SCIENTIFIC PAPER

HISTOLOGICAL STUDY OF THE SCALP IMPLANTED WITH POLYAMIDE ARTIFICIAL FIBERS PREVIOUS NOTE

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Introduction

We would like to thank the organizing committee for giving us the opportunity to discuss of a polemic topic such as implantation of artificial fibers, therefor offering a new opportunity to perform this technique.

We have 2 years experience and our work refers to the histological study of the scalp implanted with polyamide artificial fibers.

One of the greatest challenges in medicine is treatment of baldness both feminine and masculine. Preventive clinical treatment avoids hair fall and surgical treatment is carried out when baldness is already settled down.

Among the surgical treatments rotation limbs, expanders, baldness reduction, auto-transplantation and artificial fibers implantation have to be pinpointed.

Artificial fibers implantation is a very polemic topic due to the different complications described, linked to the use of inadequate techniques and fibers (2, 5, 7).

Advancements in technology showed us that more and more inorganic materials (Bioplastic, Artecoll, Metacril, Hydroxyapatite, Porex, Goretex, Titanium, etc.) are used in plastic surgery with tested successful results and a low complication rate.

This technology developed an artificial hair fiber from a polyamide, called Biofibre, which is made of the mixture of polyamides. This combination produces a fiber of pure resin which is resistant, biocompatible, non toxic, non cancerogenic and where coloring agents are incorporated in the fiber inducing no color migration. Therefor it is much more harmless than the already existing artificial fibers which lost pigments and caused constant infections.

The first publication on artificial hair was carried out in Japan in 1976, where the Japanese Health Minister recognized the validity of this technique. The stroke of genius of this method lead to imitation all over the world and various centers for implant of artificial hair were created, by using fibers manufactured in unsuitable materials. This technique lost its application in the medical field and was managed by hairdressers who did not have even the minimum qualification to perform it. This lack of criteria elicited innumerable complications to the patients (2, 5, 7).

The US FDA carried out researches on materials, on the incorporated coloring agents and the implant techniques and later prohibited the application of the technique with fibers produced in polyester (Nido), polyacrylic, modacrylic, and natural fibers such as processed human hair since they are not UV resistant, they loose their pigments, they produce chronic irritation causing severe infections (6).

In 1983 in Brazil, Liacyr Ribeiro and Paulo Matsudo, published their experiences after using Nido, the Japanese fiber in polyester, where we deduce that they abandoned the technique due to the consequent complications they experienced.

In 1985 the Brazilian Society of Plastic Surgery appointed a commission with the aim of judging this method and at that time an opinion was issued (ANNEX A, text 1). In the last three paragraphs of this paper the commission admits that: "*this topic may be discussed further in the future with other methods*". During that period Brazilian plastic surgeons were mainly using the fiber Nido, in polyester. In Europe the fibers in polyamide had not yet been produced. They were manufactured at the beginning of the 90's.

Polyamide hair fiber were tested in laboratories accredited by the Italian Ministry of Health (Italy). Tests results were that they are not cytotoxic, they do not lead to sensitization, they are harmless after histological tests (ANNEX A, texts 2, 3, and 4).

Due to their high grade and harmlessness, to the respect of production norms ruled by European Directive 93/42/EEC and other European Community reference norms (ANNEX A, text 5), the Istituto Superiore della Sanità (Superior Institute for Health) granted Mark CE 0373 to some polyamide hair fibers (Biofibre®) to be used in baldness treatment (ANNEX A, text 6). Since 1993, European Directive 93/42 is a norm which, among other things, has been ruling the production of all medical devices.

In Brazil, it was registered by the Health Ministry with registration number 10253810002 (ANNEX A, text 7).

Biofibre has been used during the last 8 years in Europe with quite a lot of success (1, 3, 4, 11, 12). The author has been using them along the last two years. The success obtained in Europe is confirmed due to the respect of a protocol where the following main topics shall be emphasized:

- Use of a suitable fiber
- Technique carried out by a qualified doctor
- Correct patient indication
- Use of suitable instruments
- Previous compatibility test
- Implantation of 500 fibers per session
- Minimum interval of 20 days among each session
- Antibiotic therapy as a prophylaxis
- Carry out surgery in a surgical center
- Rigorous cleaning of the implanted scalp.

