Thieme

Standards in the surgical treatment of leg ulcers Standards bei der operativen Behandlung des Ulcus cruris

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ABSTRACT

Nowadays we have a broad range of surgical options to heal recalcitrant leg ulcers. They rest upon uniformly recognised standards and prevail against other techniques. The elimination of reflux in venous ulcers is the main aim and reduces recurrence significantly compared to conservative treatment alone.

Beside classic venous surgery there are some modern therapeutical options such as laser, radiofrequency ablation, foam-sclerotherapy or cyaonacrylat-embolisation at disposal. For local ulcer surgery shave-therapy with simultaneous meshgraft plastic is the method of first choice to treat non healing leg ulcers. Longterm results with healing up to 85% are not achievable with any other method. Crural fasciectomy is nowadays reserved for special indications: transfascial necrosis, failure after shave therapy and severe tissue calcification are successfully treated by fasciectomy. Beside the right choice of surgical procedure longterm healing rates depend on a standardised wound care in hospital and medical home care.

ZUSAMMENFASSUNG

Die operative Therapie chronischer Beingeschwüre bietet heute ein breites Spektrum an Behandlungsmöglichkeiten, die überwiegend auf Standards als einheitlich anerkannte Behandlungskonzepte beruhen und sich gegenüber anderen Techniken durchgesetzt haben. Beim Ulcus cruris venosum steht die Ausschaltung des venösen Refluxes im Vordergrund und reduziert die Rezidivrate im Vergleich zur alleinigen konservativen Therapie erheblich. Hierzu stehen neben der klassischen Venenchirurgie moderne endovenöse Therapieoptionen wie Laser-Therapie, Radiofrequenz-Obliteration, Schaumsklerosierung oder Cyanoacrylatembolisation zur Verfügung.

In der lokalen operativen Therapie chronischer Ulzerationen hat sich die Shave-Therapie mit simultaner Meshgraft-Plastik als Methode der ersten Wahl etabliert. Langzeitergebnisse mit Heilungsraten von bis 85 % sind mit keinem anderen Verfahren zu erreichen. Der kruralen Fasziektomie sind heute einige spezielle Indikationen vorbehalten: Transfasziale Nekrosen, Mehrfachrezidive nach Shave-Therapie und metaplastische Ossifikationen sind erfolgreich durch eine Fasziektomie zu behandeln. Neben der richtigen Wahl des Operationsverfahrens ist der langfristige Heilungserfolg geprägt von einer standardisierten postoperativen und poststationären Langzeitbetreuung.

To date, there is a lack of sufficiently reliable data on the incidence of chronic leg ulcers worldwide. There are no nationwide wound registries and, due to the frequently multifactorial aetiology of chronic wounds, data on the cause of the disease or its progression are not transparent. In Germany, we have referred to the results of the Bonn vein study since 2003 and can at least draw reli-

able conclusions on venous leg ulcers. Assuming that there have been no significant changes in the 15 years since publication, we now have to reckon with 100 000 cases of acute venous ulcers (C6) currently in Germany [1, 21].

If an ulcer fails to heal permanently with conservative management, it requires our concentrated medical attention and our experience with surgical procedures.

Standards and medical evidence in ulcer surgery

In evidence-based medicine, the surgical treatment of chronic wounds is insufficiently characterised and has low grades of recommendation. This circumstance is due to the lack of scientific studies comparing the individual procedures or comparisons with conservative treatment. Such study designs, required in the form of randomised controlled trials, will probably never exist for the surgical treatment of ulcers. The reasons for this are diverse. First of all, there are only a few dedicated wound centres that specialise in surgical wound management. As a result, the number of patients with an indication for local surgical treatment is rather small, making it impossible to carry out comparative studies on a sufficiently large scale. In addition, there would be ethical problems, if patients with an indication for surgery – usually required urgently – were given comparatively less effective treatment or even subjected to a 'placebo-controlled' procedure.

