Multicenter clinical study on biocompatible artificial hair

A. Rateb Said[1], I. Salazar Reyes[2], M. Gara[3], B. Petrovic[4], S. Faddoul[5], C. Chaker[6], R. Romano[7], M. Giovannini[8], G. Griselli[9], B. Al Halabi[10], S. Kalivas[11], D. Kowalczick[12], W. Espinoza[13], Y. Gilony[14], A. Moga[15], L. De Fazio[16], M. Santiago[17], N. Serdev[18]

[1]Dermatologic Dept. University of Cairo, Egypt; [2]Biopel Clinic, Las Americas, Guadalupe, N.L., Mexico; [3]Dr Gara Clinic, Tel Aviv-Yafo, Israel; [4]CMG Clinic, Beograd, Serbia; [5]Dr Faddoul Dermatology Clinic, Lebanon; [6]Dr Rami Hamed Center, Dubai, UAE; [7]Dermaroma Clinic, Manila, Philippines; [8]Clinica Privata Villalba, Bologna, Italy; [9]Dermatologist, Private Practice, Ferrara, Italy; [10]Dr Basem Plastic Surgery, Dubai, UAE; [11]FM care Clinic, Lemesos, Cyprus; [12]DORMIO-Clinique, Warsaw, Poland; [13]Dr Espinoza Plastic Surgery, Lima, Peru; [14]Aesthetic beauty Clinic, Tel Aviv, Israel; [15]Medical Aesthetics Clinic, Paris, France; [16]LDF Hair Clinic, London, United Kingdom; [17]Plastic Surgeon, Private Practice, São Paulo, Brazil; [18]Serdev Clinic, Sofia, Bulgaria

Introduction: Baldness is a current problem in aesthetic medicine. This cosmetic defect can lead to serious psychological and emotional stress. Most of the time, the solution to this problem consists of removing or attenuating its cause: alopecia. Among the current hair restoration technique to treat alopecia, one is the biocompatible artificial hair implant.

Materials and Methods: The certified medical device used for this study is the biocompatible artificial hair Biofibre4.0. The clinical study was done by collecting clinical data from 18 clinics located in 15 different countries and 4 continents to evaluate the efficacy, safety, and performance of a new artificial hair device generation compared to previous artificial hair. Automatic and manual implanter were utilized by doctors participating in these trials. A new needles material was also used for this study. The standard medical protocol was applied with some differences in the doctor's personal experience, patient's situation, and climate.

Results: The data collected show that in a sample of about 1337 patients treated in 2020/2021, inflammation and infections are around 7%, and curling is <1%. There were no phenomena of fibre breakage. Itching appeared in about <3% of cases. The problems encountered in most cases were mild and resolvable with appropriate therapy, and only in rare cases (<1%) it was necessary to proceed with the total removal of the fibres. In some cases (<1%), it was just necessary to partially extract the fibres that cause recurrent discomfort for the patient. In most patients, satisfaction was 96%. The limitations in patient movement and lowering of the immune response in many of them caused by COVID SARS 2 might partially affect the final data.

Conclusion: This surgery does not imply scar formation and hospitalization. It can be used alone or with other treatments to provide psychological benefits and improve quality of life. Indications are poor donor area, request for immediate aesthetic result and scarce trauma. Patient selection, respect for medical protocol and proper aftercare must be complied with. Contraindicated cases must be avoided, and partial or total removal of fibres is required in case of recurrent problems. Additional improvements to this technique are expected to enable an ever vaster application.

Keywords: Alopecia, Baldness, hair Implant, Hair surgery, cosmetic surgery, artificial hair, hair loss

Corresponding author:
Dr Luca De Fazio,
LDF Hair Clinic,
9 Seagrave Road,
SW6 1RP London, United Kingdom
e-mail: drlucadefazio@gmail.com

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Alopecia is common, has a multitude of etiologies, and affects all genders and age groups. Hair restoration can be surgical or non-surgical. Hair transplant (FUT/FUE) is the most common surgical treatment to correct alopecia. This surgery has gained popularity in the years due to continuously growing technical and aesthetic improvements.