Along these 2 years the author has been rigorously following the above mentioned protocol.

Due to the polemic aspects of this topic, where themes such as **rejection, infection** and **life of the product**, were the main reasons for the technique failure, we decided to carry out some histological tests with the aim of checking which are the main alterations at the cellular level, concerning the topic under discussion (4, 10).

MATERIAL AND METHOD

Biopsies on four male patients were carried out. Age ranged from 23 to 50 years. Patients had undergone hair implantation with Biofibre (polyamide). Biopsies were carried out after 4, 8 and 30 days and after 3, 6, 12, 18, 24 months.

In all patients biopsies were carried out by using a punch of 5 mm diameter. Samples were fixed in formalin and underwent pathological examination by applying the conventional method with hematoxylin and eosin coloring.

RESULTS

4 days	**PRESENCE OF MACROPHAGES**	
8 days		(text 8)
30 days	**MODERATE MACROPHAGES** **FIBROBLASTS UNDER FORMATION**	(text 9)
3 months	**MODERATE HISTIOCYTOSIS INFILTRATE** **FIBROUS PROLIFERATION AROUND THE FIBER**	
6 months		(text 10)
12 months	**FIBROSIS AROUND THE FIBER. UNIDENTIFIED GIANT CELLS, TYPE FOREIGN BODY**	(text 11)
18 months	**PROLIFERATION OF FIBROBLASTS AND FIBRILS COLLAGEN AROUND THE FIBER**	(text 12)
24 months	**PROLIFERATION OF FIBROBLASTS AND FIBRILS COLLAGEN AROUND THE FIBER. MODERATE MACROPHAGIC REACTION**	(text 13)

- In samples of 4 and 8 days, which are the same, neutrophils and lymphocytes appeared (macrophagous reaction) as response to the acute trauma (ANNEX A, text 8).
- 30 days – concentric hoops of fibroblasts and multinucleated histioid cells surround the fiber. There are no pigments, neutrophils and lymphocytes are present. (ANNEX A, text 9).
- 3 and 6 months – fibers are surrounded by fibrosis with a small histiocyte infiltrate. There are no pigments (ANNEX A, text 10).
- 12 months – fiber surrounded by fibrosis. In this phase there are no histiocyte cells. There are no pigments (ANNEX A, text 11).
- 18 and 24 months – fiber surrounded by fibrous tissue and collagen fibrils. There are no pigments (ANNEX A, texts 12 and 13).

ANNEX A; texts no. 1-13 and pictures of the anatomic pathology analyses.

DISCUSSION

To our surprise, the more time went by after fibers implantation, the more we observed the decrease in quantity of giant histiocyte cells around the fibers, till its higher decrease around 12 months. This quantity was later maintained at the same level.

Fibroblasts increased inversely proportionally.

Our samples showed the presence of fibrosis from the 13th day after implantation. Such fibrosis increased till the 3rd month, remaining unchanged till the 24th month. This was the last sample due to the length of our experience with this technique (ANNEX B, diagram I).

In his study Tanaguchi (10) writes that from the 5th month there was a decrease in fibrosis, which justifies the fall of 25% of Nido along a period of 20 months. Fanti (4) carried out a histological study on patients who underwent polyamide fibers implantation after more than 3 years post operation and demonstrated the presence of fibrous cells in the deepest scalp layers, where the fiber knot had been deposited and which gives more adherence to the scalp.

Our fall index is quite encouraging with comparison to the ones described in literature (1, 12) and proportions are as follows:

- 6 months after fibers implantation – 2% fall
- 12 months after fibers implantation – 5% fall
- 24 months after fibers implantation – 10% fall, (ANNEX B, diagram II)

We do not know which will be the fall rate after 3 years or more, since we are linked to the presence of fibrosis at the fiber level, which will guarantee its anchorage; on the other hand studies carried out by Fanti (4) showed the fibrosis in the post operative phase after more than 3 years.

All patients are aware that there is a fall rate and that this may vary according to the individual fibrosis degree. Nonetheless it is possible to replace those fibers which fall (1, 12). During our two years experience we did not carry out any fiber replacement since the fall rate did not justify any replacement. It is important to underline that fibers we are working with do fall out with their knot, with comparison to the other type which breaks and leaves a small fiber piece into the scalp.

