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Safety and efficacy study of autologous cultured melanocytes delivered on Poly (lactic acid) membrane (*ReliDerm®M*) in the treatment of Stable Vitiligo

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Small vitiliginous patches have been treated with epidermal grafts or grafts containing epidermal cells derived from the skin. To address larger areas, cultured epidermal auto grafts have been used. In this, the cells are derived from small skin biopsies and expanded using usual tissue culture methods. The cultured cells are delivered to the site in the form of a cell suspension. In an attempt to overcome some of the shortcomings of cell suspension delivery, we have attempted melanocytes delivery using a biocompatible polymeric membrane. In order to establish the safety and efficacy of autologous cultured melanocytes on Poly (lactic acid) (*ReliDerm® M)*, a prospective, open-labelled, randomized, multi-centric clinical trial was conducted on 20 subjects. Subject's meeting all inclusion/ exclusion criteria were enrolled in the study. The skin biopsies collected at various centres' were processed in a centralized cGMP compliant facility and cultured on a biocompatible and biodegradable Poly (lactic acid) membrane. These grafts were delivered to various hospitals for implantation. The vitiliginous patches were derma braded in both the test and control sites and treated with either *ReliDerm® M* or standard dressing respectively. The subjects were followed upto 9 months to compare the efficacy in terms of percentage of regimentation achieved as compared to the controls. Data indicated that ReliDerm® *M* was safe and easy to handle. No infection or inflammation at the test and control sites was noted in the study. The reported adverse events were not related to the product. When applied topically on stable vitiliginous patch, re-pigmentation in atleast 70% area was taken as success of *ReliDerm® M.* The data evaluated at the end of 9 months after implantation indicated repigmentationin 56.6% test sites as compared to 5.6% in control sites. None of the sites reported any recurrence of vitiliginous patches at end of the study, while in the control arm; one patient had a recurrence during the study period.

Biography

Dr. Deepa Ghosh had completed her PhD work from Uniformed Services University, MD and Birla Institute of Technology and Sciences, India. She had done her post-doctoral work in the dept. of Pharmacology at Emory University, GA. She is currently heading the Tissue Engineering Department at Reliance life Sciences and has to her credit several publications and patents. She has been instrumental in developing several tissue engineered products and wound dressing.