Your Approach to Wound Care Treatment Isn't Just About the Wound

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Plastic surgeons have the capacity to transfer large volumes of viable tissue, including skin, to heal virtually every wound. Yet as someone who directs a Wound Care Center, I only use these techniques on a fraction of patients that I see. Most wounds will heal with simpler methods and surgery carries substantial risks.

We all know of conditions that delay wound healing: age, smoking, steroid medications, malnutrition, and peripheral vascular disease. Some of these conditions are modifiable, and some are not. Clearly correcting as many risk factors that slow wound healing is essential as a first step. Beyond this, there are personal desires and goals that should be taken into account when selecting therapies. Consider the following two scenarios:

SCENARIO #1

A 21-year-old, healthy woman sustains an avulsion injury of her right medial lower leg from a bicycle accident. She is left with a 4 x 3 cm wound that goes into the adipose layer. She is otherwise healthy, does not smoke, and takes no medications.

SCENARIO #2

An 86-year-old female with congestive heart failure, type II diabetes mellitus, a history of deep venous thrombosis (DVT), and swelling of her lower legs sustains a minor abrasion to the medial right lower leg. Over several weeks this expands to a 4 x 3 cm wound into the adipose tissue. She is homebound, in a wheelchair most of the time, takes large amounts of diuretics, is anticoagulated for her DVT, and is on supplemental oxygen.

In both cases, these patients have wounds of similar dimensions and anatomic locations yet the treatment and approach to these patients is likely to be substantially different. In both cases, the goals, risks, benefits, and alternative potential treatments need to be explored and discussed with patients. As there are over 1,500 wound care products available in the US market and numerous surgical procedures that could be considered, these can be complex decisions.

Both patients would ideally like rapid healing that leaves no scar, causes minimal pain, is low cost, and is without activity constraints. Unfortunately, there are no products or procedures that that will accomplish all of these goals. Therefore, the wishes of each patient need to be prioritized, and compromises will need to be made.

In scenario #1, after discussion, the long-term appearance of her leg is the most important factor for her. She is willing to undergo staged procedures to try and optimize the appearance. She could be offered basic wound care that will allow the wound to heal over a few weeks with potential scar revision several months later. As she is young and healthy, this wound will likely heal without the need for advanced wound care products. Alternatively, she could be offered surgical debridement with a skin graft immediately to expedite healing. To allow her to continue to ambulate some, this could be affixed with a negative pressure wound therapy device. A full-thickness graft from a concealed area such as the groin will minimize donor site scarring concerns. This approach will allow for a faster healing but will leave her with a depressed area in her lower leg that she could elect to have revised in the future. She would need to weigh the pros and cons of each approach to help in her decision (Table 1).

In contrast, the conversation in scenario #2 would be quite different. In this case, her main complaint is the pain the wound causes. Because of her congestive heart failure, she is not an ideal surgical candidate, and surgery would only be considered, if her health improved and other methods fail. A number of advanced wound care technologies such as bioengineered skin substitutes and placental derived constructs could be considered as well as standard compression based dressings. She dislikes compression, but understands that without it, none of the options discussed will work over the long term. After discussion,

TABLE 1: OPTIONS, SCENARIO #1

	Pros	Cons
Basic Wound Care	• Simple • Does not require a donor site • Does not require an operation • Will promote wound contraction	• May take longer to heal • Increased risks of infection • Scar could be hypertrophic • May require more physician visits
Debridement + Skin Graft	• Efficient method • Minimize infection • Low risk of scar hypertrophy • Short healing times	• More immobilization • Requires a skilled surgeon • Donor site scar • Graft may not take

TABLE 2: OPTIONS, SCENARIO #2

	Pros	Cons
Compression & Basic Wound Care	• Commonly used • Inexpensive • Can be done at home	• May delay healing • Delayed healing may cause more pain
Compression & Advanced Wound Healing Technologies	• Should heal the wound faster • Has the potential to reduce the pain of the wound	• Expense • Requires application in a wound care center

we narrow options to standard compression therapy and standard compression therapy plus an advanced wound care modality.

Comparing the pros and cons of Scenario #2, it becomes apparent how to focus the discussion on her goals (Table 2). For example, if she feels she is nearing the end of her life and doesn't want to be bothered going to a lot of physician appointments, standard dressing care may have an advantage. Many patients are responsible for high co-pays and deductibles depending on their insurance carrier. Trying to help her understand exactly how much advanced treatments cost may help her make informed value decisions. As with Scenario #1, wound debridement and a skin graft is something she may ask about. If surgery were to be considered, she would have to be compliant with leg compression and her anticoagulation would need to be adjusted in the perioperative period.

