

Avita's novel ReNovaCell™ technology offers key advantages in skin repigmentation of burn scars, when combined with medical needling

Data Published in Peer-Reviewed Journal Burns

- *Combination therapy offers new approach to burn scar revision*
- *Statistically significant, objectively measured scar repigmentation improvement*

Northridge, CA, Perth, Australia and Cambridge, United Kingdom, 9 May 2016 — The combination of medical needling with a suspension of epithelial cells provided by ReNovaCell™ can restore pigment on burn scars, according to a randomised clinical trial from Germany published in *Burns*, the journal of the International Society for Burn Injuries, Avita Medical said today.

Avita Medical Ltd, (ASX: [AVH](#)), (OTCQX: [AVMXY](#)), a regenerative medicine company specializing in new treatments for wounds and skin defects, said the research offered a new and practical combination approach for medical professionals in the aesthetic sector aiming to address long-term scarring from burns, which remains a serious physical and psychological problem for affected patients. ReNovaCell™ enables plastic surgeons to quickly create an autologous suspension of cells that can then be applied to a wound bed, supporting healing of the top epithelial skin layer. Crucially, this Regenerative Epithelial System (RES™) includes melanocytes, which govern skin colour. These new findings are supported by other clinical data showing ReNovaCell™ can restore pigmentation.

The article in *Burns*, titled *Combination of Medical Needling and non-cultured autologous skin cell transplantation (ReNovaCell) for repigmentation of hypopigmented burn scars*,¹ describes a study involving the treatment of 20 patients, mean age of 33 years (6-60 years), with scars from deep second- and third-degree burns. Researchers deployed medical needling – also called percutaneous collagen induction – to improve scar texture and appearance by inducing microtrauma using a roller covered in 3mm needles. Medical needling has been shown to improve various characteristics of scars, but the technique does not typically address depigmentation issues, particularly over large areas. The researchers hypothesized that the use of ReNovaCell would complement the medical needling technique by introducing pigment-producing cells. Scars selected for treatment were on prominent areas such as the face, neck, chest and arms, with an average treatment surface area of 94 cm² (15-250 cm²). The study was designed as a within-subject comparison of 3 treatment areas for each participant, with each area randomly assigned to receive (1) no treatment, (2) medical needling and ReNovaCell or (3) medical needling without ReNovaCell. For each participant, one needled scar area was treated with RES™, created on ReNovaCell™ medical devices. Patients were evaluated after 3, 6, 9 and 12 months by an observer blinded to treatment assignment and pigmentation levels were objectively measured using specialized instrumentation. Patients also rated the outcomes of treatment.

The blinded-observer scar ratings, patient scar ratings and objective pigmentation measures all showed statistically significant improvements 12 months after treatment with ReNovaCell. Under the Patient and Observer Scar Assessment Scale, median patient rating of pigmentation was 50% improved, and the

¹ Busch KH, Bender R, Walezko N, Aziz H, Altintas MA, Aust MC. Combination of medical needling and non-cultured autologous skin cell transplantation (ReNovaCell) for repigmentation of hypopigmented burn scars. *Burns* (2016). *In press*. <http://dx.doi.org/10.1016/j.burns.2016.04.009>

median overall scar rating improved 57.1%, while observer ratings respectively showed 37.5% and 38.5% improvements. Taken together, the pigmentation ratings and objective measures indicate individual improvement in 17 of the study's 20 participants, the researchers reported. Melanin increases seen 12 months after ReNovaCell™ treatment were also statistically significant, showing a 29.3% improvement, while control areas showed no increase, they said.

"The combination of medical needling and ReNovaCell™ is a very promising approach to repigmenting large hypopigmented burn scars," said Dr Matthias Aust, Assistant Professor, Malteser Hospital, and co-author of the paper. "These positive results suggest that medical needling is delivering the melanocytes of the cell suspension through the needling channels straight onto the basal membrane."

Plastic surgeons treating burn scars have a number of options. Split-thickness autografts can produce a good pigmentation outcome, but this is an invasive approach, requiring donor skin sites to match the scar area. Cultured skin cell transplantation can also be deployed, but it takes weeks to prepare the cells. Medical needling alone is known to improve skin elasticity, moisture, erythema and transepidermal water loss, but has not been shown to improve repigmentation of large hypopigmented scars. In this context, Avita Medical said deploying needling with ReNovaCell™ offered key advantages: the ability to cover large wounds through a small donor site, is less invasive and crucially, delivers melanocytes to address hypopigmentation.

"This new approach, of combining ReNovaCell™ with medical needling, is simple, effective and enables patients to enjoy the synergistic benefits of both procedures," said Adam Kelliher, CEO of Avita Medical. "Ultimately, scar revision is about achieving the most optimal result, and from this perspective, we believe this combination could create a new benchmark for patient outcomes."

ABOUT AVITA MEDICAL LIMITED

Avita Medical develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's regenerative product portfolio includes ReCell® for burns aimed at plastic reconstructive procedures, ReGenerCell™ for chronic wounds and ReNovaCell™ of restoration of pigmentation and cosmesis. ReCell®, ReGenerCell™ and ReNovaCell™ are patented, CE-marked for Europe. ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell® is an investigational device limited by federal law to investigational use, and a pivotal U.S. trial is well underway aimed at securing FDA approval.

To learn more, visit www.avitamedical.com.

About ReNovaCell™

ReNovaCell™ is a medical device which enables clinicians to safely and rapidly create a treatment solution for pigmentation defects from a patient's own skin.

Using a small sample of skin, the device enables the production of a Regenerative Epithelial Suspension (RES™). The autologous suspension contains the multi-phenotype cells and wound-healing factors essential for natural healthy skin regeneration and healing. The procedure performed at the patient's bedside takes about 30 minutes from collecting the biopsy to spraying of the suspension onto the affected area.

ReNovaCell™ can be used in conjunction with conventional treatments for pigmentation defects, including scars, wrinkles and lesions associated with vitiligo and piebaldism, and has been used safely in thousands of treatments worldwide.

For more information, visit: www.avitamedical.com/renovacell

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