Cochrane wounds group reviews and review updates

REVIEW: PUBLICATION IN *THE COCHRANE LIBRARY* ISSUE 8, 2022

HYDROGEL DRESSINGS FOR VENOUS LEG ULCERS

Citation: Ribeiro CT, Dias FA, Fregonezi GA. Hydrogel dressings for venous leg ulcers

Cochrane Database of Systematic Reviews 2022, Issue 8. Art. No.: CD010738. DOI: 10.1002/14651858.CD010738.pub2.

ABSTRACT

Background Venous leg ulcers are a chronic health problem that cause considerable economic impact and affect quality of life for those who have them. Primary wound contact dressings are usually applied to ulcers beneath compression therapy to aid healing, promote comfort and control exudate. There are numerous dressing products available for venous leg ulcers and hydrogel is often prescribed for this condition; however, the evidence base to guide dressing choice is sparse.

Objectives To assess the effects of hydrogel wound dressings on the healing of venous leg ulcers in any care setting.

Search methods In May 2021, we searched the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies, reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria We included randomised controlled trials (RCTs), either published or unpublished, that compared the effects of hydrogel dressing with other dressings on the healing of venous leg ulcers. We excluded trials evaluating hydrogel dressings impregnated with antimicrobial, antiseptic or analgesic agents as these interventions are evaluated in other Cochrane Reviews.

Data collection and analysis We used standard methodological procedures expected by Cochrane. We assessed the certainty of the evidence using the GRADE approach.

MAIN RESULTS

We included four RCTs (10 articles) in a qualitative analysis. Overall, 272 participants were randomised, in sample sizes ranging from 20 to 156 participants. The mean age of the included population in the trials ranged from 55 to 68 years, 37% were women based on studies that reported the sex of participants. The studies compared hydrogel dressings with the following: gauze and saline, alginate dressing, manuka honey and hydrocolloid. Two studies were multicentre and the others were single-centre trials. Length of treatment using hydrogel dressing was four weeks in three studies and two weeks in one study. The follow-up period was the same as the duration of treatment in three studies and in one study the follow-up for wound healing was at 12 weeks after four weeks of treatment. Overall risk of bias was high for all trials because at least one of the three key criteria (selection bias, detection bias and attrition bias) was at high risk.

HYDROGEL COMPARED WITH GAUZE AND SALINE

It is uncertain whether there is a difference in complete wound healing (risk ratio (RR) 5.33, 95% confidence interval (CI) 1.73 to 16.42; 1 trial, 60 participants) or change in ulcer size (mean difference (MD) –1.50, 95% CI –1.86 to –1.14; 1 trial, 60 participants) between interventions because the certainty of the evidence is very low. Data reported from one trial were incomplete for time-to-ulcer healing.

HYDROGEL COMPARED WITH ALGINATE DRESSING

It is uncertain whether there is a difference in change in ulcer size between hydrogel and alginate gel because the certainty of the evidence is very low (MD –41.80, 95% CI –63.95 to –19.65; 1 trial, 20 participants).

HYDROGEL COMPARED WITH MANUKA HONEY

It is uncertain whether there is a difference in complete wound healing (RR 0.75, 95% CI 0.46 to 1.21; 1 trial, 108 participants) or incidence of wound infection (RR 2.00, 95% CI 0.81 to 4.94; 1 trial, 108 participants) between interventions because the certainty of the evidence is very low.

HYDROGEL COMPARED WITH HYDROCOLLOID

One study (84 participants) reported on change in ulcer size between hydrogel and hydrocolloid; however, further analysis was not possible because authors did not report standard errors or any other measurement of variance of a set of data from the means. Therefore, it is also uncertain whether there is a difference in change in ulcer size between hydrogel and hydrocolloid because the certainty of the evidence is very low.

No studies provided evidence for the outcomes: recurrence of ulcer, health-related quality of life, pain and costs.

Overall, independent of the comparison, the certainty of evidence is very low and downgraded twice due to risk of bias and once or twice due to imprecision for all comparisons and outcomes.

AUTHORS' CONCLUSIONS

There is inconclusive evidence to determine the effectiveness of hydrogel dressings compared with gauze and saline, alginate dressing, manuka honey or hydrocolloid on venous leg ulcer healing. Practitioners may, therefore, consider other characteristics such as costs and symptom management when choosing between dressings. Any future studies assessing the effects of hydrogel on venous wound healing should consider using all the steps from CONSORT, and consider key points such as appropriate sample size with the power to

detect expected differences, appropriate outcomes (such as time-to-event analysis) and adverse effects. If time-to-event analysis is not used, at least a longer follow-up (e.g. 12 weeks and above) should be adopted. Future studies should also address important outcomes that the studies we included did not investigate, such as health-related quality of life, pain and wound recurrence.