The biocompatible artificial hair implant is listed in the arrays of alternative or complementary hair restoration techniques. Artificial hair is a long term implantable medical device, and it must comply with overall safety standard requirements to be certified and approved (1, 2). The implant procedure can be performed using automatic or manual devices. Biocompatible Artificial hair implant has multiple indications, including treating androgenic alopecia, depletion of a donor area, scalp scars or scalp burns (3-10). It can be used alone or with other hair restoration techniques such as FUE and FUT (11-16). It can also be used in combination with other hair treatment as PRP, Mesotherapy. Laser etc. (17). It is indicated for male and female patients to ensure immediate aesthetic results with psychological benefit and improved quality of life 18-26.

No surgical procedure is without complications. Similarly, this procedure also has certain limitations and side effects for different causes. Patients who are affected by skin diseases, diabetes, hepatitis, immune system deficits, and autoimmune diseases who do not comply with the right hygiene and psychological instability or with unrealistic expectations must be avoided. This technique is not indicated for an implant on the temples, low frontal hairline, scalp areas with very thin dermal tissue in case of no stabilized alopecia or in case of a pathologically atrophic scalp. The result of implants in unsuitable areas causes inflammation or infection.

A traumatic implant may be caused by excessive pressure of the implanter device on the scalp. That can cause small scalp injury that leads to infection in most cases. Implanting two or more fibres in the same hole leads to an infection if not removed. Space implanted fibres by 2 mm at least to avoid prospective groupings. Patients are often in a hurry to get a result, but gradual thickening is usually more natural and appreciable. In addition, it is strongly recommended not to implant more than 1500 fibres per session and wait 5 weeks between 2 sessions to allow healing of the scalp and reduce the risk of complications. The use of thin diameter and soft artificial hair fibres is propaedeutic to reduce sebum accumulation.

The timely removal of comedones, if they appear, is important to prevent infection and premature fall of the fibres. The patient's attitude is very important to maximize implant results. Patients must be informed about aftercare protocol and follow up. Use of forbidden treatment or wrong products and lack of proper hygiene can compromise implant results leading to fibre spoiling, local infection, or inflammation. These problems are solvable with appropriate therapy in the majority of cases. If problems are recurrent or not solvable satisfactorily, the partial or total removal of fibres is required.

MATERIALS AND METHODS

This randomized clinical study collected clinical data from 18 clinics spread across 15 countries and 4 continents to evaluate the efficacy, safety, and performance of the medical device Biofibre 4.0, a certified biocompatible artificial hair. The patients included in this trial are implanted with automatic and manual devices. As an additional novelty, a new improved needles material was used in this study. The clinical data are collected by sending to each clinic a form where multiple clinical information was requested to each clinic as:

- *number of patients treated,*
- *number of implanted fibres per session (average),*
- *total number of fibres for each patient (average)*
- *number of patients who perform post-operative controls,*
- *the annual rate of fall of fibres,*
- *number of patients with complications,*
- *type and grade of complications (mild, moderate, serious),*
- *percentage of solved cases,*
- *time of healing expressed on weeks (average),*
- *total number of patients in whom it was necessary for fibres removal,*
- *type of problem that required fibres removal*

Patient selection is compulsory to avoid the prospective

problem. The implant technique is based on small hooking needles that hook the artificial hair reversible knot and place it at the galea aponeurotic level to allow the fibrous tissue to avoid premature hair loss.

