

Comment on “The use of dermal regeneration template (Pelnac®) in a complex upper limb trauma: the first Italian case report”

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I would like to congratulate with N. Scuderi, P. Fioramonti, B. Fanelli, P. Fino, C. Spalvieri for the article “The use of dermal regeneration template (Pelnac®) in a complex upper limb trauma: the first Italian case report” and I would like to make some comment on this article¹.

Currently, Integra IDRT® (Integra Dermal regeneration Template) is the most used dermal substitute in several reconstructive fields worldwide, such as burns, trauma oncological defects and even in necrotizing infections. Integra® IDRT has been used to cover tissue loss bringing to a formation of histologically proven dermis with functional and texture similar to normal skin, has been reported in randomized clinical trials^{2,3}.

In this case report published by Scuderi et al¹, a 22-years old boy with a traumatic loss of the soft tissue at the level of the dorsal region of the hand and forearm associated with disruption of the extensor tendons was treated with Pelnac® an only porcine tendon-derived atelocollagen sponge. According with manufacturer’s guidelines, the authors reported that Pelnac® was dropped into a saline solution for 20 minutes. This should be a critical issue to employ a not ready to use device in emergency trauma wounds, while, according to the manufacturer’s guidelines, Integra® IDRT needs to be rinsed in saline only for 1-2 minutes and so can be consider ready to use. Concerning the quality of the tissue obtained with Pelnac® the authors reported at day 30 a formation of granulation tissue covering the tendons. I would like to underline that the presence of granulation tissue cannot be considered as regenerative process, but as a healing wound process done by scar and wound contraction that can leads to poor functional outcome. Furthermore, after one month, the authors needed to use a second template of Pelnac® to cover the residual exposed tendon. This regrafting procedure suggests to me the incapacity

of the Pelnac®, in comparison with Integra®, to cover poorly vascularized wound beds, as was described by Taras and et al⁴ who reported covering with Integra digital injuries, associated with tendon, bone and joint exposure on seventeen patients. Integra IDRT showed to be effective in create neo-dermis in poor vascularized wound beds.

As I asserted in a previous publication⁵ an ideal dermal substitute should be able to create a neo-dermis with patterns of collagen arrangement like normal skin. In particular, according to Yannas et al⁶ a dermal substitute matrix should have a pore size between 20-125 μm , a degradation time of 3-4 weeks and a specific surface biology of collagen scaffold with ligand densities that exceed 200 μm $\alpha 1\beta 1$ or $\alpha 2\beta 1$ of integrins on myofibroblast and this is possible thanks to the presence of chondroitin-6-sulfate such as in Integra IDRT.

Even in my case series in traumatic wounds Integra® DRT leads to a formation of dermis showing the peculiar light red orangish color outcome, while Pelnac® degrades early leading to a formation of granulation tissue.

At support of my findings, in a recent publication of Conese et al⁷, the authors make a difference from dermal substitute and a “new class” the bio-inductors”. For them, Integra dermal regeneration template is considered the only dermal substitute than induces neodermis formation while other scaffolds composed of derivate of hyaluronic acid, or only collagen from several sources (porcine, bovine) or synthetic materials are “bioinductors” of granulation tissue since they act only temporary for a too short time and are degraded too rapidly. These differences between Integra IDRT to have a controlled half-life of 14 ± 7 days compared to the other only collagen composed scaffolds, are related to the presence of the component chondroitin-6-sulfate (C6S). The crosslink between the collagen and chondroitin-6-sulfate

avoids a rapid degradation of the scaffold from collagenases. Furthermore, the chondroitin-6-sulfate has shown an anti-inflammatory effect in order to modulate the regeneration of wound healing. Another important activity of this macromolecule is to allow to provide sufficient specific surface for cell-scaffold interaction. The crosslink between collagen and C6S allows a formation of specific densities of integrins ligand on the surface of the scaffold in order to supply the appropriate binding of myofibroblast on scaffold surface.

According to these findings, I report that Pelnac® in USA is registered with FDA 510(k) as wound dressing (K191992) like a bioinductor because the device doesn't have an RCT to show equivalent efficacy to close wounds compared to Integra® IDRT®.

A differentiation in regenerative medicine between dermal substitutes and bioinductors should be mandatory.

References

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