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The use of mechanically powered disposable negative pressure wound therapy (dNPWT) devices for patients with acute and chronic wounds – Findings of a Consensus Conference*

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CONSENSUS

The use of mechanically powered disposable negative pressure wound therapy (dNPWT) devices for patients with acute and chronic wounds – Findings of a Consensus Conference

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Foreword

There has been an unprecedented growth in the range of negative pressure wound therapy (NPWT) devices on offer [4]. This provides clinicians and paying authorities with more choices when deciding which product to use for wound management in which situation.

The NANOVA™ Therapy System and the SNAP™ Therapy System (KCI, Acelity) are two mechanically powered negative pressure wound therapy devices that open up access to the range of electrically powered systems and – when used in the appropriate clinical setting – can prove advantageous [4].

A group of expert users met in 2017 and 2018 to critically appraise the role of these devices in the clinical setting and assess the situation with regard to the use of negative pressure wound therapy in the community setting as well as the continuity of care from the hospital to home.

The group's declared goal is to give clinicians an overview of the differences between NPWT systems and help them choose the correct product with the aid of flowcharts. It was deemed imperative to present the, indeed already well-known, treatment principles of NPWT as well as the current evidence and legal framework that determine the approach taken by the German statutory health insurance (SHI) funds to wound management. It is against that background that the following statements are made.

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Baseline situation

Every wound is a reflection of compromised bodily integrity that is accompanied by a reduction in the quality of life. Apart from the medical challenges presented by the treatment of patients with acute and chronic wounds, high costs are incurred by the health insurance funds because of the long treatment period. There are also high social costs due to incapacity to work or early retirement.

There is no uniform definition of the term "chronic wound". The Expert Working Group for Care of Persons with Chronic Wounds defines as a chronic wound any wound that shows no sign of healing after four to twelve weeks despite optimal treatment [18].

On the other hand, the Chronic Wounds Initiative (ICW) classifies a healing process lasting eight weeks or longer as a sign of a chronic wound [2].

Regardless of this temporally oriented definition, there are wounds that from the outset are viewed as chronic since their therapy requires treatment of the ongoing underlying cause. These include, for example, diabetic foot syndrome, wounds linked to peripheral arterial occlusive disease, venous leg ulcer or decubitus ulcer [2]. In general it is not possible to achieve wound healing without treating the underlying disease. In Germany there is currently no evidence- and consensus-based guidance to treatment of chronic wounds using a treatment algorithm accessible to all participating disciplines and professions.

To date, interdisciplinary and interprofessional cooperation or transsectoral networking is not optimal in Germany. There are gaps in care as well as the need for optimization of interface management [1,3]. Hence, there is currently a clear need for improvement in the care of persons with chronic wounds.

Against that background, this consensus paper describes the benefits of negative pressure wound therapy (NPWT) beyond its classic use in the inpatient setting as well as the role of mechanically powered disposable NPWT (dNPWT) systems.

In view of the current legal framework governing the standard range of care provided by SHI physicians in Germany, the signatories furthermore deem it imperative to once again elaborate on aspects of NPWT already reported in the medical literature and known to users.

Negative Pressure Wound Therapy (NPWT) – Definition

NPWT is the continuous or intermittent application of subatmospheric pressure to the wound bed to induce wound healing and reduce the time to closure of the wound [6, 7].

It is used as a method of temporary soft tissue coverage for wound bed preparation during bridging until secondary wound closure or surgical defect closure [23].

Accordingly, in the German Procedure Classification System (OPS)* codes 5-916.a0-ax specific to vacuum therapy are assigned to the chapter on temporary soft tissue coverage (5–916ff) [24].

OPS - German Procedure Classification. The German procedure classification (Operationen- und Prozedurenschlüssel - OPS) is the official classification for the encoding of operations, procedures and general medical measures in the inpatient sector and for surgical procedures in the outpatient sector.

NPWT is an effective and established treatment form for a large variety of acute, complicated, complex as well as chronic wounds of the most diverse aetiologies, causes and locations with a continuously growing spectrum of indications since the 1990s [5]. In 2016 it was used in Germany for over 189,000 hospitalized inpatients (German Federal Statistical Office: number of invoiced cases in 2016: temporary soft tissue coverage: 5-916 n = 187510) [25].

That means that around one out of every 200 hospitalized patients received treatment with NPWT [5].

NPWT is known to have a number of clinical effects that stimulate healing. The Consensus Document of the European Wound Management Association (EWMA) of 2017 [14] characterizes the effects of NPWT on the wound as follows:

- Reduction in wound size
- Increased blood flow to the wound
- Removal of excess fluid and reduced tissue oedema
- Stimulation of granulation tissue, resulting in progressive wound closure
- Increased cell proliferation
- Removal of free radicals from the wound[1]
- Wound cleansing[2]/removal of dried exudate, blood and cell debris
- Protection from outside contaminants and decrease in bacterial bioburden
- Maintenance of moist wound healing environment
- Reduced wound bed trauma
- Enhancement of the quality of life: no exudate leakage, no soiling of clothing, no wound odour

Evolution of NPWT systems

Over the past 30 years NPWT systems have undergone continuous development. The initially non-regulated mechanical systems were replaced in the 1990s with electrically powered, electronically controlled systems. These were later supplemented with an automated fluid instillation technique to treat infection. This, in turn, was followed by the extended application of preventive NPWT in cases of wound closure by primary intention. That exploits, in particular, the oedema-reducing effect of NPWT. In technical terms the recently introduced mechanically powered systems serve as a link between hydroactive wound dressings and the classic NPWT systems.