Plain language summary

Hydrogel dressings for venous leg ulcers

Key messages

We cannot be certain whether hydrogel dressings are any more effective for healing of venous leg ulcers than other types of dressing such as gauze and saline, alginate, manuka honey or hydrocolloid. There was not enough information to be sure how hydrogel dressings compare with other dressings in terms of potential side effects.

What are venous leg ulcers?

Venous leg ulcers are wounds or sores on the leg caused by alterations in the circulation of blood in the veins. They are hard-to-heal wounds. Venous leg ulcers may cause pain, itching and swelling. There may be changes to the skin around the ulcer, and it may also produce fluids. The standard treatment for this type of wound is compression therapy (bandages or stockings) to improve blood flow in the legs. Dressings are applied underneath compression bandages to protect the wound and aid healing. Different types of dressings vary in their ability to: maintain a moist environment; absorb excess fluid from the wound; soften dead tissue; cushion the wound; keep the wound clean and free of germs and keep newly healed skin intact. Hydrogel dressings are filled with a watery gel and can be used to keep the wound moist; they are intended to help remove dead tissue and help healthy skin to grow.

What did we want to find out?

We wanted to find out if hydrogel dressings compared to other dressings:

- heal venous leg ulcers;
- have any unwanted effects;
- have any effect on changes in ulcer size, time-to-ulcer healing or recurrence of ulcers;
- improve people's quality of life;
- reduce pain;
- impact the costs of treatment.

What did we do?

We searched the medical literature and collected and analysed all relevant randomised controlled trials (clinical studies where the treatment people receive is chosen at random) to answer this question. This type of trial provides the most reliable health evidence. There were no restrictions on publication language, settings where treatments were used, or sex or age of the participants, as long as they had venous leg ulcers. We excluded trials evaluating hydrogel dressings impregnated with antimicrobial (which reduce the presence of bacteria), antiseptic (which stop or slow down the growth of germs) or analgesic (painkiller) agents as these interventions are evaluated in other Cochrane Reviews.

What did we find?

We found four studies dating from 1994 to 2008, involving 272 participants with an average age ranging from 55 to 68 years. Two studies provided no information on participants' sex and the other two included 29 women and 51 men. The studies investigated the use of hydrogel dressings for either two or four weeks. Hydrogel dressings were compared with gauze and saline (salt water), alginate, manuka honey or hydrocolloid.

- It is uncertain whether there is a difference in complete wound healing when hydrogel is compared with gauze and saline or manuka honey.
- It is uncertain if the incidence of wound infection is different between hydrogel dressings and manuka honey or whether there is difference between hydrogel and gauze and saline, alginate or hydrocolloid dressings in terms of change in ulcer size.
- None of the studies reported useable results for time-to-ulcer healing, recurrence of ulcer, health-related quality of life, pain and costs, so we cannot establish the impact of hydrogel on these outcomes.

What limited our confidence in the evidence?

Most studies were small (only one with more than 100 participants) and all used methods likely to introduce errors in their results. The duration of follow-up was short (ranging from two to 12 weeks) and studies were not designed to assess time to complete healing.

How up to date is the review?

We searched for studies published up to 10 May 2021.

REVIEW UPDATE: PUBLICATION IN *THE COCHRANE LIBRARY* ISSUE 9, 2022

WATER FOR WOUND CLEANSING

Ritin Fernandez, Heidi L Green, Rhonda Griffiths, Ross A Atkinson, Laura J Ellwood

Citation: Fernandez R, Green HL, Griffiths R, Atkinson RA, Ellwood LJ. Water for wound cleansing. *Cochrane Database of Systematic Reviews* 2022, Issue 9. Art. No.: CD003861. DOI: 10.1002/14651858.CD003861.pub4.

ABSTRACT

Background Although various solutions have been recommended for cleansing wounds, normal saline is favoured as it is an isotonic solution and is not thought to interfere with the normal healing process. Tap water is commonly used in community settings for cleansing wounds because it is easily accessible, efficient and cost-effective; however, there is an unresolved debate about its use.

Objectives To assess the effects of water for wound cleansing.

Search methods For this fifth update, in May 2021 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE; Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria We included all randomised controlled trials (RCTs) that assessed wound cleansing using different types of water (e.g. tap water, distilled, boiled) compared with no cleansing or with other solutions (e.g. normal saline). For this update, we excluded quasi-RCTs, thereby removing some studies which had been included in the previous version of the review.

Data collection and analysis Two review authors independently carried out trial selection, data extraction and GRADE assessment of the certainty of evidence.

MAIN RESULTS

We included 13 trials in this update including a total of 2504 participants ranging in age from two to 95 years. Participants in the trials experienced open fractures, surgical wounds, traumatic wounds, anal fissures and chronic wounds. The trials were conducted in six different countries with the majority conducted in India and the USA. Three trials involving 148 participants compared cleansing with tap water with no cleansing. Eight trials involving 2204 participants assessed cleansing with tap water compared with cleansing with normal saline. Two trials involving 152 participants assessed cleansing with distilled water compared with cleansing with normal saline. One trial involving 51 participants also assessed cleansing with cooled boiled water compared with cleansing with normal saline, and cleansing with distilled water compared with cleansing with cooled boiled water.

