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REVIEW

Emerging Treatments and the Clinical Trial Landscape for Hidradenitis Suppurativa—Part II: Procedural and Wound Care Therapies

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ABSTRACT

Procedural treatments are a cornerstone of hidradenitis suppurativa (HS) management. New interventional therapies are being studied as part of the upsurge in HS research and clinical trials. Additionally, draining wounds can impart a significant negative impact on patients' quality of life, requiring daily dressing changes. However, standardized guidelines on how to best manage HS wounds both day-to-day and post-procedure are lacking. In part II of this emerging therapies review, procedural treatments and wound care dressings and devices that are being investigated for HS management are discussed.

Keywords: Clinical trials; Dressings; Hidradenitis suppurativa; Procedures; Wound care

Key Summary Points

Hidradenitis suppurativa (HS) often requires procedural management.

Patients may need extensive wound care for draining lesions or post procedures, and guidelines regarding optimal wound care practices in HS are lacking.

Multiple procedural and interventional techniques including lasers, radiation-based therapies, botulinum toxin, fecal microbiota transplant, and sclerotherapy are under investigation for their utility in HS management.

Wound care dressings and devices are also being studied, including an antibiofilm surfactant wound gel, bioelectric dressing, ovine forestomach matrix dressing, and wet-to-dry dressings.

Optimizing procedural management and wound care for HS patients can help mitigate HS symptoms, such as drainage, leading to improved quality of life.

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INTRODUCTION

Hidradenitis suppurativa (HS) may cause draining nodules and sinus tracts, which can drastically impact patients' quality of life. Procedural treatments, including deroofing and excisions, are a cornerstone of HS management, as patients are often recalcitrant to available medical therapies. HS tunnels require procedural interventions for clearance. In addition, the presence of epithelialized tunnels is a source of inflammation and biofilm and is associated with decreased response to medical therapy with adalimumab [1]. Recent or ongoing clinical trials have studied or are studying procedural therapies such as various laser therapies, radiation-based therapies, and botulinum toxin injections, among others. Interventional treatments often require post-procedural wound care, sometimes for weeks at a time. Patients may also require wound care dressings as part of their daily lives to manage drainage from HS lesions. In both of these settings, there is currently a lack of guidelines regarding optimal wound care strategies or dressings [2, 3]. In this review, we describe the multiple different procedural and wound care modalities that were recently or are currently under investigation for use in HS.

METHODS

For this narrative review, the term "hidradenitis suppurativa" was searched on www.clinicaltrials.gov on 8 January 2023. Emerging treatments associated with ongoing or recently completed trials within the last 5 years were included; studies that were withdrawn or of unknown status were excluded. Other relevant articles were identified based on a search of each included treatment's name and "hidradenitis" as keywords on the PubMed database or through review of reference lists of included articles.

This article is based on previously conducted studies and does not contain any new studies with human participants or animals.

RESULTS

Procedural Therapies

Multiple types of interventional therapies and wound care techniques are under investigation for their use in HS (Table 1).

Lasers are used for multiple purposes in HS management. These include treating active HS lesions through tissue destruction followed by healing by secondary intention, destruction of hair follicles in HS-prone areas, thereby preventing follicular occlusion and rupture, and also remodeling scars.

Diode Laser

The 1470 nm (nm) diode laser with intralesional fiber is a solid medium laser that targets water and deoxyhemoglobin and uses a fiber to deliver the light in a targeted, minimally invasive manner that improves penetration. It has been studied in the treatment of keloids, hemorrhoids, and perianal fistulae [4–6]. A prospective cohort study will study this procedure in 20 HS patients with at least two fistulae, with one fistula randomized to undergo the experimental treatment and the other to serve as an untreated control (ClinicalTrials.gov identifier: NCT04508374).

Alexandrite Laser

The 755 nm Alexandrite laser is a solid-medium laser which targets melanin. A nonrandomized controlled prospective study treated 20 women with the Alexandrite laser 5 times every 6 weeks. [7] At 30 weeks, 70% of patients treated with the Alexandrite laser achieved hidradenitis suppurativa clinical response (HiSCR), compared to 20% of the control group, which was a statistically significant difference. No adverse events were reported. In a retrospective study of 14 patients treated with long-pulsed Alexandrite laser, 64% achieved HiSCR at 1 month after a median of four sessions [8]. Three patients experienced a flare after the first or second treatment. Case reports have also reported the successful use of the Alexandrite laser for the treatment of HS in three patients [9–13]. The patients experienced remission for

8–12 months after two to six treatments. In an open-label trial, 30 patients with bilateral HS involvement will undergo treatment with the Alexandrite laser to one side, with the other side left untreated as a control (ClinicalTrials.gov identifier: NCT03054155). These patients will undergo four monthly treatments.

