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ReCell® combined with meshed skin graft in the treatment of acute burn injuries: a systematic review and meta-analysis

ReCell® combinado com enxerto de pele em malha no tratamento de queimaduras agudas: uma revisão sistemática e meta-análise

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ABSTRACT

Background: Burn injuries often result in prolonged hospitalization, infection, and hypertrophic scarring. Split-thickness skin grafting (STSG) remains the standard of care but is associated with notable limitations.

Objective: To evaluate the clinical efficacy of ReCell® - an autologous skin cell harvesting technology - combined with meshed skin grafts, compared to conventional STSG in the treatment of acute burns.

Method: Systematic search was conducted across PubMed, Embase, and Scopus for articles published between January 2000 and April 2025. Studies were independently screened by 2 reviewers based on predefined eligibility criteria. Primary and secondary outcomes - including wound healing time, pain (visual analogue scale), and infection rates - were analyzed using a Mantel-Haenszel random-effects meta-analysis.

Resul: From 56 identified records, 7 randomized or quasi-randomized controlled trials were included. Pooled analyses revealed no statistically significant differences between ReCell® and conventional STSG across all outcomes.

Conclusion: ReCell® is a promising and potentially less invasive alternative to standard split-thickness grafting in the surgical management of acute burns. However, current evidence does not demonstrate superiority in clinical outcomes. Further high-quality, independently conducted randomized trials are needed to clarify its role.

KEYWORDS: Burns. Skin grafting. Split-thickness skin grafts. Autologous skin cell suspension. ReCell device. Wound healing. Infection. Pain. Randomized controlled trials. Systematic review. Non-cultured skin cell suspension.

RESUMO

Introdução: As lesões por queimaduras estão frequentemente associadas à hospitalização prolongada, infecções e formação de cicatrizes hipertróficas. O enxerto de pele de espessura parcial (STSG) é amplamente utilizado como padrão terapêutico, apesar de suas limitações.

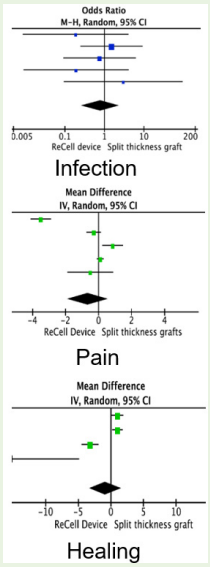
Objetivo: Avaliar a eficácia clínica do ReCell® - uma tecnologia de coleta autóloga de células da pele - combinado com enxertos de pele em malha, em comparação ao STSG convencional no tratamento de queimaduras agudas.

Método: Realizou-se busca sistemática nas bases PubMed, Embase e Scopus, abrangendo o período de janeiro de 2000 a abril de 2025. Os estudos foram selecionados por 2 revisores independentes com base em critérios de elegibilidade predefinidos. Os desfechos primários e secundários - tempo de cicatrização, dor (escala visual analógica) e taxa de infecção - foram analisados por meta-análise utilizando o modelo de efeitos aleatórios de Mantel-Haenszel.

Resultado: Entre os 56 estudos inicialmente identificados, 7 ensaios clínicos randomizados ou quase-randomizados foram incluídos. A análise agrupada não demonstrou diferenças estatisticamente significativas entre ReCell® e o STSG convencional em nenhum dos desfechos avaliados.

Conclusão: ReCell® representa alternativa promissora e potencialmente menos invasiva ao enxerto de espessura parcial no tratamento cirúrgico de queimaduras agudas. No entanto, os dados atuais não demonstram superioridade clínica em relação à técnica convencional. São necessários estudos adicionais, de alta qualidade e conduzidos de forma independente, para esclarecer seu papel terapêutico.

PALAVRAS-CHAVE: Queimaduras. Enxerto de pele. Enxerto de espessura parcial. Células autólogas. Recell. Cicatrização de feridas. Ensaios clínicos randomizados. Meta-análise.



