The text „Negative Pressure Wound Therapy: Future Perspectives" was published spring 2017 as a chapter included in the EWMA Document "Negative Pressure Wound Therapy: Overview, Challenges and Perspectives".

The text is inspired by and draws on knowledge developed in the SWAN-iCare project, which was completed in April 2017 with a successful final review by the European Commission. A final report describing the achievements of the project will be published on the SWAN-iCare website.

SWAN-iCare is partially founded under the seventh Research and Innovation Framework programme FP7 by the European Commission.

www.swan-icare.eu

Negative Pressure Wound Therapy: Future Perspectives

Excerpt from the EWMA Document "Negative Pressure Wound Therapy: Overview, Challenges and Perspectives". Published by EWMA in spring 2017

Jan Apelqvist[1,2] (editor)
Christian Willy[3] (co-editor)
Ann-Mari Fagerdahl[4]
Marco Fraccalvieri[5]
Malin Malmsjö[6]
Alberto Piaggesi[7]
Astrid Probst[8]
Peter Vowden[9]

[1] Department of Endocrinology, University Hospital of Malmö

[2] Division for Clinical Sciences, University of Lund

[3] Department of Trauma & Orthopedic Surgery, Septic & Reconstructive Surgery, Bundeswehr Hospital Berlin

[4] Department of Clinical Science and Education, Karolinska Institutet, and Wound Centre

[5] Plastic Surgery Unit, ASO Città della Salute e della Scienza of Turin

[6] Clinical Sciences, Lund University

[7] Department of Endocrinology and Metabolism, Pisa University Hospital

[8] Kreiskliniken Reutlingen GmbH

[9] Faculty of Life Sciences, University of Bradford, and Honorary Consultant Vascular Surgeon

Correspondence:
ewma@ewma.org

The document is supported by unrestricted educational grants from: Acelity, BSN medical, Genadyne, Mölnlycke Health Care, Schülke & Mayr GmbH, Smith & Nephew and Spiracur.

Introduction

In this paper we aim to reflect on where technological developments within NPWT seem to be going and continue to discuss some of the main clinical and organisational aspects that can be expected to influence future spread and uptake of NPWT in clinical practice.

TECHNOLOGICAL DEVELOPMENTS

Technological advances within NPWT are currently seen to be heading in several directions.

Hospital-based system with increased sophistication

Hospital-based devices are developing in the direction of increased sophistication and in the delivery of adjunct therapies such as saline irrigation/instillation, either intermittently or continuously with NPWT[1-4]. The benefits of powerful antimicrobial solutions for wounds with a high bioburden are under intense investigation[5-7]. In another related direction, the delivery of alternative active substances such as insulin[8] or doxycycline[9] are being investigated, as yet on a non-commercial (off-label-use) basis.

Simplified single use devices

On the other hand, there is a substantial development, almost as it were in the opposite direction, in the use of simplified single-use NPWT devices[10-16]. This movement, which includes both electrically powered and mechanically powered devices, recognises the benefits of the accessibility of NPWT "off-the-shelf" and a lower cost base. This permits the widespread adoption of single-use devices in the emerging prophylactic use of NPWT to reduce complications, such as dehiscence or infection, when used over closed surgical incisions[17,18]. In addition, single-use devices do not restrict patient mobility as they are small in dimension and self-contained.

New material for wound fillers

The properties of the wound dressing or wound interface determine most of the effects of NPWT on the wound bed.

The currently used wound fillers are commonly foam or gauze. The interaction between the wound dressing and the wound bed has been described in detail for foam and gauze[19]. Both these wound fillers cause a mechanical effect on the wound. The tissue surface is stimulated by the structure of the wound dressing. This will trigger the cells to divide to rebuild and strengthen the tissue. The amount and character of granulation tissue formed may differ between the two dressings. The use of foam as a wound interface in NPWT produces thick, hypertrophic granulation tissue. Gauze under NPWT results in less thick but dense granulation tissue[19,20].

