VERITACELL

Because cells heal.

2023 • Detailed investment deck

eit Health

Born in COMMERCIALIZATION REACTOR™

University of HUDDERSFIELD
Inspiring global professionals

Our vision

We bridge the gap between accessibility and effectiveness in post-surgical skin renewal like nobody can.

Innovating at the forefront of regenerative medicine, we aim to make skin regeneration quick, seamless and personalized, both in wound care and aesthetic medicine.

Problem

Key problem we aim to solve first

Standard of Care in burn treatment is painfully imperfect.

Standard of care (skin transplantation) still has a high risk of infection (21%) and rejection (16%), keeping the treatment lengthy and costly for hospitals. With large burns (>20% TBSA), surgeons often lack undamaged skin to transplant. On some curved areas, like fingers or the face, it is especially difficult to transplant skin on. Most importantly for patients, skin transplantation leaves unsightly scars forever.

Due to inefficiencies of the current treatment methods, patients spend on average 15 days in the hospital[1], often having to revisit multiple times. Each treatment day costs European hospitals €2500 on average[2], totaling €1.8 billion in annual costs for treatment of 50 000 patients[3]. Globally, those are 4 million patients per year[4].

But most importantly, patients suffer, during and after the treatment. Scars remain with them for the rest of their life.

This emotional harm can and should be minimized. The costs will follow.

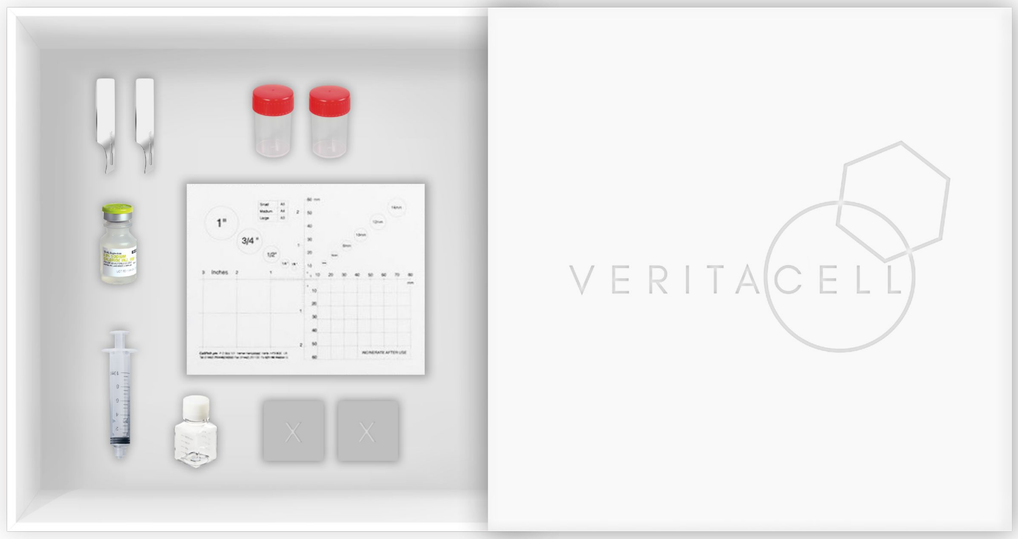
Solution

- Our solution
- Benefits for patients and hospitals
- Technological feasibility
- Intellectual property

Our solution

The simplest point-of-care solution for faster and better skin renewal

Our product is a surgical kit for quick extraction and reapplication of patient's own skin cells right in the operating theatre. It is a unique package of medical tools and a proprietary methodology for skin cell isolation in the most effective, fast and accessible way.



Mostly off-the-shelf tools to be used in a unique way to extract and reapply cells at the spot (the specific isolation steps are the proprietary part).

1. Obtain skin

The surgeon/trained medical practitioner obtains a split-thickness skin graft of a size at least 5x smaller than the wound.

2. Extract cells using the kit

The surgeon/trained medical practitioner isolates skin cells using our technology (skin is submerged into an enzyme; then, a specific cell isolation method takes place).

3. Apply liquid skin

The surgeon/trained medical practitioner immediately applies cell suspension (cells in saline solution or Ringer lactate) to the wound (no cell culture involved).

The whole procedure takes just 30 minutes, right in the operating room (at room temperature).

Benefits for patients and hospitals

Faster patient discharge, better visual outcomes and greater well-being.

For patients

- Less pain
- Faster recovery – faster return to daily activities
- Minimum to no scarring – ability to return to a similar quality of life

For surgeons & hospitals

- Minimized infection risk, no rejection risk, 20%+ faster recovery* - reduced treatment costs and better patient outcomes
- At least 5 times less donor skin needed (i.e. cells from 1cm^2 can regrow skin at least a 5 times larger wound area)[7]
- Minimum to no scarring - better functional outcomes
- Point-of-care operations - no need for a laboratory or specialist equipment

*just by removing the risk of rejection (16%) and reducing infection risk (from 21%). Further increase in healing speed comes due to high density of cells in the suspension[7]

Technological feasibility - how we know it works

Lab results, existing clinical data, acknowledgement by practitioners

- We have put significant efforts into providing scientific proof for the claims about the product's advantages:
  - All the essential skin cell types (keratinocytes, melanocytes, fibroblasts) obtained [Appendix 1];
  - Cells release Epidermal Growth Factor [Appendix 2] and a panel of well-characterized positive mediators of wound healing (IL1alpha, HMGB1, HSP90alpha) [Appendix 3];
  - Suppressed myofibroblast formation – minimizing scarring [Appendix 4];
  - Cell suspensions include stem cells [Appendix 5];
- In vivo proof-of-concept study (rat model) showed consistent improvement in wound coverage in the first week of healing, better skin structure recovery and decreased scarring [Appendix 6].
- Existing experimental and clinical evidence supports the safety and effectiveness of the autologous cell isolation approach for faster skin regeneration.
- Leading surgeons acknowledge, understand and support the underlying principle. We have a signed letter of support and acknowledgement from the President of European Burn Association.