Considering wound therapy in general and surgical débridement in particular, we are unable to draw any firm conclusions on the benefits and risks of such treatment from a purely scientific and evidence-based point of view [2, 4, 14].

This does not, however, reflect routine practice and experience or the published results of the mostly retrospective analyses from dedicated wound centres.

The surgical treatment of venous leg ulcers today is based mainly on 'standards' of comparatively uniform and widely recognised treatment concepts that have prevailed against other techniques [26].

The goal of our therapeutic efforts must ultimately be to improve the patient's health-related quality of life (HRQoL). In the ideal case, this would be permanent healing of the ulcer, as the path of suffering often stretches over decades without a cure. Chronic pain, unfitness for work and social marginalisation affect everyday life. Daily preoccupation with the clinical condition and having to be in regular contact with the doctor can ultimately lead to significant mental health issues [3, 6, 27].

Development of the methods

The treatment of chronic leg ulcers is a longstanding component of medical history. In the 19th century, patients with leg ulcers filled entire hospital wards and were considered a 'burden' on surgical wards. Most leg ulcers were incurable and associated with varicose veins, which could not be adequately treated at that time, or post-thrombotic syndrome.

Circular excisions with transection of the varicose veins, as introduced by Nussbaum (1857), Moreschi (1893), Mariani (1903) and Wenzel (1902), and the spiral incision technique of Friedel and Rindfleisch (1908) led to severe blood losses, sensory disorders, lymphatic stasis, and frequently to a loss of function of the extrem-

ity. These methods, which today we find grotesque, were quickly abandoned [5].

The first en-bloc resection of a venous leg ulcer including the crural fascia was performed by Homans in Boston in 1916. It is viewed as the forerunner of today's fasciectomy.

However, the actual development of surgical ulcer therapy in line with today's standards began only around 1980, with the introduction of paratibial fasciotomy by Wolfgang Hach. It was an incidental bonus of the subfascial dissection of perforating veins, for which the fascia had to be opened. Using a wide scoop spatula, the Argentinian surgeon Ziagora had already carried out the procedure successfully on many occasions.

Together with his co-workers, Hach quickly realised that the ulcers healed more rapidly after releasing the fascia alone, even in the absence of a successful division of the perforating veins. These observations gave rise to the idea of chronic venous compartment syndrome as the cause of refractory leg ulcers. To the best of his knowledge, the pathophysiological processes were responsible for the development of venous leg ulcers and the scarring of skin, subcutaneous tissue and fascia (dermatolipofasciosclerosis) that restricted the subfascial space. Also treating or removing the crural fascia was part of the essential causal treatment [5].

At almost the same time as Hach's initial publications (1991), Wilfried Schmeller, a dermatologist from Lübeck in Germany, reported his success in the surgical treatment of chronic leg ulcers with 'shave therapy'. Based on the findings of Hynes (1959) and Quaba (1987), Schmeller began shave therapy with a manual dermatome and simultaneous mesh grafting at the beginning of the 1990 s. The results were surprisingly good and ulcers that had been refractory for decades suddenly healed.

Relatively early on, Hynes realised that the capillary plexus of the wound bed played a decisive role in the successful healing of a graft.

Quaba came to same conclusion in 1987. He observed that granulation tissue made a poor transplant bed and that the graft took particularly well in a fresh wound after 'layered shaving'. As they were basically very different in the theoretical approach, shave therapy and fasciectomy now became competitors in the treatment of venous leg ulcers and occasioned many controversial discussions at congresses around 1995. Only one study has ever made a direct scientific comparison of the two procedures. That study and the retrospective evaluation by Obermayer and Hermanns found that shave therapy gave better long-term results than fascial resection and it is now the method of first choice in the surgical treatment of refractory leg ulcers [8, 18].