Differences in NPWT systems

Classic NPWT – electrically powered and electronically controlled

The electrically powered systems (e.g. ACTIV.A.C.™ Therapy System manufactured by KCI, Texas, USA) consist of a wound filler material (polyurethane or polyvinyl alcohol foam of different configurationsor foam with an antimicrobial silver coating, Kerlix™ gauze), a semipermeable, steam-permeable wound dressing with integrated drainage tube and, as therapy unit, an electricallypowered vacuum source (suction pump). The wound and wound filler material can in theory be of any size and can thus be used to treat even very large wounds on the trunk and chest or wounds encompassing an entire limb. Several wounds can be individually covered and using a bridging technique cared for with the same therapy unit. The therapy unit can be incrementally set to a pressure range of –200 mmHg, while the default negative pressure setting is –125 mmHg. The drained amount of exudate can be as much as 1000 millilitres before having to replace the canister. The electronic control unit features intuitive sensor technology which, by measuring the vacuum force (suction strength) close to the wound (SENSAT.R.A.C.™ Technology, KCI, Texas, USA), is able to signal every pressure drop and every vacuum fluctuation. Minor vacuum losses are automatically corrected, thus ensuring that the set negative pressure is continuously maintained. Trained personnel who must be accessible 24 hours is needed to operate an electrically powered, electronically controlled system.

Negative pressure wound therapy can

[1] Among other postulated and proven mechanisms of action of NPWT, the removal of free radicals from the wound is one of these effects.

[2] Translated from the English EWMA document, described there as Debridement.

also be successfully used with lasting effect to treat problem wounds in seriously ill patients in the community setting [11]. The infrastructure prerequisites needed to that effect are, of course, physicians, surgical centres and nurses/carers experienced in the use of NPWT [26].

In 2004, 159 multimorbid patients received ambulatory treatment with the, at that time, only commercially available NPWT V.A.C.® Therapy (V.A.C. = VACUUM ASSISTED CLOSURE™) and were followed up in 2006 [11]. The key questions explored by the paying authorities were whether the effect of V.A.C.® Therapy when administered in the community setting was as pronounced as when applied in the hospital, whether it was lasting, how high was the treatment failure rate and how high the early recurrence rate. 68 % (108 of 159) of patients with problem wounds and multimorbidity who had survived the one-year follow-up period were completely healed in the long term, i.e. more than one year. In another 20 % (n = 32) the wound healing was foreseeable on the day of review but was still not complete. In 12 (n = 19) patients treatment was not successful when evaluated in terms of complete healing. In such cases, treatment had to be discontinued, for example, because of amputation (arterial vascular occlusive disease) or for other reasons related to progression of the underlying disease.

In 21 % (n = 34) of patients V.A.C.® Therapy had been applied as a bridging measure to plastic coverage (skin transplant, secondary suture, inter alia surgical procedure).

Unlike the conventional NPWT described, the clinically important NPWT variant with integrated fluid instillation (NPWTi-d), used in particular for cleaning infected or fibrin-coated wounds, has to date only been used in the inpatient setting. (Currently available is also the V.A.C. ULTA™ Therapy System with VERAFLO™Technology from the firm KCI).

Mechanically powered devices – disposable NPWT (dNPWT)

The latest, mechanically powered smaller systems (SNAP™ Therapy System and NANOVA™ Therapy System from the firm KCI, Texas, USA) are designated by the manufacturer as disposable Negative Pressure Wound Therapy (dNPWT) systems.

These devices are supplied in combination with foam and a wound dressing. In the SNAP™ Therapy System this consists of a contour hydrocolloid, while in the NANOVA™ Therapy System it is a superabsorbent, integrated into a semipermeable, airtight wound dressing. This is connected to a spring mechanism that through manual volumetric shift generates the negative pressure. These mechanical systems have no electronic pressure monitoring or fault signalling facilities. Optical markers that can be read on the systems are used to monitor the vacuum. The vacuum can be restored at any time via the mechanical vacuum source, and by the patient too. The scope of application is defined by the foam sizes available, the negative pressure level to be set and the amount of exudate to be drained, thus constituting a major difference versus the electronicallycontrolled and electricallypowered systems.

The SNAP™ Therapy System features various negative pressure levels (–75 mmHg, –100 mmHg and –125 mmHg). The exudate amounts that can be drained are 60 or 150 ml. The maximum wound size that can be treated is determined by the dressing sizes available. However, according to the manufacturer's instructions the wound depth should not exceed 3 cm (Tab. 1). The NANOVA™ Therapy System generates a vacuum force of only –125 mmHg. The wound dressing consists of a superabsorbent which also serves as a reservoir for the exudate and continues to drain exudate even if the negative pressure has been lost. As such, the superabsorbent wound dressing acts as a protective mechanism. It can be combined with granulation-stimulating foam for a maximum wound depth of 2 cm. Here, too, the use of this system is restricted by the wound dressing sizes available (Tab. 2). The NANOVA™ Therapy System has been designed for more superficial wounds and is also suitable for the transition from the granulation to the epithelialization phase. That expands its scope of application since conventional NPWT is not suitable for the epithelialization phase.

