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Feasibility of collecting wound fluid during ongoing negative pressure wound therapy by the use of an additional container – A prospective observational study

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Abstract

Negative-pressure-wound-therapy is commonly used in clinical routine for wound management. Aim of the present study was to assess the feasibility and safety of using an additional container to collect wound fluid during ongoing negative-pressure-wound-therapy. In this present prospective observational study, patients with negative-pressure-wound-therapy were included. An additional container was inserted in the connecting tube between the wound and the vacuum generating device. The following 3 days, the container was changed daily and replaced by a new one. Further safety outcome parameters were assessed. A questionnaire was answered by the responsible surgeon. Twenty-two patients with negative-pressure-wound-therapy with a median (IQR) age of 58.5 (53.0-70.0) years were included in the present study. In median, the duration of negative-pressure-wound-therapy was 5.0 (4.6-5.5) days. In mean ± SD the collected volume of the wound fluid in millilitres (mL) was on day one 7 ± 4 on day two 8 ± 7 and 10 ± 11 on day three. In one patient, there was <0.1 mL of clear water in the additional container. No safety concerns due to the additional container were observed. This study demonstrates that collecting wound fluid during ongoing negative-pressure-wound-therapy over a time period of 3 days is feasible and safe. No safety concerns were observed.

KEYWORDS

diagnostic tool, negative pressure wound therapy, vacuum-assisted closure, wound care, wounds

Key Messages

- negative pressure wound therapy is of increasingly interesting in treating chronic wounds

List of Abbreviations: cm, centimetre; IQR, interquartile range; ml, millilitre; mmHg, millimetres of mercury; NPWT, negative pressure wound therapy; SD, standard deviation.

- inserting an additional container in the connecting tube between the wound and vacuum generating device can collect wound fluid during ongoing negative-pressure wound therapy
- we investigated the feasibility and safety of using an additional container in 22 patients during ongoing negative pressure wound therapy
- this study demonstrated that collecting wound fluid during negative-pressure wound therapy over a time period of 3 days is feasible and safe

1 | INTRODUCTION

Wounds are a globally increasing problem. Especially chronic wounds, caused by trauma, radiation, impaired wound healing due to diabetes, vascular diseases, infection or be provoked through pressure, are documented in 2% of all hospitalised patients, in developed countries.[1-3] In 34% of these wounds an infection was diagnosed.[2] Detecting wound infections at early stages remain challenging. In clinical practice, different methods are common: clinical judgement and interpreting signs and symptoms of infections, described by Cutting and Harding 1994,[4] wound swabs by using the Levine technique[5] and the considered "gold standard" tissue biopsies, both taken for microbiological culture.[6-8] In the case of an infected chronic wound, the decision to choose the optimal wound dressings is still challenging for clinicians. Further, it leads to the demand for an optimal wound dressing material that is efficient and easy to handle in acute and chronic wounds, effective and economical. Relatively newer techniques like negative pressure wound therapy (NPWT) are very promising and useful in the management of chronic wounds.[9] Throughout the last years, NPWT has been largely established in many surgery disciplines.

NPWT was first described by Argenta et al in 1997[10] as a therapeutic modality in acute and chronic wounds. The first technique integrated an open cell foam as a filler material, fitted into the wound, an adhesive drape sealing and fixing the foam, and a negative pressure generating device, providing controlled levels of pressure ranging from −25 to −200 mmHg.[9] A connecting tube between the wound and the vacuum generating device and a fluid collection canister were also incorporated with the NPWT.

