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BloodSTOP iX: A hemostatic agent that assists in tissue regeneration

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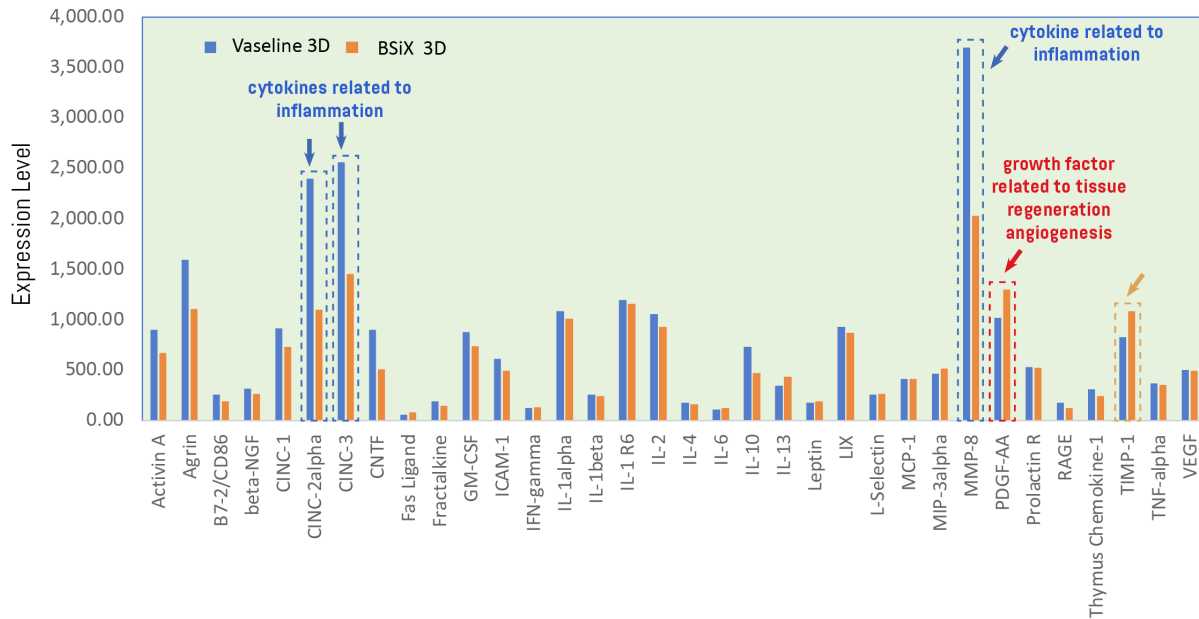
Background: BloodSTOP® iX is a novel hemostatic agent made of a water soluble, etherified sodium carboxymethyl cellulose matrix (ESCCM). Its use for hemostasis in burns and trauma is well documented, achieving hemostasis via activation of the intrinsic coagulation pathway, accelerating thrombin formation and assisting in aggregation of platelet deposition. The product has a strong safety profile and high efficacy in hemorrhage control. In recent evaluations of the product, a surprising wound healing outcome was observed, far exceeding hemostatic action alone. In over 150 burn donor sites, the product was utilized as a hemostatic agent, to assist in control of bleeding from donor site harvest in coagulopathic patients. In these same donor sites, wound healing was unexpectedly achieved at a rapid rate, with an average healing time of 7-10 days (mean of 8 days), with re-harvest possible at 14 days. This prompted an investigative study to identify factors/cytokines in an animal model that could explain the observed rapid wound healing rate.

Methods/study design: 48 SD rats were divided into 8 groups, including a sham group, a control group (gauze alone or Vaseline gauze alone) and an experimental group (BloodSTOP iX). After induction of a burn injury, the various injury sites were covered with the above products and evaluated daily for healing. Biopsies were obtained at 3, 14 and 20 days in the gauze, Vaseline, and BloodSTOP iX groups.

Results: BloodSTOP iX allowed for up-regulation of PDGF-AA and VEGF growth factors, which facilitated the tissue regeneration process and angiogenesis in the wounds, while blocking the inflammatory cytokines within the same wounds (MMP-8, CINC1 and CINC3). The cytokine PDGF demonstrated statistically significantly increased expression at days 3, 14 and 20 as compared to normal controls (gauze alone) ($p < 0.01$). The cytokine VEGF was also increased in expression vs the Vaseline gauze control at day 3 ($p < 0.01$), while not achieving statistically significant increases in regulation at days 14 and 20. BloodSTOP iX provided the scaffolding necessary to facilitate cellular infiltration and new capillary growth, all achieved by the gel effect of the product, once in contact with the burn wounds.

Conclusions: BloodSTOP iX is a functional hemostatic agent for use in burns for control of major bleeding. This study in SD rat animal models has demonstrated healing potential through modulation of cytokines PDGF, VEGF and various other factors, promoting epithelial infiltration and angiogenesis. In addition to growth factor activation, BloodSTOP iX has anti-inflammatory properties, blocking inflammatory mediators (MMP-8, CINC1 and 3) and further facilitating tissue healing. Further pre-clinical and clinical studies are warranted.

Cytokine array BloodSTOP iX vs Vaseline Gauze (3 Days)



Cytokine array BloodSTOP iX vs Vaseline Gauze (20 Days)