Table 1: Manufacturer's instructions on negative pressure, cartridge capacity and wound dimensions for the SNAPTM Therapy System manufactured by KCI

SNAP™ Therapy System Cartridges		
Cartridges and negative pressure variants	**Capacity**	**Maximum use duration**
SNAP™ Therapy System -125 mmHg	60 ml	7 days
SNAP™ Therapy System -100 mmHg	60 ml	7 days
SNAP™ Therapy System -75 mmHg	60 ml	7 days
SNAP Plus™ Therapy System -125 mmHg	150 ml	7 days
SNAP™ Therapy System Dressings		
Size*	**Maximum wound size**	**Maximum wound depth**
15 x 15 cm	13 x 13 cm	3 cm
10 x 10 cm	8 x 8 cm	3 cm
Bridge Dressing 14 x 11 cm	8 x 8 cm	3 cm

* In the meantime, KCI is supplying another dressing measuring 20 × 20 cm with maximum wound size 18 × 18 cm, which was not yet available at the time of the Consensus Meeting

Clinical indications and contraindications for NPWT and dNPWT

NPWT or dNPWT should never be used without critical appraisal. Effective wound management calls for holistic assessment of the patient and their specific problems, cofactors and comorbidities as well as the special characteristics of the wound. Causal therapy of the underlying factors inhibiting wound healing must be initiated before using NPWT or dNPWT (see Fig. 1).

This means that the wound management concept must always be based on elucidation of the aetiology of disease and commensurate treatment. Accordingly, the clinical indications for the

Table 2: Manufacturer's instructions on the capacity of the superabsorbent, which is used in this system to retain exudate, and on wound dimensions for the NANOVATM Therapy System manufactured by KCI

NANOVA™ Therapy System					
Therapieeinheit Unterdruck	**Maximum use duration**				
NANOVA Theray system™ -125 mmHg	30 Tage				
NANOVA™ Therapy System Dressings					
Dressing size	**Wound pad size**	**Maximum wound size**	**Maximum wound depth**	**Capacity with negative pressure**	**Capacity without negative pressure**
18 x 14 cm	10 x 6 cm	8 x 4 cm	2 cm	< 25 ml	< 56 ml
18 x 18 cm	10 x 10 cm	8 x 8 cm	2 cm	< 40 ml	< 94 ml
18 x 28 cm	10 x 20 cm	8 x 18 cm	2 cm	< 60 ml	< 188 ml

use of NPWT and dNPWT are multifaceted, with smooth transitions between the various systems in everyday practice. They should also be used in line with the concept of phase-specific wound management, as advocated in the revised version of the expert standard "Caring for persons with chronic wounds" from 2015 [18].

The "classic" indications include, in addition to dirty, contaminated acute wounds [23], chronic wounds that have stalled and/or hard-to-heal wounds that have not responded to standard treatment.

NPWT can be considered for any wound that

- is failing to progress to healing in the expected timeframe using standard wound treatment,
- produces high volumes of exudate and/or exudate of high viscosity that is difficult to manage with standard wound treatment,
- requires reduction in wound size to achieve surgical (primary) wound closure or healing by secondary intention [35].

In principle, NPWT or dNPWT can be used for any wound that can also be covered with a semiocclusive or occlusive dressing (Fig. 1).

Classic contraindications for semi-occlusive dressings are inadequate debridement with extensive necrosis, uncontrolled spreading infection, periwound maceration or ulcerating tumours. In such cases one would not either use any semi-occlusive dressings, such as hydrocolloids, foam dressings with border or occlusive film dressings (12, 13, 16).

However, in contrast to passive wound dressings, NPWT has the unique feature of embodying a physical treatment concept in that, because of the negative pressure, it actively drains exudate, avoids exudate congestion and mechanically stimulates the wounds [20]. That mechanical stress actively promotes wound healing [20, 27, 28, 29, 30]. NPWT results in demonstrably [31] earlier growth of granulation tissue and shortens the treatment time to definitive wound closure.

Advantages and benefits of a mechanically powered negative pressure wound therapy: dNPWT application

In principle, wounds can be cared for with the vast range of wound dressings available.The advantages and strengths of dNPWT systems over conventionaland modern wound dressings come into play, in particular, for wounds in the exudation and granulation phase, especially when these still need some time to produce granulation tissue and/or exudate [4] (Fig. 1; Fig. 2).

Compared with modern wound dressings, dNPWT systems also have advantages when it comes to improved mobility [4, 10] patient concordance [10, 11] and self-care competency as well as user safety and hygienic operation [8]. According to the guidelines of the Robert Koch Institute (RKI), NPWT and dNPWT dressings must be changed under sterile conditions or using the non-touch principle. The devices meets the requirements for sterile conditions especially under the hygienically challenged conditions prevailing in the ambulatory or domiciliary setting. Just like conventional wound dressings, so too does the use of NPWT and dNPWT systems obligatorily include the use of a dressing whose cost must be reimbursed. (See also "Reimbursability of NPWT and economic benefits".)

Since the therapy unit has no electric drive, the mechanically powered systems are lightweight and permit greater mobility, especially in the home setting, without having to worry about vacuum losses because of a discharged storage battery as in the case of an electrically powered therapy unit. Overall, the mechanical systems are easy to operate and less training is required for the user [4]. However, wounds in body cavities (abdomen, chest) cannot be treated with these small mechanical systems because of their configuration.

In terms of effectiveness the mechanical dNPWT SNAP™ Therapy System does not appear to be inferior to the electrically powered system, subject to being used for a suitable (small) wound size.