Central Message

Burn injuries often result in prolonged hospitalization, disfigurement, and functional impairment. While split-thickness skin grafting remains the standard of care, it is frequently associated with complications such as infection and hypertrophic scarring. The use of ReCell® - an autologous skin cell harvesting device - in combination with meshed skin grafts presents a promising alternative approach for the surgical management of acute burns.

Perspective

ReCell®, an autologous skin cell harvesting device, represents a novel approach for the treatment of scars and acute burn injuries. It is simpler, more cost-effective, and less time-consuming compared to conventional split-thickness skin grafting, which remains the current standard of care. However, current evidence is limited, and further high-quality, independently conducted clinical trials are needed to establish its efficacy. In this analysis, no statistically significant differences were observed between ReCell® and standard grafting in terms of key clinical outcomes.

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INTRODUCTION

Burns are a major global public health concern, responsible for approximately 180,000 deaths annually, predominantly in low- and middle-income countries, according to the World Health Organization (WHO).[1] Beyond mortality, non-fatal burn injuries are a leading cause of morbidity, often resulting in prolonged hospitalization, disfigurement, and permanent disability. In India alone, more than 1 million people sustain moderate to severe burns each year[1]. In the United States, nearly 486,000 individuals seek medical care for burns annually, leading to around 40,000 hospitalizations and 3,400 deaths.[2,3] According to the Agency for Healthcare Research and Quality, there were more than 130,000 emergency department visits and 40,000 hospital admissions related to burn injuries in 2013.[3] The economic impact is substantial, with estimated annual direct healthcare costs reaching $1.5 billion in the USA, and an additional $5 billion attributed to lost productivity.[2] These figures underscore the pressing need for effective, accessible, and cost-efficient treatment modalities for both acute and chronic burn injuries.

Split-thickness skin grafting (STSG) remains the most commonly used reconstructive technique for skin and soft tissue injuries. It involves harvesting the entire epidermis and a portion of the dermis, but this creates a secondary donor site wound. Patients often experience pain, delayed healing, infection, poor cosmetic outcomes, and reduced quality of life.[4] Partial-thickness burns, which damage the entire epidermis and varying depths of the dermis, can sometimes re-epithelialize without surgical intervention. Re-epithelialization begins within 24 h after injury.[5]

ReCell® (Avita Medical, Valencia, CA, USA) is an autologous skin cell harvesting device that has been developed as an innovative treatment for acute thermal burns. It isolates regenerative cells from a small skin biopsy, which are then applied to the wound bed to promote rapid re-epithelialization.[6] ReCell® is FDA-approved for use in patients aged 18 years or older with acute thermal burns and can be used in combination with meshed autografts, particularly for deep partial-thickness burns.

The foundational concept of ReCell® is based on the work of Stoner and Wood,[7] who demonstrated that non-cultured autologous skin cell suspensions could achieve long-term wound closure without laboratory expansion. The device includes a proprietary enzyme and buffer system, sterile surgical instruments, and a spray applicator. In addition to burns, it has been used effectively for chronic wounds, hypopigmented scars, vitiligo, and large congenital melanocytic nevi.[8]

Previous studies suggest that ReCell® is a feasible, simple, and safe method for delivering non-cultured autologous epidermal cell suspensions. It may offer advantages in terms of procedural simplicity, reduced cost, and faster application, without requiring sophisticated laboratory infrastructure.[8]

Given the ongoing search for treatment modalities that reduce pain, minimize infection risk, and enhance healing, we conducted a systematic review and meta-analysis of randomized and quasi-randomized controlled trials to evaluate the efficacy of ReCell® combined with meshed skin grafts for managing acute burn injuries.

So, the objective of this review was to assess the effectiveness of ReCell® in combination with meshed skin grafts compared to conventional treatment approaches in patients with acute burn injuries.

METHOD

Data sources and search strategy

The search strategy was developed in accordance with the meta-analysis protocol, focusing on identifying relevant studies evaluating the use of ReCell® in patients with burn injuries. Both free-text terms and controlled vocabulary (MeSH terms) were employed. Free-text search terms included "ReCell®," "meshed skin repair," and "split-thickness skin graft," combined using the Boolean operator OR. These were then cross-referenced with "burn injury" using the Boolean operator AND.

