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Review Article

Topical steroids in burn patients: A systematic review of the literature and a descriptive analysis of topical KENACOMB use at a major tertiary burn centre ☆

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ABSTRACT

Background: Topical steroids are used widely to manage excessive inflammation and hypergranulation in burns; however, their use is controversial, and current evidence is largely anecdotal. Topical KENACOMB is a steroid preparation consisting of triamcinolone acetonide, neomycin, gramicidin, and nystatin, and it is standard of care at the Royal Brisbane and Women's Hospital burns unit. To our knowledge, there is no published literature that reports the use of KENACOMB to treat wound-associated inflammation and hypergranulation.

Objective: To synthesise current evidence surrounding the efficacy and safety of topical steroid use in treating inflammation and hypergranulation in burns patients. We also describe the use of topical KENACOMB in our burns unit.

Methods: A systematic review of PubMed, Cochrane, and EMBASE databases was performed. Articles published in English that reported the use of topical steroids for granulation tissue or inflammation in burn wounds or skin graft donor sites were included.

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Results: We identified 350 articles, of which six met inclusion criteria. Four studies presented primary patient data, and two studies reported the results of surveys of burns unit professionals. A total of 54 patients were included across all studies, and no control group was reported in any study. Studies reported rapid improvements in healing, with 86.6%–100% of wounds showing complete reepithelialisation following treatment. Reported adverse outcomes included skin thinning, atrophy of granulation tissue, systemic side effects, and local wound infection.

Conclusions: This review highlights the paucity of conclusive evidence on the outcomes of topical steroids in treating inflammation and hypergranulation in burns and donor sites. While KENACOMB has shown efficacy in treating these wound types in our local experience, there is limited research available on the product. There is a clear need for quality research on the use of topical steroids in burns patients to better inform its ongoing clinical use.

Introduction

Hypergranulation and excessive inflammation in burns delay and impair healing and are implicated in the development of hypertrophic scarring and contractures.[1,2] While improvements in acute burn management have reduced overall mortality,[3] maintaining a wound environment for optimal healing remains a major clinical challenge. Excessive inflammation is a subjective phenomenon that presents as redness, hyperaemia, and increased pain levels, and is a common manifestation in burn wounds and skin graft donor sites. Prolonged and excessive inflammation contributes to hypergranulation by stimulating the overgrowth of granulation tissue above the surface of the wound, which impedes keratinocyte migration during reepithelialisation, ultimately delaying healing.[4] A wide range of therapeutic strategies are employed across burns units to improve healing outcomes with varying levels of success.[5] Due to their anti-inflammatory properties, topical steroids are widely used in inflamed and hypergranulated burn wounds.[6,7] However, despite anecdotal evidence supporting their application in treating these wound types, its use remains controversial due to concerns that steroids may interfere with the progression of healing[8] and increase vulnerability to infection.[9]

The topical application of KENACOMB ointment for the treatment of wound-associated hypergranulation and inflammation is standard of care at the Professor Stuart Pegg Adult Burns Centre at the Royal Brisbane and Women's Hospital, Australia. KENACOMB ointment is a steroid preparation consisting of a combination of triamcinolone acetonide (1 mg/g), neomycin (2.5 mg/g), gramicidin (0.25 mg/g), and nystatin (100,000 units/g). KENACOMB ointment is used to treat inflammation, pruritis, and infection associated with otitis externa, but it is regularly used off-label for inflammatory dermatoses. Prior to the introduction of KENACOMB to our unit, hypergranulation was traditionally treated with either topical silver nitrate ablation or surgical excision. To our knowledge, there is no literature that reports the use of KENACOMB ointment to treat wound-associated inflammation and hypergranulation.

This paper aims to explore current evidence surrounding the efficacy and safety of topical steroids as a treatment in burn patients. To that end, we performed a systematic search of the available literature describing the use and outcomes associated with topical steroids (including KENACOMB) in treating inflammation and hypergranulation in burn wounds and skin graft donor sites. We also describe the indications and clinical management of wounds treated with topical KENACOMB in our burns unit.