Intellectual property

International patent (PCT) pending for the method and the set of specific tools to carry it out.

Current status: The core science lies in the specific method of using specific medical instruments and components to quickly produce a cell suspension with all the necessary cells for skin regeneration in large numbers. We have an international patent pending for that method. IP is fully owned by the company.

The product's methodology seems simple, but it is based on non-obvious actions taken to extract the maximum number of highly viable cells. A slight change in the actions taken worsens the outcome.

That is one key strength of our IP.

Up next: Submitting national patent applications in key markets in 2023-2024.

Market

- Market size(s)
- Ahead of other burn care solutions

Market size(s)

We can address customers' needs in different application areas without changing the product.

burn care – first market

- faster healing
- minimized scarring
- restored pigmentation

market size: €2 billion

plastic surgery + aesthetics

- scar prevention/removal
- wrinkle prevention
- skin rejuvenation
- tattoo removal
- tumor removal

market size: €20 billion

skin 3D bioprinting

- faster and cheaper creation of bioink for point-of-care printing of skin construct

market size: €2.5 billion

Ahead of other burn care solutions

We are the first to excel in key performance parameters important for surgeons: cell yield quality, absence of need for equipment and a lab, simplicity of use.

Criteria	VeritaCell kit	Avita ReCell (in the market)	RenovaCare SkinGun (in clinical trials)	PolarityTE SkinTE (in clinical trials)
Cell yield and viability	High	Low: our in-house test showed 3x less cells than us	High	High
Point-of-care use	Yes: the kit is used in the operating room	Yes: the kit is used in the operating room	Yes: the device is used in the operating room	No: the skin is taken to the lab for 1-2 days
Simplicity of use	Simple: manual steps familiar to the surgeon	Simple: part of the procedure automated	Complex: heating, centrifuge has to be used	Simple: surgeons only obtain the skin sample and hand it over
Resource intensity	Low: everything is included; adequate pricing	High: price is too high for the results it provides (per surgeon feedback)	High: a centrifuge needed, heating element	High: transportation and processing involved; thus high price

Competition matrix with direct competitors

Indirect competition includes artificial skin grafts/skin substitutes (Organogenesis, Mimedx, Epicel, Cutiss, Stratagraft, Kerecis, Renovoderm), solutions with cultured cells, i.e. cells need to be grown over time (Histogen, Organogenesis) and other tissue engineering solutions or dressings (Medline, Organogenesis, Integra, KCI, Novosorb).

Most of the solutions above still require a skin transplant to be done or take time and need a laboratory. Both of these issues are solved with our product.

Business case

- Business model
- Go-to-market and sales strategy

Business model

Same product for each application area. Different business models.

Kit for burns

- Sold to: hospitals
- Paid by: initially, hospitals; when reimbursed, by insurance companies/government
- Pricing: per-kit payments, €500 per kit (based on competitor pricing and the goal of balancing effectiveness with accessibility).

Kit for aesthetic surgery

- Sold to: private clinics
- Paid by: private clinics
- Pricing: premium per-kit pricing as there are currently no direct competitors, and there is a high opportunity to create a clear added value for surgeons; from €1000 per kit.

Kit for skin constructs

- Sold to: bioink/bioprinting equipment manufacturers
- Paid by: manufacturers
- Pricing: per-kit payments, €500 per kit.

We will further justify the pricing in a cost-effectiveness analysis for reimbursement. We will also license the technology for product co-development, and pricing will be based on specific terms of cooperation.

Go-to-market and sales strategy

Entering the initial market of burn care in 3 phases, from generating awareness, to communicating the cost-benefit advantages, to scaling the impact.

Phase 1 - Getting data, credibility, reducing objections to reimbursement (Months 0-8)

- We will work with Key Opinion Leaders among surgeons and hospitals (currently in talks with University Hospital of Zurich, Leeds Teaching Hospital Trust), i.e. credible early adopters/influencers who would help to establish rapport with the industry and to generate initial clinical evidence and publications.
- We will be targeting mainly university/teaching hospitals as there surgeons are more open to innovative solutions. Another channel for increasing awareness and credibility for us are professional surgeon associations. We have the support of President of European Burns Association and are already in talks with 2 hospitals about cooperating in first case studies.

Phase 2 - Communication with reimbursers, marketing partnership with patients (Months 9-16)

- We will be approaching insurance companies and patient advocacy groups to communicate cost advantages and promote benefits for patients.
- We will continue generating publications for transparency and credibility within the professional community

Phase 3 - Mass market (Months 17-36)

- In this phase the goal will be to be increasingly entering hospitals on a wider scale, obtain full reimbursement in key markets and enter new segments.
- We will continue generating publications for transparency and credibility within the professional community

Sales approach

Initial sales will be conducted via direct sales to hospitals, clinics and specialist burn units in Europe using own salesforce. For broader reach, we will be promoting the product within professional associations both in wound care and aesthetics. On a later stage, for accelerated scaling, we will consider cooperating with an established industry player, providing our product to them on an OEM basis.