A prospective, randomized controlled trial with 132 patients over 16 weeks demonstrated that there was no difference between the effectiveness of the mechanically powered dNPWT with the SNAP™ Therapy System and the electrically powered NPWT, but that at the same time the quality of life of the respective patients was less affected [9]. Enrolled in the trial were patients with non-infected, non-ischaemic, non-plantar diabetic and venous wounds. The primary endpoint was the reduction in wound size after 16 weeks. Kaplan-Meier analysis did not identify any significant difference on complete wound closure between dNPWT- and NPWT-treated patients. Patients who received dNPWT treatment reported less impact on their everyday activities thanks to less sleep interruption, lower

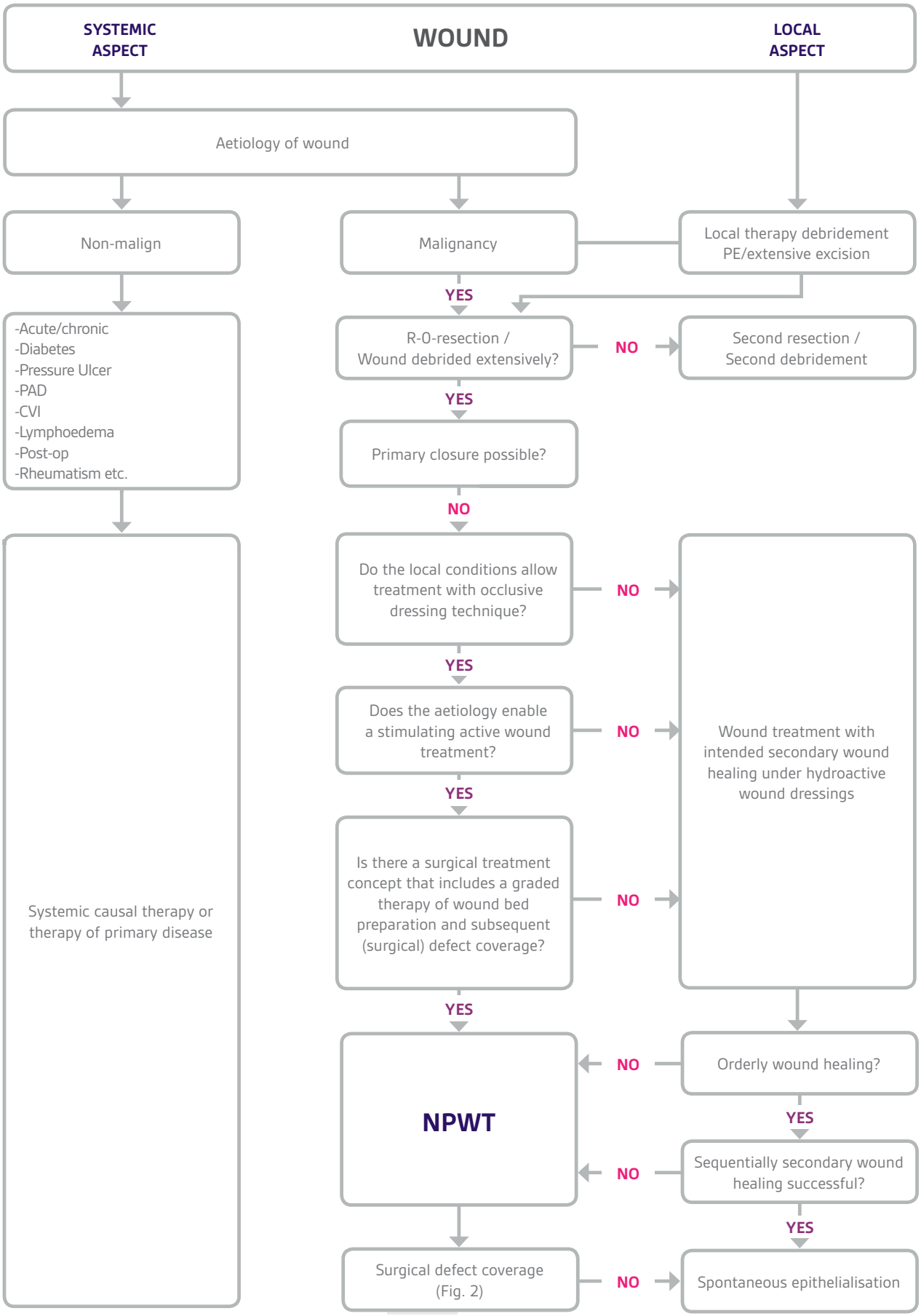

Fig. 1 Algorithm for stepwise wound treatment and for exploring under which conditions NPWT can be used. The algorithm is based on the algorithm for defining preconditions for the use of occlusive dressings [16].

noise level, less effect on their social situation and greater mobility compared with the NPWT-treated patients.