A test of 100 artificial hair is performed. After the test, it is recommended to wait 5 weeks to see if some reaction occurs. The area to be implanted is cleaned, disinfected, and draped; 2% xylocaine solution with adrenalin 1:100.000 is locally injected in the subdermal layer with 30G needles for local anaesthesia and vasoconstriction under strict aseptic conditions. There is hardly any bleeding. On concluding implantation, ice wrapped in gauze is applied for 5-10 mins to reduce implant inflammation. A broad-spectrum antibiotic is given, and the implanted area is disinfected. Normal activities were resumed immediately after implant without hospitalization. At home, cleaning and disinfection of the scalp are required with the prescribed products and 7-10 days of antibiotic intaking. The patient can start shampooing his hair from the third day onwards. A medical shampoo with Ketoconazole is recommended twice a week, at least for the first month after the implant, then once a week.

The hair should be washed frequently to remove dust, dirt, sebum and sweat. High-quality neutral shampoo can be used for this purpose. The first medical check-up is required at 4-5 weeks or before in the case of needs. The use of local anti-inflammatory therapies and systemic anti-stamina therapy is suggested in large implant sessions or cases of sensitive skin. Aftercare protocol might be adapted to the patient's situation and local climate.

RESULTS

The data collected show that on a sample of 1337 patients treated in 2020/2021. The incidence of inflammation and infections is around 7%, and curling is <1%. There was no evidence of fibre breakage. Itching appeared in about <3% of cases, but it was a transient situation resolved using medicated shampoo. The problems encountered in most cases were mild and resolvable with appropriate therapy, and only in rare cases (<1%) did patients show more pronounced complications that required the total removal of the fibres.

In some cases (<1%), it was just necessary to partially extract the fibres that cause recurrent discomfort for the patient. The average yearly fall is around 12%. Most patients are satisfied (96%) (Table I).

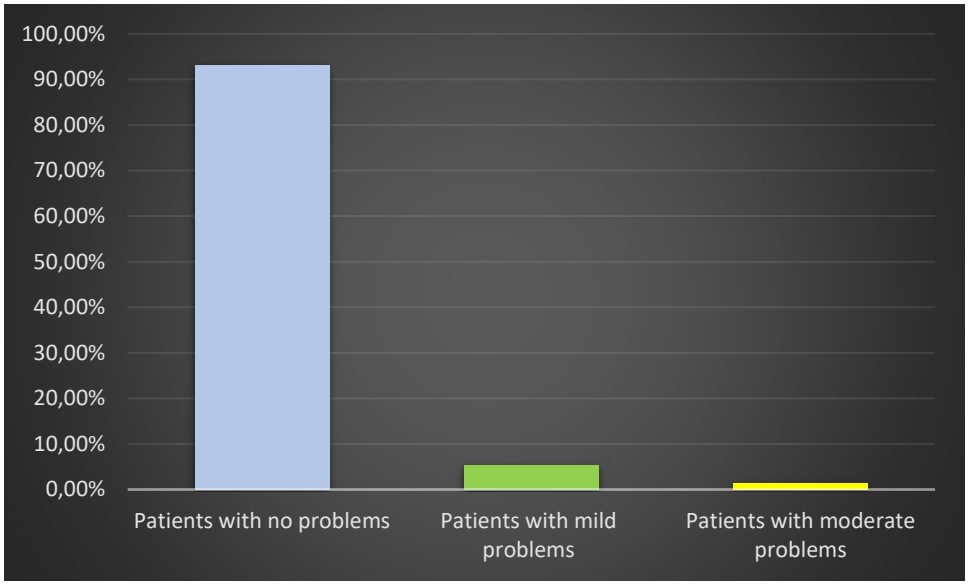
DISCUSSION

The clinical assessment of the patients before and after implantation of biocompatible artificial hair shows that it may be considered an effective alternative methodology with some good perspectives and some disadvantages.

