

Synthetic hairs: Should they be used?

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ABSTRACT

Artificial hair fibers have recently been marketed in India as an alternative method of hair restoration. However, the subject of artificial hairs is controversial, as FDA in the United States has banned them. Several side effects have been reported after their use and it is therefore important that dermatologists are aware of all aspects about these devices. This article presents the author's viewpoint on the subject and suggests guidelines for using them.

Key Words: Synthetic hairs, Hair implants, Hair transplants

Male pattern baldness causes significant cosmetic disability. Both medical and surgical methods are available for management. The surgical method is the only permanent method of hair restoration, but needs proper training and skilled manpower. Recently, synthetic hairs have become available in India and are being aggressively marketed as a method of treatment.

IMPLANTS VS TRANSPLANTS

At the outset, it is important to distinguish between implants and transplants. Implants indicate implantation of prosthetic hair fibers in contrast with transplants that use patient's own hairs, usually taken from the occipital area. Prosthetic hair are of two types synthetic fibers (such as monoacrylic, polyacrylic, and polyester); and natural fibers (such as processed human hair). They are implanted into the galea by a knot through an implanter device. The advantages claimed are the relative ease of the procedure, which can be learnt in a few days, relatively bloodless technique, and immediate

cosmetic result. However, in contrast to transplants, these fibers do not grow and hence cannot be cut or shaven—in this respect they resemble a wig, which has been fixed to the scalp.

PROBLEMS WITH SYNTHETIC HAIRS

These fibers have had a checkered history. First introduced in 1970s, they soon became the subject of much controversy because of their numerous complications including recurrent infections, rejection, and periodic loss of fibers needing frequent replacement, frequent allergic reactions leading to severe contact dermatitis, irritant effects, fears about carcinogenicity, cicatricial alopecia, granulomatous hypersensitivity, and cyst formation.^[1-5]

In 1983, the US Federal Drug Administration banned the fibers for the following reasons:

1. The fibers presented risks of illness or injury owing to non-biocompatibility of the fibers and non-

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medical performance of the implant.

2. The fibers presented fraud owing to the following:
 - a) Deceptive information on the efficacy.
 - b) Inadequate information on risks from implant.
 - c) They did not show any benefit for public health.

(The ban on prosthetic hair fibers is established in Section 895.101 of Code 21 of Federal regulations of the FDA, title 21, vol. 8, revised as of April 1, 2004.)

REINTRODUCTION OF HAIR IMPLANTS

Though the ban by FDA is yet to be lifted, the manufacturers are now trying to re-establish the credibility of these fibers and have introduced them in Europe and Australia. Presently, there are two manufacturers: (a) Medicap (Italy), which manufactures Biofibre, which has been available since 1996, and (b) Nido Corporation (Japan), whose fibers are available since 1999. Biofibre's reapplication for permission by the US FDA is pending, but the company claims that many of the previous problems associated with the fibers have been sorted out.

There are few published data to support these claims. The website of Biofibre (<http://www.biofibre.com/>) mentions one study, which could be found in the Medline search too. This report assessed 196 patients with 2-year follow-up and found that clinical subjective and photographic objective evaluation show very satisfactory improvement.^[6] Adverse events were limited to 1.02% of patients. The study concludes that careful medical follow-up with regular scalp check-up minimizes complications to a very acceptable rate and the overall results are satisfying. However, another recent publication by the same author found the yearly failure rate to be 20%.^[7] A study published in 1995 stated "despite an apparently improved complication rate, the new technique of hair fiber implantation remains a doubtful procedure and cannot be recommended in view of possible permanent sequelae."^[8]

CURRENT STATUS

In the face of marketing by the companies, and in response to queries from interested patients,

dermatologists who treat hair disorders and perform hair transplantation are frequently asked to state their opinion about these fibers. In response to several queries from its members, the International Society of Hair Restoration Surgery considered all aspects of the subject of artificial hairs, and refused to endorse the product, stating that "The International Society of Hair Restoration Surgery does not voice an official position with regard to the use of artificial hair fibers and leaves their use up to the regulatory authority within that country. It is the view of the Society that this is a surgical procedure and as such should be confined to active participation of an experienced, licensed medical doctor in a reputable medical clinic or university setting. As with any surgical procedure, complications may occur which should be handled under a physician's care."^[9]

In view of this, what should be our current position regarding these fibres? It is obvious that the matter is debatable. It is also true that recently introduced fibres represent some improvement over previous fibres and it is important that the fibres are assessed thoroughly. This is particularly so in the present days of high voltage marketing, and also consumer activism. From the data it is clear that though these fibres may be of use in selected patients, such as those with total alopecia without any donor area, more research is needed before these fibres can be accepted as a routine method of treatment. Hence it is vital that dermatologists are fully aware of all the abovementioned aspects of the subject, as they are frequently consulted for opinion on this matter. In particular:

- a) Physicians should realize that this technique though simple, can not be a standard method of treatment for hair loss or baldness till further data are available
- b) The physician should be aware that the responsibility for a decision to use these fibers at present solely rests with him/her. He should be aware of the possible legal complications that may arise in such cases.
- c) It should not be regarded as a replacement for hair transplantation in cases with sufficient donor area. Nor is this an alternative for medical treatment with minoxidil or finasteride, in early hair loss.

In view of the controversial nature of the subject, the author feels that this matter should be taken up by an appropriate body in IADVL and guidelines formulated to ensure proper standard of care for patients and also prevent possible legal complications for the dermatologists.

SUGGESTION

Finally, the author would also like to raise an issue for debate. The technique of artificial hair implantation was demonstrated at the preconference CME workshop of the SAARC dermatology conference, February 2005, held in New Delhi. The author would like to raise the question: should a technique, which is controversial and questionable, be allowed to be demonstrated in an IADVL CME workshop? The author feels that such demonstrations at prestigious national events may be misinterpreted as official approval of such techniques, particularly so by young dermatologists and postgraduate students. The author also feels that such techniques should initially be presented as free communications where they can be discussed freely or as sponsored workshops (where the ethical responsibility of the technique lies totally with the distributor), and not as IADVL CME events. The author welcomes a debate and would like to invite comments by senior dermatologists, on this issue. It is also

important for IADVL to state its official position clearly on such issues.

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