Nd:YAG Laser

The long-pulsed 1064 nm neodymium:yttrium aluminum garnet (Nd:YAG) laser is a solid-medium laser which targets melanin and hemoglobin. Histopathologic examination of HS tissue after treatment with the long-pulsed Nd:YAG laser showed an acute neutrophilic infiltrate, followed by later granulomatous inflammation surrounding hair shaft remnants, indicating that this laser may be effective in HS through destruction of terminal hair follicles [14]. Patients who responded more readily to long-pulsed Nd:YAG treatment also had fibrosis and minimal inflammation at month 2 after two sessions, compared to persistent inflammation in patients who did not show clinical improvement [15].

This laser has been studied in two split-side randomized controlled trials (RCTs) comprising 19 and 22 patients, respectively, which revealed a 31.6% average improvement after 2 months of treatment in one study and an average improvement of 72.7% after four treatments, compared to 22.9% on the untreated side in the other study [14, 15]. No adverse events other than pain with treatment were reported. A series of 27 patients with Hurley stage I disease underwent at least three treatments with the long-pulsed 1064-nm Nd:YAG laser for the purpose of laser hair reduction [16]. These patients reported a statistically significant decrease in the number of monthly flares, with the majority of patients reporting decrease in hair growth by 51–75%. One case report of refractory disease has been described. A 21-year-old woman experienced partial response to nine treatments of Nd:YAG laser and was later treated with carbon dioxide (CO_2) laser excision, resulting in disease improvement [17]. She developed residual ulceration and scar contracture but had no recurrences over 16 months.

The long-pulsed 1064 nm Nd:YAG laser is also being studied for its efficacy in combination with surgical techniques. Six participants with Hurley stage II HS will participate in a single-group study where they will undergo long-pulsed Nd:YAG treatment to a randomly selected axilla, followed by deroofing of all nodules and sinus tracts in that axilla, then monthly Nd:YAG treatments (ClinicalTrials.gov identifier: NCT05484674). The untreated axilla will serve as a control. This study is not yet recruiting.

Er:YAG Laser

Fractional 2940 nm erbium:yttrium aluminum garnet (Er:YAG) is a solid-medium laser that targets water. An open-label trial will assess efficacy and tolerability of the Er:YAG laser for axillary scarring due to HS in 19 participants (ClinicalTrials.gov identifier: NCT05470322). Participants will receive three monthly treatments and will be pre-treated with topical tretinoin, hydroquinone and hydrocortisone for 1 month prior to treatment initiation. There will also be a control group who will receive only topical treatment.

CO_2 Laser

The CO_2 laser is a gas-medium laser with a wavelength of 10,600 nm that targets water. The ablative CO_2 laser can be used to excise large areas of HS involvement, similar to a wide local excision, or may be used locally, such as for deroofing.

The prospective Nordic Registry for HS (HISREG) included 156 patients treated with unspecified CO_2 laser procedures. Statistically significant improvements in Sartorius, Dermatology Life Quality Index (DLQI), and numerical rating scale (NRS) severity scores compared to baseline were observed [18]. Additionally, multiple reports of patients treated with CO_2 laser have been described. A 2016 systematic review identified ten reports covering 212 patients, with an additional series contributing three additional patients [9, 19]. Patients were treated with CO_2 excision or deroofing/marsupialization, with the exception of one patient who was treated with fractional CO_2 laser [20].

Table 1 Emerging procedural therapies for hidradenitis suppurativa

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	Patients enrolled	(Anticipated) completion date	Results or recruitment status
Laser therapies						
Intralesional diode laser (1470 nm)	NCT04508374	Randomized, contralaterally-controlled, within-person design	Evaluate the efficacy and safety of laser fiber treatments for HS fistulas Endpoint: change in VAS pain scores for each individual HS tunnel	20	September 2025	Recruiting
Alexandrite laser (755 nm)	NCT03054155	Open label, contralaterally-controlled, within-person design trial	Patients with bilateral HS in the axilla, groin, and/or inframammary area will be treated with laser on one side and compared to untreated contralateral side Endpoint: HS-LASI every month for 4 months and then after 2 months (6 months total)	30	October 2022	Active, not recruiting
Deroofing and long-pulsed Nd:YAG laser (1064 nm)	NCT05484674	Open label, contralaterally-controlled, within-person design trial	Determine if the use of serial Nd:YAG laser treatments after deroofing of nodules and sinus tracts can improve HS outcomes compared to untreated contralateral axilla Endpoints: HiSCR, IHS4, and clinical exam after 12 months	6	December 2023	Not yet recruiting