Methods

Search Methods

This systematic review was undertaken in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines.[10] A systematic search of Cochrane, EMBASE, and PubMed databases was conducted up to 13 July 2020 using the following keywords: burn, scald, skin graft, donor site, partial-thickness, topical, steroid, KENACOMB, corticosteroid, triamcinolone, betamethasone, hydrocortisone, cortisone, wound healing, granulation, hypergranulation, over granulation, proud flesh, reepithelialisation, and hyperinflammation (Appendix 1). A research librarian was consulted to advise on search term strategy and database suitability prior to searching. No search limits were applied, and no publication date restrictions were applied. The search was supplemented by a manual search of reference lists of included articles for relevant studies.

Eligibility criteria

Articles in English reporting outcomes of the use of topical steroids as a treatment for burn wounds or skin graft donor sites in patients of any age were deemed eligible for inclusion in this review. All study designs that included primary data were accepted for review, and due to the limited number of studies identified, conference abstracts were included, although we did not have access to the full presentations. Non-original studies, such as literature reviews, clinical guidelines, and letters to the editor, were not included. Studies reporting patients with ocular, oesophageal, tracheal, or other mucosal burns were excluded. Studies based on animal models were also excluded. This review was limited to studies that describe the use of topical steroids alone, or in combination with topical antibiotics; however, any type of topical steroid preparation was considered for inclusion. Primary outcomes of interest were treatment outcomes in terms of wound healing, inflammation, hypergranulation, and adverse effects (including wound infection). Secondary outcomes included wound types and sizes treated, as well as steroid preparations used. Results reported in any form, including clinical descriptions, were sought for outcomes of interest.

Data extraction and management

One reviewer screened articles by study title, abstract, and full text and assessed articles for eligibility against predetermined inclusion criteria. A second reviewer confirmed the selected studies met inclusion criteria. Data extraction was performed for all eligible articles, including study characteristics (author, year of publication, country, study type, and study aim), patient characteristics (number of participants, gender, age, wound type, total body surface area (TBSA)), treatment, outcomes, and adverse effects. The findings are summarised by study in Table 1 and described below.

Data Analysis

Due to considerable heterogeneity between the included studies in terms of study design, methods, and outcomes measurements, no detailed data synthesis or assessment of risk of bias was undertaken. Instead, the key findings from each study were summarised. For each study, the effect of topical steroids was classified as beneficial (complete epithelialisation) or not beneficial (wound required further intervention for healing). Similarly, we used binary classification to investigate whether topical steroids caused adverse outcomes, such as wound infection, and applied simple vote-counting methods to synthesise the data. Potential limitations to the interpretability of the findings of this review are highlighted in the discussion below.

Table 1
Characteristics of included studies and results summary

Author	Year	Country	Study type	Study aim	N (gender)	Age	Wound type	TBSA (%)	Treatment	Outcomes	Adverse outcomes
Brown et al.	2018	USA	Retrospe-ctive chart review (*Abstract*)	To present a case series in which HG/US was successfully treated with topical corticosteroids.	n=7 (NR)	21y-89y	STSG (n=2), burn (n=1), unstable scar (n=2), DS (n=2)	5 - 57%	Clobetasol propionate cream 0.05%	Rapid improvements (7/7)	None
Jaeger et al.	2016	Israel	Case series	To present the use of topical hydrocortisone in the treatment of hypergranulation tissue formation resulting from burn wounds.	n=5 (4M, 1F)	3y-41y	Deep dermal/full-thickness burns	22-70	Hydrocor-tisone acetate 0.25%	Regression of hypergranulation and complete healing (5/5)	None
Saleem et al.	2017	Pakistan	Case series	To evaluate the role of short-term application of topical steroids in wound healing by suppression of over granulation, prevention of excessive inflammation, and thus promotion of quick epithelialisation and healing.	n=30 (NR)	NR	Trauma, burns, and skin grafts	NR	Steroid (not specified) with gentamycin cream	70% complete healing in 2 weeks, 16.6% complete healing in 4 weeks, and 6.6% required debridement and grafting	7.5% developed thin skin after prolonged application, 16.6% developed atrophy of granulation tissue
Shalom et al.	2003	Israel	Pre-post (*Abstract*)	To investigate the effect of a topical steroid on healing by clinical observation and histological examination	n=12 (NR)	14m-92y	Burns and plastic surgery patients	NR	Hydrocor-tisone 1%	Resolution of hypertrophic granulation and complete epithelialisation within 2-4 weeks in all patients. Marked reduction in acute inflammatory cells and shift in population towards chronic inflammatory cell population	NR