We have already carried out implantation on 190 patients, 141 men and 49 women. All patients underwent a compatibility test of 100 fibers thirty days before the beginning of the treatment. 2 patients out of 190 had rejection to the fiber during the testing period. The rejection index was of around 1,05% which indicates a low rate. Fibers were removed entirely and the problem solved (ANNEX B, pictures 1, 2, 3).

One patient had infection (index: 0,5%) due to Stafilococus Aureans during the fibers implantation period. Fibers were pulled out and infection disappeared (ANNEX B, pictures 4, 5, 6).

Our rejection index is low due to the use of an harmless material which produces non chronic irritation (see the pathologic tests results, ANNEX A: texts no. 9-12). The daily cleansing of the scalp also contributes to lower the infection index.

ANNEX B: diagram I and II, and pictures 1-8.

CONCLUSION

The implantation of artificial hair fibers seems to be an additional technique in baldness treatment. Like any other technique it has its limitations, it is not everlasting, nonetheless it is a complement to the already described techniques and can be overlapped in those patients who already had auto-transplantation or who have hair thinning (ANNEX B, picture 7).

It has its major indication in definitive alopecia, total baldness and consequences due to burns where no other donor area is present (ANNEX B, picture 8).

The aim of this histological study is to demonstrate the biocompatibility of the fiber in polyamide once rejection, infection and durability did not show compromising statistical rates (6-10).

The author follow up is still small but encouraging, if we consider that in Europe a larger follow up already exists, with an absolute success of the technique.

ANNEX C: pictures of pre- and post-operative results.

LITERATURE:

1. BOUTBOUL G.: *Implantation de cheveux artificiels*, 18° Congrés National de Médicine Esthétique et de Chirurgie Dematologique, Paris, 27-29 Sept. 1991.
2. DIGREGORIO V., RAUSCHER, G.: *Experience with the complications of synthetic hair implantation.* Plastic and Reconstructive Surgery, 68:498, 1981.
3. D'UGO A.: *Experiencia com la utilizacion de fibra sintética biocompatível Biofibre em cuero cabelludo*, XI Congreso Ibero Latino Americano de Cirurgia Plástica e XXXIII Congresso Brasileiro de Cirurgia Plástica – Rio de Janeiro, 5-10 Dec. 1996.
4. FANTI P.A., PISTORALE T., D'UGO A., MISCIALLI C., TOSTI A.: *Histological study on 5 cases of patients who underwent artificial hair implantation without complications,* 35th Annual Meeting American academy of Dermatology, New Orleans, 01-03 Feb. 1995.
5. KELLY R.I., MARDSEN R.A.: Complication of artificial hair implantation. Journal of the royal Society of Medicine. 87:291, 1994.
6. KOBAYASHI T.; KAMIYAMA G., AKAGAWA T.; AKAMATSU T.: *Research and study on the artificial hair implantation.* Japanese Society Aesthetic Plastic Surgery 3:12, 1981.
7. LEPAW M.I., *Therapy and histopathology of complications from Synthetic fiber implants for hair replacement.* Journal of the American Academy of Dermatology, 3:195, 1980.
8. MATSUDO P.K., *Cirugia da calvicel.* Annais do Simposio Brasileiro do Contorno Facial. São Paulo, 24-25 Sept. 1983.
9. RIBEIRO L.: *Técnica de implante de cabelo artificial: indicações, profilaxia e tratamento das complicações.* Annais do Simposio Brasileiro do Contorno Facial. São Paulo, 24-25 Sept. 1983.
10. TANIGUCHI S.: A histopathological study of the percutaneous implantation of polyester fibers, Aesthetic Plastic surgery, 8:67-74, 1984.
11. *TOSCANI M., CAGGIATI A., BARTOLETTI E., Valutazione critica sull'utilizzo dei capelli sintetici,* XV Congresso Nazionale di Medicina Estetica, Roma, 18-20 marzo 1994.
12. *WEBER G.,* Kunsthaar zur Deckung definitiver Alopezien, *Der Deutsche Dermatologe, 40 (5): 718-724, maggio 1992 .*