What’s Positive About Negative Pressure

Barbara Zeiger

Negative pressure wound therapy has always fascinated me. As a layperson, it’s amusing to startle my friends and relations by asking, “Did you know you could suck a wound closed?” For OWM, the early days of NPWT were filled with numerous articles and supplements promoting NPWT device manufacturing, a basically one-company monopoly. There was little variability in setting (-125 mm Hg, continuous) and almost all publications involved case studies in which physicians seeking novel approaches to chronic wound care opened their minds to closing wounds with foam dressings and fairly strong suction.

As knowledge about the science behind the devices, as well as usage, grew, variations on the theme began to evolve. More specialized dressings and devices emerged (still mostly from one company). Scientists gained a better appreciation for NPWT’s mechanisms of action and where they could (and could not) be utilized for the most patient benefit. Only recently has alternative NPWT dressing (the dreaded G word) and device pressure setting choice come to the fore. OWM has been proactive in disseminating developments in the manufacture of more patient-centered products and new findings in the scientific rationale for NPWT. Suddenly, it seems, there are clinical, marketable NPWT options.

With options come decisions. Potential users must do their reading. In the past 15 years, more than 1,000 peer-reviewed publications have made their case for NPWT used alone or often as an adjunct to other treatments. What wound types are best suited for NPWT? At what point should NPWT be initiated (and subsequently, terminated)? With what dressing? For how long? At what setting?

To address these concerns, in 2009 an NPWT International Expert Panel, supported by unrestricted funding from Smith & Nephew, was formed. Panel members (22 clinicians from 17 countries) reviewed existing English-language articles and relevant internationally published abstracts from 1996 to the present. Publications related to soft-tissue trauma, open fracture injuries, burn injuries, flaps, and skin grafts were used to develop a list of evidence-based recommendations for NPWT use. Using the Scottish Intercollegiate Guidelines Network (SIGN) that integrates levels of evidence, the Panel created graded suggestions (A: must, B: should, C: may, and D: possible) for NPWT application in 15 specific scenarios related to traumatic wounds and reconstructive surgery. Once Panel members were in complete agreement with the recommendations, 422 healthcare professionals from 29 countries weighed in; 80% consensus was necessary for each recommendation.

The results were published in Injury earlier this year; an additional complimentary article has been accepted for publication and another is in the submission process, both with surgical journals.

International NPWT Expert Panel Chairman Professor Dr. Med. Norbert Runkel insisted on three points: independence from the sponsor, a scientific approach, and an enduring commitment to the effort. With regard to the second item, Professor Runkel states that the Panel soon realized that although published papers are abundant, their scientific impact is rather low. Professor Runkel hopes that as more companies enter the NPWT arena, this situation will improve. Meanwhile, gaps in evidence need to be filled by experience-based recommendations, with the codicil that no recommendations can be drawn if there is no published supportive evidence. The middle stages of the Panel’s work will integrate specific areas of clinical interest. The final segment of the project is a blueprint for the future, with plans that include initiating and fostering clinical trials and deciding on generally acceptable wound documentation systems.

I am in awe of the scope of this project and commend the participants for their diligence. I respect them for acknowledging that findings in some instances are somewhat clouded and contradictory, as any medical approach can be fraught with challenges as factors of, at the very least, patient individuality. I also have a few questions.

First, all literature that described instances where “NPWT was incidental to other therapies/techniques” was excluded from Panel consideration. Most articles published in OWM (including De Feo et al in this issue) discuss NPWT as part of the treatment regimen. Will the Panel’s subsequent recommendations address use of negative pressure with other treatment modalities, which in my humble opinion, is where it works best?

Second, using the Panel’s grading system, the only recommendation awarded an A grade was, “NPWT must be used to improve the rate of graft success”; two Bs were given to “should be considered when primary closure is not possible after or in-between debridement as a bridge to definitive closure” and “should be stopped when delayed surgical closure is possible.” The majority of grades (12) were average or lower and the explanations provided with the grades lack decisiveness. If I had ever come home with a report card like this, I would have been told to buckle down and try harder. How does the Panel plan to reconcile levels of evidence as future recommendations are shaped?
FROM THE EDITOR

The Panel’s next endeavor addresses such concerns: the plan is to develop recommendations from clinical practice in areas where evidence is lacking and submit these once again to a wider forum, working to make the best of the “evidence” available. According to Robin Martin, PhD, Clinical Science Program Manager, Smith & Nephew UK, this next stage of investigation is “just as important because so much higher-level evidence is lacking in NPWT and Level D evidence is sometimes all we can work with. The Panel wants to find areas where there has been significant clinical experience, or clinical usage, in the absence of high-level published evidence and pool this experience in order to develop a further set of recommendations. We are holding a stand-alone meeting in Amsterdam where the panel will test NPWT recommendations in relation to open abdomen, infection, chronic ulcers, and acute/traumatic wounds. This will identify where clinical practice is filling evidence gaps and what further studies will be necessary to raise the evidence levels.” Also noteworthy is the Panel’s consideration of evidence of NPWT value when healing is not the endpoint, underscoring NPWT use as an adjunct to stepwise wound management protocols.

I have additional queries. I am a huge proponent of “less is more.” Thus, I wonder why it took until very recently for manufacturers and/or clinicians to turn things down a notch, at least as reported in the literature (to wit, an article on the Chariker-Jeter technique using 60 to 80 mm Hg of negative pressure predates the seminal Argenta and Morykwas article by 8 years, but garnered less prestige and does not appear on PubMed). One manufacturer’s indications for use specify a setting of 80 mm Hg, and settings as low as 40 mm Hg now are used in some circumstances. As I told our children when they wanted more of a tasty vitamin or medication, “Just because you can have more doesn’t mean it’s good for you. Only one works.” What other dressings work as well under less pressure?

Patient comfort has become a greater concern, not only among clinicians but also among regulatory agencies. As such, continuous or intermittent (on/off) therapy has yielded, when necessary, to variable settings where the negative pressure ebbs and flows less dramatically. Also, with the need to increasingly consider home care and patient mobility, portability has become a factor in NPWT device choice. Several “wearable” models are available and research comparing various devices has begun. How will these issues affect outcomes?

NPWT practitioners with similar or additional concerns have a useful resource in the June 2010 issue Today’s Wound Clinic (available via www.todayswoundclinic.com). The issue contains an article on orders, documentation, and coding from Kathleen Schaum, as well as side-by-side comparisons of NPWT devices manufactured by Medela, Inc., Innovative Therapies, Inc., Ohio Medical Corporation, Kalypto Medical, Spiracur, Inc, ConvaTec, and KCI. OWM readers are invited to subscribe to TWC to view this issue, as well as the NPWT Clinician’s Report published in TWC’s June 2011 issue.

At OWM, we welcome manuscripts containing quality research and patient-centered, evidence-based care protocols. We strive to present the best information available, ever aware that at one point or another many if not most wound management products and approaches have been subject to controversy. As part of that effort, we are grateful to the International NPWT Expert Panel for working to clarify exactly what is positive about negative pressure. Hopefully, our readers will turn a positive attitude about keeping abreast of the latest developments into positive outcomes for patients.

References