Indication for surgical treatment: 'resistance to treatment'

An indication for local surgery is made today only when all conservative options have failed. 'Resistance to treatment' is an important criterion, whereby the time factor is considered here rather than the aetiology of delayed wound healing. Surgical measures should be applied, if an ulcer is not showing any signs of healing or if the local findings are worse after a period of three months despite proper conservative treatment or the lesion has still not completely healed after 12 months [4].



▶ Fig. 1 (a) Shave therapy technique: tangential suprafascial necrosectomy. (b) Simultaneous mesh grafting.

Elimination of reflux with venous ulcers

Irrespective of the time scale mentioned above, eliminating the reflux should always be considered. if the leg ulcer is related to venous insufficiency. Gent and co-workers were able to demonstrate that the surgical elimination of reflux halved the probability of ulcer recurrence in comparison with conservative compression therapy alone [28].

For many years, compression therapy to relieve the pain and other symptoms of chronic venous insufficiency (CVI) was the only treatment of choice for venous leg ulcers caused by post-thrombotic syndrome. The recurrence rates of conservatively treated ulcers are considerably higher than in patients whose epifascial reflux has been selectively eliminated by various therapeutic strategies and a combination of cutting-edge technology with modern tools (vein surgery, laser or radiofrequency ablation, foam sclerotherapy, cyanoacrylate embolisation) or who have undergone endovenous stenting of the deep venous system for the appropriate indication [13]. In a systematic review of 2649 legs, Saeger et al. showed that endovenous stenting reduced the severity of CVI and improved the CVI-specific quality of life. As a result, the healing rate of post-thrombotic ulcers should also improve and their recurrence rate be reduced [23].

Surgery of leg ulcers

To date, the following methods have become established for the surgical treatment of non-healing refractory leg ulcers:

- Shave therapy with simultaneous mesh skin grafting
- Fasciectomy, partial or crural
- Grafting procedures
- VAC treatment combined with the above techniques
- Conventional débridement (sharp spoon, curettage, etc.)

Shave therapy

Shave therapy was first introduced by Schmeller and his co-workers in the years between 1994 and 1999 and the procedure has since been established scientifically. It consists of the tangential and exclusively superficial removal of necrotic tissue (necrosectomy) and fibrotic tissue (fibrosectomy) from chronic leg ulcers and the im-

mediate covering of the lesion with a split-skin graft. Preparation of a 'fresh' wound with good capillary bleeding and covering the defect directly with a split-skin graft are essential to the success of this method. Wound conditioning and granulation tissue formation in the transplant bed are deliberately omitted. The cure rate of skin grafted onto tissue that is healing by secondary intention is only 30-50% and worse than the rates seen with the technique described above.

Surgical technique: shave therapy

Shave therapy is easy for the proficient surgeon to learn. The procedure is safe, since there are only very few possible complications that could arise in the surgical field and, depending on the size of the ulcer, operating times are short.

The surgical intervention itself is not the key factor in long-term success; the correct indication and timing of surgery are more important as is standardised postoperative care and follow-up of the patient.

The first step is to harvest and prepare the skin for transplantation using the mesh procedure, which is a prerequisite for the actual treatment of the ulcer.

Whenever possible, a layer of skin to a depth between 0.2 mm and 0.4 mm is taken from the thigh of the affected leg. We ourselves prefer and recommend a depth of 0.3 mm. The recommended mesh ratio is 1:1.5, which allows an adequate drainage of blood and secretions from the wound bed. Once it has healed, a mesh graft of this nature meets the everyday demands on the skin.

Today, various manual or mechanical dermatomes are available for the tangential necrosectomy of the ulcer. Battery-operated or drive-shaft dermatomes are the best options. They allow considerably more precise removal of necrotic tissue and offer greater safety and surgical comfort.

