Artificial Hair Fiber Restoration in the Treatment of Scalp Scars

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BACKGROUND There is presently no treatment for scalp scars that is fully satisfactory. The modalities of treatment currently in use are surgery, hair transplantation, and micropigmentation. Scalp implantation with artificial hair fibers is used by some physicians as an adjunctive treatment.

OBJECTIVE The objective was to assess the utility of artificial hair fibers to treat scalp scars.

METHODS Data were collected by the principal author from 10 hair restoration practitioners who tested polyamide hair fiber (Biofibre CE 0373/TGA by Medicap Ltd., Carpi (MO), Italy) implantation for scalp scars.

RESULTS Artificial hair fiber implantation occurred between June 1996 and December 2000, and observations continued until December 2004. Data from 54 scars from 44 patients treated showed: (1) no complications in 49 scars (90.7%); (2) mild adverse outcomes in 4 scars (7.4%)—temporary superficial inflammation-infection that subsided following topical cortisone and local/systemic antibiotic treatment; and (3) moderately adverse outcomes in 1 scar (1.9%)—significant inflammation and generalized infection requiring removal of artificial implant to alleviate. Occasional minor skin reactions, sebum plugs, and hyperseborrhea were successfully controlled and well accepted by patients. Fiber fall rate was 20% on average per annum.

CONCLUSION Data show that polyamide hair fiber restoration can be considered an adjunctive treatment for scalp scars in selected cases.

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Scalp scars may result from a variety of causes, including direct scalp trauma, burns, infections, and surgery.[1–4] Scars are frequently unsightly and unacceptable to patients, with several psychological and social consequences.[5] Hair restoration surgery (flaps, scalp reduction, donor site excision), performed using incorrect or older and outdated methods, produces the majority of patients with this problem seen in the hair restoration practitioner's office.[6,7]

Surgical treatment of scalp scars is largely confined to simple linear scar revision or complex revision (Z-plasty, W-plasty).[8,9] Although the former is generally unsuccessful because it is unable to correct an unfavorable directional orientation of the scar, the latter is not favored because it distorts hair patterns.

Autologous hair transplantation, while occasionally worthwhile, can produce patchy growth while adding a further scar to the occipital donor area.[6,7] Micropigmentation can be useful as an adjunctive treatment;[10] however, it is laborious and requires significant expertise from the surgeon/tattooist if satisfactory results are to be achieved.

The implantation of artificial fibers is performed as an alternative to using hairpieces and as an adjunctive methodology for hair restoration in other types of irreversible alopecia.[11–18] It is not permanent, however;

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it needs regular follow-up and, although approved by the health authorities of many countries, it has not been approved in the United States.[11,15,17]

In this article, data obtained from the implantation of a specific polyamide fiber for the treatment of scalp scars are presented.

Materials and Methods

Materials

The hair fiber used in all cases was Biofibre CE 0373/TGA, a polyamide fiber manufactured in Italy (Medicap Ltd., Carpi (MO), Italy). The CE 0373 and TGA marks indicate that these fibers are medical devices approved by the European Union and the Australian Health Authorities, respectively.

Characteristics of these fibers are: 0.080-mm diameter, 15-cm length, and 13 colors, with straight or one of three wave types. A knot at one end of the fibers ensures correct anchorage of the implant. Fibers are packed in sterile envelopes (100 pieces each), carrying an identity label that is recorded on the patient's case sheet.

A sterile implanter (CE 0373 authorized instruments by Medicap Ltd.) is used for the procedure, either disposable (plastic) or reusable (stainless steel or titanium), carrying a sliding hooked needle (0.25-mm diameter, stainless steel), which protrudes from the inside to capture the fiber's knot with its hook-shaped tip.

Subjects and Data Collection

This study is a retrospective analysis of scalp scars treated with hair fiber implantation between June 1996 and December 2000 and observed until December 2004. Fibers used were all of the same model and quality.

Data were obtained from questionnaires completed by 10 hair restoration practitioners operating in 10 clinics located in Australia, Brazil, Egypt, Italy, Mexico, Norway, Saudi Arabia, Spain, and Russia. Data were collected by the principal author. No blinded panel of judges nor an external monitor were present.

A detailed questionnaire was conceived to collect data, and it requested the following: sex and age of patient; cause, location and physical dimensions of scars; total number of implants, timing and number of procedures including details of preliminary test; postoperative regimen; complications and treatments; subsequent treatments; objective evaluation of results; and every additional clinical event that appeared after implantation, even if apparently showing no connection with the surgery itself.

