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Clinical Assessment/Measurement of Healing: Evolution and Status

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Abstract: Recent advances in the physiology of wound repair, in particular the identification of multiple growth factors, challenge previous understanding of the healing process and demand familiarity with molecular biology and cellular physiology. In the midst of this, few, poorly tested, seldom used methods of evaluating real patient's wounds exist.

This paper analyzes some of the historical reasons underlying the present dearth of methods for systematically monitoring human healing. The discussion points out that this paucity did not occur because of a lack of interest or good will on the part of many. Knowledge of the past and the needs of the present, however, should only serve as fodder for changing the status quo. Those non-invasive instruments available for use in the clinical measurement of healing are described. Finally, suggestions for rectifying the need for valid, reliable, clinically useful methods of evaluating healing in humans are presented.

INTRODUCTION

For better or for worse, the 20th century has placed great stock in the ability of individuals to measure aspects of our reality. In many ways, this perspective has led to the conclusion that, one 'knows' only if he can measure the phenomenon of concern and, conversely, that if something has been measured it must be understood. With the advent of computerization and advances in scientific technology, vast areas once thought beyond the grasp of mere mortals have now been quantified and, consequently in many cases, assumed to be understood. Despite such advances, many more pedestrian aspects of life remain poorly charted and, as a result, poorly measured. Among these realities is the clinical assessment/measurement of human tissue healing. This paper will chronicle some of the reasons that the clinical evaluation of wounds is late in coming, as well as present an overview of the status of measurement of human tissue healing in the clinical setting. The manuscript will conclude with several suggestions for rectifying the current lack of reliable, valid, and clinically useful ways of assessing progress in tissue healing in humans.

EVOLUTION OF THE CLINICAL MEASUREMENT OF HEALING

Whether or not to measure anything, as well as the degree of precision demanded in the measuring process, is determined by multiple factors, among them: the difficulty inherent in the task, the technology available, and the belief that the exercise will produce meaningful information. Certainly the hard sciences provide stellar examples of the impact precision in measurement can have on outcomes. As a result of disciplined measurement, some scientists have: developed vaccines leading to the eradication of life-threatening diseases; created pharmacologic substances allowing individuals to lead productive lives; and unraveled aspects of the internal environment of the cell allowing gene manipulation to take place. And, although equally important discoveries have led to fairly precise monitoring of selected clinical phenomena, albeit most of them physiological in nature, this has not been the case universally, certainly not where the clinical evaluation of tissue healing is concerned.

With the exception of battlefield wounds and burns (neither of which is the focus of this paper),

little has been done to assist the bedside clinician in systematically monitoring the status of either the acute or the chronic wound. Further, even when measuring devices have been developed, none is known to this writer to have become an established part of published wound care protocols throughout the US.

Prior to discussing the current status of wound measurement, it is important to reflect on some of the reasons why the measurement of tissue healing has not progressed as rapidly as have efforts to measure other aspects of patient care. Why is there a paucity of sound, clinically useful approaches to the measurement of human tissue healing?

Prior to antibiotics, death from sepsis was frequent in those with wounds of any significance. Even more recently, until the inception of regional trauma/burn centers, many individuals burned or involved in major trauma died. Explanations for these bleak consequences ranged from the effects of transporting individuals over long distances before treatment could be rendered, to an increased awareness of the specialized knowledge required to resuscitate the critically ill. Those burn/trauma patients who died probably did so not as a direct consequence of their wounds as much as from shock. With the advent of antibiotics, the introduction of burn/trauma centers, and the 911 system, came the ability to sustain patients through crises to the point where their wounds could be cared for. Prolonging life led to an enormous population for which wound tending became necessary. Only then were large numbers of clinicians faced with the care and monitoring of extensive wounds to which they previously had not been routinely exposed. One consequence of the earlier limited exposure was the lack of a stimulus for questions regarding evaluation of wound status.

