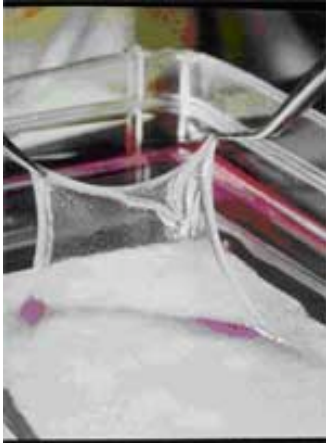


Epicel Skin Grafts

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Epicel has been the most important advance in burn care for the coverage of large total body surface area burn wounds in this decade," said Dr. Rajiv Sood, medical director, Richard M. Fairbanks Burn Center, Indiana University School of Medicine. Epicel is a product that can provide permanent skin replacement for burn victims, and is made from a patient's own skin cells and then grown on a layer of mouse cells to enhance growth. Epicel is the first xenotransplantation-classified product to be approved in the U.S. because of its inclusion of animal cells.



In full thickness burns, the outermost layer (epidermis) of the skin and all of the dermis (inner layer of the skin) is destroyed. In a larger total body surface area (greater than 30%) the patient does not have enough donor skin available to cover the wounds. Physician may need to consider another means of permanent wound closure, such as Epicel. Epicel is made from your own cells after they have grown for a period of time in an incubator. The Epicel graft replaces the epidermal or top layer of the skin which is required to close the wounds. .

Epicel is indicated for use in patients who have deep dermal or full thickness burns comprising a total body surface area of greater than or equal to 30 percent. It is supplied in grafts, which each consist of a sheet (2 to 8 cell layers thick) of cultured epidermal cells

attached with stainless steel surgical clips to a backing of petrolatum gauze. Enough skin can be grown to heal the whole wound from a biopsy (of the patient's own healthy skin) the size of a postage stamp. The cells within the epidermis of the skin sample are separated and grown by a process called "tissue culture", which involves feeding the cells with specific nutrients and maintaining strict climate controls so that the cells multiply to form sheets of skin. During this process, irradiated mouse cells, also referred to as 3T3 cells, are used to promote cell growth. The process takes approximately 16 days and the skin grafts integrate with surrounding tissue 3 to 4 weeks after surgery.

Epicel sheets are thin and fragile and need to be handled with extreme care during and after application. Studies have found that healed epithelium can be very fragile and the skin can be prone to contraction and breakdown. After the last permanent skin goes on, the earliest the patients might be considered for discharge is 10 to 14 days. Those patients are usually so weak that they end up going to an inpatient rehab center. Months of physical and occupational therapy can follow, and many of the patients will have spent three to six months at the center before they leave.

Epicel treatments may be used in conjunction with split-thickness autografts -- another type of skin graft taken from a patient's body to treat the burned area -- or alone in patients for whom these autografts may not be an option due to the severity and extent of their burns.

The cost of the Epicel procedure can range from \$6,000 to \$10,000 per 1% total body surface area.

References:

1) http://www.redorbit.com/news/health/1121436/epiceltm_wins_marketing_approval_for_severe_burn_victims/index.html?source=r_health

2) http://www.genzyme.com/business/biosurgery/burn/epicel_package_insert.pdf

3) <http://www.fda.gov/cdrh/mda/docs/H990002.html>