Adverse events were filed by implant practitioners in a specific area of the questionnaire and were classified as *serious* (all events producing irreversible damage to the health of the patient) and *nonserious* (all events which were solved without permanent damage). Nonserious events were classified as: moderate (for which fiber removal was necessary to alleviate), mild (which resolved with local and/or oral treatment), or negligible (all superficial skin reactions, which were not recorded because they subsided rapidly either spontaneously or with adequate hygiene and treatments as prescribed in postimplant protocol).

Forty-eight patients were enrolled and started the treatment. Four patients were lost for reasons not linked to hair fiber restoration. Therefore, data were obtained on 44 patients, including 36 men and 8 women, with ages ranging between 17 and 64 years (mean age, 38.9 years; Table 1) for a total of 54 scalp scars treated. Thirty scars stemmed from surgeries: autologous transplant (14), scalp reduction (9), flap rotation (6), and coronal face-lift (1). Twenty-four scars generated from other causes: burns (11), trauma (10), removal of the hook of hair pieces (1), fungal infection (1) and sclerodermatitis (1).

Scar sites were frontal (12), parietal (24), and occipital (18) with a mean surface of 59.9 cm^2 (range,

TABLE 1. Summary of Patients' Age, Surface Area Treated, Number of Sessions per Scar, Number of Fibers Implanted per Scar, and Density of Fiber Placement

	Mean	*SD*	*Range*
Age (years)	38.9	11.7	17–64
Surface area (cm^2)	59.9	39.4	8–180
Number of sessions	4.3	1.5	2–9
Number of fibers	1580	1065	200–5000
Density of fibers (fibers/cm^2)	26.7	6.4	10–40

8–180 cm^2; Table 1). Detailed histories and physical examinations were performed with particular reference to skin conditions, allergies, lifestyle, and psychological motivation.

Patients were informed of the temporary nature of the artificial hair implants, how to care for them, possible complications, adjunctive costs for postoperative medical check-ups, and the need for subsequent implants to maintain density. Informed consent was obtained in all cases. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki and standardized guidelines of hair fiber implantation agreed by the authors.

Implant Test Procedure

Two test sessions of 100 fibers each, performed at 30- to 40-day intervals, were aimed at evaluating reaction to polyamide fibers. Before the test, patients were instructed to wash their head with antiseptic shampoo and not to use any other hair product (i.e., spray, gel, foams). Preoperative antibiotics were not normally administered.

Implant Procedure

After confirming cleanliness and the absence of lesions or inflammatory processes, the scalp was cleaned with a quaternary salt-based solution and infiltrated intradermally with 1% lidocaine and 1:200,000 epinephrine. The sterile envelope holding the fibers was opened at the level of the knots. Fiber knots were hooked one by one by the hooked needle that is contained in the tip of the implanter.

The tip of the implanter is placed on the scalp at the desired inclination and on pressing the push button the needle introduces the knot into the galeal space. On releasing the implanter push button, the tip of the needle returns to the inside and the fiber knot remains anchored under the galea. After implantation of 100 fibers, the area is disinfected and sprinkled with antibiotic solution (3% erythromycin or 40 mg/mL gentamicin sulfate).

Postimplant

After the implantation procedure, patients were instructed to clean the implant site daily with antiseptic lotions (i.e., diluted quaternary salt-based), two or three times per week with keratolytic lotions (i.e., low concentrations of salicylic acid) and to report immediately any symptoms or signs deemed untoward. Use of irritating substances and excessive exposure to sun was discouraged. Hair was washed when needed with neutral shampoo and dried by blowing with lukewarm air. Sebum control products were used when needed.

Patients' scalp was checked 7 days after each implant session. Evaluation of results was carried out any time complications appeared and, as a rule, 30 to 40 days after each test session. If no adverse effects (infection-inflammation) were described after 3 months from first implant test, definitive treatment could then be commenced.

Implant Session

Patients underwent periodic implantation procedures until the entire scarred area was satisfactorily covered or the patient expressed satisfaction with the result and did not wish to proceed further.

Implant sessions were carried out with the same protocol and technique described for test sessions by implanting between 100 and 800 fibers per procedure. The interval between sessions was 30 to 40 days.