The advantages are that it offers high hair density in a short time with a natural aesthetic result and with the related psychological and physical wellness for the patient (Fig. 3-6). In addition, it's a soft

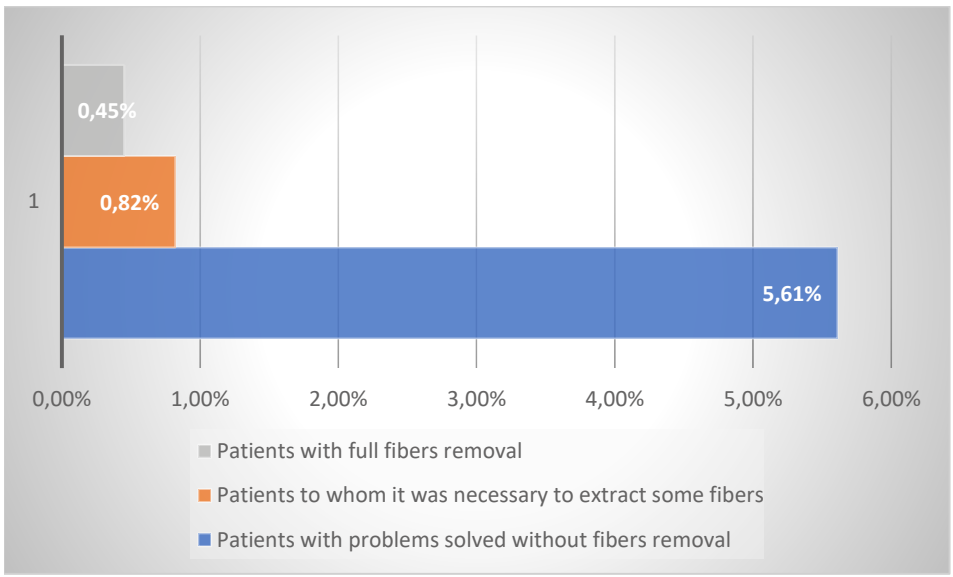
Table I. *Data source 2020/2021.*

number of patients treated in this study	**1337**
average annual rate of fall of fibers	**12%**
no. of patients showing mild complications **no. of above mild complications cases resolved with therapy**	**73** **73 (100%)**
no. of patients showing moderate complications **no. of above moderate complications cases resolved with therapy or with partial fiber removal**	**19** **13 (68,42%)**
no. of patients where total removal of fibers was required	**6**
no. of patients showing frizzy hair problem	**<1%**
average of patients satisfied for the procedure	**96%**



Patients with no problems	93,12%
Patients with mild problems	5,46%
Patients with moderate problems	1,42%

Fig. 1. *Classification rates of problems incurred .*



Patients with problems solved without fibers removal	5,61%
Patients to whom it was necessary to extract some fibers	0,82%
Patients with full fibers removal	0,45%

Fig. 2. *Fiber extraction rate*

outpatient procedure that allows the patient to return immediately to his normal social life. No donor area is required, and the artificial hair will not age. The disadvantage of this technique is that not all patients are good candidates, the artificial hair doesn't grow, not the whole scalp area can be implanted successfully, and periodical implant sessions are needed to maintain the expected results.

Aftercare maintenance is also required. Each doctor, according to its geographical location, the different ethnic groups treated, and the different uses, cultures, and habits of the patients, must face different problems.

Patients located far from the clinics have more difficulties in undergoing post-implantation check-ups. These patients have to strictly abide by the aftercare protocol necessary to reduce the risk of complications. Certain groups of patients are more prepared to develop a greater amount of sebum which often, due also to poor maintenance, accumulates at the base of the implanted fibres, creating unsightly sebum plugs. If not removed, it can lead to infection problems, and premature fibres fall. The sebum plugs can be removed directly from the clinic with forceps or can be prevented by following the instructions of

Fig. 3. *Male patient before and after implant of 1000 artificial hair implant.*

Fig. 4. *Female patient before and after implant of 1000 artificial hair implant.*

the post-implantation protocol. In case of prolonged and massive accumulation, these sebum plugs can sometimes create a skin roughness that can be attenuated or eliminated by localized infiltrations of organic silicious.

