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P5. Tissue Regenerative Devices with Allogeneic Cells – A Critical Review

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Introduction: The overall objective of this technical review is to highlight the potential health risks of incorporating living allogeneic cells (like fibroblasts, keratinocytes1, primordial somatic stem cells2, bone marrow mesenchymal stromal cells3, etc.) in skin substitutes or wound healing devices for tissue regeneration. Please make a note our emphasis is only on allogeneic cells and not of autogenic origin. At the end of this review, you may be convinced the usage of allogeneic cells may

have to be limited or restricted in clinical usage. From the Biomaterial Science perspective, the main focus of this publication is to reveal the biological safety of allogeneic cell incorporated biomaterials.

Method: A considerable amount of literature study was accomplished to fulfill the required methodology for this review article. Accordingly, we have focused on varied scientific publications about the rejection phenomenon of allogeneic cells in the host tissue. We also foresee the impact of our observation towards the FDA regulations to assess the safety and efficacy of such devices containing allogeneic cells and molecules. Additionally, this would help to seek the eligibility of reimbursement valuation by Medicare or other insurance entities.

Results & Conclusion: The cellular and molecular pathways of the immune response are recently being better understood. From the clinical perspective, the presence of allogeneic somatic stem cells in a skin substitute is quite objectionable due to possible immunogenicity to the host tissue. Several evidences4,5,6 have clearly documented the rejection of allogeneic cells in the host body. Adding fuel to fire, the additional drawback that many fail to focus on is the presence of elastin molecules in such constructs like amnion/placenta/umbilical cord, etc.

Recently, more light has been thrown on the potential carcinogenicity of elastin due to its biodegraded byproduct peptides7. It is well-known that fibroblast is responsible for the secretion of elastin8. In the case of allogeneic stem cell implantation, it is evident that the stem cell-derived fibroblast in the host tissue will secrete elastin molecules native to the donor fibroblasts. Naturally, the recipient body degrades the donor's elastin releasing the carcinogenic byproduct, elastokines.

References:

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