In summary, for seemingly similar wounds, the approach to wound care and possible surgery can be dramatically different depending on the specific patient. Understanding the medical history, the risks and benefits of each potential therapy, and the goals of the patient are essential in weighing the tradeoffs of each therapy (Table 3 and Figure 1).

TABLE 3: PERSONALIZED QUESTIONS TO CONSIDER WHEN PROPOSING A WOUND TREATMENT

What are the co-morbid conditions?
What medications are being taken?
How mobile is the patient?
How important is the cosmetic result?
How much effort is the patient willing to exert?
How much will it cost?

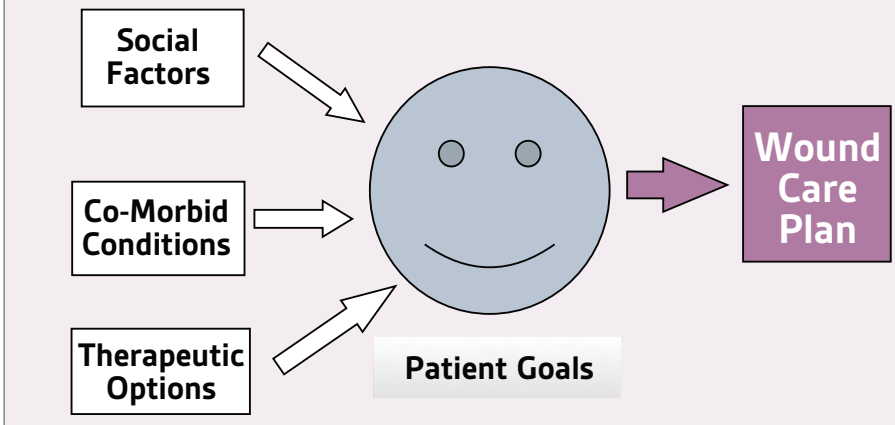

Figure 1. Considerations in consideration of wound healing strategies

Reporting Honest Healing Rates: Drive Quality, Improve Outcome, Admit Failure, and Think Like an Oncologist

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WHAT'S WRONG WITH SAYING WE HEAL EVERYONE?

A recent analysis of Medicare claims data by the Alliance of Wound Care Stakeholders demonstrated that chronic wounds affect nearly 15% of Medicare beneficiaries and that the annual cost of caring for them could be as high as $96.8 billion dollars.[1] What surprised everyone except wound care clinicians is that the majority of these charges accrue in the outpatient setting. That is, in part, because outpatient services are still billed primarily as "fee for service," which has no cap on total spending, and patients often need care for months.

Yet, a recent systematic analysis found that the vast majority of hospital-based wound centers publicly report healing rates better than 92% in less than four weeks.[2] The contradiction between the multibillion dollar cost of treating chronic wounds and the reported outcome of that treatment creates a looming crisis for the field of wound care. The Centers for Medicare and Medicaid Services (CMS) are implementing the Quality Payment Program (QPP). The majority of practitioners are now subject to the Merit-Based Incentive Payment

System (MIPS)[3] under which a practitioner's Medicare Part B payments can be assessed either a bonus or a penalty based on a complex formula that includes quality performance (reported outcomes) and per-patient spending. This means that CMS will claw back money from practitioners who are "big spenders" unless it is possible to demonstrate that the complex needs of their patients justified the spending. If we do not report the outcomes of the sickest patients, it will not be possible to justify the high cost of their care. Under MIPS, CMS requires that patient outcomes be reported using "risk stratification." That is the reason that virtually every medical specialty has developed a risk stratification system (e.g., vascular surgery, anesthesia risk, pregnancy risk, etc.). Doing so enables us to depict how difficult it is to heal some wounds. The problem is that until 2013, we didn't have a risk stratification system for chronic wounds. Now that we do, practitioners fear that reporting less than perfect healing rates will reflect badly on them. Given the realities of the QPP, it's time for wound care practitioners to think more like oncologists.

Reputable cancer centers do not report that they cure 92% of all cancers. Thanks to the transparent and uniform way that oncologists report outcomes, we know that whether a patient is likely to be cured of their cancer is determined in large part by the type they have and the stage at which it is diagnosed. The higher mortality rate of more aggressive cancers is not interpreted as an indictment of the oncologist, but an argument for developing better treatments. Standardized and honest reporting makes it possible to assess the performance of a given specialist by comparing their reported survival rates to the expected survival rates for that cancer. Honest outcomes reporting also creates the value proposition for new treatments because it is possible to identify when a new treatment has made a substantial improvement in outcome. When we report that we heal everyone, we bury data that could justify more funding for wound healing research, and we make it less likely that novel advanced therapeutics can demonstrate their true value.