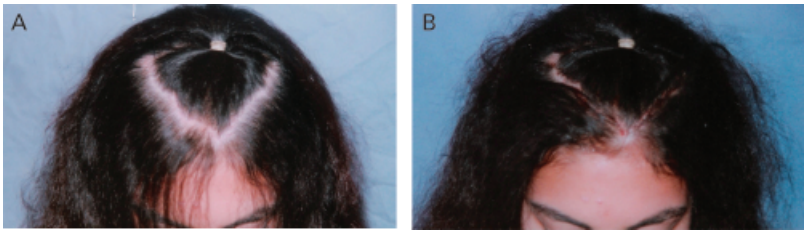

Figure 1. Female patient, age 26, with a ''V''-shaped posttraumatic scar localized in the front-parietal region. (A) Before treatment; (B) after six implant sessions (total 1000 fibers implanted).

Follow-up

Once coverage was complete, patients were instructed to follow the norms described in the post-implant instructions and to attend the clinic at 30- to 90-day intervals for examination and possible mechanical removal of comedones that may have accumulated. Sebum plugs were removed by pressure on the surrounding scalp area, followed by the application of disinfectant.

Maintenance Sessions

Every 6 to 12 months, patients underwent maintenance sessions to replace fallen fibers. Subsequent sessions were performed upon request by patients.

Results

Implant sessions totaled 230, with a mean of 4.3 sessions per each scar. A total of 85,300 fibers in toto were implanted, with a mean of 371 fibers per session and 1,580 fibers per each scar. Distance between fibers varied from 1.6 to 3.1 mm, with a mean density of 26.7 fibers/cm^2 (data summarized in Table 1).

Practitioners performed evaluation of results, which consisted of objective assessment. A score ranging from 1 to 10 was assigned to the final result of hair fiber restoration sessions: 1 to 3, negative; 4 to 5, poor; 6 to 8, good; and 9 to 10, excellent (case examples, Figures 1–4).

The outcome was judged excellent for 25% of patients (11), good for 63.6% (28), poor for 9.1% (4, of which 2 patients suffered a high spontaneous fall rate of the fibers together with an implant density considered insufficient, and 2 who developed mild recurrent infections), and negative for 2.3% (1 patient who developed inflammation and generalized infection in the frontal area, which required removal of the fibers). Histologic biopsy results on the device in situ have been performed by one of the authors (MS) over the following time periods:

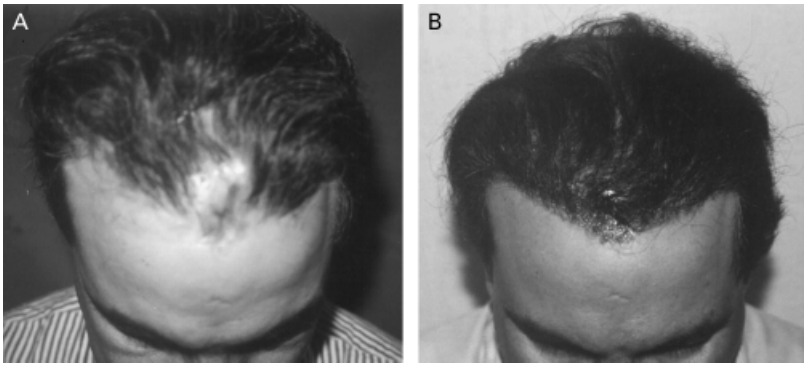

Figure 2. Male patient, age 48, with two frontal scars due to necrosis developed after flap rotation. (A) Before treatment; (B) after two implant sessions (total 1500 fibers implanted).

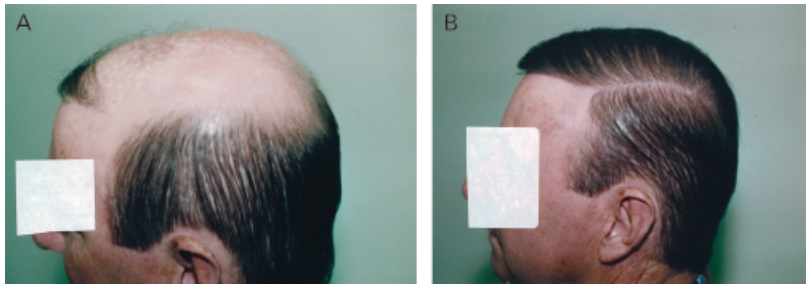

Figure 3. Male patient, age 56, with several frontal-parietal scars after hair transplant procedure. (A) Before treatment; (B) after treatment, lateral view (four implant sessions, total 3600 fibers implanted).