The next step consists of 'layered shaving'. Areas of necrosis and fibrotic tissue are now removed layer by layer until sufficient capillary bleeding is obtained in the wound bed. The aim is not to remove all the fibrosis, as the punctate bleeding necessary for the graft to heal tends to decrease macroscopically at the fascial level. The depth of the layers removed depends on the depth of the ulcer that needs to be evened out. Ideally there should be a flat wound surface. After haemostasis with adrenaline-soaked compresses,



▶ Fig. 2 (a) Ulcer involving the entire circumference of the leg, 21 years without healing. (b) Result after shave therapy.



▶ Fig. 3 Arterial ulcer on the foot: 89-year-old patient, ABI 0.5; Appearance before surgery, (b) Result 6 months after shave therapy.

the fresh wound is covered with the prepared mesh skin and the graft is fixed in place without tension. It may be fixed either with interrupted sutures, adhesive strips, staples or with only an adhesive dressing (> Fig. 1).

A protective sterile dressing and a compression bandage are then applied. Very firm compression is not required and tends to damage the graft. The first dressing change takes place on about the fourth postoperative day, with restricted bed rest until then to fix the graft and encourage the initial healing of the skin [12, 22].

Results of shave therapy

The results of shave therapy with simultaneous mesh grafting depend not only on the aetiology of the ulcer but also on many concomitant factors such as obesity, neurological disorders, reduced joint mobility (static/arthritic problems) and immunological disorders. The causes of non-healing ulcers are almost always multifactorial and require additional therapeutic approaches (e. g. weight loss, bariatric surgery). Even so, vascular ulceration is still the most common cause, accounting for 80 to 90 % of ulcers.

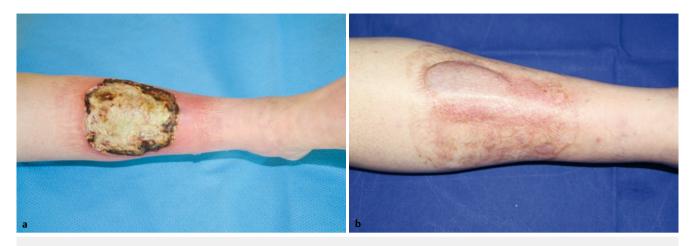
Results of shave therapy in venous leg ulcers Long-term results with healing rates of 70–85% have been confirmed in various retrospective analyses (Hermanns, Obermayer, Popescu). The

patients all had non-healing chronic ulcers with a history of more than 16 years prior to surgery (**Fig. 2**). Some had extensive ulcers affecting the entire circumference of the leg that had showed no tendency to heal for up to 40 years. No other procedure has yet yielded such good long-term results [8, 9, 10, 11, 18].

The recurrence rate of venous ulcers after shave therapy depends on the severity of the CVI and the possibility of also treating the venous reflux. A higher recurrence rate must be anticipated in patients with post-thrombotic disorders. If only primary varicose veins are present, which can be eliminated adequately, and if a stable tissue situation can be achieved through additional local ulcer surgery, we can assume that healing will be permanent [7].

Results of shave therapy in mixed vascular leg ulcers When leg ulcers occur in the presence of both venous and arterial disorders, but the venous insufficiency predominates, a combination therapy to eliminate the reflux and local ulcer surgery produces good results without the need for arterial revascularisation.

In the evaluation of his patients, Obermayer was already able to demonstrate in 2008 that 68% of the ulcers in the mixed ulcer group healed permanently with elimination of the varicose veins and local ulcer surgery. In the group with purely venous ulcers, 85% of the ulcers were healed at follow-up [17, 19].



▶ Fig. 4 Pyoderma gangrenosum (a) before and (b) 10 years after shave therapy.



▶ Fig. 5 (a) Post-thrombotic syndrome with secondary lymphoedema. (b) Result 12 months after shave therapy.

Results of shave therapy in arterial ulcers When vascular diagnostic investigations have shown that refractory ulcers of the leg or foot are due to reduced arterial perfusion alone and the findings are not consistent with critical leg ischemia, patients may also benefit from shave therapy without it being absolutely necessary to carry out a revascularisation procedure beforehand.