There are other differences in properties between foam and gauze in that the porous structure of foam allows greater volume reduction under pressure. The effect on the wound is also dependent on the size of the foam or amount of gauze filler, e.g. a higher tissue pressure i achieved by a small foam filler compared to a large foam filler[21].
In the instances when the wound bed is covered ▶

by a wound contact layer, the micro deformational effect is lessened compared to when the foam or gauze is in direct contact with the wound bed, which will affect granulation tissue formation.

One novel wound filler is a bacteria and fungus binding mesh. It produces a significant amount of granulation tissue in the wound bed, more than with gauze, without the problems of ingrowth, as is the case with foam[22,23]. Like gauze, bacteria and fungus binding mesh has the advantage of being easy to apply to irregular and deep pocket wounds. In addition, efficient wound fluid removal in combination with its pathogen binding properties makes hydrophobic mesh an interesting alternative wound filler in NPWT[22,23].

There are vast possibilities for further development of novel wound fillers and this will presumably focus on tailoring the compressibility of the wound filler for altering the effect on wound contraction (or macro deformation). Attempts have been made on altering the pore sizes in the wound filler. There is also an opportunity for development of the surface structure of the wound filler in order to tailor the micro deformational effect on the wound bed, to hinder ingrowth in the wound filler or even to make the dressing material resorbable.

Systems with integrated sensors for long-distance monitoring

Next generation NPWT are devices seen to be incorporating sensors with the ability to continuously measure selected wound parameters and some form of basic remote communication capabilities. The use of different types of wound sensors combined with technologies that are able to analyse and process this data will make it possible to collect, record and analyse data streams quickly and accurately over time and in this way be capable of identifying early signs of infections, and specific bacteria's and point out direction for personalized therapy[24,25].

The use of sensors and remote communication facilities holds potential benefits and is stated to be able to increase the quality of care delivered, reduce costs and improve access to specialized care for people living in remote places. The quality of care is improved by the availability of prompt and detailed clinical outcome data that will allow the healthcare provider to define an optimal and timely treatment pathway and to possibly accelerate the healing of the patient.

Savings are to be achieved through the possibility of taking preventive actions and avoiding acute and severe complications due to delays in diagnosis.

Better access to care is achieved for people living in remote areas since this will allow for specialist attention towards the care given at a distance. The remote monitoring function could also lead to better compliance in the community care setting to the treatment prescribed since deviances can be promptly discovered and addressed. Another positive effect of these distant linkages between community carers and specialist care is the learning opportunity for community nurses achieved through ongoing feed-back from in-hospital specialists.

The ability to measure and collect continuous data on the development of different wound parameters also holds potential in terms of collecting BIG data for research due to the possibility of pooling individual outcome data.
This type of device holds great potential but there are still some essential development challenges to be addressed before we can expect to see these devices available in clinical practice. Some of the biggest challenges appear, to be not so much related to what is technologically possible but more about what wound parameters are the most importance to gather data on in order to impact wound healing. Furthermore, more research on critical thresholds and time intervals for the measurements of these variables, in addition to a clearer understanding of how the interaction of various wound parameters should be interpreted, is critical to establish if the data should add value to clinical practice. This information needs to come from clinical research and be fed into the technical developers. Once this information is available, it seems that, despite the fact that there is still some way to go, most issues of a technical nature could feasibly be solved[26].

In summary, NPWT devices could be seen as heading in three directions: increasingly complex devices for specialist applications within the hospital, progressively simpler devices for lower cost settings such as the out-patient clinic or the home, and sensor-based devices with remote communication technologies to be used for distant monitoring. It is yet unclear as to what the ultimate proportions of patients will be treated with each type of device.

CHANGES IN DEMAND – SUPPORTING AND CONSTRAINING FACTORS

How advanced and technological appealing a device might be is not the only determinant of how popular a medical device will be, as several stakeholders in the health care delivery system will have the potential to influence whether or not a medical device is adopted into routine care or not. Payers at various levels of the system as well as clinicians and patients are driven by different rationales. There are several theories and models that describe and explain the underlying mechanism of the determinants behind diffusion of innovations; however, the evidence

of it is complex[27]. The selected topics highlighted here are not based on a thorough and systematic analysis of the decisional environment around NPWT but simply based on a general impression among the authors of the document as to what are the main issues that seem to be affecting and influencing future uptake of NPWT.