More recently, advances in surgical skill and medical technology have brought with them the ability to modify potentially life-threatening conditions, thus prolonging the life span of an already aging population. These positive changes are not without their consequences, however, for the elderly and debilitated are prone to other conditions (e.g. wound infections, pressure ulcers) which in and of themselves are difficult to treat. Nonetheless, this scenario also has increased the likelihood that clinicians in all settings now are faced with the care of tissue wounds once seen far less frequently. As distinct types of wounds are seen repeatedly, protocols are devised, and clinicians ask new

questions concerning how to best assess/measure patient progress.

From a more pragmatic view, health care costs increased, the government intervened, more and sicker patients now remain in the acute care hospital for limited periods of time before they must be transferred elsewhere. In this system, clinicians can no longer wait for subtle changes in conditions to become overt before taking action. On the contrary, all aspects of patient care, including tissue healing, must be monitored in such a way as to expedite the patient's return to wholeness and to society. Arriving at a gestalt about clinical phenomena was not in the past and is not now 'good enough.' And, so on retrospective analysis another historically based impetus for better approaches to the measurement and objectification of clinical phenomena, among them healing, becomes evident.

Although each generation likes to consider itself unique, and no less so individuals involved in health care, few professionals caring for wounds would argue that the last two decades could not be described as the 'era of the wound.' With the translation of the theory of moist healing^{1,2} into clinically useable products, came a marketplace inundated with choices for wound care and a new appreciation of the complexity of healing as a process. At the same time, traditional approaches to wound care held to unquestioningly for so long were challenged head on. As new products appeared, both clinicians and industry were faced with the realization that there was little or nothing available to track the healing process objectively and systematically in humans. As a result, both purchasers and clinicians had little to assist them in determining the superiority of one product over another. In a health care system based on efficient and effective quality care, the pragmatics of assuring that the patient will get the best for the health care dollar spent drives the need for sound measurement approaches to support good practice, no less so in the selection of wound care products.

With the appearance of new products, the empiricism used by some in the treatment of wounds was soundly challenged and those with a strong theoretical basis in tissue healing were increasingly heard. At the same time a growing appreciation of the role the nurse plays in 'tending' the wound emerged.³⁻⁵ Long the meticulous carers of wounds, nurses have identified the lack of adequate evaluation criteria and have begun to establish methods of assessing and measuring healing.⁶⁻²⁰ Nurses know that such approaches will assist them with their

growing responsibility in the day to day monitoring and describing of what it is they see in patients' wounds. But nurses do not act in isolation; clinically they interact with numerous members of other disciplines and at times collaborate in research. When the focus of a project is the evaluation of healing, because of the state of the art, the measurement methods available are oftentimes anecdotal and untested. As a result, enormous energy is expended by sincere individuals collecting data for a study the results of which will be evaluated as 'soft', unscientific, and lacking in generalizability. Consequently, studies using measurement devices for which validity and reliability have not been established are judged as possessing less merit than those analyzing esoteric phenomenon for which precise measurement tools exist. As a result, clinicians now are being driven first to develop approaches to the measurement of healing in order to proceed in a scientific mode with the evaluation of potentially significant clinical therapies. They do so, for the most part however, with inadequate educational preparation in instrument development.

An attempt at explaining some of the reasons for the state of the art of clinical assessment/measurement of tissue healing continues. For instance, the issues include the fairly recent evolution of healing as a science, the educational preparation of clinicians regarding tissue healing and wound care; the lack of research expertise on the part of many clinicians; the relative newness of industry's participation in wound care; and the age-old separation of academics and clinical practice. All these factors crowd in to substantiate the fact that the lack of clinically useful ways to measure healing is not an accident; rather, the basis is historical.

The care of wounds has become a part of almost every clinician's practice. New products, new understanding of the theoretical basis of healing, new interest and enthusiasm about wound care, increasing health care costs, and the transfer of health care across settings demand standardized methods of monitoring healing. Prior to initiating attempts at resolving this need, however, an overview of the measurement tools already developed is warranted.

STATUS OF ASSESSMENT/MEASUREMENT OF HUMAN HEALING

The literature on the measurement of healing is replete with descriptions of effective approaches for

use with animals: hydroxyproline content, tensile strength, and angiogenesis are each examples of measurements cited repeatedly. Seen less often are studies suggesting approaches to measurement of healing in humans that are 'safe, minimally invasive, comfortable, acceptable to the patient, and capable of producing data precise enough to be analyzed' (see Ref. 21, p. 394).