Within the framework of the aforementioned trial, a further study was conducted to compare the use of dNPWT with NPWT in an enrolled cohort of 40 patients with venous ulcers [10]. It should be pointed out that the wounds in the NPWT cohort were on average larger at treatment baseline compared with the dNPWT group. The primary endpoint was the reduction in wound size. In these patients dNPWT performed better than NPWT. After 30 days a 50% reduction in the wound area was noted for 52.6% (10/19) of patients treated with dNPWT versus 23.8% (5/21) of those treated with NPWT. On day 90, complete wound closure was seen in 57.9% (11/19) of patients treated with dNPWT and in 38.15% (8/21) of those treated with NPWT. The authors ascribe the differences to better clinical implementation rather than to another effect of dNPWT. For example, it was possible to change or replace the dNPWT system at any time also in the home. Conversely, the patient had to visit the hospital to change the electronically controlled, electrically powered NPWT system. Patients with the dNPWT system were more mobile and more active in their everyday activities, something that particularly benefits venous function. In summary, an increase in patient mobility was observed on using dNPWT.

The members of the Consensus Group believe that the clinical benefits bestowed by dNPWT on users are as follows:

- Reduction in microbial entrainment thanks to closed system
- Less training required (patient, relatives, nurses/carers, physician)

Besides, patients can derive the following benefits thanks to an improvement in the individual quality of life:

- Mobility
- Participation in social life
- Adherence
- Restoration or maintenance of self-care competency

Treatment algorithm

NPWT/dNPWT can be considered for all patients with wounds who have no explicit contraindications. It should be used selectively and as soon as possible as part of a clearly defined treatment process for a period of days to several weeks in order to actively influence the wound healing process. Meticulous debridement is recommended in principle before using NPWT/dNPWT (Fig. 1). That must be repeated over the treatment course for chronic wounds. Foam dressing changes at regular intervals as prescribed have a wound cleansing effect in that they remove exudate and adherent slough and stimulate cell proliferation.

The use of dNPWT is greatly limited by the wound size and exudate amount unlike the NPWT electric systems. Given a suitable wound size (see Tab. 1 and 2), wound care with dNPWT can be commenced immediately after primary wound debridement to promote wound cleansing and granulation. Furthermore, in the event of stagnating granulation of a wound healing by secondary intention, and which had not hitherto been treated with NPWT, dNPWT can be used to stimulate wound healing (Fig. 1, Fig. 3).

Evaluation of treatment with dNPWT should be documented at regular intervals. The expected effects include a reduction in the wound size and exu-

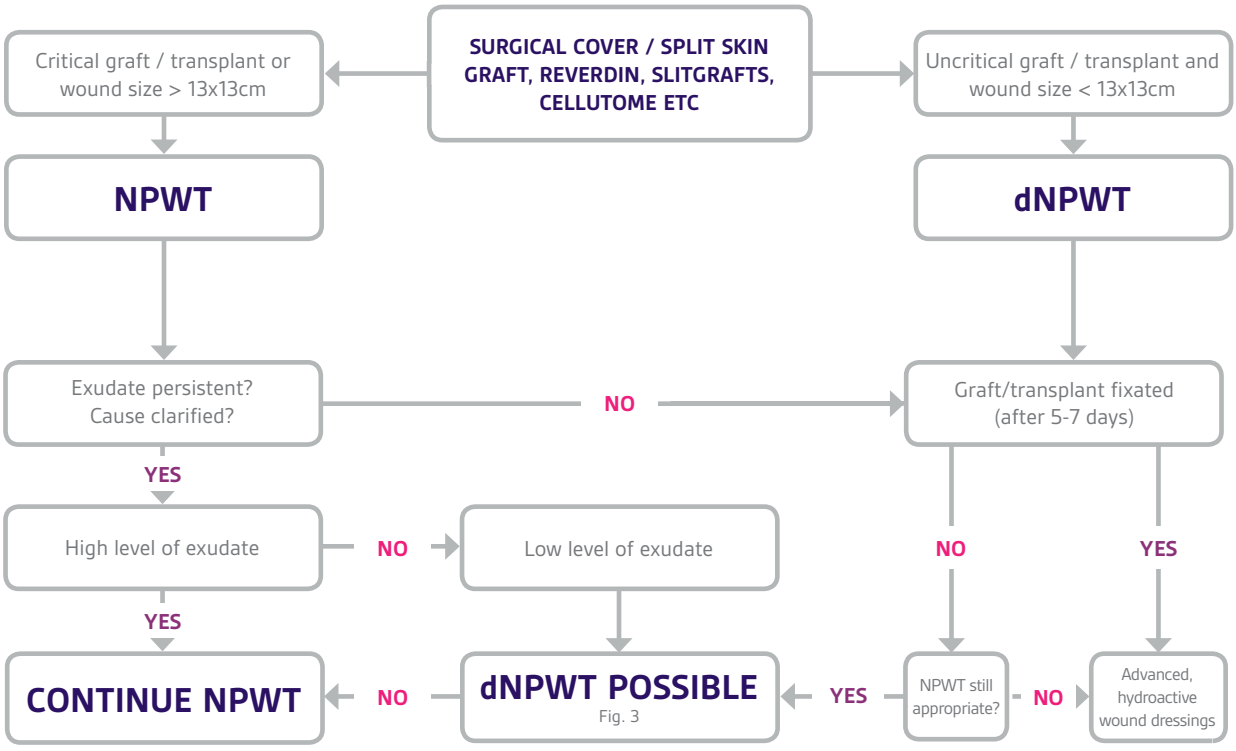

Fig. 2 Algorithm: Using NPWT for and after surgical defect closure and for choosing between dNPWT and NPWT systems

date amount and an increase in granulation tissue [14] as well as a reduction in pain and, not least, increasing patient mobility [4]. Besides, in everyday practice the authors have often already observed epithelialization.