Controlled vocabulary searches utilized the Medical Subject Headings (MeSH) terms: "ReCell® device," "meshed skin graft," "split-thickness skin graft," and "burn injury." Searches were conducted in PubMed, Embase, and Scopus, covering literature published from January 1, 2000, to April 1st, 2025.

Additionally, the reference lists of all included articles were manually reviewed to identify further eligible studies. Titles and abstracts of identified articles were screened independently by 2 reviewers. Full-text reviews were then conducted to determine eligibility. Disagreements during the screening or selection process were resolved through discussion or adjudicated by a third independent reviewer.

Studies were included if they met the following criteria: 1) published in English; 2) involved human participants with acute burn injuries; 3) evaluated the use of ReCell® combined with meshed skin grafts as a treatment modality; and 4) reported relevant clinical outcomes, such as wound healing, pain management, functional recovery, or safety. Non-original research publications, including reviews, editorials, and case reports, were excluded. Study selection followed the PICO framework as detailed in Table 1.

TABLE 1 — Inclusion and exclusion criteria for study selection in the ReCell® meta-analysis

	Inclusion	Exclusion
Participants	Humans of all age groups with partial-thickness burn injuries or split-thickness skin graft donor site wounds	Animal studies
Intervention	ReCell® device-derived autologous skin cell suspension Split-thickness skin grafts	Use of autologous skin cells not prepared in suspension; cultured epithelial autografts; treatments for conditions other than burns
Comparator	Studies assessing wound re-epithelialization, pain, and secondary infection outcomes	Studies lacking standard care or skin graft-based comparators
Outcomes	Wound healing, pain relief, infection rates	Studies reporting only cost-related outcomes
Study design	Randomized controlled trials (including crossover and pilot RCTs)	Non-randomized designs: editorials, surveys, systematic reviews, observational studies, quasi-experimental studies, animal studies
Time frame	Studies published from 1975 to 2025	Studies published before 1975

Protocol and reporting

This study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[9] A summary of the methodology, including the number of studies retrieved from each database, the search strategy applied, and reasons for study exclusion, is presented in Figure 1 as a PRISMA flow diagram.

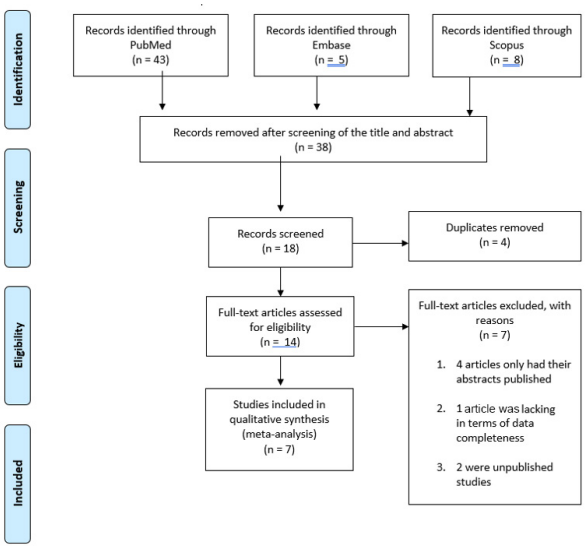

FIGURE 1 — PRISMA flow diagram

The primary objective of this review was to assess the effectiveness of ReCell®-derived autologous skin cell suspension compared to split-thickness skin grafting in accelerating wound re-epithelialization in patients with acute partial-thickness burns. The secondary objective was to evaluate differences in acute pain, infection rates, and the need for further surgical interventions between the two treatment modalities.