Expanded indications

The technological developments in NPWT have already led to expansions of the indications of what types of wounds can benefit from NPWT treatment, compared to what was originally envisioned for NPWT devices first arriving in clinic. As examples the availability of smaller, single-use disposable pumps has meant that new types of wounds can be treated (small, surgical) and in new settings such as short-term home care[28]. Adding to this, the new interventions underway as described above may even further contribute to the increased uptake.

Increased focus on evidence and cost containment

Health care providers are increasingly asking for evidence of a treatment's clinical effectiveness if they are going to provide reimbursement. In addition to this some health care systems are also starting to require health economic analyses providing an economic cost calculation in favour of the treatment mode.

The clinical benefits of NPWT in varied wound types has been reported in over 1000 peer-reviewed articles, and NPWT has been described as the gold standard in some areas of wound care. However, there is as yet no definitive clinical evidence supporting NPWT as a better and faster method for wound healing than the use of advanced dressing[28].

This lack of strong evidence has several explanations. NPWT is a generic multimodal technology that can deliver a broad range of treatment goals depending on the patient being treated and these goals can be achieved by altering a range of variables which all add to the complexity of studying the therapy as part of an RCT. The strict inclusion criteria in RCTs lead to recruitment problems and in turn limit real-world relevance and reproducibility[28]. When it comes to cost estimations, the natural variations in treatment outcomes combined with variations in treatment regimens depending on e.g. wound type, size, and amount of exudate makes it very difficult to come up with a solid figure that can be universally applied across health care settings, wound types and patients. Underlying figures of importance for such calculations such as duration of treatment, number and frequency of dressing changes, training required, in combination with great variations in pricing models offered by the companies delivering the products are only examples of some of the key figures expected to vary between each individual case.

This lack of strong evidence could potentially become a hindrance for health care providers' access to use NPWT as health authorities and payers are increasingly focusing on prioritization and shifting of resources to treatment areas where a strong clinical evidence and health economic rationale can be proven.

This is already the case in England where "The National Institute for Health and Care Excellence" (NICE) is well established and in Scandinavia where similar set ups are being discussed at political level. Also at the level of the individual clinicians the lack of evidence in some instances makes care givers reluctant to use this mode of therapy[28].

On this background it becomes evident that the current problems relating to lack of high level evidence supporting the clinical effectiveness of NPWT on different types of wounds can prove to become be an important hindrance in terms of getting reimbursement for the treatment and hereby pose an important barrier to get access to treatment with NPWT. Thus for the use of NPWT to gain in popularity and receive backing from health care systems in the form of continued reimbursement the issue of providing strong evidence needs to be addressed.

Changes in organisation of care and community care

A major and general trend across health care settings around Europe is an increased move of specialized health care services from in hospital, ambulatory and acute health care settings to community care.

Length of in hospital stay decreases and patients are transferred early to community care. This means that more complex and exudating wounds that would previously have been managed and taken care of by specialised staff in hospitals are now being cared for by community care nurses in the home setting. This in combination with the availability of smaller lightweight and disposable devices has led to an increased use of NPWT in community settings. Also the development within sensors based systems with remote communication facilities might further support introduction of NPWT in community care settings. To guarantee optimal usage of NPWT in community settings future emphasis must focus on how to ensure that more nurses that do not have direct access to specialist doctors for expert advice are able to handle the products correctly and are compliant to the prescribed treatment regimes. This requires training and availability of reliable support systems with easy access. If these aspects are not carefully dealt with this might impact treatment out- ▶

comes and potentially undermine the backing of the use of NPWT in the long run.