The effect of sub-atmospheric pressure induces wound contraction, microdeformation of cells at the wound surface interface, including an increased growth of granulation tissue, increased blood flow, the removal of wound secretion, and the stabilisation of the environment of the wound, through minimising the risk of wound contamination due to reduced bacterial load during ongoing NPWT.[11-13] Tissue hypoxia, as a result of decreased perfusion due to the negative pressure, stimulates neoangiogenesis and local vasodilatation as a result of higher amounts of nitric oxide in the tissue.[14-16] Due to these effects, NPWT is used for "preparation" of the wound bed for further coverages of the wounds.[12,17]

The study question and study rational of this observational study was to evaluate if it is feasible and safe to collect wound fluid during ongoing NPWT with an additional container *Argyle Specimen Trap* (Covidien, Mansfield, U.S.A.) and to enable a further analysis of this wound fluid. We would assume that this collected wound fluid may help us providing information about the current wound situation without changing the wound dressing.

The primary aim of this present prospective observational study was to evaluate only the question of the feasibility and safety of collecting wound fluid during ongoing NPWT with the additional container *Argyle Specimen Trap*.

We hypothesized that wound fluid collection during ongoing NPWT is feasible and safe.

2 | METHODS

A prospective feasibility study was conducted from October 2018 to November 2020 at the Division of Plastic, Aesthetic, and Reconstructive Medicine, Department of Surgery, Medical University of Graz. This trial was registered at the cliniclatrials.gov (Identifier: NCT04507724). The Regional Committee on Biomedical Research Ethics of the Medical University of Graz approved the study protocol (EC number: 30–236 ex 17/18). All patients gave written informed consent before inclusion in accordance with the Declaration of Helsinki.

2.1 | Study population

Included were inpatients older than 18 years treated with NPWT at the Division of Plastic, Aesthetic, and Reconstructive Medicine. Exclusion criteria for this analysis were patients receiving *V.A.C. VERAFLO* (3M/KCI, St. Paul, MN, U.S.A.) therapy, as we expect that the collected wound fluid would excessive diluted.

2.2 | Sample size and outcome parameters

For this pilot study, a sample size of 22 patients receiving NPWT was set. The primary outcome parameter of the present study was the possibility of collecting wound fluid during ongoing NPWT. Secondary outcome parameter included the amount of the daily collected wound fluid in the additional inserted container, the handling assessed by clinicians, and the perception of the patients. Further important safety parameters including maintaining the set negative pressure by the vacuum generating device, error message of the vacuum generating device, need to change the wound dressing prematurely and leakage of the wound fluid, were assessed.

2.3 | Additional container – Argyle Specimen Trap

Argyle Specimen Trap 40 mL is a product mainly used in thoracic surgery or pulmonology to procedure bronchoalveaolar lavage. The product is packed sterile and consists of a collecting container with a capacity of 40 mL, an additional screw cap for possible transports of the liquid-filled container and a latex-free tube.

2.4 | Study protocol

Swabs of the wound were taken before surgery/debridement. The sterile cotton swabs were rotated for 5 seconds with a small amount of pressure on an area of one square centimetre in the wound using the Levine technique.[5] The swab *eSwab* (Copan, Murrieta, CA, U.S.A.) was microbiologically analysed in the laboratory of the local Diagnostic and Research Institute of Hygiene, Microbiology, and Environmental Medicine, Medical University of Graz, Austria, as performed in clinical routine. Furthermore, the surgeons provided their own assessment of the situation of the wound in the handed out questionnaire before operation started. This questionnaire included origin, duration, localisation, expansion, condition of the wound, description of the edge of the wound, odour of the wounds, and necrosis. After the NPWT as dressing was installed at the end of the surgery, the additional container *Argyle Specimen Trap* was inserted according to the study protocol. Therefore, the clamp of the connecting tube between the wound and the vacuum generating device was closed first. This ensured that there was no contamination of the wound via the connecting tube. Then the connecting tube was cut, and the additional container was inserted. Finally, the clamp was opened again (Figure 1A-F).

The following days, at least 3 days, the container was changed daily according to protocol. The change of the additional container was made by clamping the connecting tube between the wound and the vacuum generating device, screwing down the additional container, and screwing up a new one. Then the clamps were opened and it was checked whether the previously set suction was reached again. On the last day, when a routinely change of the negative pressure wound dressing device was performed, a wound swab of the wound bed for microbiological analysis was performed and the responsible doctor answered the questionnaire.