- 4–8 days—Neutrophils and lymphocytes (macrophagic reaction).
- 30 days—Concentric fibroblasts and histiocyte cells.
- 3–6 months—Fibrosis around the fiber. No pigment seen.
- 12–18 months—Fiber surrounded by fibrosis and collagen. No pigment seen.
- 2, 3, 4, and 5 years—Fiber surrounded by fibrosis and collagen. No pigment seen.

Patient tolerance of the procedure and postoperative regimen of care was well accepted in all cases.

Complications (Figure 5)

No serious adverse events were reported. One (1.9%) nonserious moderately adverse event was a case of frontal scar resulting from flaps rotation that required fiber removal due to inflammation and generalized infection resistant to standard topical and systemic steroids and antibiotic treatments. Reaction appeared 13 months after the first implant session. After fiber removal, inflammation of the scar tissue slowly resolved and skin returned to its original aspect both in color and in consistence after 30 to 60 days.

Four (7.4%) nonserious mild adverse events were recorded where mild superficial inflammation-infection occurred between the 4th and the 12th weeks after the first implant session in frontal ($n = 1$), parietal ($n = 1$), and occipital ($n = 2$) scars. Reactions were successfully treated with topical cortisone and local/systemic antibiotics. Skin always returned to its previous state.

Sporadic temporary low-grade infections subsided rapidly in 2 to 3 days, either spontaneously or after medical shampoos or application of local antibiotics. Occasional mild reddening and itching phenomena were controlled with topical application of steroids. Hyperseborrhea was controlled with sebolytic-kera-

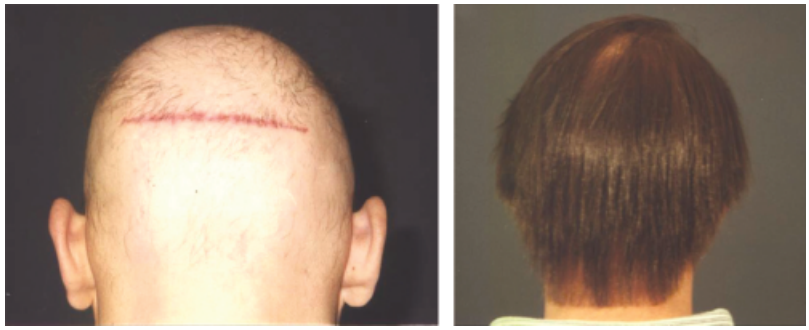

Figure 4. Male patient, age 17, with alopecia totalis and an occipital scar after hair transplantation (nuchal graft). Scarred area was covered with 1000 fibers. Remaining bald area was covered with 22,000 fibers.

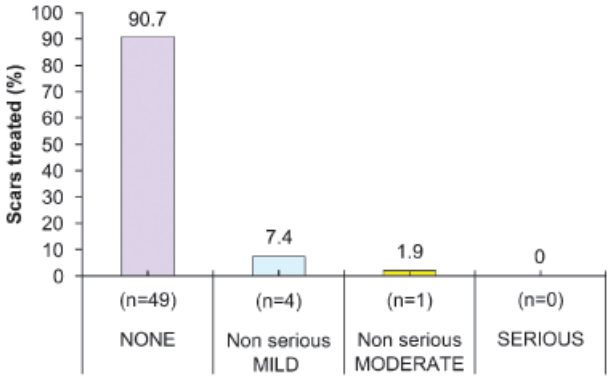

Figure 5. Diagram summarizing adverse events observed during the study. Data are expressed both in percent and in absolute number.

tolytic products. The mean spontaneous fiber fall rate was estimated to be 18% per year in the frontal-parietal region and 23% per year in the occipital region.

Discussion

Scalp scars may result from a variety of causes including direct scalp trauma, burns, infection, surgery, and hair restoration surgery (flaps, scalp reduction, donor site excision).[1–4,6,7] They are frequently unsightly and unacceptable to patients, with several psychological and social consequences.[5]

Surgical treatment of large scalp scars (Z-plasty, W-plasty) is often unsuccessful.[8,9] Hair restoration surgery is a possible approach, leading to variable outcomes.[6,7] Micropigmentation is occasionally useful and worthy of consideration.[10] Artificial hair fiber implantation is performed by some physicians sometimes as an adjunct to other hair restoration techniques.[11–18]