(*continued on next page*)

Table 1 (*continued*)

Author	Year	Country	Study type	Study aim	N (gender)	Age	Wound type	TBSA (%)	Treatment	Outcomes	Adverse outcomes
Shoham et al.	2019	Israel/USA	Survey (*Abstract*)	To explore the use of topical steroid for suppression of hypergranulation tissue in burns amongst members of the ABA and compare it to that of the EBA.	n=84 (52 physicians, 23 nurses, and 9 others)	N/A	Burns	70% treated 1-10% TBSA; 15% treated up to 11-20% TBSA; 15% treated >20% TBSA	Topical steroids (not specified)	60% inexperienced in use of topical steroids for suppressing granulation tissue in burns Major reason was that they were unfamiliar with treatment option. 97% of those experienced found use safe and effective	67% witnessed possible systemic side effects
Shoham et al.	2018	Israel/USA	Survey (*Abstract*)	To explore trends in the use of topical corticosteroids for suppression of granulation tissue amongst burn care professionals.	n=82 (61 physicians, 21 non-physicians)	N/A	Burns	NR	Topical steroids (not specified)	77% experience the use of topical steroids for suppression of granulation tissue in burns. Of those experienced, all found it safe and effective	11 % witnessed infection in <10% of patients 1 respondent witnessed possible systemic side effects

Abbreviations: DS = Donor site; HG/US = Hypergranulation tissue/unstable scar; NR = Not reported; STSG = Split-thickness skin graft