2.5 | Data collection and statistical analysis

Demographics of study patients, characteristics of the wound and wound dressing and parameters of hospital stay were recorded. Descriptive analysis of the primary and secondary outcome parameter was performed. The data are presented as mean ± SD for normally distributed continuous variables and median (IQR) when the distribution was skewed. Absolute values were described as n (%). Data analysis was per intention-to-treat analysis. The statistical analyses were performed with IBM SPSS Statistics 24 Software (PSS Inc., Chicago, IL).

3 | RESULTS

One hundred five patients received a NPWT from October 2018 to November 2020 at the Division of Plastic, Aesthetic and Reconstructive Surgery, Medical University of Graz. Thirty patients were not eligible for inclusion in our present study due to no consent (decline the consent or e.g., intubated patients, who were not able to give consent) or not being an inpatient at the Division of Plastic, Aesthetic and Reconstructive Surgery. Seventy-five patients were eligible for inclusion. Fifty-three patients were excluded due to *V.A.C. VERAFLO* therapy or could not be included due to no research team available. Finally, 22 patients with NPWT were included in this prospective study (Figure 2).

The demographic and clinical patient data are presented in Table 1. Median (IQR) age of the included patients was 58.5 (53.0-70.0) years. Eight patients stated that they smoked and 11 patients were diagnosed for diabetes mellitus. Eighteen patients received antibiotics, adjusted according to an antibiogram at time point of inclusion, in median (IQR) 6[4-15] days.

