted of bimonthly visits in the first 6 months and with telephone calls later.

The graft material did not shift in all cases but one (Case 3), where it was used as a batten graft for

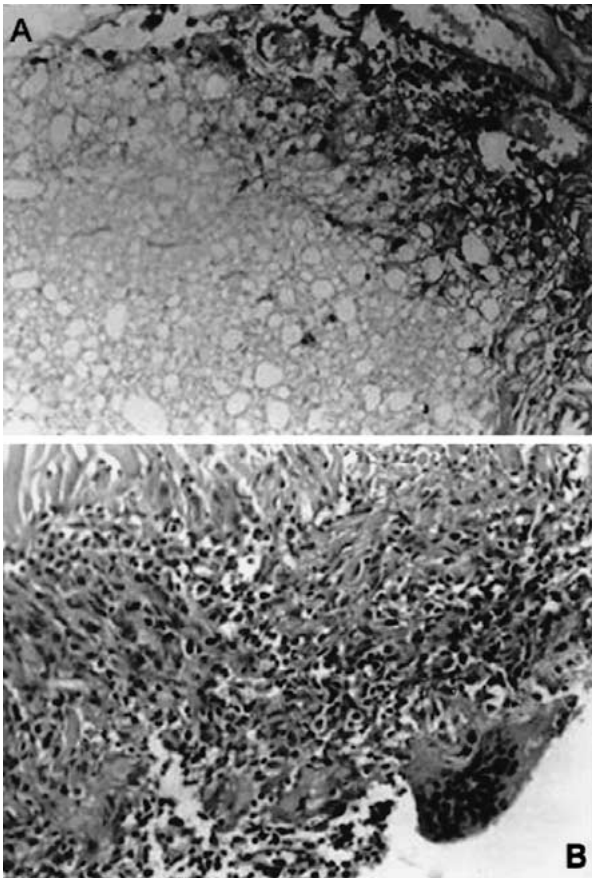

Fig. 7. Histopathological view of the Permacol implants removed from the cheek pocket. (**A**) Massive lymphocytohistiocytic cell infiltration surrounding the Permacol implant was observed. (**B**) Remnants of the implant were surrounded by numerous multinucleated giant cells. Infiltrates of giant cells were intermingled with elastic and collagenfibers. One area demonstrated acellular, foamy, and basophilic staining surrounded by inflammatory cells.

correction after excessive alar cartilage resection. The graft material was found to be soft and natural, and did not develop any contour irregularities over time. However, patients should be advised in advance that the implant area could develop transient firmness in the the early postoperative period. This feeling of firmness was particularly evident in the patient with hemifacial atrophy. Swelling was also noted postoperatively but subsided spontaneously in all cases by the second week. In the case where Permacol was used for correction of saddle nose, nasal skin was covered with transversely applied paper tape. In the presence of infection, there was partial absorption of the Permacol implant in the patient operated on for restoration of facial contour in hemifacial atrophy (Case 4). Partial degradation, edema and subsequent infection in that patient may be attributed to excessive inflammatory reaction elicited to the implant; no loss of permanence or partial resorption was observed in the other patients. Skin thickness was noted to have atrophied in the nasolabial fold and cheek, and reaction against the buried implant was obvious.

Permacol seems to give more satisfactory outcomes in facial regions where skin is thicker or has not thinned due to any cause. Choice of tissue plane for insertion should also be emphasized. Deeper dermal or subcutaneous planes seem safer for implantation. Implant was safely used for forehead contour in the first patient. Placing the implant just above the periosteum and bone below the remnants of the frontal muscle has not raised any problems. Use of Permacol requires no overcorrection in all cases (Figs. 1–5).

Complications occurred in patients operated on for hemifacial atrophy and unsuccessful nasal surgery. Re-operation was necessary in these patients and implants were removed with difficulty because they had firmly intermingled with the surrounding connective tissues. This clinical finding concurs with the histopathological observations of Griffiths and Shakespeare [11]. In the patient with Romberg's disease, the implant pocket was found to be infected; inflammatory reaction and infection caused scar contracture and subsequent ectropion in the lower eyelid. Infection responded adequately to oral antibiotics and topical rifampin treatment. The histopathological evaluation revealed multinucleated giant cells showing foreign body reaction.

Discussion

Augmentation of the subcutaneous tissues of the face, whether for congenital volume deficiencies, traumatic defects, dermatological disease, or age-related rhytids is a commonly performed or requested procedure. New products are continually appearing at an increasing rate, sometimes with great fanfare, but often fail to fulfill the promise of a better alternative to what is currently available [3,18]. Repair materials have been developed from synthetics (e.g., nylons, polyesters) or from natural sources (bovine or porcine) [4,7,12–14]. Often synthetic materials cause allergic reactions in the donor. However, since the major component of the skin is collagen and collagen from one animal looks very much like collagen from another animal, there are hypothetically fewer allergic reactions when natural materials are used. Composite grafts or flaps of autogenous tissue are theoretically the ideal material for replacing damaged or defective tissue because they should be devoid of allergic reactions or tissue rejection. Among choices of autologous soft tissue filler materials, fat and dermis used either alone or in combination are the most popular choices. Autologous mature adipose tissue has been used as a free graft for the reconstruction of soft tissue defects for more than 100 years and is still in use for lack of a superior alternative, although the results are poor and unpredictable [9,10,16,18]. Fat transplants are largely absorbed