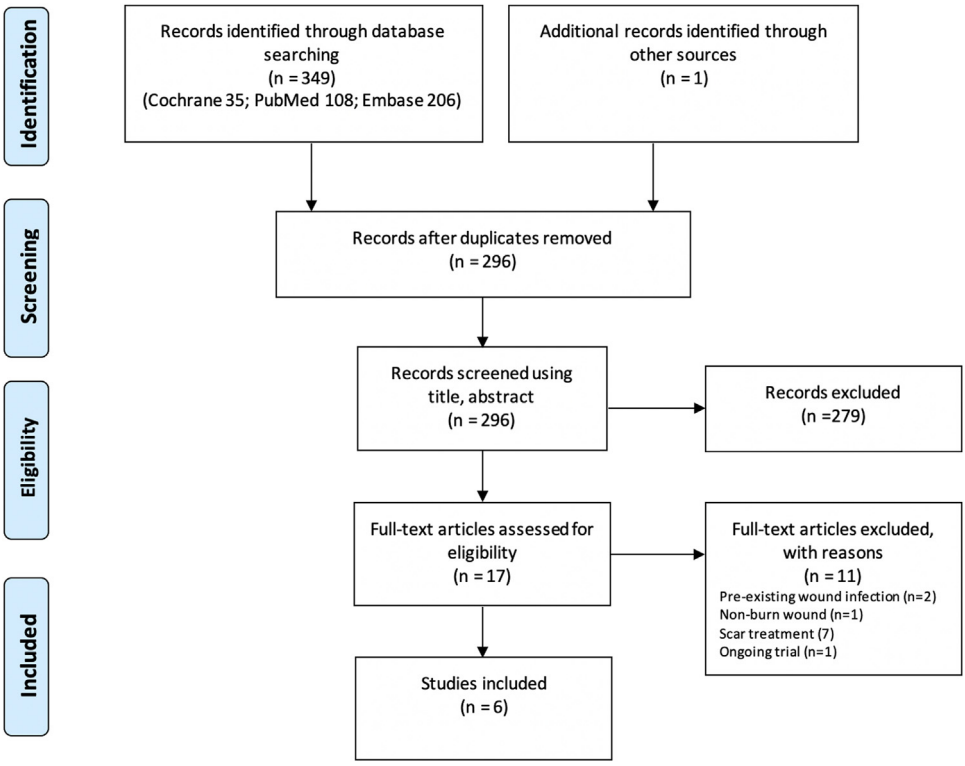

Figure 1. PRISMA flow diagram showing the study selection process

Results

Study characteristics

The results of the systematic search are shown in Figure 1. The primary search yielded 350 articles, which were screened by title and abstract, then full text. Six articles met the inclusion criteria for review (Table 1). The publication years ranged from 2003 to 2019, comprising two case series,[11,12] one retrospective chart review,[13] one pre-post study,[14] and two surveys of burns unit professionals.[6,7] Patient age ranged from 14 months to 92 years with a total of 54 patients across all studies. One ongoing clinical trial comparing topical steroids to traditional dressings for non-healing wounds in burn patients was identified.[15]

Study outcomes

Wounds treated with topical steroids included burns, split-thickness skin grafts, skin graft donor sites, and unstable scars. Of the studies that reported burn wound characteristics, the range of severity was wide, with the percentage of TBSA treated between 5–70%. There was significant heterogeneity in the treatment regimens across studies, with described topical steroids including clobetasol propionate (0.05%),[13] hydrocortisone acetate (0.25%),[11] hydrocortisone (1%),[14] and one study reporting the use of a topical steroid and gentamycin preparation,[12] not otherwise specified. Steroids were applied every 12 hours,[11,14] daily,[12] or second daily[13] either through soaked gauze dressings[11] or directly on the skin.[12,13]

The reported outcomes across all studies were binary assessments of treatment efficacy, such as rates of complete epithelialisation,[11,12,14] reduction of granulation tissue,[11,14] or requirement for further surgical intervention.[12] Quantitative assessment of treatment effect size was measured in one study,[14] although these results were not reported in the conference abstract, and we did not have access to the full presentation. Three studies reported complete epithelialisation following treatment in 86.6%–100% of patients,[11,12,14] and one study reported rapid improvements in wound healing[13] with epithelialisation occurring within 2 to 4 weeks.[12,14] Only one clinical study reported adverse outcomes, including skin thinning in 7.5% of patients and atrophy of granulation tissue in 16.6% of patients.[12] Notably, each of these clinical studies reported no incidence of wound infection following tropical steroid treatment.

Two articles surveyed members of the American and European Burns Associations, finding that 60%[6] and 77%[7] had experience in using topical steroids for suppressing granulation tissue, respectively. Of those experienced, 97–100% found topical steroids safe and effective, although 67% of American and 1.2% of European members had witnessed possible side effects, and 11% of European professionals witnessed wound infection in $<$10% of patients. Of those inexperienced in using topical steroids to suppress granulation tissue, the major reason was unfamiliarity with the treatment option.

Discussion

Wound healing in burns follows a similar trajectory to non-burn wounds through a series of overlapping phases: inflammation at the site of injury, epithelial proliferation, and scar remodelling.[16-19] However, healing in deep partial-thickness and full-thickness burns is characterised by a heightened and prolonged inflammatory phase, with the upregulation of pro-inflammatory mediators such as IL-6 and IL-8.[20] Sustained inflammation is considered a major factor in delayed wound healing and contributes to changes in the expression of growth factors and consequent overproduction of granulation tissue.[21] When granulation tissue extends above the surface of the wound, peripheral keratinocyte migration and reepithelialisation are impeded, ultimately delaying wound healing. This not only increases the window of time in which wounds are susceptible to microbial colonisation and infection, but there is also a clear correlation between time to reepithelialisation and the risk of subsequent hypertrophic scarring.[22] Therefore, identifying therapies with the capacity to effectively suppress inflammation and accelerate healing is an important focus of burns research.