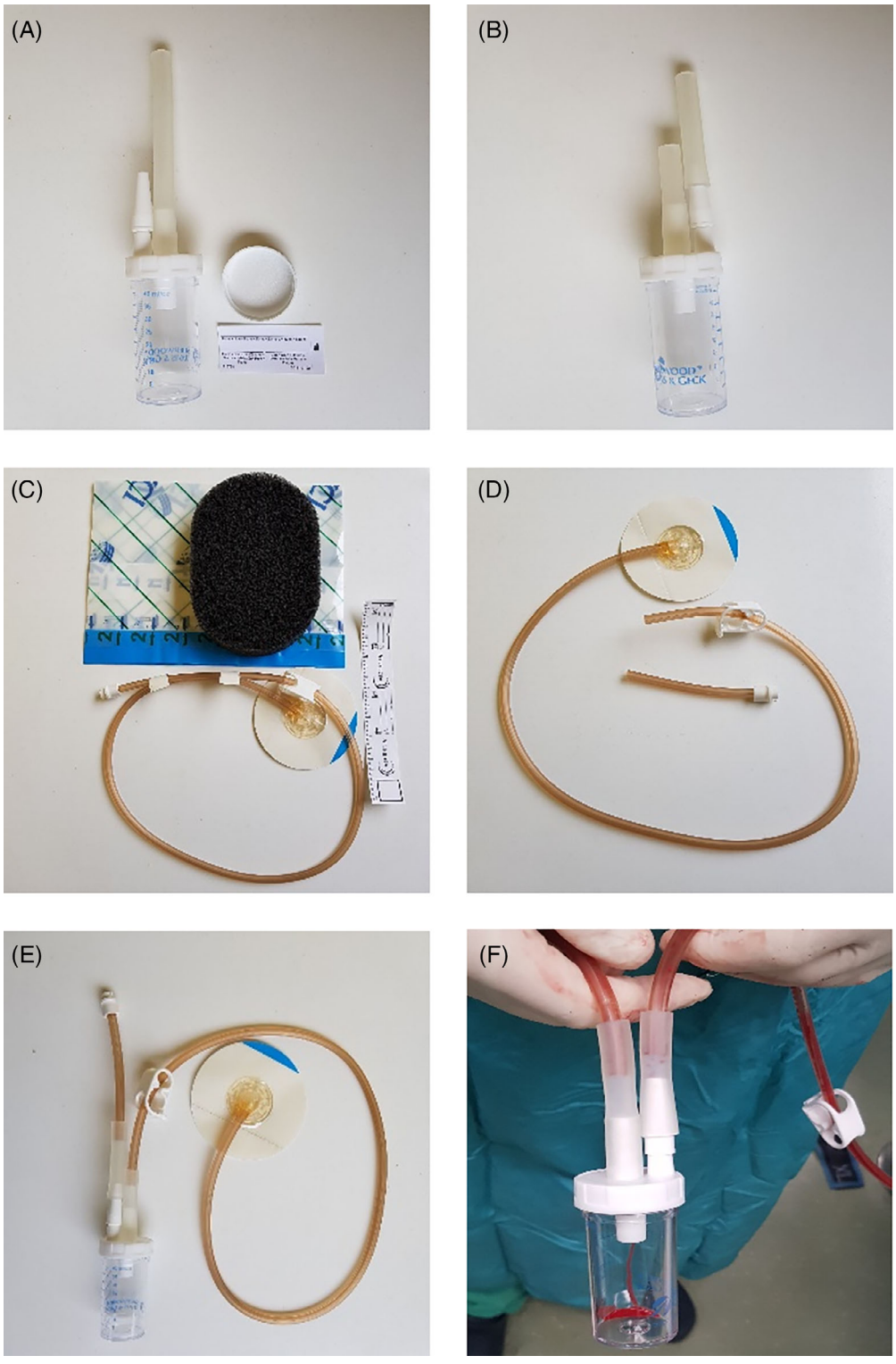

FIGURE 1 Insertion of the additional container *Argyle Specimen Trap*. (A) *Argyle Specimen Trap*. (B) Biscet the tube of the *Argyle Specimen Trap* and plugging the free halve of the tube on the adapter. (C) Negative pressure wound therapy dressing *V.A.C. GranuFoam* dressing und *SENSAT.R.A.C.* Technology + Pad. (D) Closing the clamp and cutting the connecting tube between the wound and the vacuum generating device. (E) Assembling the modified additional container *Argyle Specimen Trap* and the modified connecting tube. Afterward the clamp was opened again. (F) Already promoting wound fluid after installing the additional container into the connecting tube

Characteristics of the wounds are described in Table 2. The expansion of the wounds ranged from a minimum of 4 cm × 3.5 cm to a maximum of 30 cm × 30 cm. Data describing the NPWT are displayed in Table 3. Twenty-one patients received *V.A.C. GranuFoam dressing* (3M/KCI, St. Paul, MN, U.S.A.) as wound dressing during NPWT, and one patient's wound was covered with *Kerlix AMD* (Covidien, Mansfield, U.S.A.). The range of initially set negative pressure was from −75 to −125 mmHg. In 21 patients the initial set pressure lasted till the planned changing of the NPWT. In one patient, the one who received *Kerlix AMD* as wound dressing, the

