# Adopting an Innovative Acne Grading Scale into Practice

A straightforward, three-part naming convention efficiently and accurately describes the type, number, and location of acne lesions.

By Joseph Bikowski, MD

cne is a ubiquitous skin condition that represents a significant proportion of patient visits to dermatology clinics. Yet, despite the prevalence of the disorder, dermatologists lack a consistent standard classification system by which to describe the severity of the disease. Our own American Academy of Dermatology, noting the "pleomorphic" nature of acne, highlighted the difficulty of establishing a grading scale that could accurately consider the mixture of lesion types and sites of involvement, variable characteristics of inflammatory lesions, and variability of the natural history of acne lesions.[1] Clinical trials have employed various classification systems—one review identified more than 25 methods of assessing acne severity and more than 19 methods for counting lesions—but these do not readily adapt to daily practice.[2]

An easy-to-use and easy-to-understand classification system aids initial diagnosis and treatment selection, facilitates clinician assessment of therapeutic response, and provides patients a context for understanding acne symptoms and their progression or improvement. A novel classification system allows for efficient and accurate description of each acne presentation.

## Previous Systems

The earliest acne grading scales, introduced by Pillsbury, Shelley, and Kligman in 1956,[3] categorized acne into four grades:

Grade I: Simple, banal; no significant inflammation.

Grade II: Moderate severity, occasional inflammatory lesions

Grade III: More severe with more papules and inflammation

Grade IV: Most severe with nodulocystic component.

The grading scales with which contemporary clinicians are

familiar expanded on this basic structure and largely emerged during clinical trials for topical retinoids and other various acne therapies developed over the last quarter-century. For the most part, these trials equated efficacy with reduction of lesions and therefore emphasized the total number of lesions as a basis for assessing acne severity. For example, multiple early publications assessing the efficacy of benzoyl peroxide or tretinoin focus on lesion count reductions.[4-8]

Accurately counting lesions is notoriously difficult, and Kligman, who pioneered many early acne trials, has reported results of a study in which an experienced evaluator provided significantly different acne lesion counts for the same patients seen on the same day.[9] Of course, the total number of lesions tells just part of the story; identifying the type(s) of lesion(s) present is important to assess the patient's condition and ini-

tiate appropriate therapy. Lesions of acne vulgaris include papules, pustules, open and closed comedones, and nodules/cysts. It is important to note that in clinical practice, the number of lesions rarely reflects the patient's concern about his or her condition. Instead, patients frequently voice concern about specific qualities (size, inflammation) of the lesions they have. Just a few painful, nodular lesions or an inflamed sinus tract will likely pose a greater concern than several dozen comedones along the jawline.

Trials have assessed the efficacy of each agent relative to its efficacy in reducing specific types of lesions. Based on these trials and clinical experience, it is now generally accepted that retinoids, hydroxy acids, and azelaic acid target comedones, while topical antibacterials (and azelaic acid) or systemic antibiotics treat papules and pustules. Nodulocystic acne typ-

ically requires systemic antibiotics or oral isotretinoin.[10]

The notion of global severity emerged to assess and reflect not just the number of acne lesions but also the type and quality of those lesions. This more comprehensive assessment approach may consider factors like the types of lesions, presence of inflammation, total area of involvement, and patient's subjective assessment. However, even when used in controlled trials, there is variability in global assessment criteria from one study to another.[11]

As long ago as 1979, Cook, et al. proposed a photographic grading system for acne based on a zero to eight scale that espoused a more "global" construct. Photographic standards were provided to illustrate grades zero, two, four, six, and eight, and serial photographic records for each subject were graded based on their comparability to these anchors. With each progressive stage of disease, the number of lesions as well as the degree of inflammation increases. The authors note that photographic grading proved "useful and reliable" in large-scale clinical trials.[12]

A similar but expanded 10-point photographic reference scale, termed the Leeds Technique, was introduced by Burke and Cunliffe in 1984.[13] As with previous systems, this was developed primarily for use in clinical trials to help ensure consistency across studies.

Results of a double-blind clinical comparison of minocycline and tetracycline again suggested reliability and reproducibility of photographic grading. In the randomized, double-blind trial, photographs of facial or body acne were taken at baseline and every two weeks over the 12-week course of the study. Two independent dermatologists provided assessments of acne severity based on photographs. Meanwhile both on-site blinded graders and patients made assessments at each visit. The researchers reported "reasonable agreement" between assessments by on-site investigators, patients, and photo reviewers.