In 2014, we followed up our own surgical patients with disorders of the arterial circulation alone (clinical stage II a and b based on the Fontaine classification). Following tangential necrosectomy and simultaneous mesh skin grafting, 70.9% of the ulcers healed completely (**Fig. 3**).

If the less stressful shave therapy does not have the desired success and the skin graft is rejected, invasive arterial diagnostic investigations (e.g. angiography) can be performed without undue delay and all the necessary revascularisation measures initiated [12].

As would be expected from the increase in arterial perfusion disorders associated with the human aging process, the long-term results of healed arterial ulcers are not as good as those of purely venous ulcers. However, no data or prognoses are currently available.

Results in non-vascular leg and foot ulcers The pathogenesis of some 5-10% of all ulcers is not directly vascular. In our patient

population, such findings have increased in recent years. We have obtained good or excellent results in the following conditions:

- Obesity, grade I to III
- Post-traumatic ulcers:
 - Burn scars
 - Chemical burns
 - Residual conditions after severe soft tissue trauma
- Underlying neurological diseases:
 - Spastic spinal paresis
 - Paralysis of the legs
 - Poliomyelitis
- Pyoderma gangrenosum (► Fig. 4)
- Primary and secondary lymphoedema (► Fig. 5)

Hach's fasciectomy

Based on the pathophysiological concept of a chronic venous compartment syndrome, it is necessary to remove the crural fascia in addition to decompressing the subfascial compartment. This only concerns ulcers that show definite signs of dermatolipofasciosclerosis and are primarily of venous origin. The fascia is resected en bloc with the necrotic and fibrotic parts of the ulcer (> Fig. 6). The surgical technique is considerably more demanding and carries the risk of intraoperative and postoperative complications. After fas-





▶ Fig. 6 (a) Resection of crural fascia. (b) Operation site after mesh grafting. Photos courtesy of Dr. Alfred Obermayer (MD).







► Fig. 7 (a) Ulcer with dystrophic calcification. (b) Intraoperative calcification. (c) Result 4 years after partial fasciectomy.

cial resection, the selected graft bed consists of subfascial structures such as muscles, tendons and bone. Graft rejection reactions are more likely, if any of these structures are damaged during the preparation of the wound bed (e. g. the tendon sheath is opened). Injuries of the vessels and nerves in the subfascial space may occur and call for an experienced surgeon, who knows how to handle such complications [5, 18, 25].

Results after fasciectomy To date, there are unfortunately only a few reports of the outcome after fasciectomy and only one comparative analysis of a small number of cases (14/17 patients) from Hach's (Schwahn-Schreiber's) and Schmeller's patient populations. Seven years after surgery, 70.6% of ulcers were recurrence-free following shave therapy, but only 50% following fasciectomy [24].

The obvious advantages of shave therapy have changed the range of indications for crural fasciectomy.

Today, only the following clinical conditions are treated by necrosectomy with fascial resection:

- Primary transfascial necrosis with exposed tendons:
 The fascial structures have already been damaged by necrotic processes. These cases require a complete en bloc resection of the lesion with clear tissue margins.
- Multiple recurrences after shave therapy: In 20–30% of ulcers that have been operated on, small residual or larger recurrent lesions may develop in the graft over time. If these defects, which are usually smaller than the original lesion, do not heal with conservative measures, repeat shaving should lead to definitive healing. If repeat shaving also fails, the ulcer has to be excised together with the fascia and a new graft bed prepared.
 Extensive time consuming revision surgery of this nature is

Extensive time-consuming revision surgery of this nature is seldom required.

Dystrophic calcification:

Marked calcification in the layers around the ulcer may make it technically impossible to perform a tangential necrosectomy using a dermatome. Excision may also be difficult, as the calcification often extends far beyond the ulceration and a circumscribed resection is not possible. The cause of this calcification is not usually known (**Fig. 7**).