Data extraction and risk of bias assessment

A standardized data extraction form was used to collect information on study characteristics, patient demographics, intervention details, outcome measures, and results. Two independent reviewers performed the data extraction, resolving discrepancies through discussion or third-party adjudication when necessary. Risk of bias was assessed for each randomized controlled trial using the Cochrane Risk of Bias 2.0 (RoB 2.0) tool, which evaluates five domains: randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selection of reported results. A summary of these assessments is presented in Table 2.

Data synthesis and statistical analysis

Extracted data were analyzed using RevMan version 5.[3] Given the substantial heterogeneity among included studies ($I^2 > 50\%$), a random-effects model was applied. For each outcome, pooled effect sizes were calculated and presented as relative risk (RR) with 95% confidence intervals (CIs). Results were visualized using forest plots for key endpoints, including complete wound healing, pain scores, and infection rates.

Protocol registration

This systematic review and meta-analysis was prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the registration number CRD420251037574.

RESULT

Search results and study characteristics

A total of 56 articles were identified through searches in PubMed, Embase, and Scopus. After title/abstract screening and full-text evaluation by 2 independent reviewers, 7 studies met the inclusion criteria. These studies collectively enrolled 903 participants with superficial or deep partial-thickness burns.

Four studies [4,7,11,14] employed a within-subject design in which patients received both ReCell® and split-thickness skin graft (STSG) treatments on different wound areas, serving as their own control. In total, 296 burn wounds were treated using the ReCell® device, while 607 wounds received conventional STSG.

TABLE 2 — Summary of risk of bias (RoB 2.0) assessment for included studies

Study	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall risk of bias
Gravante, 200710	Some concerns	Low	Low	Low	Some concerns	Some concerns
Holmes, 2018 (Burns)7	Low	Low	Low	Low	Low	Low
Holmes, 2018 (JBCR)11	Low	Low	Low	Low	Low	Low
Sood, 201512	High	Some concerns	High	Low	Some concerns	High
Hu, 20174	Low	Low	Low	Low	Low	Low
Park, 201313	High	Some concerns	Low	Some concerns	Some concerns	High
Wood, 201214	Low	Low	Low	Low	Low	Low

The studies evaluated outcomes including pain scores, time to complete re-epithelialization, and post-treatment infection rates. The characteristics of the included studies are presented in Table 3.

TABLE 3 — Characteristics of the included studies

Study name	Sample size	Control site intervention	Experimental site intervention
Gravante et al. 200710	82	Split thickness skin grafting	ReCell device
Holmes JH et al. 201811	166	Split thickness skin grafting	Meshed Split thickness skin grafting + Autologous skin cell suspension (using ReCell device)
Sood et al. 201512	20	Split thickness skin grafting	ReCell device
Hu et al. 20174	106	Split thickness skin grafting	Autologous skin cell suspension (using ReCell device)
Wood et al. 201214	9	Split thickness skin grafting	ReCell device
Holmes et al. 20187	60	Split thickness skin grafting	ReCell device
Park et al. 201313	460	Split thickness skin grafting	ReCell device

Primary outcome

Post-treatment healing[4,7,10,14]

Four studies evaluated the time to complete healing of burn wounds, defined as >95% re-epithelialization of the affected Total Body Surface Area (TBSA). As shown in the forest plot (Figure 2), there was no statistically significant difference in healing time between the ReCell® and split-thickness skin graft (STSG) groups. The pooled mean difference, calculated using the Mantel-Haenszel random-effects model, was -0.85 days (95% CI: -3.29 to 1.58; p = 0.49; Z = 0.69), indicating comparable healing durations across both treatment modalities.

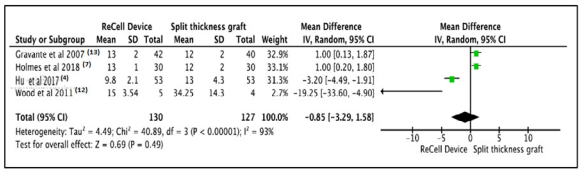

FIGURE 2 — Pooled analysis of time to complete re-epithelialization

Secondary outcomes

Pain scores [4,10-12,14]

Post-treatment pain was assessed using the Visual Analogue Scale (VAS), a 10-point tool in which 0 indicates no pain and 10 represents the worst imaginable pain. As shown in the forest plot (Figure 3), pooled analysis demonstrated no statistically significant difference in pain scores between the ReCell® and split-thickness skin graft groups. The mean difference was -0.67 (95% CI: -1.91 to 0.58; p = 0.29; Z = 1.05), indicating comparable pain levels across both treatment modalities.