Wound infection: no trials reported on wound infection for the comparison cleansing with tap water versus no cleansing. For all wounds, eight trials found the effect of cleansing with tap water compared with normal saline is uncertain (risk ratio (RR) 0.84, 95% confidence interval (CI) 0.59 to 1.19); very low-certainty evidence. Two trials comparing the use of distilled water with normal saline for cleansing open fractures found that the effect on the number of fractures that were infected is uncertain (RR 0.70, 95% CI 0.45 to 1.09); very low-certainty evidence. One trial compared the use of cooled boiled water with normal saline for cleansing open fractures and found that the effect on the number of fractures infected is uncertain (RR 0.83, 95% CI 0.37 to 1.87); very low-certainty evidence. This trial also compared the use of distilled water with cooled boiled water and found that the effect on the number of fractures infected is uncertain (RR 0.59, 95% CI 0.24 to 1.47); very low-certainty evidence.

Wound healing: results from three trials comparing the use of tap water with no wound cleansing demonstrated there may be little or no difference in the number of wounds that did not heal between the groups (RR 1.04, 95% CI 0.95 to 1.14); low-certainty evidence. The effect of tap water compared with normal saline is uncertain; two trials were pooled (RR 0.57, 95% CI 0.30 to 1.07) but the certainty of the evidence is very low. Results from one study comparing the use of distilled water with normal saline for cleansing open fractures found that there may be little or no difference in the number of fractures that healed (RR could not be estimated, all wounds healed); the certainty of the evidence is low.

Reduction in wound size: the effect of cleansing with tap water compared with normal saline on wound size reduction is uncertain (RR 0.97, 95% CI 0.56 to 1.68); the certainty of the evidence is very low.

Rate of wound healing: the effect of cleansing with tap water compared with normal saline on wound healing rate is uncertain (mean difference (MD) -3.06, 95% CI -6.70 to 0.58); the certainty of the evidence is very low.

Costs: two trials reported cost analyses but the cost-effectiveness of tap water compared with the use of normal saline is uncertain; the certainty of the evidence is very low.

Pain: results from one study comparing the use of tap water with no cleansing for acute and chronic wounds showed that there may be little or no difference in pain scores. The certainty of the evidence is low.

Patient satisfaction: results from one study comparing the use of tap water with no cleansing for acute and chronic wounds showed that there may be little or no difference in patient satisfaction. The certainty of evidence is low. The effect of cleansing with tap water compared with normal saline is uncertain as the certainty of the evidence is very low.

AUTHORS' CONCLUSIONS

All the evidence identified in the review was low or very low certainty. Cleansing with tap water may make little or no difference to wound healing compared with no cleansing; there are no data relating to the impact on wound infection. The effects of cleansing with tap water, cooled boiled water or distilled water compared with cleansing with saline are uncertain, as is the effect of distilled water compared with cooled boiled water. Data for other outcomes are limited across all the comparisons considered and are either uncertain or suggest that there may be little or no difference in the outcome.

Plain language summary

The effects of water compared with other solutions for wound cleansing

Background

Infection can interfere with the normal wound-healing process. In order to reduce the risk of infection, wounds are routinely cleansed to remove dirt, contamination or impurities. In this review, a wound is defined as a break in the skin.

What is the aim of this review?

The aim of this review was to investigate the effects of wound cleansing using different types of water (e.g. tap water, distilled, boiled) compared with no cleansing or with other solutions (e.g. normal saline). We measured effectiveness by looking at wound-related infection rate and wound healing.

Researchers from Cochrane searched for all randomised controlled trials (RCTs) relating to this question and found 13 relevant studies. RCTs are studies where people are chosen at random to receive different treatments. Allocating participants in this way provides the most reliable evidence about possible relationships between the treatment used and any reported health outcomes.

Key messages

We compared wound cleansing with tap water, distilled water, cooled boiled water or saline with each other or with no cleansing. It is unclear if any of these interventions have an effect on the number of wounds which become infected. It

is also unclear if they have an effect on healing (number of wounds healed; change in wound size; and rate of wound healing); costs; pain; or patient satisfaction.

What was studied in the review?

Wounds are commonly cleansed to prevent infection. The cleansing solution can be tap water, distilled water, cooled boiled water or saline. Tap water is commonly used in the community because it is easily accessible, efficient and cost-effective; however, there is an unresolved debate about its use. We compared the effects of cleansing wounds with water with other types of water, normal saline and no cleansing.