WHAT ARE HONEST HEALING RATES?

Very little has been published about real-world patients and their healing rates. To understand this better, we analyzed real world data (RWD) from the US Wound Registry (USWR) consisting of 62,964 diabetic foot ulcers (DFUs), 97,420 venous leg ulcers (VLUs) and 66,577 pressure ulcers (PUs). At 12 weeks, about 45% of VLUs were healed, but only about 30% of DFUs and PUs.[2] Real-world healing rates do increase somewhat if no time constraint is placed on the time at which outcome is reported, but healing rates never reach 50% when all wounds are reported. Why are these numbers so low? Chronic wounds are not so much a disease as a *symptom* of disease. The average patient in the USWR has 8 major comorbid diseases and is on 15 medications. Approximately 12% have heart failure, 8% require prednisone, 4% have had an organ transplant, 10% are on dialysis, and malnutrition is common.[4] For example, more than 70% of patients with venous leg ulcers (VLUs) are obese, 20% have concomitant arterial disease, and 40% have diabetes as a co-morbid condition. Yet, when randomized controlled trials (RCTs) are performed on VLUs, diabetes and arterial disease are excluded.[5] That means, unlike oncology, we are not investigating treatments to help the typical patient. We have previously shown that 88% of typical patients would have been excluded from nearly every wound care RCT performed over a decade.[4] The downstream effect of non-generalizable RCTs is that Medicare Administrative Carriers (MACs) and other private payers craft coverage policies for advanced therapeutics that mirror the exclusion criteria of clinical trials. Private payers simply refuse to authorize the use of certain advanced therapeutics. Since Medicare does not require prior authorization for most treatments, physicians have ignored the fine print on MAC policies and used treatments like cellular and/or tissue-based therapies (CTPs) on the patients they felt needed them even if they did not meet the coverage criteria. When MACs enforce their policies by performing audits, hospitals and practitioners may be required to pay back the money for treatments provided outside of these narrow coverage policies.

The exclusion of certain patients from clinical trials might have had a profound impact on the way negative pressure wound therapy (NPWT) was provided. In 2007, the Food and Drug Administration (FDA) demanded that KCI (now an Acelity Company) provide them with an assessment of the safety of "V.A.C.® Therapy" in comparison to moist wound care among patients undergoing NPWT in the home setting. Thanks to the availability of real world data in the USWR, it was possible to analyze the risk of possible complications like infection and bleeding in nearly 1,000 V.A.C.® Therapy-treated patients, 200 of whom were on coumadin, compared to nearly 9,000 moist wound care patients. The analysis demonstrated to the FDA that "V.A.C.® Therapy" was no less safe than moist wound care in home use.[6] Despite the fact that V.A.C.® Therapy and non-V.A.C.® Therapy cohorts were closely matched on many aspects of wound and patient characteristics, journal reviewers expressed concern that a better method was needed to stratify and match wounds in patients with so many co-morbid diseases. Perhaps, as a result of this experience, in 2009, KCI was alone among wound care manufacturers in understanding the need for a risk stratification system when it partnered with the USWR and Dr. Susan Horn of the Institute for Clinical Outcomes Research (ICOR) to fund such a project. We had hoped to create one model that worked for all wound types but, because different factors affected different wound types, 7 models were ultimately developed, one for each major ulcer category. Termed the Wound Healing Index (WHI),[7,8,9] the nearly four-year project involved analyzing the structured data from almost 70,000 wounds in the USWR, identifying individual factors associated with failure to heal, creating predictive models, and validating them from additional data.