As potent anti-inflammatory agents, topical steroids are a logical approach to treating wounds displaying excessive inflammation and granulation tissue. The use of topical steroids for hypergranulation has been reported in the non-burn literature to reduce granulation tissue, decrease pain, and accelerate reepithelialisation.[2,23,24] Concordantly, this review found some evidence that steroids are successfully used to treat inflammation and hypergranulation in burns, with all studies reporting improvements in timely reepithelialisation and regression of granulation tissue. On the other hand, topical steroids are historically equated with a reduction in the body's capability to heal wounds. Administration of high doses of corticosteroids in the early stages of wound healing is shown to attenuate the inflammatory response and delay proliferation of fibroblasts and capillaries, collagen deposition, wound contraction, and epithelial migration.[8,25] Moreover, a persistent concern is the potential for an increased incidence of localised wound infection due to the immunosuppressant effects of steroids, as well as the risk of systemic adverse effects particularly when administered in large doses. Consequently, some clinicians remain reluctant to use topical steroids to treat burns, which typically cover large surface areas of the body.[24,26]

This systematic review aimed to identify and synthesise evidence evaluating the effects of topical steroids on inflamed and hypergranulated burn wounds and skin graft donor sites. Overall, the included studies provide some evidence that topical steroids may be advantageous in these wound types, with six out of six studies describing the intervention as beneficial. On the other hand, three of the six studies reported adverse effects associated with the treatment. Additionally, the reported incidence of wound infection was specifically described in one non-clinical study. It is important to note, however, that the interpretability of these findings is significantly reduced by the absence of rigorously designed clinical trials. In our search, we did not identify published results from any randomised-controlled studies, and no study included a control arm for comparison. Given the widespread util-

