Lab to OR - the evolution of fibrin sealants in regenerative medicine and reconstructive surgery.

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Publication Date: 2012

Abstract:

Reconstructive surgery of diseased or injured organs is a major medical challenge that will keep growing with the expansion and aging of the population. The promise of bioengineered materials to replace or cover defective anatomical areas depends on the ability to position and fixate transplants in a secure and compatible way and to allow it to template and regenerate with the local tissue. Fibrin Sealants (FS) have been utilized in plastic surgery with skin and tissue-engineered substitutes for reconstructive & aesthetic procedures. Particular benefit has been reported in burns and in procedures requiring flaps or grafts in complex grafting sites. FS can improve graft take, provide local haemostasis, reduce infections and stimulate wound healing. These effects are achieved by providing a supportive matrix enhancing cellular motility and consequently allowing an improved migration of keratinocytes, fibroblasts and other repair cells into the wound area. FS were also shown to be a good vehicle to deliver agents like stem cells or growth factors thus further contribute to wound healing acceleration. Here we review the development of a new fibrin sealant - ARTISS from the lab to the OR. The review will cover the in-vitro assessments, the preclinical activities, dose finding studies and the outcomes of the prospective randomized clinical trials performed to achieve the regulatory approvals for plastic & reconstructive indications.