If these effects are not exhibited within a period of around four weeks [4], causal therapy of the underlying factors inhibiting wound healing should be critically reviewed and, if necessary, dNPWT treatment discontinued. If the switch from an electronically controlled NPWT to a mechanically powered dNPWT is not deemed conducive to the healing process, it must be established whether switching back to an electronically controlled NPWT system would be beneficial.

Contraindications and complications of NPWT / dNPWT

There are reasons to contraindicate the use of NPWT and dNPWT. However, the authors believe that these do not constitute absolute contraindications, which in some cases may contradict the internal guidelines of the firm KCI. The user instructions and manufacturer's specifications as per the marketing license must be observed. Deviation from these is possible in individual cases.

Bleeding wounds

In principle, adequate haemostasis must be assured following debridement

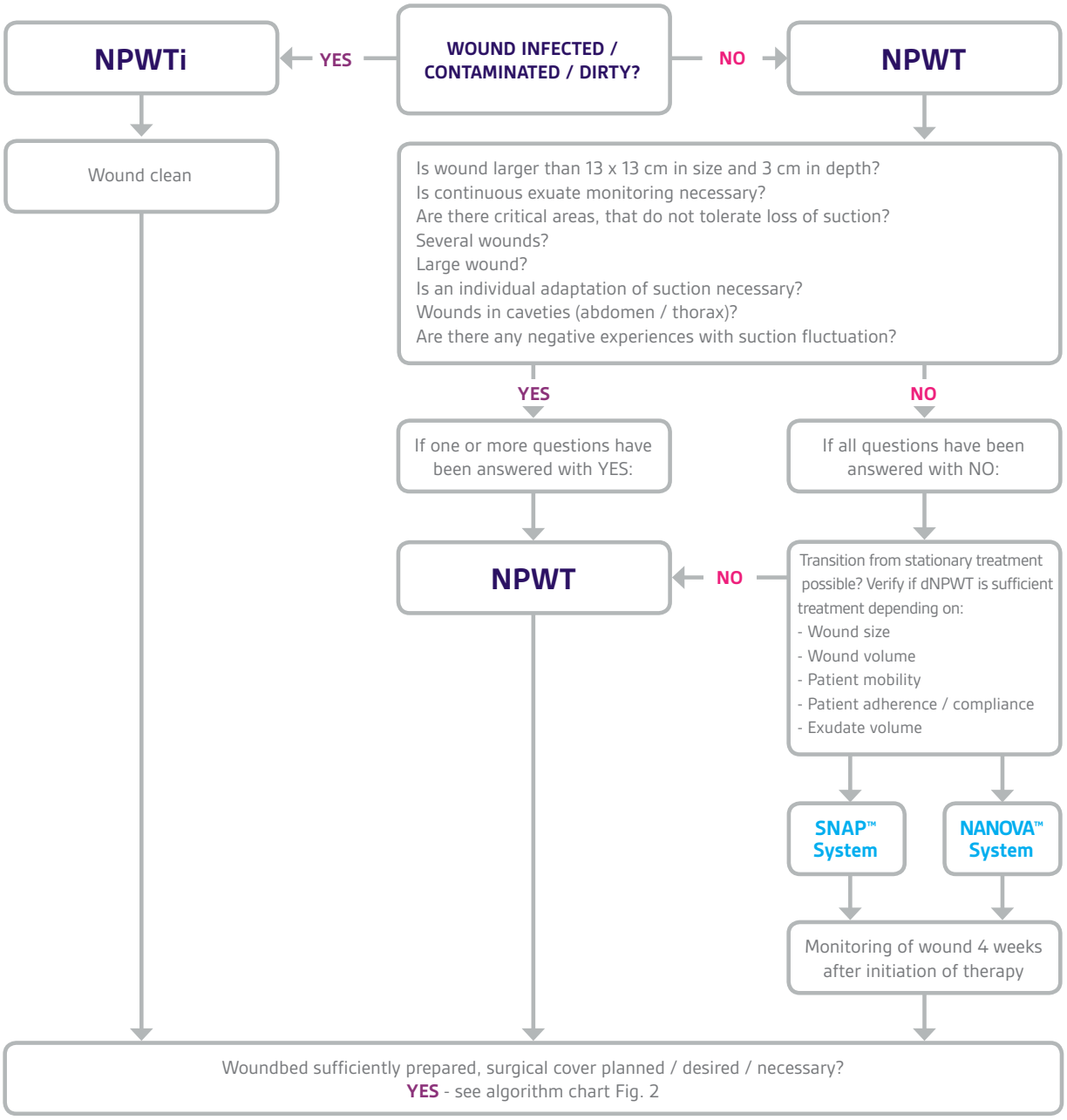

Fig. 3 Algorithm for choosing NPWT systems

before using NPWT. Otherwise, there is a risk of large amounts of blood being drained off, with the NPWT dressing remaining intact, and this could be hazardous for patients. That risk appears to be lower in dNPWT since for technical reasons the actively drained blood volume is less. Depending on the composition of the wound, NPWT/dNPWT can be accompanied by blood loss. This must be monitored and replaced if necessary. NPWT or dNPWT are not primarily intended for haemostasis of active bleeding from a traumatic wound.

Increased bleeding risk (patients with haemophilia, on anticoagulants or platelet antiaggregant therapy)

There is a risk of onset of bleeding due to the negative pressure and the mechanical stress exerted on the wound. Patients in the community setting must be made aware of this and closely monitored; they must also be capable of detecting bleeding early on and be conversant with the countermeasures needed.