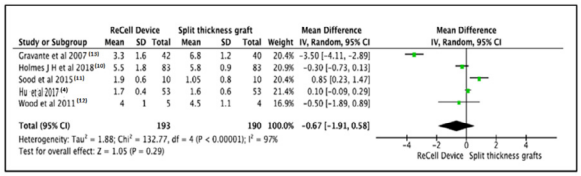

FIGURE 3 — Forest plot comparing pain intensity between ReCell® and STSG

Incidence of infection[4,7,11,13,14]

Burn wound infection (BWI) is a key indicator of treatment efficacy. It is typically defined as bacterial colonization of the burn site, often by gram-positive cocci - common skin commensals - that invade the wound bed within 48 h. BWI is associated with prolonged hospital stays and the need for intensified antibiotic therapy.

Five studies assessed the incidence of infection following treatment. As shown in the forest plot (Figure 4), pooled analysis revealed no statistically significant difference between the ReCell® and split-thickness skin graft (STSG) groups. The odds ratio, calculated using the Mantel-Haenszel random-effects model, was 0.79 (95% CI: 0.26 to 2.37; p = 0.67; Z = 0.43), indicating similar infection rates across both arms.

In four of the included studies, participants served as their own controls, receiving ReCell® and STSG treatments on different wound areas. While this within-subject design facilitates direct comparison, it may introduce bias due to the lack of individual-level randomization.

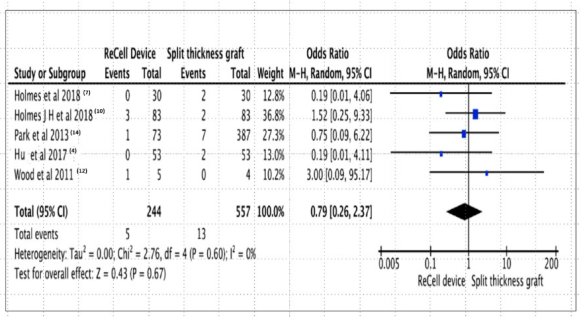

FIGURE 4 — Forest plot of post-treatment infection rates

Exploration of heterogeneity and publication bias

Heterogeneity among the included studies was assessed using both the I^2 statistic and Egger's test. To evaluate potential publication bias, inverted funnel plots were constructed for each outcome (Figure 5A–C). Substantial heterogeneity was observed, with I^2 values of 97% for pain scores and 93% for complete healing, indicating a high degree of variability across the included studies.

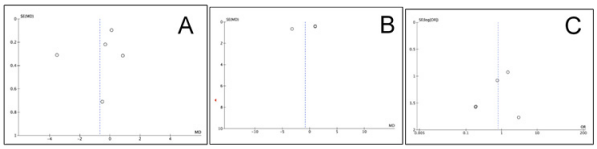

FIGURE 5 — Funnel plots for: A) pain score; B) complete healing; C) incidence of infection

Certainty of the evidence (GRADE assessment)

To assess the strength and reliability of the findings, the GRADE approach was applied to each of the primary outcomes. The certainty of the evidence was rated as very low for both wound healing and post-treatment pain due to serious concerns related to risk of bias, high inconsistency (I^2 > 90%), imprecise estimates with wide confidence intervals,

and potential publication bias. For the outcome of infection, the certainty was rated as low, primarily due to imprecision and suspected conflicts of interest in some of the included studies. These ratings indicate limited confidence in the effect estimates and suggest that further high-quality randomized trials may change the current conclusions.