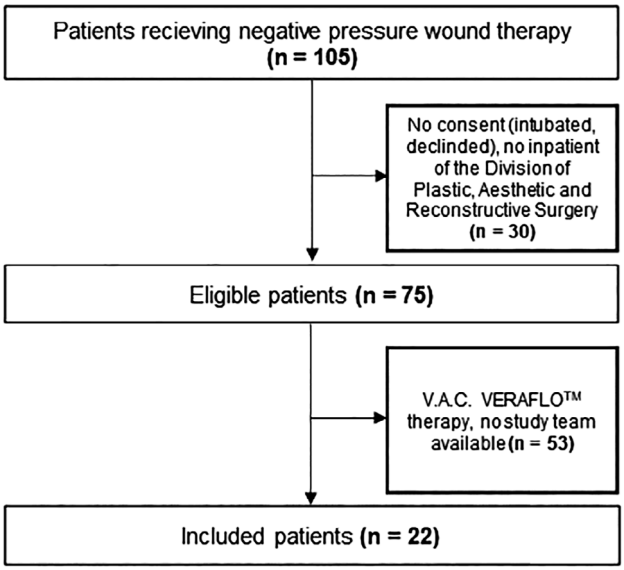

FIGURE 2 Study flow chart demonstrating enrolment, allocation, and data analysis

TABLE 1 Demographic and clinical patient data

	All patients n = 22
Age [years]	58.5 (53.0–70.0)
Female (n%)	4 (18)
Smoking (n%)	8 (36)
Pack years	31.4 ± 18.2
Diabetes (n%)	11 (50)
Type I	1 (5)
Type II	10 (45)
Receiving antibiotics at time point of inclusion (n%)	18 (82)
Days of antibiotics before time point of inclusion (days)	6 (4–15)
Counts of pre-existing illness (n%)	4 (1–10)
Counts of permanent medication (n%)	6 (3–11)

Note: Data are presented as mean ± SD, median (IQR) or (n%).

initial set negative pressure of −75 mmHg had to be reduced to −50 mmHg due to pain. In mean ± SD the collected volume of the wound fluid was on day one 7 ± 4 mL, on day two 8 ± 7 mL and 10 ± 11 mL on day three. The overall collected wound fluid was in mean 8 mL. The minimum amount of collected wound fluid in the additional container was 0.4 mL. In one patient, again the one who received *Kerlix AMD* as wound dressing, only <0.1 mL of clear water, could be collected. When the maximum amount of wound fluid was in the additional container and it was therefore completely filled, the remaining wound fluid was collected in the NPWT canister.

TABLE 2 Wound characteristics of the 22 included patients

	All patients n = 22
Wound (n%)	
Ulcera (not diabetic foot syndrome)	4 (18)
Diabetic foot syndrome	3 (14)
Phlegmon	5 (23)
Osteomyelitis	3 (14)
Others	8 (36)
General anaesthesia during first installation of NPWT (n%)	20 (90)
Operation at time point of inclusion (n%)	
Debridement	7 (32)
Necrectomy	15 (68)
Duration of wound [days]	70 (25–102)
Localization (n%)	
Forefoot	7 (32)
Plantar	3 (14)
Heel	4 (18)
Lateral malleolus	1 (5)
Forearm	2 (9)
Others	5 (23)
Description of the wound (n%)	
Bloody	11 (50)
Serum	13 (59)
Fibrin	3 (14)
Dry	3 (14)
Purulent	4 (18)
Necrosis (n%)	
Edge of the wound	13 (59)
Wound base	18 (82)
No necrosis	3 (14)
Smell of the wound (n%)	4 (18)
Microbiologically proven germ growth (n%)	15 (68)

Note: Data are presented as mean ± SD, median (IQR) or (n%).
Abbreviation: NPWT, negative pressure wound therapy.

3.1 | Safety parameters

In none of the patients, the NPWT had to be changed prematurely. No error message of the vacuum generating device was observed that could be in context with the additional container. Common error message including "battery low alert", "canister full" or "canister not engaged" occurred. No error message of "leak alarm", "low pressure alarm" or "blockage alarm" was documented, which showed that there was no leakage in the system and that

TABLE 3 Data concerning the negative pressure wound therapy

	All patients n = 22
Duration of the NPWT [days]	5.0 (4.6–5.5)
Changing the NPWT prematurely	0 (0)
Error message of the vacuum generating device due to inserting and additional container	0 (0)
Leakage of wound fluid	0 (0)
Wound dressing (n%)	
V.A.C. GranuFoam dressing	21 (95)
Kerlix AMD	1 (5)
Set negative pressure (n%)	
−125 mmHg	11 (50)
−100 mmHg	2 (9)
−75 mmHg	9 (41)
Volume in the additional container [ml]	
Day 1	7 ± 4
Day 2	8 ± 7
Day 3	10 ± 11
Following days	n.a.

