Kerecis

Fish skin grafts compared to human amnion/chorion membrane allografts: A double-blind, prospective, randomized clinical trial of acute wound healing

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Study: Randomized double blind comparative trial on 85 patients with 170 full thickness acute wounds.



Proportion of healed wounds at each time point with fish skin graft and dHACM. Wounds treated with fish skin healed significantly faster with a hazard ratio of 2.37 compared to dHACM allograft-treated wounds (p = 0.0014).

Method:

Each patient received two full thickness, 4 mm punch biopsy wounds. Participants acted as their own control, one wound randomized to treat with Kerecis and second wound on the same forearm treated with Epifix (dHACM). Wounds are assessed at 7, 14, 21, 25, 28 by four independent medical proffessionals.

Statistical Analysis

To estimate whether the differences in time to heal between the studied materials in this accumulated data was significant, a mixed-effects Cox proportional hazard model was used. The model incorporates a fixed effect for the treatment, a random individual effect to account for each individual receiving both wounds, and a random wound effect to account for the variance introduced by the different reviewers of each wound

Results

Wounds treated with fish skin healed significantly faster with a hazard ratio of 2.37 (95%CI: 1.75–3.21) and a p-value of 0.0014 compared to dHACM-treated wounds. Healing trajectories of the materials at each day and per evaluator show consistent superiority of the fish skin grafts.



Representative subject followed up to the healing of punch wounds. From top to bottom: D0, D7, D14, D25. Wound on the left side of the figure was treated with fish-skin graft, while the right wound was treated with dHACM.

Conclusion

Full-thickness acute wounds treated with fish-skin grafts heal significantly faster than wounds treated with dHACM. When chronic wounds are treated with products such as the fish skin graft and dHACM, they need to be thoroughly debrided. With debridement, the chronic wounds approach the physiological state of an acute wound. Therefore, results derived from studying acute wounds can have logical implications for debrided chronic wounds.



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Trajectories of the number of healed wounds to time by evaluator and wound-healing material. Orange: Intact fish skin. Blue: dHACM.