Team

- Our team’s story
- The people
- Industry competence supporting the company

Our team’s story

Our team is built around the scientific excellence of two cell biology experts from the Institute of Skin Integrity and Infection Prevention at University of Huddersfield, UK and business expertise of two Latvian entrepreneurs.

The team formed in 2018 in Riga, Latvia at a matchmaking session by Commercialization Reactor, a platform that brings together inventors of breakthrough technologies and entrepreneurs willing to commercialize them. The Reactor also accelerates the startups, giving them the tools and network for utilizing prior professional experience for successful commercialization of technology, as well as initial funding for market validation.

The team came together thanks to having an aligned vision of simplifying and improving wound healing, helping patients recover faster. For one of the team members there was also a personal motive as their relative was in hospital at that time with complex, hardly healing wounds. So developing a product that would contribute to helping patients in a similar position was a great opportunity for creating impact with business.

Within 2 years from starting the company based on a 4-year research, our team has validated the need for the product in the market, established contacts with practitioners and researchers in the industry, identified a regulatory shortcut accelerating market launch and formed an experienced advisory board. We are committed to creating impact for patients and will be adding experienced healthcare executives to our core team to strengthen the company and prepare it for rapid growth.

The people

Arseniy Sergeyev, CEO & Co-founder

BSc in Business and Economics, 8 years in project management, sales, innovations, 2 lifestyle startup attempts. Establishes relationships with surgeons, potential partners and funders, is ready to risk for large scale impact innovation and provides fresh vision for the strategic planning of company and product development.

Evija Vascenko, Co-founder, COO

MBA, 25 years of international business development experience in both corporate and entrepreneurial settings, more than 10 years of experience in management consulting, coaching and mentoring. Contributes a network of stakeholders across the Baltics, orients well in the regulatory frameworks and asks the right questions to help strategically steer company's development.

Dr. Nikolaos Georgopoulos, Co-founder, CSO

PhD in Biochemistry & Molecular Biology, more than 20 years of research work in the field. Associate Professor in Cell Biology. Co-inventor of the VeritaCell methodology.

Dr. Michael Peake, Co-founder, CTO

PhD in Biology/Biological sciences. Research Associate at the University of Manchester.

Industry competence supporting the company

David Houldridge, Advisor on wound care product strategy.

Former SVP of Strategy at Smith & Nephew.

30 years in medical devices and wound care, most of them for Smith & Nephew, a global medical device company. Initially working in research and product development, David was involved in bringing to market and launching 19 new products, some of which form key pillars of the current business portfolio.

Girts Cimermans, Advisor on go-to-market and sales strategy.

CEO medmix, former President Sulzer Applicator Systems, former CEO Hoya Vision Care, GE Healthcare North East Europe.

Senior Executive with over 20 years of leadership tenure in healthcare sector. Strong experience in strategy and operational leadership through proven success record in US, European and Japanese corporate cultures. He has a solid track record in designing, communicating and executing on business strategies, accelerated growth, and change management.

Dr. Clemens Schiestl, Advisor on clinical development, first case studies.

President, European Burns Association; University Children's Hospital Zurich.

Pediatric surgeon with over 20 years of experience in children's plastic and reconstructive surgery and treatment of burns. Currently, he is President of European Burns Association, head of Pediatric Burn Centre, Division of Plastic and Reconstructive Surgery of the University Children's Hospital Zurich. Recently, he also took the role of titular professor at the University of Zurich.

Traction & roadmap

- Traction
- Roadmap

Traction

Product-market fit found, team competence strengthened, industry support gained

Key traction points summary

- **Proof of concept** has been done in the lab, international patent pending.
- Existing research supports **effectiveness and safety** of the method in animals and patients.
- **Product-market fit** validated, received support and commitments from leading European surgeons (burns and aesthetics) (10 of 12 KOLs said they would use it; 2 commitments in aesthetic surgery, 1 commitment in burn surgery to conduct **pilot studies** after product registration).
- Interest in **partnership** expressed by a leading European research institution to co-develop a **product for chronic wounds** and solve a huge problem with very little alternative solutions. Negotiations delayed to focus on the first version of the product for burns.
- **Proof-of-concept in the rat model performed with positive results** with financing from EIT Health RIS Innovation Call 2022 grant (see results in Appendix)

High-level roadmap

On our way to demonstrate the proof-of-concept in animals and proceed to first-in-man

2022 Q3-Q4
Proof-of-principle in rats

2024 Q1
First-in-man, proof of concept – Phase I/II.

2024 Q4
Product registration

2025
Post-marketing studies,
First sales

2025-2026
Phase III starts

eit Health

€50 000 grant

Ask

What we are looking for?

1. Strategic partners

Strategic partners (wound care / dermatology companies) for co-financing of clinical trials and market entry, marketing authorization, distribution and sales

2. Funding

€2m for financing the first clinical study stage and market entry (up to €250k already committed by our pre-seed investor)

3. Regulatory expert(s) and Chief Medical Officer

Experts with deep understanding of the regulations and guidelines for Medical devices / Advanced Therapy Medicinal Products (ATMP). Someone who could guide us closely through the clinical work (timelines, data requirements, costs, appropriate shortcuts etc.) in our specific case with certainty, joining our advisory board or the core team.