Also, the education of patients and caregivers becomes even more central when treatment with NPWT shifts towards the outpatient setting. Studies show that patients express the need for thorough education in managing the treatment[29,30]. Therefore, it is important to educate patients and caregivers and not only to inform them, which requires a structured teaching program. Digital platforms and tools for self-treatment where patients and health care personnel can communicate while being treated at home, development of telemedicine in the treatment with NPWT is an interesting aspect for the future.

Another important aspect of this shift to community care is the adding of yet another complex layer of payer structures and decision making processes. The question about who will pay for the treatment, and when, will become even more complex to map as the answer to the question will differ according to the specific setup. This complexity and unclear roles of responsibilities might in the end affect the patients. It may delay appropriate care and lead to reluctance between decision making levels to take on the final responsibility of providing the most optimal treatment if perceived expensive. In some cases it might not be the one having to pay for the treatment that will ripe the potential economic benefit of providing it.

This shift of responsibility for more specialised care to community settings therefore calls for a need to rethink reimbursement models and furthermore increase pressure on safety aspects and training needs.

In the case of adoption of systems with remote monitoring facilities implementation barriers related to integration with existing EHR systems, changing care patterns (e.g. insufficient staffing or time to monitor and follow up on data) and professional roles (e.g. clarify legal liability of responsibilities etc.) will need to be addressed to be successful[31].