Medical literature on new artificial fibers has recently reported encouraging results and no severe complications.[12–14,16,17] The implantation of these artificial fibers is approved in many countries; however, their use has led to the development of opposing opinions. These opposing opinions stem from the fact that this form of treatment is not permanent, needs to be followed up, and was banned in the United States in 1983[12,13,15,17,19] because of occasional severe reactions and infections.[20] These adverse reactions were provoked by the use of pioneering, unsuitable artificial fibers that were used at that time without any medical protocol.[21]

Recent clinical and histologic studies on various fibers have shown that the reactivity and the frequency of problems varies according to the type of fiber implanted and to the protocols applied. Relevant conclusions were drawn in a histologic study after 3 years on patients who underwent polyamide artificial hair implantation without complications, conducted at the University of Bologna (Italy). ". . . Our study showed the same modifications in patients without inflammatory complications as in patients with inflammatory complications, except for the presence of inflammatory infiltrates. In our cases, the density of the fibers was lower than found in patients with cutaneous complications. In particular, the fibers were surrounded by closely adhering sleeves of keratin at the level of the pseudoinfundibula. This aspect was absent in cases with inflammatory complications. In conclusion, if the hairs are implanted at low density and the physical and chemical characteristics of the fiber allow the adherence of a sleeve of keratin inside the pseudoinfundibulum, it is possible that no clinically evident inflammatory complications will appear." (Fanti PA, Pistorale T, D'Urso C, Misciali C, Tosti A, poster presented at the American Society of Dermatopathology, 32nd Annual Meeting, New Orleans, LA, February 1–3, 1995). Therefore, materials and methods play a crucial role in determining the success of this treatment.

If the implantation technique is faulty (e.g., lack of sterility, use of irritating chemical substances, fibers implanted too close or too shallow, multiple fibers in one hole, use of poorly compatible non-flexible fibers, irregular fiber surface), there is an increase in the frequency of adverse reactions.[22,23]

In contrast, if the implantation technique is correct [e.g., asepsis, single fibers implanted at the right

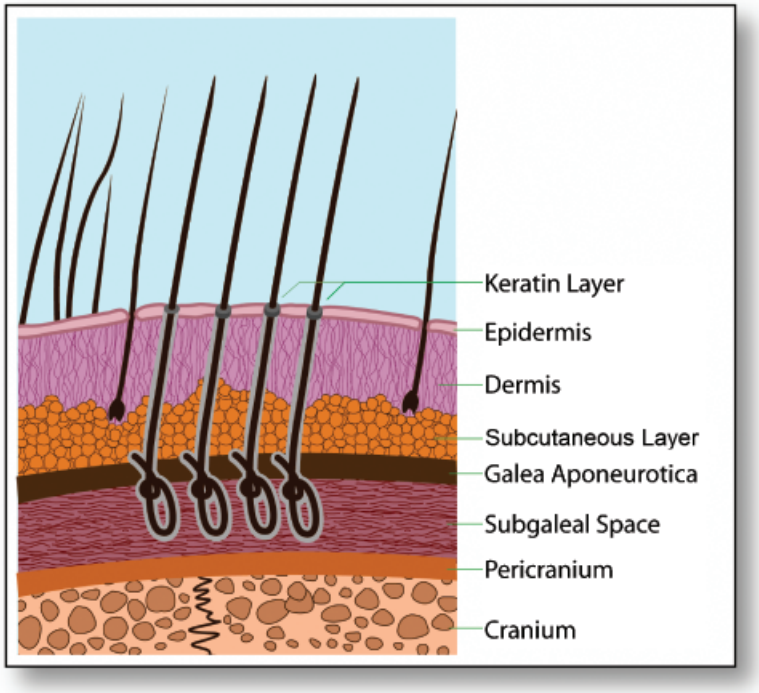

Figure 6. Keratin sleeve (gray color) surrounding implanted polyamide fibers.

distance and depth—and the fibers allow keratin adhesion (Figure 6) and are thin, smooth, flexible, and highly biocompatible and the recommended hygiene and medical control measures are followed], superficial inflammation is negligible and infections are rare.[12–14,16,17]

It should be considered and recognized, however, that other hair restoration techniques still result in many minor and major complications[17] sometimes requiring hair repair, modification, or integration.[6,7,11–13,15,18] All surgical methods (transplants, scalp reduction, flaps, artificial fibers) have been successfully used in skilled hands and with proper patient selection.[24]

Here we evaluated the results of polyamide fiber (Biofibre CE 0373/TGA) implant treatment for scalp scars. This study is a retrospective analysis at 4 years. The subjects were observed until December 2004 (no blinded panel of judges nor an external monitor were present).