On initial inspection, it is difficult to bring order to the various approaches purported to measure human healing. This can perhaps best be explained by the lack of consensus regarding the definition of healing itself. The immediate consequence of such nonuniformity leads individuals (be they researchers, clinicians, or members of industry) to focus on different aspects of healing based on personal interest or perspective. Once a definition is selected, these same individuals go on to identify varying approaches to measure healing they believe to be congruent with the definition chosen.

Even a quick review of several definitions of healing points up the range available and thus the dilemma faced particularly by clinicians: For one writer, healing is 'a normal reaction to injury' (Ref. 22, p. 4); for another the 'filling of a defect with connective tissue' (Ref. 23, p. 45); still others describe it as a 'spectacular progression of biochemical, physiologic and morphologic changes' (Ref. 24, p. 288); yet again, some researchers regard healing as an 'imperfect' (Ref. 25, p. 118) or 'pathological process',^{25, 26} while others describe it globally delimiting its multiple overlapping sub-processes, each of which contributes to the whole in ways not thoroughly deciphered.²⁷

In the midst of all this, clinicians, a great many of whom are novices regarding the intricacies of the basic processes, are left unclear on the best indices of healing. What is it, they ask, will best tell us that a wound is healing? Researchers, on the other hand, focus on selected aspects of the overall process and, having devised methods of measuring particular variables, at times, infer myopically that a single isolated component is a reflection of the entire healing process. Industry, particularly those companies concerned with wound treatment, focus on outcome criteria that they believe demonstrate benefit to the patients and clinicians treating wounds. Multiple perspectives abound then, on how to go about measuring what perhaps too many have assumed is a single, quantifiable phenomenon.

Given the disparity of definitions and the lack of consensus on how to best measure each, the following scenario is understandable: Accepting the

Table 1. Instruments to assess/measure human healing

<i>Predict</i>	1. The Braden scale ⁸⁻¹⁰ 2. Gosnell pressure sore risk assessment ¹²⁻¹⁵ 3. The Norton scale ^{6,7} 4. 'The chosen wound dimension' ³⁵
<i>Classify</i>	1. Pressure ulcer staging ^{36,37,49} 2. 'Wound severity score' ⁴⁰⁻⁴² 3. 'RYB' Color code ^{38,39}
<i>Measure/assess</i>	
<i>Invasive</i>	<i>Non-invasive</i>
1. Gortex/hydroxyproline ²¹	1. Ruler/concentric circles ⁵⁵
2. Subcutaneous tissue PO2 ^{33,34}	2. Acetate tracings ^{47,55}
3. Hydroxyproline ³²	3. Photographs ^{43,48}
4. Cellstic/collagen ³⁰	4. Wound molds ^{28,29,50-54}
5. Polyvinyl sponges/collagen ³¹	5. Wound characteristics instruments ¹¹
	6. Wound assessment inventory ¹⁸
	7. Wound gauge ^{16,17}
	8. AESPSIS ^{44,46}
	9. Home assessment tool ¹⁹
	10. Transcutaneous oxygen ^{60,61}
	11. Time

definition that healing 'is the filling in of a defect with connective tissue' (Ref. 23, p. 45), the selection of a molding substance, which when poured into a wound is allowed to solidify, removed, and weighed, would appear to be an optimal and congruent approach to measurement. Serial molds could indicate whether or not the wound volume was changing. If wound volume decreased, less molding material could be instilled into the wound and the resultant molds would become smaller. Logically one could infer that new tissue synthesis was occurring and that the overall status of the wound and the treatments were optimal. If, on the other hand, serial molds remained the same size, or became larger, one might conclude that healing was retarded or regressing and that approaches to care should be altered. Considering mold size alone, clearly does not account for contour changes, due to debridement. When molds are used as the approach to measurement, healing is judged to be reflected in the synthesis of new tissue and wound contraction and the measurement device is appropriate for the definition selected.