We included all RCTs that compared wound cleansing using different types of water (e.g. tap water, distilled, boiled) compared with no cleansing or with other solutions (e.g. normal saline). Participants were from any age group and any setting e.g. hospital, community, nursing homes, general practice, wound clinics. We excluded trials that compared solutions for dental procedures or for patients with burns.

What are the main results of the review?

We included results from 13 RCTs in this review, with a combined total of 2504 participants. The participants were adults or children with a range of different types of wounds who were treated in the community, emergency departments or hospital wards. Eight trials assessed cleansing with tap water compared with cleansing with normal saline. Three trials compared cleansing with tap water with no cleansing. Two trials assessed cleansing with distilled water compared with cleansing with normal saline, one trial also assessed cleansing with cooled boiled water with cleansing with normal saline and cleansing with distilled water compared with cleansing with cooled boiled water.

We compared wound cleansing with tap water, distilled water, cooled boiled water or saline with each other or with no cleansing. It is unclear if any of these interventions have an effect on the number of wounds which become infected. It is also unclear if they have an effect on healing (number of wounds healed; change in wound size; and rate of wound healing); costs; pain; or patient satisfaction.

We are unsure if the interventions have an effect because not enough participants received each intervention to reliably assess their effects. The way that the studies were designed and conducted also means that the results may not reliably reflect the effects of the interventions. This is partly due to uncertainty over how participants were assigned to the treatments. It is also possible that many participants and healthcare professionals were aware of which treatments were being used.

How up to date is this review?

We searched for studies that had been published up to 20 May 2021.

REVIEW: PUBLICATION IN *THE COCHRANE LIBRARY* ISSUE 9, 2022

LASER THERAPY FOR TREATING HYPERTROPHIC AND KELOID SCARS

Rafael Leszczynski, Carolina AP da Silva, Ana Carolina Pereira Nunes Pinto, Uliana Kuczynski, Edina MK da Silva

Citation: Leszczynski R, Da Silva CA, Pinto AC, Kuczynski U, Da Silva EM. Laser therapy for treating hypertrophic and keloid scars.

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ABSTRACT

Background Hypertrophic and keloid scars are common skin conditions resulting from abnormal wound healing. They can cause itching, pain and have a negative physical and psychological impact on patients' lives. Different approaches are used aiming to improve these scars, including intralesional corticosteroids, surgery and more recently, laser therapy. Since laser therapy is expensive and may have adverse effects, it is critical to evaluate the potential benefits and harms of this therapy for treating hypertrophic and keloid scars.

Objectives To assess the effects of laser therapy for treating hypertrophic and keloid scars.

Search methods In March 2021 we searched the Cochrane Wounds Specialised Register, CENTRAL, MEDLINE, Embase, CINAHL EBSCO Plus and LILACS. To identify additional studies, we also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses, and health technology reports. There were no restrictions with respect to language, date of publication, or study setting.

Selection criteria We included randomised controlled trials (RCTs) for treating hypertrophic or keloid scars (or both), comparing laser therapy with placebo, no intervention or another intervention.

Data collection and analysis Two review authors independently selected studies, extracted the data, assessed the risk of bias of included studies and carried out GRADE assessments to assess the certainty of evidence. A third review author arbitrated if there were disagreements.

MAIN RESULTS

We included 15 RCTs, involving 604 participants (children and adults) with study sample sizes ranging from 10 to 120 participants (mean 40.27). Where studies randomised different parts of the same scar, each scar segment was the unit of analysis (906 scar segments). The length of participant follow-up varied from 12 weeks to 12 months. All included trials had a high risk of bias for at least one domain: all studies were deemed at high risk of bias due to lack of blinding of participants and personnel. The variability of intervention types, controls, follow-up periods and limitations with report data meant we pooled data for one comparison (and only two outcomes within this). Several review secondary outcomes - cosmesis, tolerance, preference for different modes of treatment, adherence, and change in quality of life - were not reported in any of the included studies.

Laser versus no treatment:

We found low-certainty evidence suggesting there may be more hypertrophic and keloid scar improvement (that is scars are less severe) in 585-nm pulsed-dye laser (PDL) -treated scars compared with no treatment (risk ratio (RR) 1.96; 95% confidence interval (CI): 1.11 to 3.45; two studies, 60 scar segments).

It is unclear whether non-ablative fractional laser (NAFL) impacts on hypertrophic scar severity when compared with no treatment (very low-certainty evidence).

It is unclear whether fractional carbon dioxide (CO_2) laser impacts on hypertrophic and keloid scar severity compared with no treatment (very low-certainty evidence).

Eight studies reported treatment-related adverse effects but did not provide enough data for further analyses.

Laser versus other treatments:

We are uncertain whether treatment with 585-nm PDL impacts on hypertrophic and keloid scar severity compared with intralesional corticosteroid triamcinolone acetonide (TAC), intralesional Fluorouracil (5-FU) or combined use of TAC plus 5-FU (very low-certainty evidence). It is also uncertain whether erbium laser impacts on hypertrophic scar severity when compared with TAC (very low-certainty evidence).