Table 1 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	Patients enrolled	(Anticipated) completion date	Results or recruitment status
Fractional ablative Er:YAG laser (2490 nm)	NCT05470322	Open label trial	Evaluate the efficacy and tolerability of a Sciton fractionated ablative laser in the treatment of HS scarring (in patients without active HS lesions) Endpoints: GAIS and mSHSS scales at various times from months 0 to 6	19	December 2023	Not yet recruiting
Fractional ablative CO_2 laser (10,600 nm)	NCT05580029	Early phase 1 open label trial	Understand the efficacy of fractional ablative CO_2 laser therapy combined with topical triamcinolone acetonide in mild-moderate HS disease Endpoints: lesion counts, pain/itch levels, scar measurements, physician/patient assessment after every treatment session	10	March 2023	Not yet recruiting

Table 1 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	Patients enrolled	(Anticipated) completion date	Results or recruitment status
Radiation-based therapies						
Low-dose radiotherapy	NCT03040804	Phase I open label trial	Evaluate the safety of low-dose radiotherapy for the treatment of stage II or III HS Endpoint: number of participants who have treatment-related grade ≥ 3 adverse events during treatment or within 3 months of treatment completion, assessed using CTCAE version 4.0 (follow-up for 3–6 months post treatment)	2	December 2020	Terminated due to Covid-19, no adverse events reported in 2 participants
RF-based selective electrothermolysis	NCT05066113	Open label trial	Assess the tolerability, safety, and histometric changes in skin-RF interactions in the axillary skin of participants with HS and healthy volunteers Endpoint: safety and tolerability of skin-RF interactions in axillary skin at 4 months	50	August 2025	Recruiting

Table 1 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	Patients enrolled	(Anticipated) completion date	Results or recruitment status
Other procedural and interventional treatments						
Battlefield acupuncture	NCT04218422	Single-blinded, randomized trial	Evaluate battlefield acupuncture versus sham acupuncture for treatment of pain in HS Endpoint: change in pain NRS score	32	February 2023	Recruiting
Botulinum toxin	Grimstad et al. 2020 [46]	Randomized, triple-blinded trial	Determine if intradermal injection with Botulinum toxin B is an effective treatment for HS Endpoint: improvement in DLQI after 3 months in treatment versus placebo group	20	September 2018	Median DLQI decreased from 17 at baseline to 8 after 3 months in the treatment group compared to a change from 13.5 to 11 in placebo group ($p < 0.05$)
Botulinum toxin	NCT05403710	Observational (patient registry)	Determine if non-specific inhibition of neuropeptide release reduces IL-17-driven skin inflammation, relieves pain, and improves quality of life in HS patients Endpoint: quantification and phenotyping of skin resident dendritic cell, macrophage, and T cell populations in patients before and after treatment (1–2 months after first treatment)	20	July 2025	Recruiting

Table 1 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	Patients enrolled	(Anticipated) completion date	Results or recruitment status
Fecal microbiota transplantation	NCT04924270	Phase 2 randomized, quadruple-blind	Explore efficacy, safety, and patient acceptability of capsule fecal microbiota transplantation in newly diagnosed, untreated patients with chronic inflammatory rheumatic, dermatological, gastrointestinal, and pulmonary diseases Endpoint: change from baseline in physical component score of the 36-Item Short Form Health Survey	20	December 2024	Not yet recruiting
Sclerotherapy	Porter et al. 2022 [56]	Phase 2 open label trial	Analyze the effects of 23.4% hypertonic saline injection in sinus tracts of adults with HS Endpoint: HS Physician Local Improvement Assessment at baseline and after 8 weeks	21	November 2022	Statistically significant improvement in drainage ($p = 0.035$), erythema intensity ($p = 0.008$), and swelling ($p = 0.025$) at week 8 compared to baseline

