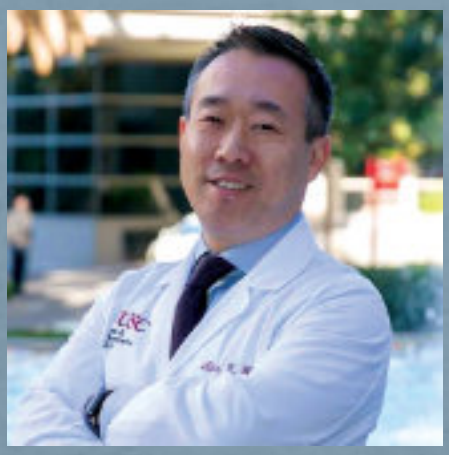
3dTH fibronectin therapy for non-healing irradiated head & neck skin wounds



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Clinical Need

Over 500,000 individuals develop head & neck cancer annually and up to 70% of these patients require radiation to treat their disease. Despite improvements in delivery, unintended cutaneous damage from radiation to the head & neck can result in chronic non-healing wounds which are painful, disfiguring, and at risk for infection. Basic wound care, such as moist dressing changes, may be effective for a small fraction of irradiated wounds but most require advanced wound care strategies or surgical debridement and reconstruction with non-irradiated vascularized skin flaps. However, not all patients are eligible surgical candidates, which in the case of a non-healing wound, presents an unsolvable clinical scenario.

Solution

Our proposal is an innovative solution to this difficult problem. We have demonstrated that treating irradiated skin with topically-applied fibronectin (FN) in a murine model led to improved rates of wound healing by >20%. The next phase will be to incorporate a FN into a patented 3-D transglutaminase hydrogel (3dTH) which allows for controlled delivery of FN. This prototype will be tested in minipig in order to study its therapeutic effects and work toward the development of a prefabricated wound dressing. Since the current standard of care involves frequent, costly, and painful office visits for wound care and debridement, development of a user-friendly dressing would improve patient outcomes and reduce the healthcare burden. Ideally, this technology could be exported beyond the craniofacial area to any irradiated location on the body.

Competitive Advantage

Fibronectin is a naturally occurring human protein. The hydrogel drug delivery system is biocompatible and offers predictable slow release that increases the drug's wound healing efficacy.

Target Market

It is estimated that 50% of head and neck cancer patients who receive radiation have some form of delayed wound healing, which would equal 250,000 patients per year in the US alone. However, this drug-device has the potential to be applied to non-healing radiation wounds all over the body (not limited to head & neck) thus significantly increasing market potential. A conservative estimate would be 10% of the total wound healing market – which will be $35B by 2025.

Regulatory Pathway

Combination product (drug-device) with the PMOA being the drug. Regulatory pathway will be IND with CDER as the lead agency. PMOA is well defined so no Request for Designation should be necessary.

Intellectual Property

Systems and Methods of Cell Activated, Controlled Release Delivery of Growth Factors for Tissue Repair and Regeneration (US20130202564A1)

Related Publications

Johnson MB, Pang B, Gardner DJ, et al. (2017) Topical fibronectin improves wound healing of irradiated skin. Sci Rep 7(1):3876.