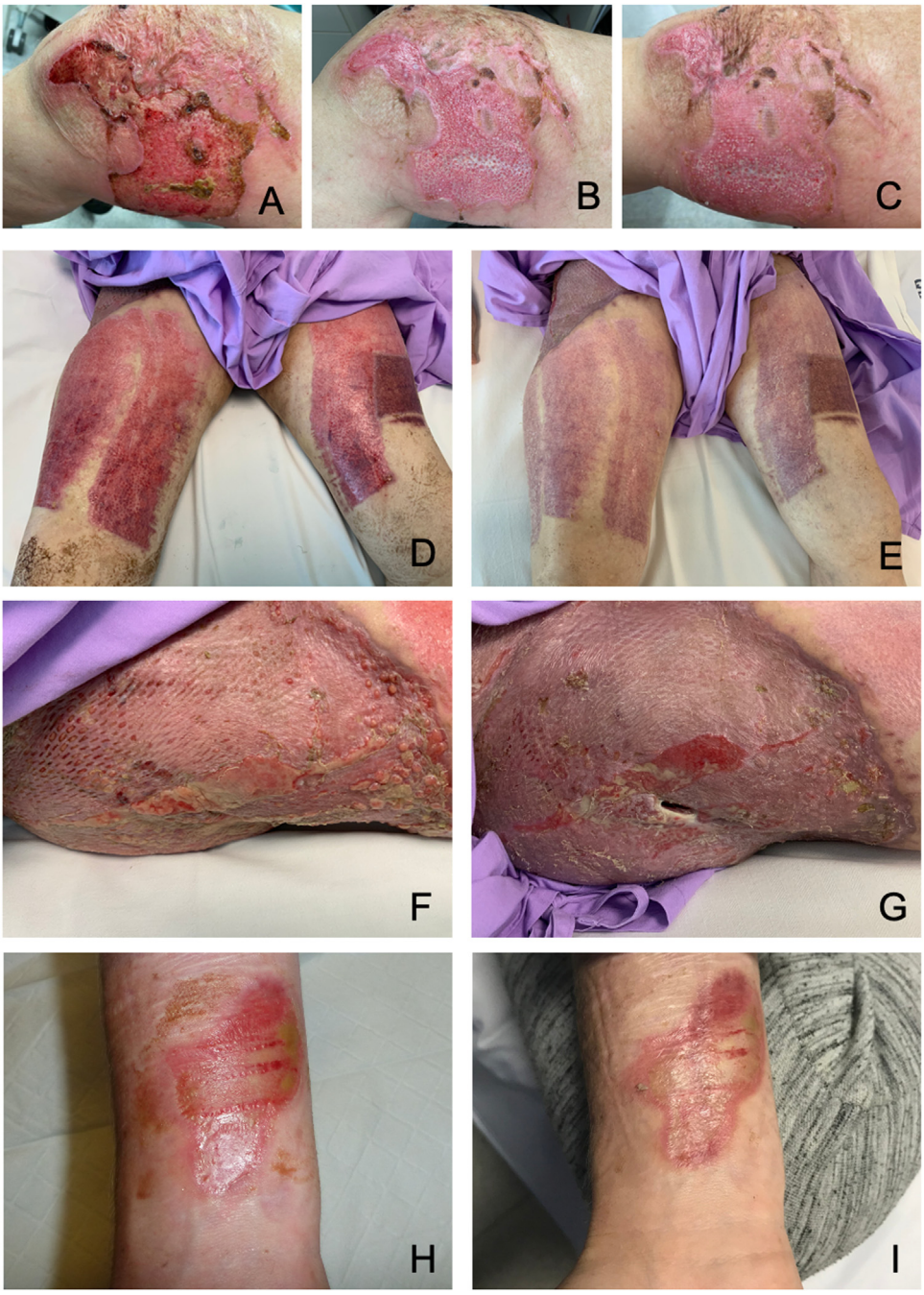

Figure 2. Indications for topical KENACOMB application. **(A)** Inflamed neglected partial-thickness scald burn from hot water. Pictured 7 days post-burn prior to treatment with KENACOMB, **(B)** after 3 days, and **(C)** after 5 days of topical KENACOMB application; **(D)** inflamed split-thickness skin graft donor site closed with cultured epithelial autograft. Pictured 10 days post-harvest and **(E)** after 5 days of treatment with topical KENACOMB; **(F)** hypergranulating full-thickness wound initially treated with Novosorb Biodegradable Temporising Matrix. Pictured day 10 post-grafting with 2:1 mesh autograft split-thickness skin graft and **(G)** after 5 days of daily application of topical KENACOMB; **(H)** infected flame burn pictured 4 days post-burn and **(I)** 3 days after treatment with topical KENACOMB and oral antibiotics.

Table 2
Clinical indications and management of wounds treated with topical KENACOMB ointment

Indication	Initial dressing	Management
Inflamed partial-thickness burns that are treated conservatively with dressings and expected to heal spontaneously.	Thin layer of KENACOMB followed by a single or double layer of paraffin-based gauze dressing.	Dressing is changed daily or second daily
Inflamed skin graft donor sites that are still in the healing phase or inflamed donor sites that have just healed. Topical KENACOMB may be commenced at the first donor site dressing change if the donor site appears inflamed.	The choice of donor dressings is varied but, in our unit, this typically comprises of either one of the following:	
	i. Alginate sheet directly on the donor site, followed by silver-impregnated dressing, absorbent outer layer, and tape/bandage	Dressing is changed between days 3 and 5, depending on individual patient needs. After the initial dressing change, a paraffin-based gauze dressing is typically used and changed every two days until reepithelialisation occurs
	ii. SUPRATHEL/BACTIGRAS or SUPRATHEL/MEPITEL followed by an absorbent outer dressing, bandaging, or tape.	This dressing is left alone until reepithelialisation occurs. Sometimes, SUPRATHEL is removed earlier due to non-adherence, bleeding, or pain. In these cases, it is replaced by paraffin-based gauze dressings, and changed every two days.
	iii. SILVERCELL, followed by an absorbent outer dressing, bandaging or tape.	This dressing is left alone until reepithelialisation occurs. Sometimes, SILVERCELL is removed earlier due to non-adherence, bleeding, or pain. In these cases, it is replaced by paraffin-based gauze dressings, and changed every two days.
Granulation tissue and hypergranulation in chronic wounds, interstices of meshed split-thickness skin grafts, and full-thickness burn wounds.	Paraffin-based gauze dressing, absorbent outer layer followed by bandaging or taping.	Granulation tissue is sometimes removed surgically or when dressings are done, treated topically with KENACOMB. Typically, the granulation tissue is treated with topical KENACOMB either daily or second daily
Heavily colonised or infected wounds.	Single or double layer of paraffin-based gauze followed by outer absorbent dressings.	Dressing is changed once per day and wounds are cleaned at each dressing change with aqueous chlorhexidine.