REFERENCES

1. Raad W, Lantis JC, 2nd, Tyrie L, Gendics C, Todd G. Vacuum-assisted closure instill as a method of sterilizing massive venous stasis wounds prior to split thickness skin graft placement. Int Wound J. 2010;7(2):81-5.
2. Fluieraru S, Bekara F, Naud M, Herlin C, Faure C, Trial C, et al. Sterile-water negative pressure instillation therapy for complex wounds and NPWT failures. J Wound Care. 2013;22(6):293-4, 6, 8-9.
3. Kim PJ, Attinger CE, Oliver N, Garwood C, Evans KK, Steinberg JS, et al. Comparison of Outcomes for Normal Saline and an Antiseptic Solution for Negative-Pressure Wound Therapy with Instillation. Plast Reconstr Surg. 2015;136(5):657e-64e.
4. Kim PJ, Attinger CE, Steinberg JS, Evans KK, Lehner B, Willy C, et al. Negative-pressure wound therapy with instillation: international consensus guidelines. Plast Reconstr Surg. 2013;132(6):1569-79.
5. Lehner B, Fleischmann W, Becker R, Jukema GN. First experiences with negative pressure wound therapy and instillation in the treatment of infected orthopaedic implants: a clinical observational study. Int Orthop. 2011;35(9):1415-20.
6. Back DA, Scheuermann-Poley C, Willy C. Recommendations on negative pressure wound therapy with instillation and antimicrobial solutions - when, where and how to use: what does the evidence show? Int Wound J. 2013;10 Suppl 1:32-42.
7. Matiasek J, Djedovic G, Mattesich M, Morandi E, Pauzenberger R, Pikula R, et al. The combined use of NPWT and instillation using an octenidine based wound rinsing solution: a case study. J Wound Care. 2014;23(11):590, 2-6.
8. Scimeca CL, Bharara M, Fisher TK, Kimbriel H, Mills JL, Armstrong DG. Novel use of insulin in continuous-instillation negative pressure wound therapy as "wound chemotherapy". J Diabetes Sci Technol. 2010;4(4):820-4.
9. Scimeca CL, Bharara M, Fisher TK, Giovinco N, Armstrong DG. Novel use of doxycycline in continuous-instillation negative pressure wound therapy as "wound chemotherapy". Foot Ankle Spec. 2010;3(4):190-3.
10. Gabriel A, Thimmappa B, Rubano C, Storm-Dickerson T. Evaluation of an ultra-lightweight, single-patient-use negative pressure wound therapy system over dermal regeneration template and skin grafts. International Wound Journal. 2013;10(4):418-24.
11. Colli A, Camara ML. First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. J Cardiothorac Surg. 2011;6:160.
12. Matatov T, Reddy KN, Doucet LD, Zhao CX, Zhang WW. Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients. J Vasc Surg. 2013;57(3):791-5.
13. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. Wound Repair Regen. 2012;20(3):332-41.
14. Hudson DA, Adams KG, Van Huyssteen A, Martin R, Huddleston EM. Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system. Int Wound J. 2015;12(2):195-201.
15. Nordmeyer M, Pauser J, Biber R, Jantsch J, Lehrl S, Kopschina C, et al. Negative pressure wound therapy for seroma prevention and surgical incision treatment in spinal fracture care. Int Wound J. 2015.
16. Holt R, Murphy J. PICO incision closure in oncoplastic breast surgery: a case series. Br J Hosp Med (Lond). 2015;76(4):217-23.
17. Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. J Thorac Cardiovasc Surg. 2013;145(5):1387-92.
18. Pellino G, Sciaudone G, Selvaggi F, Canonico S. Prophylactic negative pressure wound therapy in colorectal surgery. Effects on surgical site events: current status and call to action. Updates Surg. 2015;67(3):235-45.
19. Borgquist O, Gustafsson L, Ingemansson R, Malmsjo M. Micro- and macromechanical effects on the wound bed of negative pressure wound therapy using gauze and foam. Ann Plast Surg. 2010;64(6):789-93.
20. Fraccalvieri M, editor Negative pressure wound therapy using the gauze and the foam: immunohistological and ultrasonography morphological analysis of the granulation tissue and the scar tissue. Preliminary report of a clinical study presented at the 3rd Congress CORTE 4-6 March 2010. . Conferenza Italiana per lo studio e la Ricerca sulle ulcere, piaghe, ferite e riparazione tessutale (CORTE); 2010.
21. Anesater E, Borgquist O, Hedstrom E, Waga J, Ingemansson R, Malmsjo M. The influence of different sizes and types of wound fillers on wound contraction and tissue pressure during negative pressure wound therapy. Int Wound J. 2011;8(4):336-42.
22. Malmsjo M, Ingemansson R, Lindstedt S, Gustafsson L. Comparison of bacteria and fungus-binding mesh, foam and gauze as fillers in negative pressure wound therapy--pressure transduction, wound edge contraction, microvascular blood flow and fluid retention. Int Wound J. 2013;10(5):597-605.
23. Malmsjo M, Lindstedt S, Ingemansson R, Gustafsson L. Use of bacteria- and fungus-binding mesh in negative pressure wound therapy provides significant granulation tissue without tissue ingrowth. Eplasty. 2014;14:e3.
24. Salvo P, Dini V, Di Francesco F, Romanelli M. The role of biomedical sensors in wound healing. Wound Medicine. 2015;8:15-8.
25. Consortium Si. SWAN iCare Project Objectives http://www.swan-icare.eu/en/objectives2016 [cited 2016. Available from: http://www.swan-icare.eu/en/objectives
26. Pantelopoulos A, Bourbakis NG. A survey on wearable sensor-based systems for health monitoring and prognosis. IEEE Transactions on Systems, Man, and Cybernetics, Part C (Applications and Reviews). 2010;40(1):1-12.
27. Hall BH, Khan B. Adoption of new technology. National bureau of economic research; 2003.
28. Ousey KJ, Milne J. Exploring portable negative pressure wound therapy devices in the community. Br J Community Nurs. 2014;Suppl(SUPPL. 3):S14, S6-20.
29. Fagerdahl AM, Bostrom L, Ottosson C, Ulfvarson J. Patients' experience of advanced wound treatment-a qualitative study. Wounds. 2013;25(8):205-11.
30. Fagerdahl A-M, editor The Patient's Conceptions of Wound Treatment with Negative Pressure Wound Therapy. Healthcare; 2014: Multidisciplinary Digital Publishing Institute.
31. Davis MM, Freeman M, Kaye J, Vuckovic N, Buckley DI. A systematic review of clinician and staff views on the acceptability of incorporating remote monitoring technology into primary care. Telemedicine and e-Health. 2014;20(5):428-38.