Necrotic wounds

Extensive debridement is a precondition for successful application of NPWT therapy. However, since NPWT/dNPWT promotes autolysis small areas of necrosis and fibrin deposits are removed when changing the wound filler material. This wound cleansing process is further stimulated by means of fluid instillation with the instillations vacuum seal (NPWTi).

Infected wounds

Infected wounds constitute, in principle, an indication for treatment with NPWT. But the infection should be contained or susceptible to treatment. Treatment can be based on surgical measures such as debridement, if necessary also using an instillation vacuum seal (NPWTi). As in the case of necrotic wounds, extensive debridement is a precondition for successful application of NPWT therapy.

The use of NPWT should be critically appraised or rejected in cases of uncontained or spreading infection. Nor are occlusive dressings recommended in such cases.

Changes to the periwound skin (maceration, intolerances/ allergies, aged skin, parchment skin)

There is a risk that the systems may be poorly sealed when applied and of the periwound skin beneath the film being adversely affected or torn when removing the film. However, the dNPWT devices presented here need no film as they are applied via the integrated hydrocolloid dressings.

Exposed vessels or bypasses e

These patients should be treated with NPWT or dNPWT only under medical supervision and generally as inpatients.

Tumour wounds /tumorous wounds

There is a risk of tumour growth being stimulated with NPWT. Therefore tumorous wounds should not be treated with NPWT or dNPWT, apart from in the palliative setting where dNPWT can be useful in the management of exudate and odour [32].

Following R0 resection of a malignant tumour, wound bed preparation or wound treatment with NPWT/dNPWT can, however, be applied as in the case of any other non-malignant wound [33].

Wounds in body cavities (abdomen, chest)

Such wounds cannot in general be treated with mechanically powered dNPWT systems because of their configuration.

Special situations

Situations in which NPWT is specially indicated include the care of osteomyelitis, exposed organs and their structures or fistulae. It is likely that dNPWT systems may only be used here in exceptional cases.

Patient selection is an important determinant of a successful NPWT /dNPWT treatment outcome. The patient and their carers must be able to understand the technological principles and respond appropriately.

Patients using NPWT with electronic sensor technology and electric drive must have access to trained personnel since such systems can only be managed to an extent by the patients themselves. For dNPWT systems, too, it is important that a trained person should be able to restore the negative pressure. However, dNPWT systems such as NANOVA™ also serve as a primary dressing even without a vacuum.

But patient education is required for both NPWT and dNPWT.

Reimbursability of NPWT and economic benefits

Since 2017 the costs incurred for NPWT and dNPWT in the community setting in the USA are reimbursed separately by Medicare and Medicaid despite the questionable evidence (19) because, regardless of the perceived inadequate proof of evidence, the use of NPWT and dNPWT also involves a reimbursable dressing change.

The German Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany and stipulates which services are, or may be, reimbursed by the statutory health insurance (SHI) funds.

The G-BA is subject to the statutory supervision of the Federal Ministry of Health and discharges its duties essentially by issuing directives that are legally binding for the all persons insured by, or participants of, the SHI funds. The G-BA defines the content of the catalogue of services/benefits reimbursed by the SHI funds.

Medical devices classified as “New examination and treatment methods” (NUB), which also include NPWT, must be assessed according to the pertinent legislation to determine whether they should be used in the inpatient or outpatient setting.

In the clinical setting NPWT is an established therapy and can be used without any obligation to seek permission to do so. The additional costs incurred are to some extent reimbursed through the flat-rate, case fee system.

In the community setting such an approach cannot be adopted to the use of medical devices. They must always be assessed by the G-BA if:

- The method has hitherto not been reimbursed as an eligible standard benefit of the SHI funds, i.e. is considered to belong to the “New examination and treatment methods”

or

- The indication for an already reimbursable method has essentially changed.

Reimbursement of NPWT as a standard benefit covered by the SHI funds is not possible without being approved for ambulatory use by the G-BA. But to date no such decision approving the use of NPWT as a standard benefit has been taken by the G-BA. In practice this means that at present reimbursement for the use of dNPWT can only be decided on a case-by-case basis by the health insurance funds. Essentially, this means that at present the costs for inpatient NPWT are included in the flat-rate case fee of the Diagnosis-Related Groups system or are partially additionally reimbursed. So far, in the outpatient setting the catalogue of standard benefits makes no provision for reimbursement.

An overview of randomized controlled trials in the latest Cochrane Review from 2018 [34] concluded that NPWT possibly had a positive effect on wound healing.Its main benefits were expedited granulation and earlier definitive wound closure [9, 17].

However, according to the study data available, a Cochrane Review from 2006 [21], an assessment from 2006 [37] by German Institute for Quality and Efficiency in Health Care (IQWIG) and another review from 2008 [22], there is not enough evidence to demonstrate the superiority or additional benefits of NPWT over conventional wound therapy in terms of the number of fully healed wounds of different aetiologies.

Experts know that it is very difficult to devise a standard assessment procedure for chronic wounds because of the specific characteristics and inhomogeneity of the patients [14].

But it is incumbent on the G-BA and IQWIG to discharge precisely that task.

They must demonstrate that NPWT is more economical than conventional dressing-based wound management.

To that effect, a more in-depth study has been undertaken at the behest of the G-BA to investigate these issues [5].