CO_2 Carbon dioxide, *CTCAE* Common Terminology Criteria for Adverse Events, *DLQI* Dermatology Life Quality Index, *GAIS* Global Aesthetic Improvement Scale, *HiSCR* hidradenitis suppurativa clinical response, *HS* hidradenitis suppurativa, *HS-LASI* hidradenitis suppurativa lesion, area, and severity index, *IHS4* International Hidradenitis Suppurativa Severity Score System, *IL* interleukin; *mSHSS* modified Hidradenitis Suppurativa Score (for scar severity), *Er:YAG* erbium yttrium aluminum garnet, *ND:YAG* neodymium:yttrium aluminum garnet, *nm* nanometer, *NRS* numerical rating scale, *RF* radiofrequency, *VAS* visual analog scale

These reports described mostly favorable outcomes, with recurrence rates ranging from 0% to 29.3% [19–29]. Obesity was a risk factor for recurrence [30]. Adverse effects included contractures and granulation tissue.

Fractional ablative CO_2 laser will be studied in an early phase I trial of ten participants with mild to moderate HS for its use in combination with steroid delivery (ClinicalTrials.gov identifier: NCT05580029). Treatments will consist of laser treatment followed immediately by topical application of triamcinolone acetonide 40 mg/mL to the area. The participants will undergo three to five treatments every 4–6 weeks.

Combination Laser Treatment

The use of CO_2 laser has also been reported in combination with other lasers. In one study, the combination of ablative fractional CO_2 laser and non-ablative fractional Ga–As laser (1540 nm) was used for eight patients who had previously failed topical treatment and at least one systemic treatment [31]. All eight patients reported improvement, with one patient demonstrating complete improvement after six treatments. However, the treatment did not prevent flares. In another study, four female patients were treated with long-pulsed Nd:YAG laser to remove hair, followed by deroofing performed with CO_2 laser 15 days later [32]. No recurrences were reported after at least 8 months. In a third study, the combination of fractional CO_2 laser and long-pulsed Nd:YAG laser was demonstrated to be superior to Nd:YAG laser alone in a prospective randomized split-body study of 20 patients [33]. The active arm comprised fractional CO_2 treatment followed immediately by Nd:YAG, and 55% of patients in the combination arm were recurrence free at 3 months after treatment, compared to 20% of patients in the single laser arm (comparative statistics not reported).

Radiation-Based Therapies

Low-Dose Radiotherapy

Radiotherapy is the utilization of high-energy particles delivered to diseased tissue to induce cell damage [34]. Low-dose radiotherapy is defined as less than 100 millisievert (mSv), where 1 mSv represents the average accumulated radiation dose produced by 1 milliGray (mGy) of radiation [34].

A 2021 systematic review described multiple case series and reports covering 122 patients since 1950 who were treated with radiotherapy in doses ranging from 1 to 24 Gy [34]. These patients had mostly positive results, with many patients achieving remission over the follow-up periods (ranging from 2 months to 6 years, where specified), although patients with chronic generalized disease and groin/perineal disease had poorer response. Few side effects were reported, and those reported were mostly local side effects, such as erythema, scarring, and hyperpigmentation. An additional case published in 2022 was of a 26-year-old woman with stage III HS treated with 7.5 Gy, with reported improvement, though not resolution, at the 3-month follow-up [35]. A phase I trial of low-dose (total of 7.5 Gy delivered in five fractions of 1.5 Gy over 1 week) radiotherapy in patients with stage II or III HS was terminated for safety reasons due to Covid-19 (ClinicalTrials.gov identifier: NCT03040804). Two female patients completed the study but outcome measures were not performed. No adverse events were reported.

The risk of fatal tumor development after a regimen of 6 Gy of radiotherapy for HS has been estimated to range from 3 to 0.3 per 1000, decreasing based on patient age at time of treatment [36]. Interestingly, high-dose radiotherapy for non-related malignancies has been reported to cause HS flares [37].

Radiofrequency-Based Selective Electrothermolysis

Radiofrequency (RF)-based selective electrothermolysis utilizes the electrical properties of the skin to deliver energy via heat through an insulated needle [38]. A prospective split-body study of ten patients demonstrated improvement in the HS-Physician Global Assessment (HS–PGA) score 6 weeks after three biweekly treatments with fractional microneedling RF (FMR) [39]. The use of RF devices for HS has also been described in several case reports, with improvement at 6 months reported for one

patient and remission for 4 months for another patient who was treated with RF epilation applied via acupuncture needles [40, 41].

An open-label trial is currently recruiting 50 participants, including patients with HS and healthy volunteers, to undergo RF-based selective electrothermolysis in axillary skin (ClinicalTrials.gov identifier: NCT05066113). This technique has demonstrated successful treatment of acne with no serious adverse events [42].