THE WOUND HEALING INDEX (WHI)

The WHI makes it possible to predict with reasonable accuracy, at the conclusion of the first visit, whether a wound of a given type is likely to heal with standard wound treatment alone. It is not necessary to wait weeks to establish a wound healing "trajectory." The WHI allows the early identification of patients who will likely need an advanced therapeutic to achieve healing, or perhaps more importantly, those who will not, allowing better targeting of healthcare resources. More than a decade ago, a predictive model had been developed that identified which diabetic foot ulcers would benefit from hyperbaric oxygen therapy (HBOT). [10] We recently suggested combining these mathematical models to first identify which DFUs will not heal spontaneously, and then which of those DFUs will benefit

from HBOT. This two-step approach reduces both unnecessary and futile care.[11] Together, these two models are statistically superior to Medicare's current method of selecting DFUs appropriate for HBOT which requires four weeks of conservative care to establish treatment failure, after which all Wagner Grade 3 or worse DFUs may be treated with HBOT (assuming the proper work-up has been performed, and all other Medicare criteria have been met). It is interesting to note that, despite all the hype about the possible use of artificial intelligence (AI) in wound care, there is no apparent interest in using the AI currently available in the form of predictive models. Wounds in the USWR repository are stratified with the WHI, which makes it possible to create matched cohorts for comparative effectiveness studies (CER) and to determine, for example, the incremental benefit of a specific treatment or factor of care such as visit frequency.[12] When KCI helped fund the WHI project, the planned second phase was to identify the factors which predicted the benefit of specific advanced therapeutics. The recent analysis of the cost of chronic wound care suggests that this second phase should still be undertaken. The USWR recently published a paper establishing standards for the use of registry data obtained from electronic health records (EHRs) which we refer to as the ABCs or Analysis of Bias Criteria.[13]

IMPROVING OUTCOMES THROUGH QUALITY REPORTING

The USWR is a 501(c)(3) non-profit organization that develops quality measures for wound care practitioners since there is no wound care subspecialty society to do this work as in other areas of medicine.[14] The only source of funding for the USWR are the nominal fees that practitioners pay for quality reporting services. Money obtained from the small fee for accessing the WHI calculations is being used to develop the next generation of predictive models. In 2008, the USWR was among the first 31 registries recognized by CMS for reporting the Physician Quality Reporting System (PQRS), and in 2014 was among the first Qualified Clinical Data Registries (QCDRs) recognized by CMS. CMS has approved 11 wound care relevant quality measures as part of the USWR 2018 MIPS registry. The USWR also hosts several specialty registries to enable practitioners to satisfy the requirements of Advancing Care Information (previously Meaningful Use of the electronic health record). These include the cellular product registry, the negative pressure wound therapy registry, the diabetic foot ulcer registry, the podiatry registry, and the hyperbaric oxygen therapy registry.[15] Approximately 600 wound care practitioners participate in the USWR by transmitting their EHR data to the USWR nightly, a subset of whom participates in MIPS through the USWR. Nearly 1,000 additional practitioners participate in the various specialty registries of the USWR by transmitting Continuity of Care Documents (CCDs).

In a recently published article,[5] we detailed the way in which we linked a consortium of clinics together through their EHR to create a Learning Healthcare System, providing clinical suggestions at the point of care relevant to the specific wound for which the patient was being seen (e.g., arterial screening, diabetic foot off-loading). Practitioners were motivated to act on these reminders because doing so improved their MIPS quality score, thus increasing their chances of bonus money under the QPP. This is the first use of AI to implement protocolized wound care of which we are aware. On March 31, their 2017 quality scores were submitted to CMS. There was only a 3.5% difference between MIPS-participants and non-MIPS participants in documenting venous ulcer compression at each visit (53.3% vs. 49.8%). However, MIPS participating practitioners documented DFU off-loading at every visit 65% of the time compared to non-MIPS participants at 32% of encounters. Since the DFUs and VLUs are stratified by the WHI, it was possible to determine in a fair way whether these differences in off-loading and compression had a meaningful impact on outcome. They did. MIPS reporters significantly outperformed their non-reporting colleagues in DFU and VLU healing rate. For MIPS reporters, the DFU healing rate was 9.8% higher than non-MIPS participants, and their VLU healing rate was 10.7% higher (p value of < 0.0001 in both). The explanation for their better performance may lie in the results of the arterial screening measure. MIPS participants were 31.9% more likely to document arterial screening (66.8%) compared to non-MIPS participants, suggesting that their improved healing rates were in part because MIPS-participants were more likely to identify patients with co-existing arterial disease. The USWR has prepared all of its quality measures as SMART apps, suitable for installation into Epic® as hospitals gradually move to the "2015" EHR certification standard. If hospitals install the USWR quality reporting apps, it will be possible for any provider to report honest outcomes using the WHI. The WHI is the way to harness RWD for wound healing research now that the Food and Drug Administration has opened the door to real-world data. It is ironic that the key to future success in wound care may be in honestly reporting our failures. It seems that Ben Franklin was right, "honesty is the best policy."

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