Certainly wound molds have been used effectively in selected clinical research protocols,^{28,29} but would that the solution to the assessment/measurement of wounds/healing were that easy. Instead, in addition to the numerous definitions of healing proposed, one must consider as well a whole host of wound types, many of which would be ill-served by having molds placed in them. Additionally, researchers and clinicians alike have come to the realization that a 'wound is not a wound is not a wound.' Instead,

one notes an emerging trend to cluster wounds by type, assigning them to categories. As similarities within each category are identified, methods by which healing in specific wound types can be measured begin to be identified: The incision closed by primary intention, for example, is assessed differently than the wound healing by secondary intention; the partial thickness wound differently from the full thickness, and the chronic wound has characteristics that distinguish it from the acute wound, regardless of how it was acquired. Other categories also come to the fore. These are based on the etiology of the wound and can be seen reflected in: the burn wound, the surgical wound, the pressure ulcer, the venous or arterial ulcer, the radiation burn wound, and a whole host of skin conditions. This is not to mention those wounds that for various reasons fit more than one category. In sum, because a particular approach to wound measurement 'fits' for one type of wound, does not mean it can be readily applied to all healing situations.

Although the enormity of the task of clarifying all that is involved in attempting to measure a wound can become overwhelming, it is equally important to begin to bring some order to the status of clinical wound evaluation. One way is to classify approaches to wound measurement by separating them into two categories: those that assess parts of the process, or aspects/mechanisms of healing (i.e. microscopic,^{21,30-34} and those that measure the status of a wound as a reflection of the underlying processes (i.e. macroscopic).^{6-20,28,29,35-55}

Braden,⁵⁶ attempting to bring some order to instruments developed for use with pressure ulcers divided them into those that: (1) measure the etiologic factors directly; (2) provide a direct measurement of a secondary effect; (3) assess etiologic factors indirectly; and (4) describe the stage of the ulcer. Recently this writer^{57,58} offered an approach to organizing wound instruments by clustering them into categories that: (a) *predict* wounding/healing; (b) *classify* wounds; and (c) *measure/assess* some aspects of the healing process (see Table 1). Although this latter schema is by no means perfect, it provides a framework for beginning to review methods available to evaluate wounds in the clinical setting.

It is beyond the scope of this paper to discuss in detail each of the organizational frameworks. The discussion will focus on the category of measurement/assessment, emphasizing the non-invasive approaches to evaluating wounds that are available to the clinician involved in the direct care of the patients.

APPROACHES TO MEASUREMENT/ASSESSMENT OF WOUNDS

The largest number of instruments for evaluating wounds cluster under the category of measurement of healing. While this is so, it by no means implies that the instruments contained therein have been tested any more rigorously or that they are more precise than those comprising other categories. Similarly, although several approaches can be assigned to the measurement/assessment category, the particular aspects/components of healing on which they focus vary.

Linear measurements

Beginning with the obvious, for years clinicians have used rulers, tongue blades, and cotton swabs in an attempt to objectify the width, length, and depth of wounds.⁵⁵ Although each of these approaches lacks reliability, they should not be totally discredited; for, used carefully and consistently, these simple devices provide greater objectivity in monitoring healing than the all too frequently heard observation that the wound 'looks a little bigger (or smaller) today.'

Modifications of the classic ruler and the appearance of concentric circles and premarked

acetate sheets/templates that can be easily placed over open wounds, thereby increasing visualization, have enhanced the ease with which measurements can be obtained.^{47,55} Despite these modifications, precision in obtaining the measurement can vary greatly given the number of individuals assessing a wound. Few wounds are square or perfectly round, thus tracing the wound perimeter can provide a better reflection of the wound status than linear estimations. Tracings, however, are also not problem free, for deciding what constitutes the edge of the wound is not without difficulty; some clinicians identify new epithelial tissue and trace that, while others mark the perimeter farther back on the skin. The presence or absence of an epithelial edge denotes markedly different states of repair. This difference might seem irrelevant, but when one considers that small changes in measurements are often interpreted as great changes in the course of healing, the lack of reliability of this approach becomes apparent.⁴⁸

Area/volume measurements

Concern with the inability to determine the area and volume of the wound led to the development and use of the 'wound gauge'^{16,17} and wound molds.^{28,29,50-54} The wound gauge consists of three rulers, joined centrally. This design facilitates simultaneous measurement of wound depth, length and width. Because of the irregularity of the base of most open wounds, however, the reliability of measurements taken with this device comes into question. A recent report evaluating the wound gauge against acetate tracings and wound photographs subjected to image analysis, indicated that all three approaches provided similar results when evaluating small, regularly shaped wounds. When applied to large, irregular wounds, however, the wound gauge consistently underestimated the area of the wound; acetate tracings were, in fact, found to be more reliable.⁴³ In addition, the wound gauge costs approximately \$2.00/per gauge and can be used only once.