VERITACELL

We are creating the future without scars, now. Will you be in it?

Let’s get to work on making people heal, feel and look better, with their own cells.

Arseniy Sergeyev, CEO & Co-founder
arseniy@veritacell.com
cell +371 26 44 63 50
veritacell.com

Appendices

- References
- Appendices 1-4

References

Select papers showing the safety and effectiveness in vivo and clinically; other data

[1] Sierra-Zuniga et al. (2013) https://doi.org/10.1016/j.burns.2012.11.007

[2] Hop, M. J. (2015). Improving burn care efficiency.

[3] Germany (12000): https://www.aerzteblatt.de/int/archive/article/66060; Switzerland (130): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3219295/; France (13000): https://injuryprevention.bmj.com/content/16/Suppl_1/A126.4; UK (15000): https://www.cbtrust.org.uk/news-and-events/burn-accidents-costing-the-nhs-20-million-per-annum-show-latest-statistics-released-on-national-burn-awareness-day/; Belgium (1150): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4092799/; Italy (2070): https://www.ncbi.nlm.nih.gov/pubmed/21334821; Austria (130): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3219295/; Netherlands (770): https://www.researchgate.net/publication/261406594_Epidemiology_and_trends_in_severe_burns_in_the_Netherlands

[4] https://www.who.int/news-room/fact-sheets/detail/burns

[5] Holmes et al. (2018) https://doi.org/10.1016/j.burns.2018.11.002

[6] Butler et al. (1998) https://doi.org/10.1097/00006534-199805000-00021

[7] Svensjo et al. (2001) https://doi.org/10.1006/jsre.2001.6197 : 5x10^5 per 1 cm^2 freshly isolated cells enhanced porcine full thickness wound healing with doubling of re-epithelialisation speed, less protein leakage and 3x greater numbers in epithelial colonies. As we obtain an average of 5x10^5 viable cells , that gives the ratio of 1:5 (5x10^5 / 1x10^5 = 5). For example, 1 cm^2 of donor skin should effectively heal 5 cm^2.

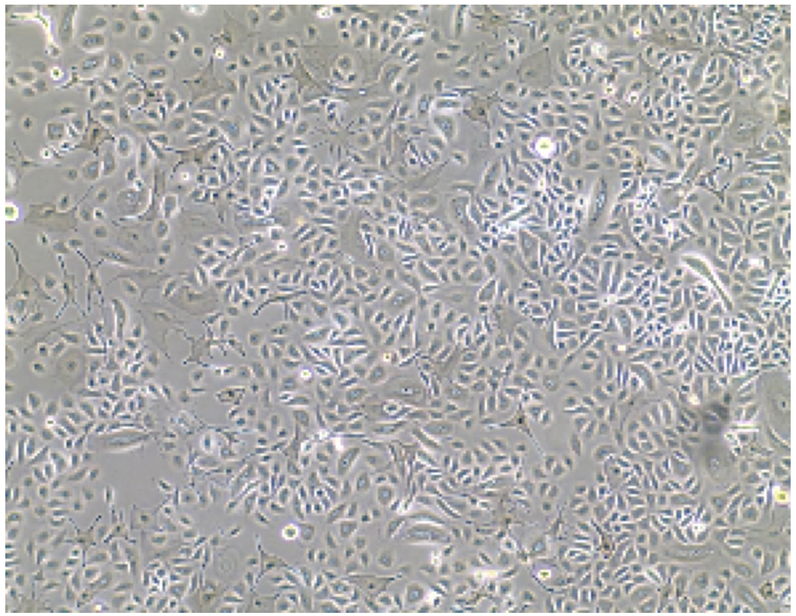
[8] Navarro et al. (2000) https://doi.org/10.1097/00004630-200021060-00007