The use of new pharmacological treatments and specific post-implantation treatments (e.g., targeted use of PRP, LEDs, trace elements, etc.) further assisted in the control of the problems that might emerge after the procedure. The fall proved to be highly variable. The reduced possibility of going to the clinics caused by the COVID-19 lockdown had an impact and highlighted the limitations in movement and the lowering of the immune response in many patients caused by COVID-19; this could partially affect these data that would have been better as a result of a higher standard of biocompatibility of this new generation of artificial hair. It is also interesting to note that the number of explanted fibres is often inversely proportional to the doctor's experience. Less experienced doctors tend to remove fibres more frequently than experienced doctors, who can normally prevent or solve problems that may appear.

CONCLUSION

The data emerging from this multiple centre's clinical studies show the reliability of the medical device Biofibre 4.0. The aseptic prophylaxis and non-fragmenting, scarcely accessible to corrosion, non-migrating fibres are propaedeutic to prevent the risk of bacterial niche and related complications.

Fig. 5. *Young female patient before and after implant of 1500 artificial hair long/ curly.*

Fig. 6. *Front line after 500 artificial hair implants.*

Most of the unsatisfactory cases reported in this study are due to post-operative complications caused by wrong patient selection, implant in an unsuitable area and lack of proper aftercare. Patients' aftercare must include the indications that patients have to follow after implant and must provide a list of products and treatments that must be avoided. According to these premises, the authors might consider providing this procedure to an ever-greater number of patients.

Ethical statements:

The authors received no specific funding for this work.

The authors have declared that no conflict of interest exists.

The authors declared that they received approval and written informed consent.

REFERENCES

1. Universal Medical Device Nomenclature System, Prostheses, Hair, Universal Medical Device Code 16611.
2. Directive 93/42/EEC of the Council concerning Medical Devices.
3. Santiago M, Perez Rangel R, D'ugo A, Griselli G, Igitian G, Garcia Martin I, Nesheim GB, Saad Eddin U, Smith G, Brady GW, Chaker C. Artificial Hair Fiber Restoration in the Treatment of Scalp Scars, Dermatologic Surgery 2007; 33(1):35-44.
4. Franca K. Current and Emerging Therapies in Hair Transplantation and Hair Implants, Oxford Clinical Handbook, May 2017.
5. M. Roccia, K. França, D. Castillo, G. Tchernev, U. Wollina, M. Tirant, Y. Valle, C. Guarneri, M. Fioranelli, T. Lotti. Artificial Hair: By the Dawn to Automatic Biofibre® Hair Implant, OAMJMS, Global Dermatology-2, https://doi.org/10.3889/oamjms.2018.001, eISSN: 1857-9655
6. D'ugo A., Santiago M., Chaker C., Perez Rangel R., Saad Eddin U., Ramponi V. Safety of Biofibre® CE 0373/TGA artificial hair implants: importance of the scalp anchoring system. International Society of Hair Restoration Surgery, 10th Annual Meeting, Chicago, USA, October 9-13, 2002 G. Tchernev Et Al, Biofibre Hair Implant: What is New, What is True? JBRHA, 2016 Apr-Jun;30(2 Suppl 2):27-34
7. A. Rateb, B. Al Bzour, M. Santiago, G. Tchernev, U. Wollina, M. Agrawal, M. Rovesti, F. Satolli, J. Lotti, T. Lotti. Automatic Artificial Hair Implant: Safety and Efficacy in Androgenetic Alopecia. A Prospective Study with a Highly Biocompatible Fiber, OAMJMS, Global Dermatology-2, oamjms.2018.052 eISSN: 1857-9655
8. Gonzalez M. Biofibre hair replacement. ASAPS 35th Anniversary Meeting, Las Vegas, NV, USA, April 27-May 3, 2002
9. A. Rateb, Prosthetic hair fibers. Is there a role ? Twenty years' experience with artificial hair insertion for the treatment of alopecia, FACE Conference, 17-19 June 2017, London, UK
10. T Lotti, M Tirant, A Rateb Said, B Albzour, M Santiago, M Agrawal, A Dutta, T Van Nguyen, M Vadala', B Palmieri, A Vojvodic, M Fioranelli, Clinical updating Study at 3 years on 278 patients treated by modern Artificial hair Implant technique (Automatic Biofibre®) https://onlinelibrary.wiley.com/doi/abs/10.1111/dth.13194
11. Perez Rangel R., How and when to combine the different methods for baldness, 8th World Congress of Cosmetic Dermatology, Cancun, Mexico, February 2012
12. Careno N. - Injerto de pelo: qué hacer cuando no hay pelo donante?, Jornadas Universitarias de la Asociacion de Dermatologia de Chile, Santiago, Chile, 23 of June, 2015
13. Brady G., Case Presentation: 23 Years of Hair Restoration Procedures in a Single Patient, International Society of Hair Restoration Surgery, 11th Annual Meeting, New York, USA, October 15-19, 2003 – poster presentation
14. Seery G., Hair Repair. ISHRS Hair Transplant Forum International 2003; 13(1): 260-261
15. Brady G., Fukuta K., Santiago M., Shiell R., Synthetic Fibers in Hair Restoration: Potential Benefits, Patient Selection, Possible Complications, International Society of Hair Restoration Surgery, 11th Annual Meeting, New York, USA, October 15-19, 2003
16. Morselli M., D'ugo A., Griselli G., Ramponi V., Anichini N., How to achieve a good hair covering in patients without donor area after autotransaplantation, International Society of Hair