Wound molds, (composed of an alginate compound used to make dental impressions), have been used to measure wound volume. Once the substance is instilled into the open wound, it assumes the shape of the cavity as it solidifies, and subsequently can be removed, stored, and weighed. Of the drawbacks of this approach already presented, reliability is perhaps most easily flawed. Insuring that the external alginate surface at the wound edge

is level is imperative. Imprecise instillation results in volume changes that could be erroneously interpreted. Although wound molds have been used in research protocols,^{28,29} this approach does not seem practical for use by clinicians carrying out routine functions with patients. Additionally, not all open wounds lie in positions on the body that are receptive to proper placement of this substance, let alone those with tracts or fistulae, for which this medium would be precluded.

Silicone-based polymers, introduced in Europe in the 1970s mimic the characteristics of the alginate molds, providing a reflection of wound status. Outside the US they are also used as dressing materials in granulating wounds.⁵⁰⁻⁵⁴

Before leaving this section, it should be noted that Gilman⁵⁹ recently cautioned against comparing measurements of wound area when studies 'include wounds of different shapes and sizes' and offers formulas to insure that wounds are appropriately compared when variations in size exist (Ref. 59, p. 95).

Wound assessment

Three instruments, the 'Wound Characteristics Instrument' (WCI),¹¹ the 'Wound Assessment Inventory' (WAI),¹⁸ and AESPSIS⁴⁴⁻⁴⁶ fall into this category. The WCI was developed by this writer and evolved out of concern for the lack of a systematic method for observing wounds. This instrument, designed for use in assessing post surgical, soft tissue wounds healing by secondary intention, is a 17 item criterion-referenced rating scale. It directs the clinician to observe the wound in a systematic manner, based on geographical regions. Within the wound regions, the clinician evaluates essential characteristics, scoring them from optimal to suboptimal manifestations of that attribute. In addition to providing a standardized assessment device, this instrument also establishes a vocabulary for soft tissue wounds, separating healthy manifestations of healing from unhealthy. The WCI has undergone tests of content and construct validity, as well as reliability testing. Evaluation of the psychometric properties of the WCI is ongoing.

The WAI¹⁸ was developed to assess the affect of guided imagery on wound healing, in particular the inflammatory response in post surgical patients. Three major signs of inflammation (i.e. edema, erythema, and exudate) were identified and a four point rating scale created. Content validity of this

instrument has been reported, as well as interrater reliability scores.

AESPSIS, an acronym for a series of characteristics of post-surgical wounds healing by primary intention, was designed to evaluate the effect of antibiotic therapy on wound sepsis.⁴⁴⁻⁴⁶ It has been used with both cardiac and general surgery patients and although additional testing is warranted, this instrument encourages standardization of the visible manifestations of post-surgical infections and appears to be relatively easy to use.

One additional approach to wound assessment for which reliability and validity data are not reported is that described by Siddall.¹⁹ This tool, designed specifically for use in monitoring post-surgical wounds of patients post hospital discharge, logs distinct observable and palpable characteristics of the surgical incision. This effort points up the growing need for instruments that are adaptable across settings. Increasingly, patients are discharged home with wounds that continue to require observation and direct nursing care. Lacking standardized measurements, community health nurses find it difficult to communicate about the wound over the phone with physicians regarding wound status.⁵⁷ All clinicians involved in the care of patients are dependent upon one another for assessments, no more so than in the home where an increasing amount of care is rendered.