Other Procedural and Interventional Treatments

Battlefield Acupuncture

Battlefield acupuncture (BFA) is a type of auricular acupuncture which is used in military and Veterans' Administration healthcare settings, and has also been reported to be effective in relieving different types of pain, including scar pain, surgical pain, and low back pain [43, 44]. However, a systematic review including 692 patients with multiple causes of pain across nine RCTs did not demonstrate statistically significant pain improvement in groups receiving BFA compared to control groups [44]. A single-blinded randomized trial investigating BFA in 32 HS patients is currently recruiting (ClinicalTrials.gov identifier: NCT04218422). The participants will be randomized to receive BFA or sham acupuncture for two weekly treatments.

Botulinum Toxin

Botulinum toxins (BTXs) are produced by strains of the bacteria *Clostridium botulinum* and cause chemodenervation of muscle. Botulinum toxin A (BTA) binds synaptosomal-associated protein 25 (SNAP-25) on the SNARE protein while botulinum toxin B (BTB) binds synaptobrevin to prevent acetylcholine release through the neuromuscular junction. BTX has been proposed to treat HS through the reduction of sweating and its pro-inflammatory effect on skin bacteria or possibly by reducing secretion of sebaceous and apocrine glands, thereby preventing follicular rupture [45]. BTB has a similar effect on sweat glands as BTA, while having a weaker effect on motor neurons, thereby increasing safety when utilized over larger body surface areas, such as in HS [46].

An RCT of BTB injection included 20 patients with Hurley stage I–III who were treated with placebo or a maximum of 4000 units of BTB once, followed, 3 months later, by all participants receiving treatment with BTB [46]. Compared to placebo, the group of patients who received active intervention initially had a significantly improved DLQI score at 3 months. This result was not maintained at 6 months, although median DLQI score was still improved compared to baseline. The group of patients who received BTB after 3 months also had an improved DLQI score at 6 months although the difference was not statistically significant from baseline ($p = 0.07$). No adverse effects were reported.

The use of BTA has been previously detailed in 13 patients across six reports, including one prospective analysis of five patients [47–52]. The five prospectively followed patients failed to improve, with only one patient experiencing a decreased nodule number, and three patients reporting worsening pain scores [51]. The remaining seven patients reported at least moderate improvement, although most patients had waning efficacy between 5 and 10 months and required additional treatments. Patients were treated with 50–250 units per side (across multiple sites, if applicable) for up to five rounds of treatment.

A trial of BTA will test the hypothesis that BTA can reduce interleukin (IL)-17-driven inflammation in HS by recruiting 20 participants who will receive 50 units per axilla (ClinicalTrials.gov identifier: NCT05403710). Punch biopsies obtained 1–2 months after treatment will be compared to punch biopsies taken prior to treatment to evaluate changes in skin inflammation.

Fecal Microbiota Transplant

Fecal microbiota transplant (FMT) involves the transfer of gut microbiota from pre-screened healthy donors to patients via ingestion of capsules containing fecal microbiota precipitate. This process can induce changes in the patient gut microbiota to become more similar to that of the donor [53]. This procedure has

been effective in patients with atopic dermatitis [53] and systemic lupus erythematosus [54], but has not yet been reported in the treatment of HS. A series of 59 patients with HS were found to have altered gut microbiota compared to healthy controls, and FMT has been proposed as a possible therapy for HS [55].

A phase II trial in 200 participants with chronic inflammatory diseases, including 20 patients with HS, will be randomized to receive placebo or FMT once weekly for 4 weeks (ClinicalTrials.gov identifier: NCT04924270).

Sclerotherapy

Sclerotherapy involves injecting a sclerosant into vessels, which causes the denaturation of cell surface proteins and occlusion of the vessel. The use of sclerotherapy to occlude hidradenitis fistula tracts has been reported in one open-label pilot study of 21 patients, as well as two patients in case reports [56, 57]. In the trial, 17 patients who completed the study underwent injection of up to 0.4 mL of 23.4% hypertonic saline every 2 weeks for a maximum of three injections and were assessed 2 weeks later [56]. Over 80% of patients had improvement based on both physician and patient assessments. The TDLQI score significantly improved with increasing number of injections. Adverse events were mild and not felt to be related to treatment, except for an event of draining clotted blood from a fistula site which resolved [56]. One case series described two women with Hurley stage II disease who were treated with two rounds of hypertonic saline sclerosant with subsequent decrease of drainage [57]. One patient demonstrated fistula closure on ultrasound.