Note: in all uses, KENACOMB is not typically used for greater than 7 days at a time due to theoretical slowing of wound healing/reepithelialisation.

isation of topical steroids in burns units, in addition to persistent concerns regarding the side effect profile of steroids, it is significant that we were unable to identify any randomised-controlled trials evaluating the beneficence or safety of this treatment.

Limitations

The findings of this review provide low-quality evidence resulting from (i) the uncontrolled, single-arm designs of the identified studies; (ii) imprecision of results due to reporting of subjective outcome measures; and (iii) unclear reporting of methods and outcomes across the studies. This is in part due to the inclusion of abstracts where the full text or conference presentation was not available. Given that there is no objective characterisation for excessive inflammation and hypergranulation in burns, there is likely variation in how this is defined and assessed within and across burn centres. Similarly, subjective assessments of the outcomes associated with topical steroids in these wound types may also contribute to disparities in conclusions about treatment effectiveness. The small sample size of the combined body of literature significantly limits the ability of this review to account for heterogeneity across studies in terms of patient selection, treatment regimen, and outcome measurements. Therefore, our ability to synthesise the data and draw valid conclusions in this setting is limited.

Topical KENACOMB ointment

At the Professor Stuart Pegg Adult Burn Centre at the Royal Brisbane and Women's Hospital, Queensland, Australia, we routinely use topical KENACOMB for inflamed burn wounds. The rationale underlying this treatment choice is to address the theoretical increased susceptibility to localised infection associated with steroid application with the addition of topical antimicrobials. It is also hypothesised to treat bacterial or fungal colonisation and biofilms that may be present within burn eschar[27] to further accelerate healing. Typical indications are described in Table 2 and include inflamed partial-thickness burns (Figure 2A-C), inflamed donor sites (Figure 2D-E), granulation and hypergranulation tissue (Figure 2F-G), and heavily colonised or infected wounds (Figure 2H-I).

In partial-thickness burns, excessive inflammation may develop 5–7 days after the initial injury and is present until, or sometimes beyond, the point of reepithelialisation. Donor sites may also be prone to excessive inflammation, presenting as redness or hyperaemia in the healing phases or just after healing. Chronic wounds, interstices of meshed split-thickness skin grafts, and full-thickness burns tend to form granulation tissue as they heal. In wounds which develop hypergranulation, the granulation tissue is typically treated with topical KENACOMB as described in Table 2. If the patient is brought to the operating room with granulation tissue, this is removed by blunt or sharp excision. Given the potential side effect profile of topical steroids and their association with skin atrophy after prolonged use,[9] KENACOMB is not typically applied for greater than seven days.

Conclusion

This review demonstrates that topical steroids are used widely across burns units, despite the limited and low-level evidence surrounding their efficacy and safety. While the overall results of this study suggest that topical steroids are beneficial in improving healing in inflamed burn wounds and hypergranulation tissue, reported adverse outcomes were not absent. In our local experience, we observe a subjective improvement in skin and wound inflammation and a reduction in the volume of granulation tissue present on wound surfaces following topical KENACOMB application. However, we found no strong evidence that topical steroids significantly increase the incidence of local wound infection, and so treating these wounds with a topical steroid and antimicrobial combination, such as in KENACOMB ointment, may not be routinely necessary, and a direct comparison of KENACOMB ointment and topical steroids alone is warranted. This review highlights the paucity of evidence currently available on this topic and underlines the need for further investigation to assess the outcomes of topical steroid use in burn patients and evaluate its safety for ongoing clinical use.

Declaration of Competing Interest

The authors declare that they have no competing interests.

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Ethical Approval

Not required

Author's contributions

M.D. literature review, quality assessment, data extraction, and manuscript draft.
C.L. literature review, manuscript revision, and supervision.

Supplementary materials

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