[9] Zweifel et al. (2008) https://doi.org/10.1016/j.bjps.2007.07.015

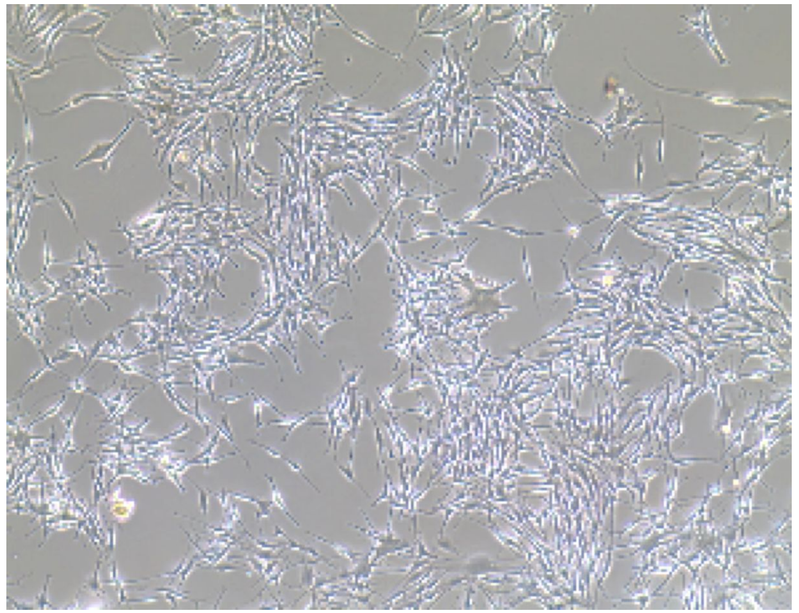
Appendices

Appendix 1 - Skin cells obtained and yields

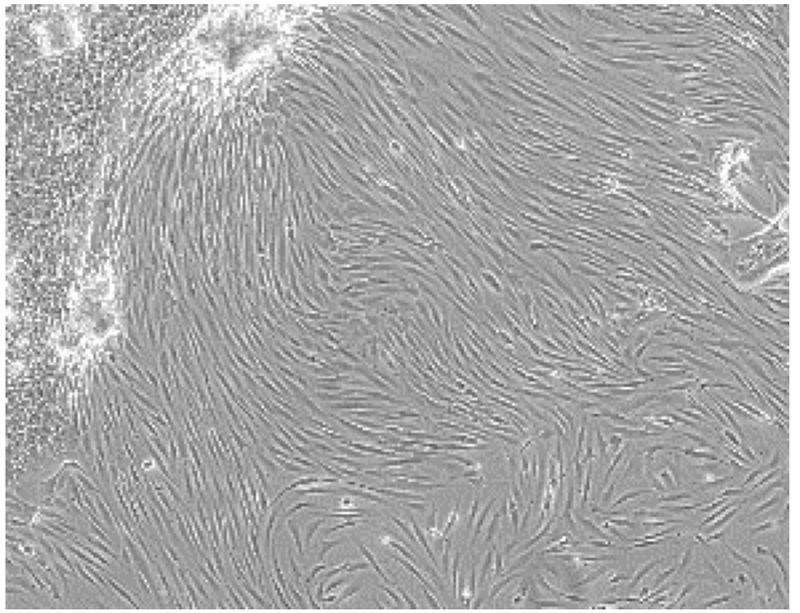
All essential cells are obtained. Average total cells yield: 5±1 x 10^5 cells/cm^2 skin.