Restoration Surgery, 10th Annual Meeting, Chicago, USA, October 9-13, 2002

17. Melissa AB, Angela MC, Lindsey AB, Treatment Options for Primary Cicatricial Alopecia: established Therapies and New Concepts, International Journal of Cutaneous Disorders e Medicine, Vol 2, Issue 2, October 2019
18. Williamson D1, Gonzalez M, Finlay AY. The effect of hair loss on quality of life. J Eur Acad Dermatol Venereol. 2001 Mar;15(2):137-9.
19. Lotti T. Aesthetic Disability, SIME 38TH congress, 12-14 May 2017, Rome, Italy
20. França, et al. Psychological Impact of Scars. In Scars and Scarring. Ed Yongsoo Lee. NovaScience Publishers 2013
21. Rahoui M., Biofibre et Cicatrice de Brulure du cuir Chevelu, 6° Congres National Algérienne de Chirurgie Esthétique, 28-29 Avril 2016, Alger, Algérie
22. Cash TF1, Price VH, Savin RC. Psychological effects of androgenetic alopecia on women: comparisons with balding men and with female control subjects. J Am Acad Dermatol. 1993 Oct;29(4):568-75.
23. Van Der Donk J1, Hunfeld JA, Passchier J, Knegt-Junk KJ, Nieboer C. Quality of life and maladjustment associated with hair loss in women with alopecia androgenetica. Soc Sci Med. 1994 Jan;38(1):159-63.
24. Ramos Et Al, Biofibre Hair Implant – Impact on the Quality of Life, Journal of Biological Regulators & Homeostatic Agents, 2016 Apr-Jun;30(2 Suppl 2):21-5.
25. Santiago M., Fiber Hair Restoration – A Surgical Option to Treat Female Pattern Baldness, International Society of Hair Restoration Surgery, 11th Annual Meeting, New York, USA, October 15-19, 2003 – poster presentation
26. R. Dell'avanzato, B. Al Bzour, R. Perez Rangel, M. Agrawal, N. Serdev : Automatic Biofibre Hair Implant an Innovative Hair Restoration Technique for the Improvement of Quality of Life, Journal of Cosmetology and Trichology, Vol 4, Issue 1, ISSN:2471-9323 https://www.biofibre.com/wp-content/uploads/2018/08/186-dell-avanzato-et-al-JCTT.pdf.