Note: Data are presented as mean ± SD, median (IQR) or (n%).
Abbreviation: NPWT, negative pressure wound therapy; n.a., not available.

the negative pressure could be maintained through the predefined time without any problems. To ensure, that no error message in context with the additional collector occurred, when changing the additional container and screwing up the new one, it had to be checked, that the initially set negative pressure can be built up again. Further, before leaving the patient, the closing clamp of the connecting tube had to be opened again. Otherwise, the error message of "blockage alarm" would alert. Further, no wound fluid leaked out of the additional container, which could result in a potential contamination of the patients' environment.

4 | DISCUSSION

In this present study, we were able to demonstrate that in patients with wounds treated with a NPWT, it is feasible and safe to insert a collecting piece in the tube to collect wound fluid during ongoing NPWT. To the best of our knowledge, this is the first study using an additional container, which is inserted in the connecting tube between the wound and the vacuum generating device, to collect wound fluid, during ongoing NPWT over a time period of 3 days.

4.1 | Collecting wound fluid

In our present observational study, collecting wound fluid during ongoing NPWT by the help of an additional container was feasible.

Collecting wound fluid during undergoing NPWT has been described by Cagnoni et al.[18] They investigated whether a different sample collection device helped to increase the detection of micro-organism in patients undergoing NPWT. The primary aim of the study performed by Cagnoni was not to test the feasibility of this wound fluid sampling methods, nevertheless, they described the procedure to obtain wound fluid during ongoing NPWT: At first, the NPWT canister was removed from the patient and afterwards it was opened under sterile conditions. A syringe with a large needle was used to aspirate the gel placed in the container, through a small window. To perform gel extraction an enrichment broth was used. Further a blood culture with drainage from NPWT was performed. In contrast to the method of Cagnoni et al[18] our described study, enabled the collection of the wound fluid continuously and bed-side without changing the NPWT. One possible disadvantage of the method described by Cagnoni might be, that the canister has to be removed from the patient and has to be rechanged. The handling seems much easier by screwing down and rechange just the container in our described study. After the rechange in our study, the collected wound fluid can be analysed without further processing. In contrast, in the method described by Cagnoni the wound fluid accumulated in the gel has to be aspirated and afterwards an enrichment broth is necessary to perform the gel extraction. Further, the handling of using the additional container as a wound fluid collecting device during ongoing NPWT was assessed by the attending surgeons. Assessed were time needed to change the device and feasibility of handling. In all cases the time for changing the additional container was less than 5 minutes. No problems during the changing procedure were described.

4.2 | Volume of the daily collected wound fluid

In our present study collected wound fluid was in mean 8 mL. In one patient with a post traumatic (minor trauma) chronic leg forefoot ulcer with *Kerlix AMD* as dressing filling material and an initially set negative pressure of −75 mmHg and a reduction to −50 mmHg due to pain, 1 day after the first installation, no wound fluid could be collected in the additional container. When changing the additional container on three consecutive days, it was observed, that only a few drops, less than

<1 mL clear liquid was collected. Macroscopically it looked like condensation, which was confirmed by a biochemically analysis. Moreover, no wound fluid was collected in the canister of the negative pressure generating device. We assume that the initially set pressure of −75 mmg and the further reduction to −50 mmHg was too low. This assumption is in accordance with the work of Borgquist et al,[19] who examined in a swine model with peripheral wounds the effects of low and high pressure levels during NPWT on wound contraction and fluid removal. They observed that there is a linear association between the amounts of wound fluid evacuation with increasing levels of negative pressure, whereby −125 mmHg lead to the maximum removal of wound fluid.