Keratinocytes



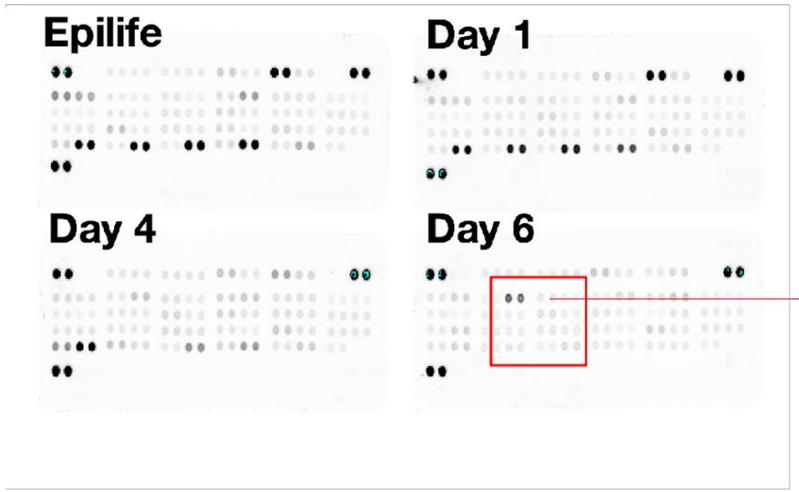
Melanocytes

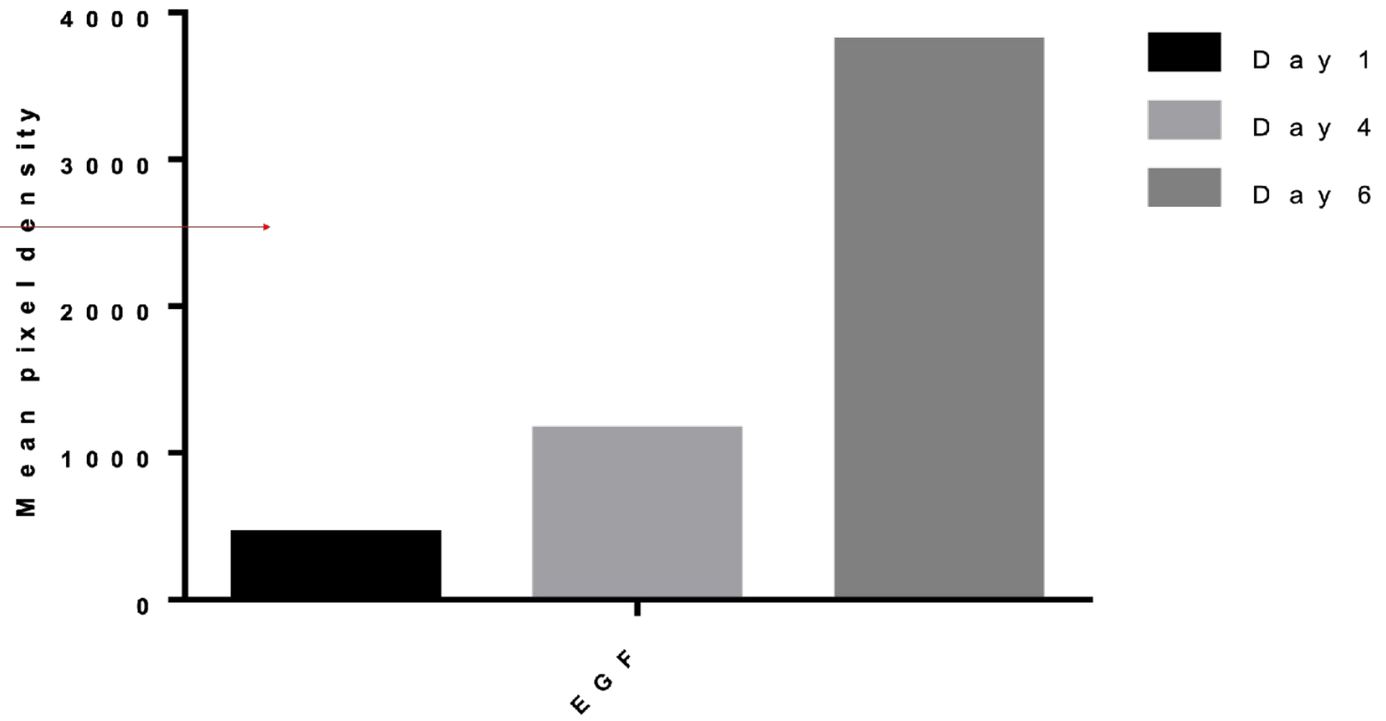


Fibroblasts

Appendix 2 - Epidermal Growth Factor (EGF)

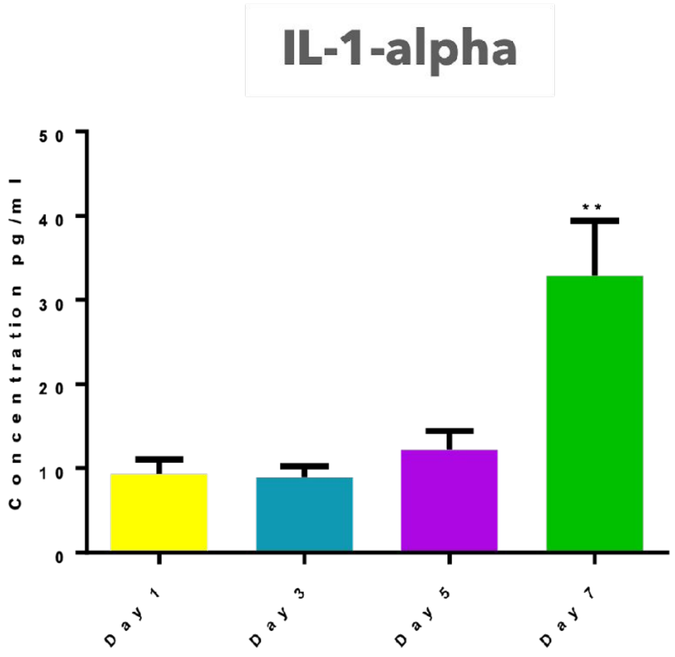
Cells release Epidermal Growth Factor (accelerates growth)

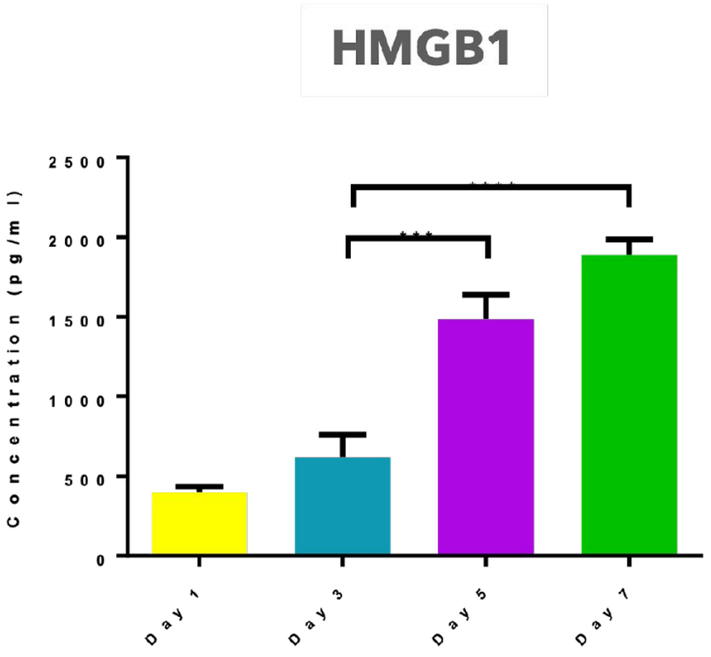


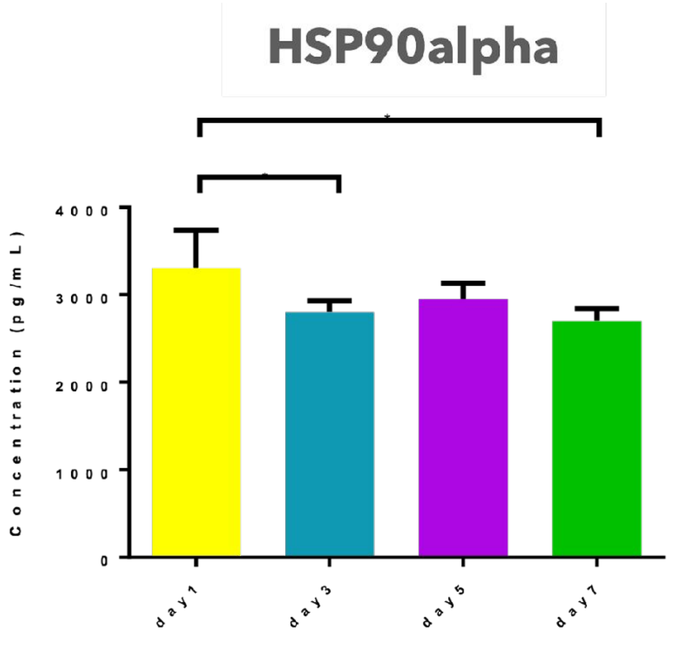


Appendix 3 - Mediators of wound healing

Cells release a panel of well-characterised positive mediators of wound healing.