DISCUSSION

For nearly 3 decades, autologous skin cell suspensions (ASCS) have been investigated in clinical trials.[15] Despite advancements in preparation techniques, delivery systems, and the ongoing publication of randomized trials, the role of ASCS -particularly in the treatment of partial-thickness burns - remains uncertain.[11]

ReCell® is a novel approach that offers theoretical and practical advantages over conventional split-thickness skin grafting (STSG), notably through the use of non-cultured autologous cell suspensions that promote rapid re-epithelialization with minimal donor skin. This meta-analysis evaluated the efficacy of ReCell® in comparison to STSG across key clinical outcomes: wound healing, pain, and infection.

Although 56 studies were initially identified, only 7 met the inclusion criteria, underscoring a limited pool of high-quality evidence in this domain. Among the selected trials, 4 employed a within-subject design in which patients received both treatments across separate wound areas.[4,7,11,14] Our pooled analysis showed no statistically significant differences between ReCell® and STSG in time to complete wound healing, pain scores, or infection rates. These findings suggest that ReCell® performs comparably to the current standard of care in the short term.

Importantly, ReCell® has demonstrated potential logistical and clinical benefits. The device requires approximately 1/80th the donor skin surface area needed for STSG, reducing the need for extensive harvesting by over 97%.[7] Additionally, the shallower donor sites and rapid processing may translate into less pain, faster healing, and lower morbidity - especially relevant in patients with limited donor tissue or extensive burns.

Despite these promising features, several caveats must be considered. Some adverse events reported in the included studies were attributed to suboptimal post-application care. Since ReCell® delivers disaggregated skin cells, the wound environment must be carefully optimized - avoiding cytotoxic agents and ensuring proper dressings - to support successful epidermal regeneration.

This review also highlights critical limitations in the existing evidence base. Two studies - by Park et al.[13] and Wood et al.[14] - involved F. Wood, a co-inventor of ReCell® and non-executive director at Avita Medical, raising concerns about potential conflicts of interest. Moreover, most studies were small, industry-sponsored, and focused on adult populations, limiting the generalizability of results to broader or pediatric settings. The lack of long-term follow-up data and head-to-head trials comparing ReCell® with other emerging therapies further complicates interpretation.

A sensitivity analysis excluding industry-affiliated studies could not be conducted due to the limited number of available trials, but such analysis would be essential in future larger meta-analyses.

While this meta-analysis followed robust methodological standards - including protocol-based selection, independent review, and validated risk of bias assessment - it is important to critically acknowledge its own limitations. High statistical heterogeneity ($I^2 > 90\%$) in key outcomes, absence of meta-regression or subgroup analyses, and inclusion of trials with within-subject designs limited the precision and interpretability of the pooled estimates. Furthermore, potential conflicts of interest in some of the included studies and the small number of eligible trials reduced the overall certainty of the evidence. These factors highlight the need for more rigorous, independently conducted trials and underscore the methodological challenges in synthesizing data on novel technologies like ReCell®.

A recent meta-analysis[16] also evaluated the use of autologous skin cell suspension for burn management and concluded that ReCell® significantly reduced time to re-epithelialization compared to standard treatments. However, the findings did not demonstrate statistically significant improvements in secondary outcomes such as pain, scar quality (POSAS and Vancouver scales), infection rates, or the need for reintervention. Compared to that study, our meta-analysis offers several methodological advantages aligned with Cochrane guidelines. First, we applied the GRADE approach to evaluate the certainty of evidence, which was not included in reference.[16] Second, our protocol involved a more rigorous risk-of-bias assessment using the RoB 2.0 tool, with full domain-level reporting and critical commentary on conflicts of interest - particularly in studies involving device co-inventors. Third, while reference16 reported moderate heterogeneity ($I^2 = 58\%$) for healing, our study identified substantial heterogeneity ($I^2 > 90\%$) and explicitly discussed the statistical and clinical implications of this variability, including the confounding impact of within-subject designs. Finally, our analysis focused specifically on ReCell® combined with meshed STSG versus STSG alone, enhancing internal validity and reducing clinical heterogeneity. Together, these methodological strengths enhance the transparency, reproducibility, and critical appraisal of our findings and offer a more robust framework for interpreting the clinical utility of ReCell® in acute burn care.