Other comparisons included 585-nm PDL versus silicone gel sheeting, fractional CO_2 laser versus TAC and fractional CO_2 laser versus verapamil. However, the authors did not report enough data regarding the severity of scars to compare the interventions.

As only very low-certainty evidence is available on treatment-related adverse effects, including pain, charring (skin burning so that the surface becomes blackened), telangiectasia (a condition in which tiny blood vessels cause thread-like red lines on the skin), skin atrophy (skin thinning), purpuric discolorations, hypopigmentation (skin colour becomes lighter), and erosion (loss of part of the top layer of skin, leaving a denuded surface) secondary to blistering, we are not able to draw conclusions as to how these treatments compare.

Laser plus other treatment versus other treatment:

It is unclear whether 585-nm PDL plus TAC plus 5-FU leads to a higher percentage of good to excellent improvement in hypertrophic and keloid scar severity compared with TAC plus 5-FU, as the certainty of evidence has been assessed as very low.

Due to very low-certainty evidence, it is also uncertain whether CO_2 laser plus TAC impacts on keloid scar severity compared with cryosurgery plus TAC.

The evidence is also very uncertain about the effect of neodymium-doped yttrium aluminium garnet (Nd:YAG) laser plus intralesional corticosteroid diprospan plus 5-FU on scar severity compared with diprospan plus 5-FU and about the effect of helium-neon (He-Ne) laser plus decamethyltetrasiloxane, polydimethylsiloxane and cyclopentasiloxane cream on scar severity compared with decamethyltetrasiloxane, polydimethylsiloxane and cyclopentasiloxane cream.

Only very low-certainty evidence is available on treatment-related adverse effects, including pain, atrophy, erythema, telangiectasia, hypopigmentation, regrowth, hyperpigmentation (skin colour becomes darker), and depigmentation (loss of colour from the skin). Therefore, we are not able to draw conclusions as to how these treatments compare.

AUTHORS' CONCLUSIONS

There is insufficient evidence to support or refute the effectiveness of laser therapy for treating hypertrophic and keloid scars. The available information is also insufficient to perform a more accurate analysis on treatment-related adverse effects related to laser therapy. Due to the heterogeneity of the studies, conflicting results, study design issues and small sample sizes, further high-quality trials, with validated scales and core outcome sets should be developed. These trials should take into consideration the consumers' opinion and values, the need for long-term follow-up and the necessity of reporting the rate of recurrence of scars to determine whether lasers may achieve superior results when compared with other therapies for treating hypertrophic and keloid scars.

Plain language summary

Laser therapy for hypertrophic and keloid scars

What was studied in the review?

Hypertrophic and keloid scars are raised and bumpy scars that form when a wound does not heal correctly. These scars can be discoloured or reddened and can also cause pain and itching. A range of treatments are available, including silicone gels and steroids.

Laser therapy may be an alternative treatment for these types of scars. During laser therapy, areas of skin are targeted by a powerful beam of light which can break down damaged tissue. Different types of laser therapy are available depending on the patient's skin type and the nature of the scar. Laser therapy is expensive and has potentially harmful side effects, so it is important to establish whether it is safe and effective.

What is the aim of this review?

The aim of this review was to investigate whether laser therapy is an effective treatment for people with hypertrophic and keloid scars. To answer this question, researchers from Cochrane collected and analysed all relevant studies to answer this question and found 15 randomised controlled trials.

What are the main results of the review?

We included 15 studies dating from 1999 to 2019, involving 604 participants (children and adults of both sexes). The study sizes were small (10 to 120 participants), with the length of participant follow-up varying from 12 weeks to 12 months. The studies analysed the change in the severity of scars assessed by health professionals or participants.

In the studies, different kinds of laser devices were compared with no treatment and with other treatment methods. Laser therapy combined with another treatment was also compared with this treatment alone.

We cannot be sure whether laser therapy alone or combined with other treatments improves hypertrophic or keloid scars severity when compared with no treatment or other treatments, as the certainty of all available evidence is low or very low. This is due to the small number of studies, different comparisons, conflicting results, small number of participants, and lack of available data.

Some side effects of laser treatment such as damage to the skin or underlying blood vessels, redness, and numbness were reported. However, the certainty of the evidence is too low to be sure how common these side effects are.

Key messages

Taken together, the results of these studies do not allow us to be sure if using any kind of laser therapy is more or less effective than other available treatments for hypertrophic and keloid scars. As the studies provided only very low-certainty evidence regarding possible side effects, we are not very confident in the results of the currently available studies, and we cannot be sure whether any type of laser therapy leads to more harm than benefits compared with no treatment or other treatments.

How up to date is this review?

We searched for studies published up to 23 March 2021.

