

Clinical updating study at 3 years on 278 patients treated by modern artificial hair implant technique (automatic biofibre[®])

Torello Lotti¹  | Michael Tirant² | A. Rateb Said³ | Bogdan Morad Albzour⁴ | Mariangela Santiago⁵ | Manjula Agrawal⁶ | Ash Dutta⁷ | Van Thuong Nguyen⁸ | Mary Vadalà⁹ | B. Palmieri⁹ | Aleksandra Vojvodic¹⁰  | Massimo Fioranelli¹¹ 

¹Department of Dermatology, University of Rome G. Marconi, Rome, Italy

²University of Rome G. Marconi, Rome, Italy

³Department of Dermatology, University of Cairo, Giza, Egypt

⁴Department of Dermatology, University Cluj-Napoca, Cluj-Napoca, Romania

⁵Department of Plastic Surgery, Hospital of Face Defects, Sao Paulo, Brazil

⁶Department of Dermatology, Fortis Hospital, Shalimar Bagh, India

⁷Education Committee member of World Academy of Cosmetic Surgery (WAOCS)

⁸Dermatology and Venereology, National Hospital, Hanoi, Vietnam

⁹Department Surgery, University of Modena Medical School, Modena, Italy

¹⁰Department of Dermatology and Venereology, Military Medical Academy, Belgrade, Serbia

¹¹Department of Nuclear Physics, Sub-Nuclear and Radiation, G. Marconi University, Rome, Italy

Correspondence

Massimo Fioranelli, Department of Nuclear Physics, sub-nuclear and radiation, G. Marconi University, Rome, Italy.

Email: massimo.fioranelli@gmail.com

Abstract

In this study, we report our multicentric experience of synthetic medical certified polyamide hair implants in male androgenetic, female menopausal, and chronic alopecia. Biofibre hair implantation was performed by means of a standardized, minimally-invasive technique followed by regular postoperative care along 3 years. From May 2015, 278 patients were enrolled and 253 completed the trial; 202 men (79.9%) versus 51 women (20.1%). The average age was 43(± 4.29); 179 patients (70.1%) had taken previous treatments for alopecia. We evaluated efficacy (as judged by Hamilton scale grading, covered area percent, surgeon, and patient's subjective evaluation) and safety (as judged by adverse events). The overall scalp surface restored with artificial hair (mm² spaced) and pre-postoperative general customers' satisfaction (by Hamilton scale grading) are reported, showing a significant (98.14%) subjective and objective improvement of the self-image. Twenty-two cases (8.75%) declared minor side effects generally counteracted by topical or short course systemic antibiotic and anti-inflammatory treatment. The average number of implanted fibers was 2,295 (SD 2.805; SE 200.9) ranging from 300 to 16,000. The average duration of pain and tenderness at the implant area was 2.2 days (SD 4.096; SE 0.2933) ranging from 1 to 20 days. A diagrammatic comparison of the Hamilton scale grading before and after the trial showed a dramatic improvement with the majority of the patients being in Hamilton grade II after implantation.

KEYWORDS

automatic artificial hair implant, biofibre, hair implant

Both subjective (physicians and patients') and efficacy evaluation data which were recorded on a three-grade scale (1 = slight improvement, 2 = moderate improvement, 3 = marked improvement) showed moderate to marked improvement at the end of the study. Average patients, surgeons, and efficacy evaluation grades were 2.54, 2.53, and 2.34, respectively. Overall, a successful result was noticed in 98.14% of the patients with psychological satisfaction. Paired *t* test for Hamilton Scale Grading and for Covered Area Percent gave statistically significant results (Tables 1 and 2).

The fibers were found safe in 91.31% of cases. Adverse events were clinically classified in three categories (insignificant, mild, and moderate) and were observed in only 22 cases (8.69%). Insignificant adverse events like fiber curling were observed in three cases (1.18%).

Mild side-effects comprising localized slight inflammation and infection were recorded in 15 cases (5.92%). Moderate adverse events observed in four cases (1.58%) also required some fiber removal, when frank abscess or pustular inflammation were not

TABLE 1 Patients' inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age 20 to 70	Psychological disorders
Clinical diagnosis of androgenetic alopecia and grading with Hamilton scoring	Dermatitis or any dermatosis of the scalp
Good general health without any other pathology of the scalp	Chronic metabolic disorders, immunodeficiency, allergies
Patients willing to return for follow up	Patients not willing to return for follow up or with reduced therapeutic compliance
Informed consent	Jobs where hygiene could not be guaranteed and maintained
	Alopecia for which medical therapy is available

TABLE 2 Previous alopecia treatments

Topical treatments	121 patients (47.8%)
Systemic treatments	34 patients (13.4%)
Surgery	24 patients (9.5%)

reversed by topical and systemic therapy. No residual damage or permanent scarring was observed during the follow up period in any of these cases. In conclusion, Biofibre® hair implant technique is safe and well tolerated by patients and can be totally reversible in case of need. This technique can be performed to correct androgenetic alopecia, improve hair thinning, to hide scalp scars and burns (Rahoui, 2016. Santiago et al., 2007). It can be used alone or also successfully coped with other hair restoration treatments (FUE/FUT) both for reconstructive and aesthetic purposes (Brady, 2005. Avram, Finney, & Rogers, 2017. Seery, 2003. Careno, 2015) to ensure immediate quality of life

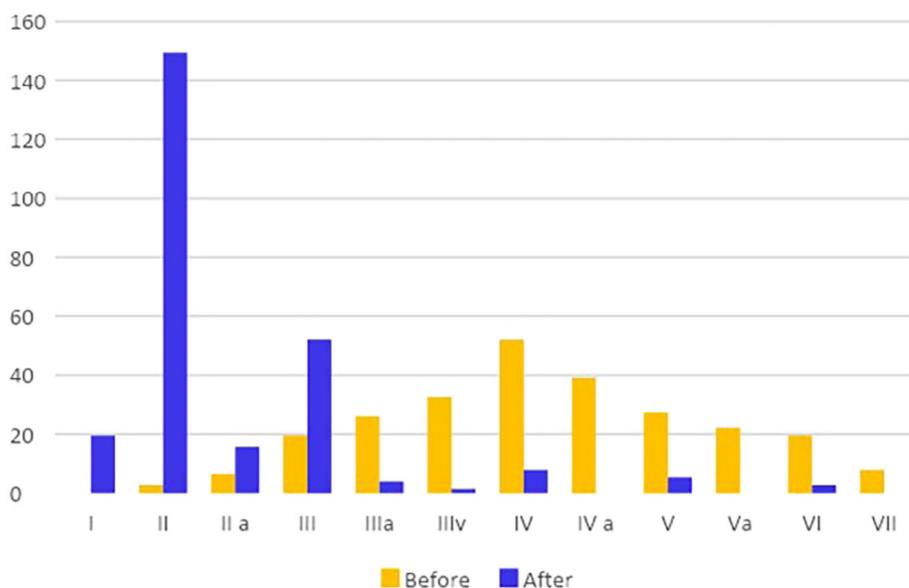
improvement with quick positive psychosocial impact (Figure 1) (Agrawal et al., 2017).

ORCIDTorello Lotti  <https://orcid.org/0000-0003-0840-1936>Aleksandra Vojvodic  <https://orcid.org/0000-0002-2057-3776>Massimo Fioranelli  <https://orcid.org/0000-0002-1319-8779>**REFERENCES**

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Hamilton scale: before and after**FIGURE 1** Yellow: Before; Blue: After