▶ Fig. 8 (a) Ulcer on the foot, patient with diabetes. (b) Shave procedure. (c) Mesh graft. (d) VAC dressing. (e) Result 5 years after surgery.

Lateral leg ulcers:

In 2016, Obermayer and co-workers published a further indication for **fasciectomy**. They reported excellent results in ulcers located laterally on the lower leg (98% complete healing) after fasciectomy with exposure and protection of the peroneal nerve [20].

Hach proposed muscle transposition surgery for these ulcers. The frequently exposed distal fibula was first covered by mobilising the surrounding muscle and then closed with a mesh

skin graft [5].

In this area, we also prefer **shave therapy**, which produces the same good results as in other regions of the lower legs.

Grafting to cover lower limb defects

Free or pedicle muscle flap grafts to cover chronic ulcers on the lower leg are hardly ever performed today.

Transposition onto the bed of a defect that has been damaged by fibrosis and sclerosis is not very promising of success. In addition, these musculocutaneous flaps have little or no sensation and are at risk from unnoticed pressure or trauma, especially around the ankle.

Negative wound pressure therapy (NWPT): vacuum-assisted closure

Wound closure with vacuum dressings can be used as an adjunct to both shave therapy and fasciectomy [13, 25]. We combine shave therapy with simultaneous mesh grafting and a vacuum dressing in about 10% of our operations. When we are not sure that the skin graft will take and in cases with stepped lesions or exposed bony structures, we expect a certain booster effect from an additional primary vacuum dressing (> Fig. 8). A trend towards better healing has been reported for the combination of split-skin grafts and VAC dressings, but it was not statistically significant. In general, there is not yet sufficient evidence for the use of NWPT in the treatment of chronic wounds [16, 30].

Conventional surgical wound débridement

The removal of dead tissue, necrotic areas and deposits using various instruments is the oldest and most basic surgical approach in the treatment of non-healing wounds. Instruments for this purpose include scalpels, sharp spoons and curettes. They are used to remove as much of the dead tissue as possible, in order to reveal intact anatomical structures. Extensive débridement requires adequate analgesia and, in some cases, even a general anaesthetic.

There are only a few studies on the value of surgical wound débridement; they have methodological deficiencies and show no statistically significant results. However, débridement seems to have a positive effect on the reduction of the wound surface and on wound healing, a finding that is clearly supported by the routine practice of wound therapists [2].

Postoperative care

The most important factor to ensure good long-term results is a standardised treatment strategy, both for the immediate post-operative period and after the patient has been discharged from hospital.

This strategy should stipulate fixed intervals for dressing changes and treatment from all the therapists involved and include the hospital's physiotherapeutic and exercise facilities. Routine complex decongestive therapy seems to be important and we start this from the seventh day after surgery. It prevents oedema and protects grafts with only a small supply of lymphatic capillaries from rejection reactions.

Mobilisation of the ankle in cases of arthrogenic stasis syndrome, strengthening of the frequently atrophied leg muscles, education about skin care, the use of protective bandaging and compression stockings after discharge are all important parameters of long-term success.

SUMMARY FOR CLINICAL PRACTICE

Today, successful treatment strategies are available for the surgical treatment of refractory chronic wounds on the lower limb.

Shave therapy has become established as a procedure that achieves hitherto unknown success with healing rates of 70% to 85%. The technique is safe and rarely leads to complications; it is easy to learn and operating times are short. There is little stress for the patient and it is also a suitable procedure for those of advanced age.

For surgical success, it is essential to prepare a fresh wound by removing necrotic tissue in layers with a state-of-the-art dermatome and to perform a split-skin graft immediately. The procedure achieves good local results and patients are rapidly free of pain with a better health-related quality of life. Other procedures, such as fasciectomy, adjunctive vacuum-assisted closure and conventional débridement are reserved for specific indications.

Conflict of interest

H.J. Hermanns declares that he has no conflicts of interest

Compliance with ethical guidelines

This article does not contain any studies on humans or animals carried out by the author.

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