REVIEW UPDATE: PUBLICATION IN *THE COCHRANE LIBRARY* ISSUE 10, 2022

RECONSTRUCTIVE SURGERY FOR TREATING PRESSURE ULCERS

Gill Norman, Jason KF Wong, Kavit Amin, Jo C Dumville, Susy Pramod

Citation: Norman G, Wong JK, Amin K, Dumville JC, Pramod S. Reconstructive surgery for treating pressure ulcers.

Cochrane Database of Systematic Reviews 2022, Issue 10. Art. No.: CD012032. DOI: 10.1002/14651858.CD012032.pub3

ABSTRACT

Background There are several possible interventions for managing pressure ulcers (sometimes referred to as pressure injuries), ranging from pressure-relieving measures, such as repositioning, to reconstructive surgery. The surgical approach is usually reserved for recalcitrant wounds (where the healing process has stalled, or the wound is not responding to treatment) or wounds with full-thickness skin loss and exposure of deeper structures such as muscle fascia or bone. Reconstructive surgery commonly involves wound debridement followed by filling the wound with new tissue. Whilst this is an accepted means of ulcer management, the benefits and harms of different surgical approaches, compared with each other or with non-surgical treatments, are unclear. This is an update of a Cochrane Review published in 2016.

Objectives To assess the effects of different types of reconstructive surgery for treating pressure ulcers (category/stage II or above), compared with no surgery or alternative reconstructive surgical approaches, in any care setting.

Search methods We used standard, extensive Cochrane search methods. The latest search date was January 2022.

Selection criteria Published or unpublished randomised controlled trials (RCTs) that assessed reconstructive surgery in the treatment of pressure ulcers.

Data collection and analysis Two review authors independently selected the studies, extracted study data, assessed the risk of bias and undertook GRADE assessments. We would have involved a third review author in case of disagreement.

MAIN RESULTS

We identified one RCT conducted in a hospital setting in the USA. It enrolled 20 participants aged between 20 and 70 years with stage IV ischial or sacral pressure ulcers (involving full-thickness skin and tissue loss). The study compared two reconstructive techniques for stage IV pressure ulcers: conventional flap surgery and cone of pressure flap surgery, in which a large portion of the flap tip is de-epithelialised and deeply inset to obliterate dead space. There were no clear data for any of our outcomes, although we extracted some information on complete wound healing, wound dehiscence, pressure ulcer recurrence and wound infection. We graded the evidence for these outcomes as very low-certainty. The study provided no data for any other outcomes.

AUTHORS' CONCLUSIONS

Currently there is very little randomised evidence on the role of reconstructive surgery in pressure ulcer management, although it is considered a priority area. More rigorous and robust research is needed to explore this intervention.

Plain language summary

What are the benefits and risks of reconstructive surgery for treating pressure ulcers?

Key messages

- We are uncertain about the benefits and risks of reconstructive surgery (sometimes known as plastic surgery) for treating pressure ulcers (sometimes known as bedsores, pressure sores or pressure injuries).
- We found one small study (20 participants) that investigated reconstructive surgery in deep, hard-to-heal pressure ulcers, but we were unable to reach any conclusions from the reported results.
- Larger, well-designed studies are needed to explore this priority area.

What are pressure ulcers?

Pressure ulcers are skin and tissue injuries that are usually caused by people staying in the same position for long periods of time. When external pressure is constantly applied to parts of the body, blood flow is restricted to the skin and underlying tissues. This can cause the skin or underlying tissue to break down, especially in areas that have less fat such as the lower back and heel.

People at risk of developing pressure ulcers include older adults, people with mobility problems (e.g. wheelchair users) and people who spend long periods in hospital.

How are pressure ulcers treated?

Pressure ulcers are serious wounds that are costly to treat, so care is mainly focused on preventing them. When ulcers do occur, treatment options include wound dressings, antibiotics and antiseptics.

Reconstructive surgery is usually reserved for deep or hard-to-heal pressure ulcers. There are different types of reconstructive surgery, but most involve removing dead tissue from the wound then using soft tissue such as muscle, fat or skin from other parts of the person's body to fill the wound cavity.

What did we want to find out?

We wanted to assess the benefits and risks of reconstructive surgery for treating pressure ulcers compared with no surgery; and the benefits and risks of different types of reconstructive

surgery compared with each other. The results we were interested in were:

- complete wound healing;
- wounds reopening or new ulcers occurring at the same site as previous ulcers;
- resource use and costs;
- health-related quality of life;
- wound infection; and
- new ulcers occurring at different sites from previous ulcers.

What did we do?

We searched electronic databases and trials registers for randomised controlled trials, which are clinical studies that randomly allocate participants to different treatment groups. This type of study design can provide the most reliable evidence about the effects of a treatment. We included studies that investigated the effects of reconstructive surgery for treating pressure ulcers compared with no surgery. We also included studies that compared different types of reconstructive surgery for treating pressure ulcers. We applied no restrictions on language, date of publication, or where the study was conducted. We rated our confidence in the evidence, based on factors such as study methods and the number of people included.