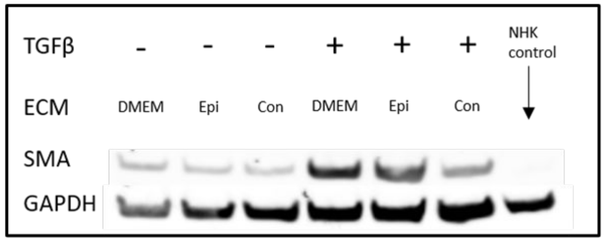


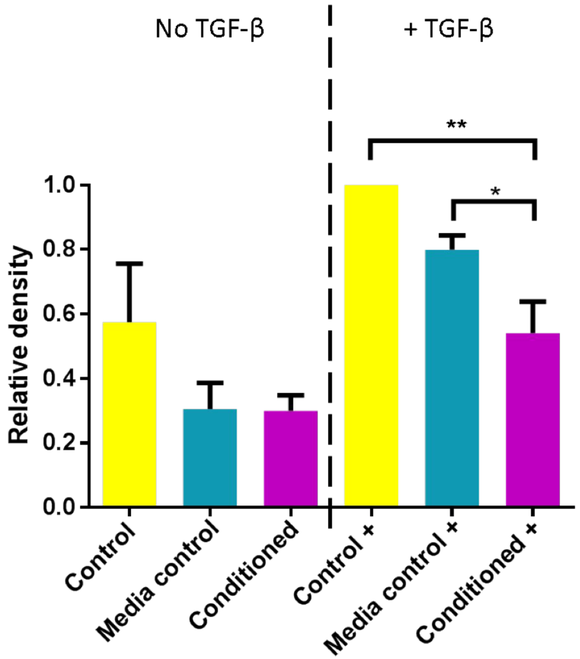


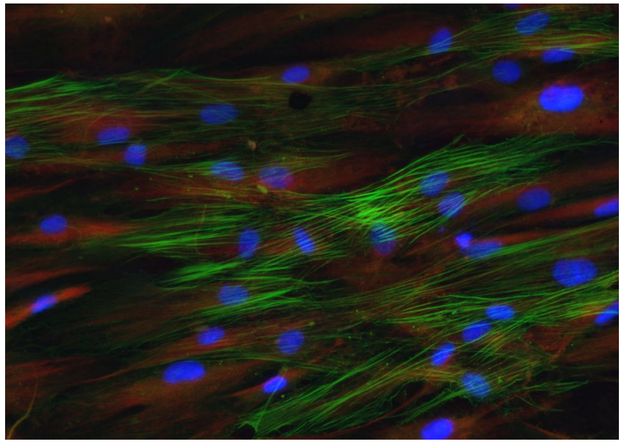


Appendix 4 - Anti-scar signals

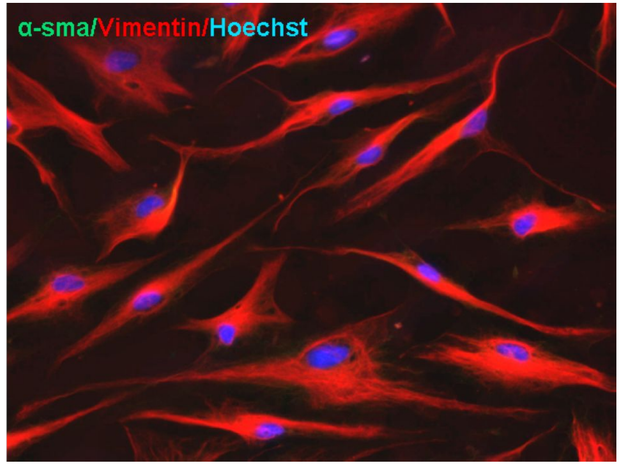
‘Conditioned’ medium from our cell isolates suppresses myofibroblast formation, minimizing scar formation.







