Skin substitutes laboratory - past, present, future

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Since 1985, the progress in intensive care burns resuscitation and surgical procedures have made possible to keep alive burn patients with more than 50% TBSA. The main challenge remained the skin cover and most of them could not survived beyond 6 months due to lack of coverage. Coming from clinical demand, our laboratory has started intensive research for new technologies.

We have started with preparing the substrate as per Yannas and Burke in order to obtain the guidance for healing, but we did not use glutaraldehyde. At the same time we have been developing cultured epithelial cells as per Green (1975), taking into consideration that epidermal regeneration is the key point for healing.

CNRS and Hospices Civils de Lyon offered their support to create the Skin Substitutes Laboratory into the Burn Centre at Edouard Herriot Hospital. We started at beginning working under a flow cabinet in wound dressing bathroom closed to operating room. At that time there were not any specific rules.

In 1998 on 16 and 29 December we had the legal documents giving the rules, the constraints and the responsibilities but as well creating an official presence of Cell Therapy. The rules were very strict but we found the way to overcome the difficult time.

Since European Regulation on 13th Nov 2007, cultured epithelial cells as Epidermal Sheets were classified as Advanced Therapeutical Medicinal Products (ATM) and they are considered as a drug. This means they need to be prepared in a pharmaceutical environment following the GMP (Good Manufactory Practices) requirements. Overall it will make the price to increase at least ten times, for a product that was already expensive.

As we know the treatment in burns is not a business, it cannot work as in industrial environment to play efficiently by increasing the production. The number of major burns has decreased in the last years, the impact being significant as cultured epithelial cells are applied for severe major burns over 50-70% TBSA depending of age and severity.

At beginning the sheets of epithelial cells were applied once or twice on large surfaces. Nowadays surgeons prefer them as well for donor sites cover, aiming for a faster healing. In this way the donor sites can be harvested many times and at shorter intervals. So the patient can benefit of autograft, gold standard treatment. Moreover the cultured epithelial cells can be produced as well very quickly as frozen allograft of cultured epithelial cells.

Our competent authorities should help us to find reliable solutions for making possible to continue the activity of skin substitutes laboratory in proximity to the with Burns Centre keeping the costs at a feasible level and preserving the necessary close collaboration

The future?! We are at the sunrise of this new regulation.
I prepare the Process authorization file for epidermal sheet as ATMP hoping to survive.
I hope I can give you more information about our pharmaceutical experience in the near future.