Other approaches to measurement

Other non-invasive instruments for use in measuring wounds have been described. Approaches like photographs of the wound, logging the number and kind of dressings placed in the wound, and careful awareness of the time involved in the healing process have been reported. Certainly a photograph of a wound 'is better than a thousand words' but only if the print is readily available and the individual taking the picture has the time to skillfully take the photograph carefully. Planimetry and the use of stereophotography have also been used in the clinical setting. When used to study chronic leg ulcers and compared with direct tracings or photographs, stereophotogrammetry is said to be 5 to 10 times more accurate.⁴⁸ Regardless, both of these approaches require time and expertise in excess of those possessed by the average clinician.

Despite these latter reports, this paper has focused purposefully on those instruments that do not require the skills of an expert to complete or interpret, or those that require an inordinate

amount of time to implement. The reader is, no doubt, amazed to have read so far only to be told about so few instruments. And yet, that is precisely the point of this article; few instruments exist, almost none have undergone rigorous testing, and none are a part of routine care.

SUGGESTIONS FOR RECTIFYING THE NEED FOR MEASUREMENT TOOLS FOR HUMAN HEALING

The assumption that because something can be measured, it therefore is understood, is in fact not true in all cases and must be challenged. Before adequate instruments for measuring human healing in the clinical environment can be developed, the concept 'healing' must be operationalized through more concrete and universally held definitions. Perhaps healing is too global and abstract a concept to be thoroughly operationalized, but that cannot be used as an excuse to not begin the effort. If it is difficult to contain within a single definition, than its clinical components and manifestations need to be isolated. Recalling the recent laudable efforts of the National Pressure Ulcer Advisory Panel,⁴⁹ it is only when commonly held, clearly articulated definitions are established that clinical scholars will be able to go about determining how best to measure a phenomenon, in this case healing. Adherence to the premise that the clinical manifestations of healing can be defined will result in the emergence of a body of knowledge regarding that will: (1) optimize the healing environment; (2) increase the overall understanding of clinicians regarding the process; (3) reduce costs; and (4) accelerate the patient's return to wholeness.⁶²

The aspects of healing that are of significance to the clinician must be isolated and viewed alongside and of equal import as the invisible mechanisms/components. In all this, the burden of developing adequate descriptions of the clinical concept of healing falls squarely on the shoulders of clinicians. It is those who have seen human wounds over and over again and possess the expertise of knowing when healing is progressing and when it is regressing that are the most significant contributors to this process. Because of this, it is this writer's contention that the clinical measurement of healing must of its very nature be developed by clinicians.

Once commonly held definitions are established, the empirical indicators and the best approaches to measuring healing clinically will evolve.^{63,64} Where no measurement tools presently exist, they must be

developed and submitted to all the rigorous testing required. In the meantime, every clinician must question the reliability and validity of instruments currently in use, weighing the data gathered in the light of that. Those with expertise in the clinical measurement of healing must continue to publicly share constructive critique of new approaches to measurement as they evolve.

Regardless of who develops a measurement device (be it clinician or researcher of the microscopic aspects of the process), there should be greater effort in articulating the variable(s) being measured and justification for the congruency of the measurement approach utilized. Only in this way can instruments truly be assessed for their validity and not misconstrued as accomplishing more than originally intended. In this way as studies using the same measurement approach grow, patterns within the healing process will emerge.

When scientists of both the visible and invisible aspects of healing come together, greater appreciation for the difficulties involved in each others efforts needs to grow. Communication between these researchers should be ongoing, at times leading to collaboration, so as to bring order to this body of knowledge.

Within his lifetime, no reader of this paper has gone unwounded. For many, healing is an unquestioned and inevitable process.^{22,62} Yet, the potential of anyone acquiring a serious or chronic wound that does not follow predictable patterns is not outside the realm of possibility. Given the current state of evaluation of human healing, one can only speculate on how the progress of an atypical wound would be monitored. Furthermore, one wonders what criteria the clinician would use to determine the treatment, or even more importantly, if the wound was moving towards optimal resolution. In conclusion, if this paper has accomplished no other purpose than to raise the reader's awareness of the unacceptable state of the measurement of human wound healing in the clinical setting and the need for aggressive efforts to change the status quo, than it will have been worth this author's effort.

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