and replaced by fibrous tissue and oil cysts [6,15]. Aspirates of fat-harvested liposuction also have unsatisfactory results, ranging from 50% volume reduction to complete resorption. Other disadvantages are the necessity for repeated fat injections, risk of infection, hematoma, persistent edema, multiple operation sites, calcification and liposuction-related complications [15]. As a refinement, lipocytic dermal augmentation, described by Coleman et al. [9], theoretically utilizes the post-wounding repair response to generate soft-tissue augmentation and reports improved outcome. Use of the time-honored dermal or dermal-fat graft for contour enhancement during primary and secondary volumetric restoration is safe and convenient; however, these have certain drawbacks such as donor site scarring, limited availability and prolonged operating time [16,18]. In addition, loss of volume and hardness because of incomplete "take" are the reasons for a compromised result at the recipient site [1,8,16]. Even the most popular autologous materials lack long-term permanence, and the quest for such an ideal material has stimulated interest in allogeneic, xenogenic and synthetic materials [1,3,7,14,17,20–22].

Recently, a newer group of materials has emerged for soft-tissue augmentation in the face, mainly manufactured for soft tissue replacement. These materials have ranged from nonbiologic, synthetic substances such as porous polyethylene to biologic ones such as collagen and "acellular" dermis [3,9,17,20–24]. Currently, value of synthetic implants remains controversial because of the issues of firmness, extrusion, and unnatural feel. Despite these problems, only alloplastic materials do not require a donor site, are not limited by natural boundaries, and are always readily available "on the shelf".

Biological substances have fared better in soft tissue sites but remain handicapped by concerns about long-term efficacy and maintenance of volume, especially in sites with potential mobility. In rare cases, patients may refuse harvesting of autogenous grafts because of religious reasons. Bovine collagen is the simplest and most commonly used biological filler material [21,22]. Currently it appears to be the ideal material but allergic sensitivity in 3% of patients and relatively rapid resorption are the main drawbacks that may preclude its use [22].

Permacol is a sterile, off-white, tough, but flexible sheet of fibrous acellular porcine dermal collagen with its constituent elastin fibers. It has a CE Mark Class III and therefore is fully approved for use as a permanent biological implant in humans. All epithelial cells lining sebaceous glands and hair follicles and sweat ducts have been removed and the process of trypsinization destroys all dermal fibroblasts. Thus, Permacol is an acellular dermal matrix that is devoid of any material likely to elicit allergenicity. The patented process maintains the original three-dimensional architecture of the collagen matrix, further decreasing the likelihood of inducing an allergic reaction. Furthermore, no allergic, cytotoxic, mutagenic or systemic response and intra-cutaneous reactivity have been shown in animal tests and in a large population of patients who have received Permacol implants, of which 140 are documented case reports (unpublished data, Manufacturer's technical statement, Tissue Science Laboratories plc, 2002). Thus, skin testing is not necessary before implantation. To overcome the slow absorption phenomenon, porcine collagen has been processed by a special and patented cross-linking treatment, which is imperative.

Permacol has been licensed for permanent implantation into humans since 1998 and has been used in varying surgical specialties with success. It has been used with good clinical results for treatment of anterior and posterior vaginal prolapse [19], female urinary stress incontinence [4], inguinal hernia repair [13], and reconstruction of the abdominal wall due to postoperative recurrent dehiscence [2]. However, long-term objective studies have not been performed. Belcher and Zic [5] have used interposition of porcine collagen for treatment of osteoarthrosis of the trapeziometacarpal joint after trapeziectomy but this study was terminated because of apparent reactions to Permacol, characterized by pain, diffuse erythema, and edema at the site of implantation. We have also observed similar findings in one case that resulted in abscess formation and eventual implant removal in the late postoperative phase.

To date, there is only one brief communication in which Permacol was used for augmentation of hollowed cheek contour following a facial fracture [12]. The present paper reports our limited experience with Permacol implants in facial contour enhancement. Infection, allergic reactions and extrusion are potential complications for implants either alloplastic or heterologous. Infection seems uncommon but insufficient correction might be a more serious problem in soft tissue contouring. All patients but two were very satisfied with the result and two disappointing outcomes were due to implant migration and infection. It is unlikely that an infection introduced at the time of implantation could present 5 months after surgery. The subcutaneous pocket dissected for insertion of the implant was walled with atrophied dermis and subcutaneous tissue outside and with thinned oral mucosa inside. Thus, dissection and subsequent inflammation might have paved the way for a chronic inflammation that evolved into an abscess formation.

Permacol offers many advantages for correction of soft tissue deficits and contour deformities. However, further studies with larger number of patients are needed to evaluate porcine dermal collagen graft and compare it with the current standards of treatment. Long-term safety and reliability need to be proved with longer follow-up periods. From another perspective, use of materials, either autologous or heterologous, depends largely on the surgeon's own initiative, skill, and experience. Whether autologous or heterologous, materials have potential

advantages and the disadvantages and the final decision depends on the compromise between the surgeon and patient.

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