Mild inflammation, which subsided spontaneously after a few days, sometimes appeared immediately after implantation. Inflammation-infection that occurred (7.4%) was superficial, mild, and solvable with targeted therapy.

Complications requiring fiber extraction to alleviate (inflammatory pustular skin infection not controlled by topical and systemic steroids and antibiotic therapy) were lower than 2%. In those cases fibers were entirely extracted by manual traction, and the skin always returned to its previous state after 30 to 60 days.

Sporadic minor superficial infections were successfully controlled by the application of local antibiotic. Occasional mild reddening and itching and excessive seborrhea were successfully controlled by application of cortisone-based creams or lotions and antisebum and keratolytic products, as indicated.

In some patients the implanted skin surface shows small depressions and dilatations, which are caused

by unremoved sebum plugs. Sebum that collects within the pseudo-infundibula around the fibers may act as an irritant. Removal of comedones is indicated. In scar tissue, there is reduced or absent sebum output, and therefore the rate of comedone removal and hyperseborrhea is very low.

A higher rate of spontaneous fiber loss (mean, 20%), with respect to studies previously published (mean, 10%),[12–14] was attributed to a reduced "hold" of the implanted fibers in a scarred scalp, which is relatively thinner than the normal scalp. Histologic observations after 5 years (MS) have shown that, in the deepest dermis and hypodermis, all implanted fibers were surrounded by a slight granulomatous infiltrate. No pigments nor inflammatory phenomena were noticed.

Granulomatous infiltrate seems to have a negligible clinical importance, since as also stated in other clinical studies, it is present both in patients without any skin reaction[12] and in those with skin reaction.[23] No fiber migration, fiber breakage, or frizzing was observed during the whole length of this study (September 1996–December 2004).

All patients, except one, were very appreciative of the cosmetic result and the rapidity of hair restoration, not adversely affected by the maintenance program, and 80% of them continue to have maintenance sessions. Results that emerged from this study confirm those reported by other authors and hair transplant practitioners who have been performing artificial hair fiber restoration for more than 4 years.[11–14,16,17]

Figure 7. Microscopic picture of one polyamide fiber extracted.

Conclusion

At present, there is no treatment for scalp scars that is fully satisfactory, and adjunctive modalities of treatment are promising.[6,7,11–18,25] During the past 10 years, the quality of artificial hair fibers and implantation procedures has improved significantly; implants show only reversible data and are approved by various health authorities.

As shown by this and by other clinical-histologic studies, the risks associated with these new fiber implants (infection, inflammation, foreign body reaction, and related sequelae) in general are modest; they can be prevented by following the treatment protocols and resolved with adequate drug treatments or manual extraction of the fibers.[12–14,17]

In rare, but possible, cases (around 2%) of complications not responding to pharmacologic treatments, fibers can be entirely extracted (Figure 7) by manual traction and skin returned to its original aspect after 30 to 60 days, and this allows subsequent repair surgeries with good results.[26]

Patient selection, suitable hair fibers, correct implant technique, and postimplant hygiene and regular scalp check-ups are regarded as sine qua non for a satisfactory outcome. Sporadic reddening, itching, and microinfections are, in general, successfully controlled by topical therapy, well tolerated, and not a source of significant patient dissatisfaction. Periodic checks and top-up sessions maintain the esthetic result.

Implantation with these devices is still in its infancy. Results collected by the authors (more than 5,000 patients treated with $\pm$ 10 million polyamide fibers)

and by other hair transplant practitioners,[12,16] however, give hope that future clinical trials in the United States and in Canada, performed according to a more standardized clinical protocol and with a larger number of patients, will further demonstrate the efficacy of this treatment.[11,12,15,17,19]

In conclusion, these new polyamide fiber implants are well tolerated by the majority of the patients,[12–14,21,27,28] and the authors agree that this is a possible adjunctive treatment for scalp scars and as a viable alternative to nonsurgical solutions (toupees, hairpieces, wigs, and similar).[11–18]

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COMMENTARY

This is an interesting subject about which most American dermasurgeons lack personal experience. I have treated a few patients with complications of older fiber therapy and the problems were similar to those the authors describe. Most of us still treat scalp scars with a variety of modalities that include expander assisted excision, micrografting, punch and linear excision, and occasionally, dermabrasion. Artificial fibers, if FDA-approved, might offer an acceptable alternative with a procedure whose complication rate does not seem to exceed the aforementioned procedures currently employed.

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