To answer the question whether this collected wound fluid can be biochemically analysed by measuring enzyme activities and giving information about the state of the wound during ongoing NPWT, in comparison with microbiological analysis, will be part of further publications.

4.3 | Perception of the patients

Beside to the handling of the additional container, assessed by the clinicians, the perception of the patients was assessed. The first insertion of the additional container was performed in all cases in the operation room, when the patient was anaesthetized. The changing procedure, on the following days was performed within less than 5 minutes. The patients described that they noticed the loss of set negative pressure when the clamp of the connecting tube between the wound and the vacuum generating device was closed. The exchange of the additional container, which took less than 1 minute, was not remarked by the patients. The last step of the changing procedure was to open the clamp of the connecting tube, which was again noticed by the patients, as the set negative pressure was generated again. None of the patients described neither discomfort nor pain. In the time between the changes, the patients stated that they did not notice the *Argyle Specimen Trap* as an additional container, as it was rigidly fixed with the connecting tube. The container did not cause any problems during mobilisation.

4.4 | Safety parameters

Safety parameters including maintain the set negative pressure by the vacuum generating device, error message of the vacuum generating device, need to change the wound dressing prematurely and leakage of the wound fluid were assessed during the daily changing procedure.

The initially set negative pressure maintained till the time point when the dressing was routinely changed in all cases. In one case, the negative pressure of initially −75 mmHg had to be reduced to −50 mmHg on day two after application due to pain. The origin of the wound of that patient was a post-traumatic (minor trauma) chronic leg forefoot ulcer. Before the application of the NPWT a debridement was performed, and as dressing a *Kerlix AMD* was applied. The reduction of the initially set pressure due to pain is in no context to the inserted additional container.

In none of the patients in our present study, a leakage of the wound fluid was assessed during the daily changing procedure or in the time periods between these procedures. To ensure this, the clamps of the connecting tube between the vacuum generating device and the wound dressing had to be closed throughout the changing procedure. This prevents the wound fluid from leaking out of the tube. Furthermore, the closed clamps ensure, that no contamination of the wound occurred. After screwing up the additional container it was necessary to check if the initially set negative pressure can be build up. This indicated that the system of the NPWT is leakproof and that no wound fluid could leak out.

5 | CONCLUSION

In conclusion, collecting wound fluid during ongoing NPWT is feasible. This collected wound fluid can afterwards be easily analysed regarding inflammation markers (enzymes) or the presence of bacteria. No safety concerns were observed. The handling of changing the collecting device, assessed by the surgeons, was described as easy to handle and quick to perform. The patients did not feel disturbed by the procedure of changing the additional collector, additionally, no pain was described. No safety concerns were observed.

Further research is desirable in a larger patient population to confirm our results and to investigate the different devices used in NPWT.

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CONFLICT OF INTEREST

CW, AT, and MS were paid for conducting the study described in the manuscript. ES and AH are cofounder of Qualizyme Diagnostics GmbH & Co KG, Austria. SW, DL, and CG are employees of this company. EM and PS have no financial interest to declare in relation to the content of this article.

AUTHOR CONTRIBUTIONS

Christina Helene Wolfsberger, Emanuel Maitz, Michael V. Schintler and Eva Sigl: conception and design. Christina Helene Wolfsberger, Emanuel Maitz, Philipp Schmachtl, Alexandru-Cristian Tuca and Michael V. Schintler: collection and assembly of data. Christina Helene Wolfsberger, Emanuel Maitz, Eva Sigl and Andrea Heinzle: drafting of the article, Christina Helene Wolfsberger, Emanuel Maitz, Philipp Schmachtl, Sonja Winkler, Daniel Luschnig, Andrea Heinzle, Clemens Gamerith, Eva Sigl, Alexandru-Cristian Tuca and Michael V. Schintler: analyses and interpretation of data, critical revision, editing and final approval of the article.

DATA AVAILABILITY STATEMENT

The data presented in this study are available on request from the corresponding author.

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