What did we find?

We found one small study, which was carried out in the USA and recruited 20 participants in hospital. This study investigated two different reconstructive surgical techniques for treating stage IV pressure ulcers, which have full-thickness skin and tissue loss. The study did not provide enough information on wound healing, wound reopening, ulcer recurrence or wound infection for us to judge the effectiveness of the different surgical techniques.

What are the limitations of the evidence?

We are uncertain what effect the two surgical techniques had on wound healing, reopening or recurrence, because the trial was not well conducted or reported, and it included a small number of participants.

We are uncertain about the benefits and harms of reconstructive surgery, and of different surgical techniques, for treating pressure ulcers. More rigorous research is needed in this area, as patients, carers and health professionals consider it a priority issue.

How up to date is this evidence?

This is an update of a previous review. The evidence is up to date to January 2022.

REVIEW: PUBLICATION IN *THE COCHRANE LIBRARY* ISSUE 1, 2023

SILICONE GEL SHEETING FOR TREATING KELOID SCARS

Fan Tian, Qingling Jiang, Junjie Chen, Zhenmi Liu

Citation: Tian F, Jiang Q, Chen J, Liu Z. Silicone gel sheeting for treating keloid scars.

Cochrane Database of Systematic Reviews 2023, Issue 1. Art. No.: CD013878. DOI: 10.1002/14651858.CD013878.pub2.

ABSTRACT

Background Keloid scarring is one of the most common types of pathological scarring. Keloid scars that fail to heal can affect a person's physical and psychological function by causing pain, pruritus, contractures, and cosmetic disfigurement. Silicone gel sheeting (SGS) is made from medical-grade silicone reinforced with a silicone membrane backing and is one of the most commonly used treatments for keloid scars. However, there is no up-to-date systematic review assessing the effectiveness of SGS for keloid scars. A clear and rigorous review of current evidence is required to guide clinicians, healthcare managers and people with keloid scarring.

Objectives To assess the effectiveness of silicone gel sheeting for the treatment of keloid scars compared with standard care or other therapies.

Search methods We used standard, extensive Cochrane search methods. The latest search date was December 2021.

Selection criteria We included randomised controlled trials (RCTs) that recruited people with any keloid scars and assessed the effectiveness of SGS.

Data collection and analysis Two review authors independently performed study selection, risk of bias assessment, data extraction and GRADE assessment of the certainty of evidence. We resolved initial disagreements by discussion, or by consulting a third review author when necessary.

MAIN RESULTS

Two studies met the inclusion criteria. Study sample sizes were 16 and 20 participants. The trials were clinically heterogeneous with differences in causes for scarring (e.g. surgery, infected wounds, and trauma), site (e.g. chest and back), and ages of scars. The duration of follow-up was three and four and a half months. The included studies reported three comparisons; SGS compared with no treatment, SGS compared with non-silicone gel sheeting (a dressing similar to SGS but which does not contain silicone), and SGS compared with intralesional injections of triamcinolone acetonide. One trial had a split-body design and one trial had an unclear design (resulting in a mix of paired and clustered data).

The included studies reported limited outcome data for the primary review outcome of scar severity measured by health professionals and no data were reported for severity of scar measured by patients or adverse events. For secondary outcomes some data on pain were reported, but health-related quality of life and cost-effectiveness were not reported. Both trials had suboptimal outcome reporting, thus many domains in the risk of bias were assessed as unclear. All evidence was rated as being very low-certainty, mainly due to risk of bias, indirectness, and imprecision.

SGS compared with no treatment

Two studies with 33 participants (76 scars) reported the severity of scar assessed by health professionals, and we are uncertain about the effect of SGS on scar severity compared with no treatment (very low-certainty evidence, downgraded once for risk of bias, once for inconsistency, once for indirectness, and once for imprecision). We are uncertain about the effect of SGS on pain compared with no treatment (21 participants with 40 scars; very low-certainty evidence,

downgraded once for risk of bias, once for inconsistency, once for indirectness, and once for imprecision). No data were reported for other outcomes including scar severity assessed by patients, adverse events, adherence to treatment, health-related quality of life and cost-effectiveness.

SGS compared with non-SGS

One study with 16 participants (25 scars) was included in this comparison. We are uncertain about the effect of SGS on scar severity assessed by health professionals compared with non-SGS (very low-certainty evidence, downgraded once for risk of bias, once for indirectness, and once for imprecision). We are also uncertain about the effect of SGS on pain compared with non-SGS (very low-certainty evidence, downgraded once for risk of bias, once for indirectness, and once for imprecision). No data were reported for other outcomes including scar severity assessed by patients, adverse events, adherence to treatment, health-related quality of life and cost-effectiveness.