General Wound Care Topicals and Dressings

Antibiofilm Surfactant Wound Gel

Hydrogels are water-soluble cross-linked polymers that have significant hydrating properties due to their structure containing multiple hydrophilic chains [58]. They can be used to deliver medications such as antibacterials due to their porous nature and ability to provide prolonged release [58]. This feature in particular may be useful in the treatment of biofilms in HS. An antibiofilm surfactant wound gel (ABWG) containing polyethylene glycol hydrogel, high osmolarity pH buffer system, and benzalkonium chloride degrades biofilm matrix components and is effective in inhibiting biofilm formation [59, 60].

A series of three patients with Hurley stage I and III HS underwent punch incision followed by injection of ABWG into tunnels once daily for 5–7 days [61]. Two of three patients reported subjective increased speed of healing and decreased pain within 5–6 days. The third patient reported no changes. There were no serious adverse events; all patients reported stinging during injections.

An open label single group trial aims to characterize the change in the microbiome and wound healing response of an HS tunneling wound in 15 participants after treatment with ABWG (ClinicalTrials.gov identifier: NCT04648631). This trial has been completed as of February 2023.

Autolytic and Exudate Management Dressings

Multiple specialized dressings have been developed to treat different characteristics of wounds, ranging from degree of exudate to need for debridement and prevention of bacterial superinfection. Several specialized dressings that promote autolysis and exudate management have recently been studied for their use in HS wounds. Cutimed® Sorbact Hydroactive B (ABIGO Medical AB, Askim, Sweden) contains a hydropolymer gel matrix dressing which promotes autolytic debridement. It also contains dialkylcarbamoyl chloride (DACC), a synthetic hydrophobic fatty acid that mimics naturally-occurring fatty acids in spider webs and which binds hydrophobic bacteria, allowing them to be removed from the wound with dressing changes [62]. Cutimed® Siltec (BSN medical Inc., Charlotte, North Carolina, USA) is a superabsorbent silicone foam dressing for highly exudative wounds [63]. Cutimed® Sorbion® Sana Multi-Star (BSN medical Inc.) is a gelling fiber exudate management dressing with a unique shape that is designed to fit areas that are difficult to dress with traditional dressings such as the axilla [64] (Table 2).

Table 2 Emerging wound care treatments and wound dressings/devices for hidradenitis

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	No. of patients enrolled	(Anticipated) completion date	Results or recruitment status
General wound care topicals and dressings						
Antibiofilm surfactant wound gel	NCT04648631	Open label trial	Examine changes in the microbiome of HS tunneling wounds after treatment Endpoint: change in microbiome as measured by quantitative 16S ribosomal DNA PCR for bacterial enumeration from punch biopsy samples at baseline and week 4	15	July 2022	Completed
Wound bed preparation and exudate management dressings (Cutimed Sorbact Hydroactive B, [ABIGO Medical AB, Askim, Sweden], Cutimed Siltec, and Cutimed Sorbion Sana Multi-Star [both BSN medical Inc., Charlotte, North Carolina, USA])	Schneider et al. 2022 [65]	Open label trial	Determine how different wound dressings affect QOL for people with HS Endpoint: DLQI scores at 6 weeks versus baseline	28	March 2021	Decrease of DLQI score from a median of 15.5 at baseline to 12.5 at week 6 ($p = 0.0048$)

Table 2 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	No. of patients enrolled	(Anticipated) completion date	Results or recruitment status
HidraWear AX Dressing (HidraMed Solutions, Galway, Ireland)	Moloney et al. 2022 [3]	Open label trial	Determine ease of use of HidraWear dressings compared to existing product/dressing us as well as improvement on QOL and comfort Endpoint: change in QOL as measured by DLQI at 3 weeks and VAS pain score at day 21 versus day 0	15	October 2020	Significant improvement in dressing-related pain ($p < 0.001$) and DLQI score (19.3–4.5, $p < 0.001$) at week 3
Post-operative wound care						
Biodegradable temporizing matrix (BTM)	NCT05477225	Phase 4 randomized, controlled, comparative study	Compare the efficacy of NovaSorb® BTM (PolyNovo, Port Melbourne, Australia) and human cadaveric allograft Endpoint: mean days to wound coverage with split skin graft after excision of HS between wounds treated with either BTM or the allograft	10	July 2024	Recruiting