Study limitations

This meta-analysis has several limitations. First, the included studies were relatively small and exhibited considerable methodological and clinical heterogeneity - particularly regarding pain scores and complete wound healing. Such variability

likely stems from differences in study design, patient demographics, burn depth, and treatment protocols.

Second, the follow-up duration in many trials was short, limiting the ability to evaluate long-term outcomes such as scar quality, functional recovery, and recurrence of complications. Additionally, ReCell® remains a relatively new technology, and high-quality, independent data on its long-term safety and efficacy are still lacking.

Finally, the limited number of eligible randomized controlled trials, along with the potential for industry sponsorship bias in several studies, restricts the generalizability of our findings. Further well-designed, adequately powered, and independently conducted studies are essential to confirm these results and better define the clinical role of ReCell® in burn care.

Future research points

To strengthen the current evidence base and optimize the clinical use of ReCell®, future studies should aim to:

1) Conduct large-scale, multicenter randomized controlled trials with homogeneous populations to validate the findings of this meta-analysis and reduce heterogeneity.
2) Evaluate long-term outcomes, including quality of life, functional recovery, scarring, and cost-effectiveness, following ReCell® and split-thickness skin graft (STSG) treatments.
3) Compare ReCell® with other advanced therapies such as cultured epidermal autografts, synthetic dermal substitutes, and bioengineered skin products in terms of efficacy, safety, and resource utilization.
4) Determine the optimal clinical indications for ReCell®, including its role in partial- vs. full-thickness burns and its application across different anatomical regions.
5) Develop evidence-based clinical guidelines for standardized application of ReCell® in burn care, including patient selection, procedural protocols, and postoperative management.
6) Investigate its role in contracture prevention, especially in high-risk anatomical areas and pediatric patients.
7) Explore synergistic effects with adjunctive therapies, including hyperbaric oxygen therapy, negative pressure wound therapy, and antimicrobial dressings.
8) Encourage innovation in ReCell® technology, including device miniaturization, automation of processing steps, and cost-reduction strategies.
9) Assess ReCell® in other clinical contexts, such as chronic wounds, pressure ulcers, diabetic foot ulcers, and pigmentary disorders.

Overall, there is a clear need for rigorous, independently conducted research to define the long-term clinical value, cost-effectiveness, and optimal use of ReCell® in both acute burns and broader wound care applications.

CONCLUSION

This meta-analysis found no statistically significant differences between ReCell® combined with meshed split-thickness skin grafts (mSTSG) and conventional autologous skin grafting in terms of pain reduction, wound healing time, or infection rates in patients with acute burn injuries. However, these findings should be interpreted with caution due to the limited number of included studies, substantial heterogeneity, and methodological concerns - such as high risk of bias, inclusion of non-randomized trials, and potential conflicts of interest, particularly in studies involving authors affiliated with the device manufacturer. Additionally, the predominance of adult patient populations limits the generalizability of results to pediatric cohorts. Given the overall low certainty of evidence, further high-quality, independently conducted randomized controlled trials are essential to determine whether ReCell® offers clinically meaningful advantages over standard treatment in the management of acute burns.

Authors' contribution

Rafael Dib Possiedi – Conceptualization, Formal analysis, Investigation, Methodology, Writing – Original draft preparation, Writing – Review & Editing

Bruce Charles Friedman – Conceptualization, Formal analysis, Methodology, Project Administration, Writing – Original draft preparation, Writing – Review & Editing

Francesco Mazzarone – Conceptualization, Methodology, Project Administration, Writing – Review & Editing

Marcelo A F Ribeiro Jr – Conceptualization, Investigation, Writing – Original draft preparation, Writing – Review & Editing

Lee Seng Khoo – Conceptualization, Writing – Original draft preparation, Writing – Review & Editing

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