SGS compared with intralesional injections of triamcinolone acetonide

One study with 17 participants (51 scars) reported scar severity assessed by health professionals, and we are uncertain about the effect of SGS on scar severity compared with intralesional injections of triamcinolone acetonide (very low-certainty evidence, downgraded once for risk of bias, once for indirectness, and once for imprecision). This study also reported pain assessed by health professionals among 5 participants (15 scars) and we are uncertain about the effect of SGS on pain compared with intralesional injections of triamcinolone acetonide (very low-certainty evidence, downgraded once for risk of bias, once for indirectness, and twice for imprecision). No data were reported for other outcomes including scar severity assessed by patients, adverse events, adherence to treatment, health-related quality of life and cost-effectiveness.

AUTHORS' CONCLUSIONS

There is currently a lack of RCT evidence about the clinical effectiveness of SGS in the treatment of keloid scars. From the two studies identified, there is insufficient evidence to demonstrate whether the use of SGS compared with no treatment, non-SGS, or intralesional injections of triamcinolone acetonide makes any difference in the treatment of keloid scars. Evidence from the included studies is of very low certainty, mainly driven by the risk of bias, indirectness, and imprecision due to small sample size. Further well-designed studies that have good reporting methodologies and address important clinical, quality of life and economic outcomes are required to reduce uncertainty around decision-making in the use of SGS to treat keloid scars.

Plain language summary

What are the benefits and risks of silicone gel sheeting for treating keloid scars?

Key messages

We are uncertain whether silicone gel sheeting improves a scar's appearance more than:

- no treatment;
- treatment with a dressing similar to silicone gel sheeting that does not contain silicone;
- injections of triamcinolone acetonide (a medication) directly into a lesion or below the skin.

We are uncertain about the effect of silicone gel sheeting on pain compared with no treatment.

We do not know if silicone gel sheeting has an effect on pain compared with non-silicone gel sheeting or intralesional injections of triamcinolone acetonide.

What are keloid scars?

A scar is a mark left on the skin after a wound or injury has healed. Sometimes scars can develop abnormally, forming keloid scars which are raised and unsightly and these can affect people physically and emotionally. Keloid scars often occur after minor injuries and can spread to the skin surrounding the original wound. Keloid scars are difficult to treat and can affect both sexes and occur at any age.

How are keloid scars treated?

Silicone gel sheeting is a soft and flexible wound dressing containing an elastic form of silicone. It has a soft, rubbery texture and can be easily attached to the skin. Silicone gel sheeting is thought to be an optimal option in the treatment of keloid scars. It can be used on healing skin to help soften and flatten a keloid scar.

What did we want to find out?

In this Cochrane Review, we wanted to find out what the benefits and risks of treating keloid scars with silicone gel sheeting are.

What did we do?

We searched for studies that investigated using silicone gel sheeting to treat keloid scars. We searched for randomised controlled trials only, in which the treatment each person receives is chosen at random. These studies give the most reliable evidence about the effects of a treatment.

What did we find?

We found two studies with a total of 36 participants (85 scars) (33 participants (76 scars) completed the study). The participants had keloid scars caused by surgery, infected wounds or trauma. The studies compared the effects of silicone gel sheeting with:

- no treatment;
- treatment with a dressing similar to silicone gel sheeting that did not contain silicone;
- injections of triamcinolone acetonide (a medication) directly into a lesion or below the skin.

One study was conducted in Brazil and another study was conducted in Singapore. They lasted for different lengths of time: three months and four and a half months.

Both studies reported assessments of scars by healthcare professionals but no data were reported in a way that was usable for this review. No studies reported useful results for the person's own assessment of their scar after treatment. Both studies also reported assessments of pain but no data were reported in a way that was usable for this review.

No studies reported useful results for people's well-being (quality of life); whether people stayed on the treatment (adherence); whether the treatments had any unwanted effects; or whether the treatments were cost-effective (the benefits of treatment outweighed any extra costs).

MAIN RESULTS

We are uncertain whether silicone gel sheeting improves a scar's appearance more than: no treatment; treatment with non-silicone gel sheeting; or intralesional injections of triamcinolone acetonide.

We are uncertain about the effect of silicone gel sheeting on pain compared with no treatment. We do not know if silicone gel sheeting has an effect on pain compared with non-silicone gel sheeting or intralesional injections of triamcinolone acetonide.

CONCLUSIONS

We are uncertain whether the use of silicone gel sheeting compared with no treatment, treatment with non-silicone gel sheeting or intralesional injections of triamcinolone acetonide makes any difference in the treatment of keloid scars.

What are the limitations of the evidence?

We are not confident in the evidence because it comes from very few studies with small numbers of people and poorly reported results, so we are not sure how reliable the results are. Our conclusions would be likely to change if results from further studies become available.

How up-to-date is this evidence?

This review includes evidence published up to 15 December 2021.