Table 2 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	No. of patients enrolled	(Anticipated) completion date	Results or recruitment status
Bioelectric dressing (Procellera™; Vomaris Innovations Inc., Tempe, AZ, USA)	NCT05057429	Randomized contralaterally-controlled, within-person design open-label trial	Determine if a bioelectric dressing is more efficacious for wound healing after de-roofing compared to a standard gauze dressing with petroleum jelly Endpoint: healing rate of post-surgical wounds reported as the area reduction in cm^2/per day up to 8 weeks	12	March 2024	Recruiting
OFM (Endoform™; AROA Biosurgery, Auckland, New Zealand)	NCT04354012	Open label trial	Monitor time and outcome of healing of wounds associated with HS using combination dressing of OFM (Endoform™), Hydrofera Blue (methylene blue and gentian violet), and Hypafix tape Endpoint: wound healing time and percentage of wound healing up to week 8	5	December 2023	Not yet recruiting

Table 2 continued

Treatment(s)	Author or clinical trial no. (ClinicalTrials.gov identifier)	Study type	Study goal and primary endpoint(s)	No. of patients enrolled	(Anticipated) completion date	Results or recruitment status
OFM sheet graft and morelized extracellular matrix (Myriad Matrix™ and Myriad Morcells™) (AROA Biosurgery)	NCT05243966	Phase IV observational patient registry study	Evaluate the safety and clinical outcomes of OFM (Myriad™) in soft tissue reconstruction procedures Endpoint: proportion of patients with TEAEs during 3 years	300	January 2026	Recruiting
Petrolatum with non-stick bandaging	NCT05194969	Randomized, triple-blinded trial	Compare wet-to-dry versus petrolatum and non-stick dressing for second intention healing following HS surgery Endpoints: change in wound QOL survey score, change in pressure ulcer scale for healing score, and change in pain with dressing changes measured at 1, 2, 4, and 6 weeks post-surgery	80	April 2023	Recruiting

BTM Biodegradable temporizing matrix, *OFM* ovine forestomach matrix *QOL* quality of life, *TEAE* treatment emergent adverse events

An open label prospective cohort trial provided 28 participants with all three dressings (hydrogel, silicone foam, gelling fiber) and allowed them to choose which dressings to use on their lesions for 2 weeks, after which time they were allowed to continue using their preferred dressing [65]. Patients experienced a decrease of DLQI score from a median of 15.5 at baseline to 12.5 at week 6 ($p = 0.0048$), as well as improvement in ease of use and dressing satisfaction. However, there was not a significant trend in pain, sleep disturbance, drainage, or odor.

Wound Dressing System

HidraWear AX (HidraMed Solutions, Galway, Ireland) is a wound dressing system that combines multiple underlayer garments with adhesive-free dressings that are held in place by the underlayers. Adhesive dressings or adhesive tape can cause pain and skin injuries, and patients have reported negative impact on their quality of life related to regular dressing changes [3, 66]. HidraWear was studied in 15 female patients with axillary HS in a single arm open label pilot study [3]. After 21 days, patients reported significant improvement in dressing-related pain and DLQI score (decrease from mean of 19.3 to 4.5, $p < 0.001$). They also reported the trial dressing was more comfortable and required less time to change compared to their prior standard dressings.

Post-Operative Wound Care

Various different dressings are under investigation for postoperative HS wound care. In addition, one study seeks to evaluate whether petrolatum with a non-stick dressing for post-op HS care is equal or superior to the commonly utilized wet-to-dry dressing strategy. Other post-operative HS wound care modalities that do not currently have ongoing clinical trials but are potential future modalities to investigate include negative pressure wound therapy and hyperbaric oxygen therapy.

Biodegradable Temporizing Matrix

NovoSorb™ biodegradable temporizing matrix (BTM) made by PolyNovo (Port Melbourne, Australia) consists of two layers, including a synthetic dermal replacement 2-mm-thick polyurethane foam matrix which facilitates growth of the dermis into the wound bed and revascularization [67, 68]. This layer is topped with a non-biodegradable polyurethane seal which functions as an epidermal replacement to prevent water evaporation [68]. The top layer is removed after the foam is integrated into the underlying wound, then split-thickness skin graft (STSG) can be applied on top [68].

An RCT will enroll up to ten subjects to undergo a wide excision followed by application of NovoSorb™ BTM (PolyNovo) or human cadaver allograft to the wound (ClinicalTrials.gov identifier: NCT04648631). Patients will later be autografted with a STSG to evaluate the number of days between initial excision and STSG placement.