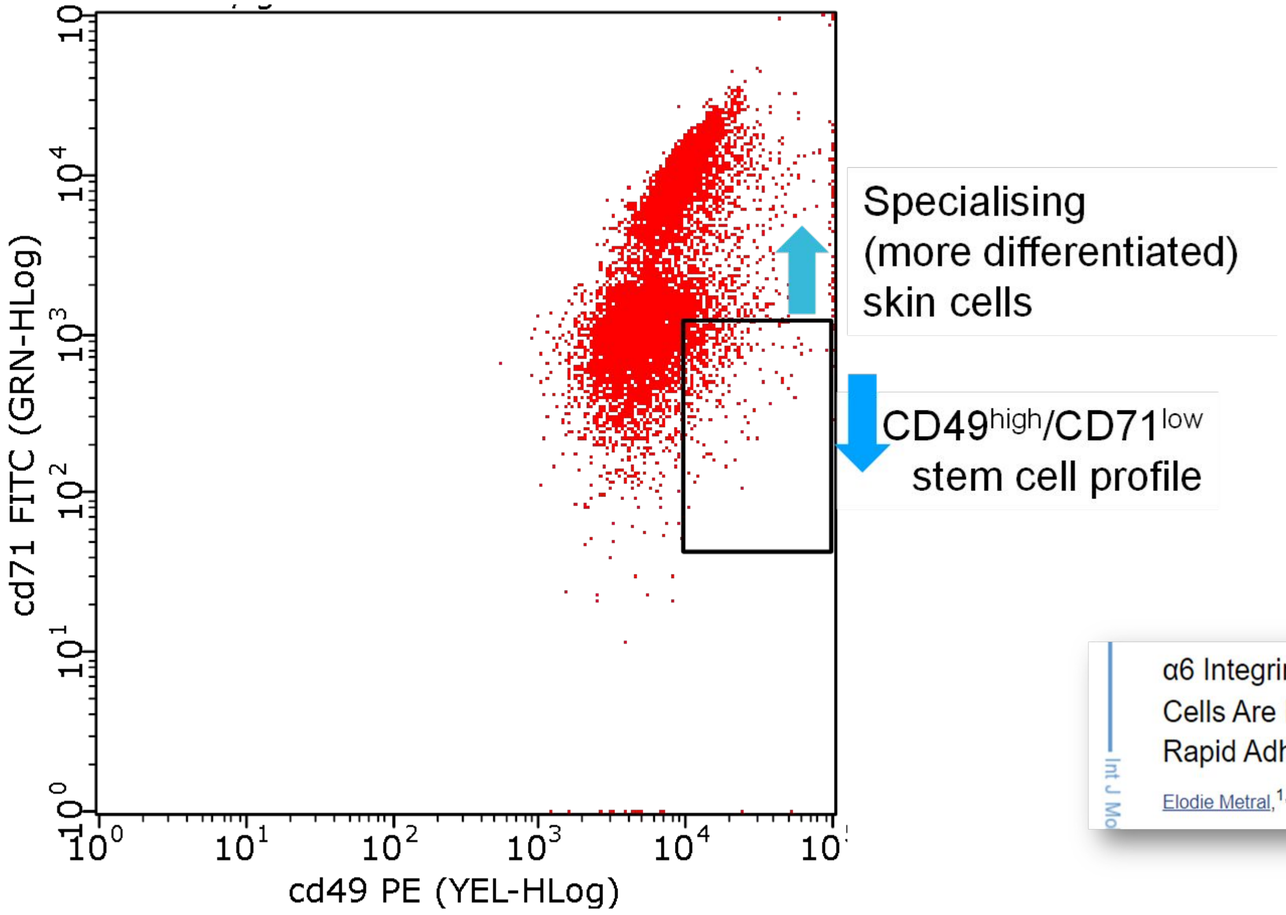
- TGFbeta-induced myofibroblasts (green cells) with fibroblasts (red cells)



- TGFbeta-induced myofibroblasts treated with conditioned media – cells do not express alpha-SMA

Appendix 5 - Stem cells

VeritaCell procedure permits isolation of cell with stem cell properties



- CD49/CD71marker expression profile which is typical of a "basal" cell phenotype that includes skin stem cells (based on published studies)

STEM CELLS
TISSUE-SPECIFIC STEM CELLS

Functional Characterization of Quiescent Keratinocyte Stem Cells and Their Progeny Reveals a Hierarchical Organization in Human Skin Epidermis

HOLGER SCHLÜTER,[a] SOPHIE PAQUET-FIFIELD,[a] PRADNYA GANGATIRKAR,[a] JASON LI,[b] PRITINDER KAUR[a]

α6 Integrin (α6^{high})/Transferrin Receptor (CD71)^{low} Keratinocyte Stem Cells Are More Potent for Generating Reconstructed Skin Epidermis Than Rapid Adherent Cells

Int J Mo

Elodie Metral,[1,2,3,4] Nicolas Bechetoille,[1] Frédéric Demarne,[1] Walid Rachidi,[2,4,*] and Odile Damour[3]

Appendix 6 - Conclusions from in vivo work

Wound closure studies

- Untreated (Control) wounds exhibited gradual closure within a 14-day follow-up period and significant healing (% wound closure) was **only** observed **after** Day 8
- Treatment of wounds with VeritaCell suspensions of 3 different concentrations (1:1, 1:10 and 1:20) led to significant % wound closure within the first week (Days 6 & 8)
- Treatment with the 1:10 suspension showed strikingly good evidence of wound closure improvement (and was the most significant throughout)
- VeritaCell treated wounds showed more rapid formation of protective wound-healing (epidermal) layer and reduced exudate

Therefore:

- *VeritaCell suspensions enhanced wound closure during the critical, early-stages of wound healing*

Appendix 6 - Conclusions from in vivo work

Histological assessment of wounds

- Untreated wounds displayed a) thickening of skin epidermis (EP) and b) induction of synthesis of extracellular matrix proteins in the dermis
- Therefore, **control** (untreated) wounds showed clear evidence of **scarring**
- Control wounds were also highly variable in thickness
- Addition of VeritaCell suspensions was associated with a more consistently well-organised EP layer
- Treatment resulted in tissue architecture that was representative of **normal, unwounded** epithelium

Thus:

- *VeritaCell suspension-treated skin exhibited striking improvements in tissue organization*
- *Overall, treatment with VeritaCell suppressed scarring and enhanced the quality of wound healing process*