The findings of that study are still pending. Regardless of such findings, the basic issue is that NPWT systems are being used for the most diverse aetiologies and for wounds of variable complexity with different therapy goals. Hence, no single study can produce the evidence required. Accordingly, the Cochrane Reviews from 2018 broke down the evidence in terms of the different wound aetiologies (for NPWT a separate review for open traumatic wounds, leg ulcer, burns, diabetes mellitus foot wounds, skin transplants and surgical wounds with primary preventive NPWT, surgical wounds with healing by secondary intention and pressure ulcers [34].

The long wait for a decision on whether or not to approve NPWT and thus clarify whether the incurred costs can be reimbursed as a standard benefit has economic implications for the health insurance funds because:

- The insured persons' hospital stays are longer than necessary,
- The costs for inpatient treatment rise without any added value for the insured persons.

For example, due to the fact that NPWT costs cannot be reimbursed by the SHI funds, in the case of just one German health insurance fund DAK-Gesundheit (with 5,958,008 insured persons) [36] in 2016 around 3,200 insured persons were treated for an average of 21 days longer in hospital (DAK Gesundheit 2016 Hospital Report, G. Kostka,Presentation on Health and Care Management of DAK-Gesundheit, Focus Project "Chronic wounds", personal communication) than would have been the case had, following a corresponding diagnosis, continuity of care with NPWT from the hospital to home been possible. That translates into considerable additional costs. The only solution at present for treatment of acute and chronic wounds in the community setting with NPWT/dNPWT is to draw up contracts for special care on the basis of Section 140 of Book V of the German Code of Social Law (SGB V). In which case, the burden of proof for demonstrating the economic efficiency is borne exclusively by the respective health insurance fund.

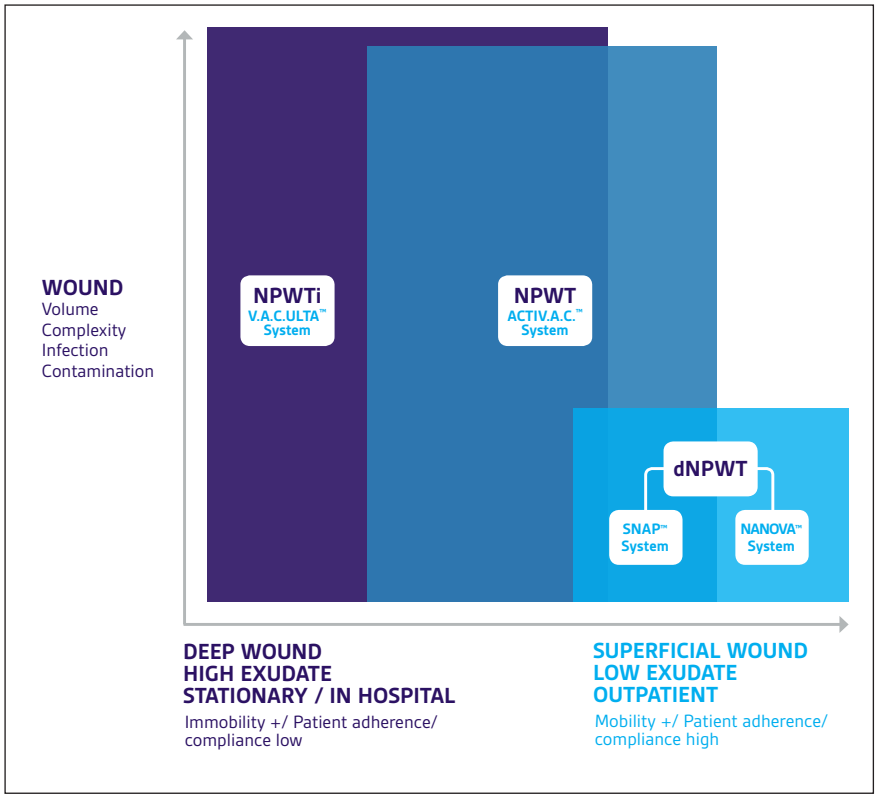

Fig. 4 Spectrum of indications for the various NPWT systems in relation to the wound situation

Conclusion

Mechanical dNPWT systems are a graduated addition to the more consumable-intensive electrically powered, electronically controlled NPWT systems, which can be used as an adjunctive approach. In certain cases there is an overlap of the indications for NPWT and dNPWT systems (Fig. 4). dNPWT systems do not constitute a fundamental alternative to the electrically powered NPWT systems since, because of

their configuration, their scope of application is restricted to smaller and low-exudate wounds. However, for suitable wounds the switch from an electrically powered NPWT to a mechanically powered dNPWT system bestows many cost advantages.

Compared with conventional wound dressings, they offer the essential advantages and additional benefits of NPWT.

For continuity of care from hospital to home of suitable wounds these systems are a futuristic cost-effective alternative to the more cost-intensive electrically powered NPWT systems.

NPWT and dNPWT are a logical, wound-phase specific and economical treatment form that selectively stimulates wound healing and can greatly contribute to maintenance of the individual quality of life of patients.

It is one of the wound treatment forms most commonly used in hospitals but in the community setting in Germany it has since 1998 been absurdly classified as belonging to the "New examination and treatment methods". From the Expert Group's perspective this results in inadequate care of patients diagnosed with the cost-intensive disease entity "chronic wounds". The authors deem NPWT and dNPWT to be an adequate, appropriate, necessary and economical treatment form.

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