Bioelectric Dressing

A bioelectric dressing contains a single-layer polyester matrix of silver and zinc microcell batteries embedded in a binder that produces a direct current when activated by a conductive fluid, such as wound exudate [69]. Physiologic current is altered in wounds, and exogenous electrical stimulation has been shown to increase wound strength and healing rate, as well as reduce scarring [70]. Bioelectric dressings can support the role of physiologic current in wound healing, and can also serve as an antimicrobial through the electric charge of the metal ions. Negatively-charged microbes are attracted to the positive pole of the battery where silver ions denature respiratory proteins. Zinc ions may also contribute to antimicrobial activity through the disruption of cell membranes.

The Procellera™ bioelectric dressing (Vomaris Innovations Inc., Tempe, AZ, USA) has demonstrated antibacterial activity against methicillin-resistant *S. aureus* (MRSA), *Escherichia coli*, *Pseudomonas aeruginosa*, and *Klebsiella pneumoniae*, and bacteriostatic activity against strains of *Enterococcus faecalis* [69]. A randomized trial will study the healing rate in 12 participants who undergo deroofing surgery on both axillae, with one axilla randomized to receive bioelectric dressing with hydrogel for up

to 8 weeks, and the other axilla treated with standard gauze dressing with petroleum jelly (ClinicalTrials.gov identifier: NCT05057429).

Ovine Forestomach Matrix Dressing

Ovine forestomach matrix (OFM) dressing is an extracellular matrix (ECM)-based biomaterial derived from ovine forestomach which acts as a scaffold to be replaced by endogenous ECM during the process of wound healing [71]. Ovine forestomach is useful for its size and thickness with low risk of prion infection [71]. OFM can also stimulate angiogenesis, reduce inflammation, and recruit mesenchymal stem cells, and has been utilized in multiple wound healing applications including HS (see below) [71, 72].

A series of six patients with eight anatomic areas of axillary Stage III HS underwent wide excision with the subsequent use of Myriad Matrix™ OFM (AROA Biosurgery, Auckland, New Zealand) either as a dermal substitute in two participants (three surgical fields) or as part of a fasciocutanous advancement flap reconstruction in four participants (5 surgical fields) [72]. These patients experienced complete granulation at 3–4 weeks and one wound closed via secondary intention while the second patient received two STSGs to the bilateral axillae. Patients who underwent flap and OFM treatment had complete healing at 1–3 months. There were no recurrences noted through 3–12 months of follow up.

Two trials will evaluate the use of several brands of OFM for HS wounds. First, an open-label prospective series will study wound healing in five participants treated with a combination dressing consisting of Endoform™ OFM (AROA Biosurgery), an antibacterial foam dressing containing methylene blue and gentian violet (Hydrofera Blue), and Hypafix tape (BSN medical Inc.) (ClinicalTrials.gov identifier: NCT04354012). Second, a multi-center single arm phase IV trial will seek to enroll 300 participants undergoing soft tissue reconstruction procedures, including an unspecified number undergoing reconstruction for HS (ClinicalTrials.gov identifier: NCT05243966). Investigators will study the use of Myriad Matrix™ and/or Myriad Morcells™ (morcellized/powdered) OFM (AROA Biosurgery) for dermal regeneration as part of the surgical reconstruction.

Petrolatum with Non-Stick Bandaging

Wet-to-dry dressings are commonly used in post-operative care, including for HS patients. Wet-to-dry dressings consist of the application of gauze that has been moistened with normal saline to the wound bed, followed by removal of the bandage after it has been allowed to dry and replacement with another piece of wet gauze for the duration of wound healing. However, petrolatum with non-stick bandaging may have equal, if not superior benefit to wet-to-dry dressings. A randomized blinded trial will study petroleum with non-adherent gauze versus wet-to-dry dressings after HS surgery in 80 participants, hypothesizing that wet-to-dry dressings may actually cause more pain and take more time to apply (ClinicalTrials.gov identifier: NCT05194969).

CONCLUSION

New procedural treatments and wound care dressings and devices are on the horizon for HS. These therapies are of particular importance as patients with advanced disease often require both medical and surgical management, as well as wound care strategies, to optimize their HS care. Limitations of interventional and wound care trials include challenges performing double-blinded studies, lack of standardized outcomes reporting and surgical protocols, and small sample sizes. Patients may also be limited by access to devices and cost of treatments and dressings, especially those individuals who are reliant on insurance coverage. Further studies are needed to guide procedural and wound care strategies for HS.

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