Unfortunately, effective use of an acne grading system based on photographic standards requires that the initial evaluator as well as any individual subsequently reviewing the patient's record be familiar with or have access to the photographic standards in order to appreciate the degree of patient involvement.

Furthermore, while a "global severity" measure is intended to reflect qualities such as erythema, inflammation, and type of lesion, overall lesion counts still figure prominently and may overshadow other considerations. In fact, one set of researchers sought to determine how global severity grades correlated with lesion counts and determined they were highly correlated.[14] Their findings were based on analysis of data from two 12-week, placebo-controlled acne therapy trials.

The so-called Cunliffe scale[15] may most closely reflect the approach to acne evaluation and grading typically used in the practice setting today. This classification provides for four levels of severity:

Left, top: Grade I; Severe; Forehead:
More than 20 comedones on the forehead

Left, bottom: Grade II/III; Moderate; Chin:
11-20 papules and pustules on the chin

Above: Grade IV; Mild; Left cheek:
Fewer than 10 nodules on the left cheek.

Consistent with the prevailing opinion of most clinicians, the presence of just a few nodulo-cystic lesions immediately increases the assessed level of severity on this scale.

However, the clinical reality is that, while the Cunliffe system attaches specific criteria to each acne grade, many dermatologists use the terms "mild," "moderate," "moderately severe," or "severe" either without specific reference to this proposed scale or based on their own similar but not necessarily identical determination of what constitutes each grade of acne. Use of these terms remains somewhat subjective, as the meaning of each grade may be relative to the clinician assessing the patient and the individual interpreting that assessment.

Finally, it is worth noting that late last year, researchers proposed yet another classification scheme, this one an update of the Investigator Global Assessment to include truncal acne.[16] The Comprehensive Acne Severity Scale, as it is called, was designed for use in investigational studies as well as in clinical practice, and was shown to correlate with the Leeds scale.

## A New Proposal

Simple lesion counts fail to consider the impact of lesion type and location. A straightforward mild/moderate/severe grading system lacks specificity; despite efforts to define each grade of acne, these may be relative designations or too commonly used outside the defined scale to permit meaningful, consistent use. Grading systems based on photographic standards, while reproducible and effective for trials, do not effectively translate to clinical use, as both the initial assessor and any subsequent reviewer would have to be familiar with or have access to the standards used.

Rather than seek to create and define various categories of severity, a meaningful acne grading system should convey in a clear manner the:

1. quality,
2. number, and
3. location of lesions.

I propose a straightforward three-point convention for grading acne. Because it influences treatment selection, it is important to first establish lesion type. We can identify four types or grades of lesions:

*Grade I* - Comedo
*Grade II* - Papule
*Grade III* - Pustule
*Grade IV* - Nodulo-cyst

Next, we can establish extent of disease based on the objective measure of lesion number independent of the lesion type. Whereas 15 papules and 10 comedones (25 total lesions) qualified as "moderate" involvement on the Cunliffe scale, three nodules immediately qualified as "moderately

*Mild*: Mainly comdedones with only a few (generally less than 10) small and papules and pustules.

*Moderate*: About 10 to 40 papules and pustules as well as a similar number of comedones. Mild trunk involvement possible.

*Moderately severe:* About 40 to 100 each of papules/pustules and/or comedones. Occasional (five or fewer) larger, deeper nodular inflamed lesions may be present. Chest and back involvement is typical.

*Severe*: Nodulocystic acne and acne conglobata with many large, painful nodular or pustular lesions as well as smaller papules, pustules, and comedones.

Strengths of this system are that it considers the type of acne lesion present as well as the sites of involvement.

## BASIc Knowledge

Dermatologists seem to favor acronyms for their severity indices. Clinicians are already familiar with the well-known PASI (Psoriasis Area and Severity Index) and EASI (Eczema Area and Severity Index) grading tools. The addition of the Bikowski Acne Severity Index or BASI to this family of dermatologic disease assessment scales makes sense, and we suggest this title and acronym for the Grade; Number; Location severity grading system described in this article.

— PD Editorial Staff

severe." Lesion type and quantity are interdependent in old scales. This new system assigns a severity level based only on total lesion counts:

*Mild* disease is one to 10 lesions.

*Moderate* disease is 11-20 lesions.

*Severe* disease is more than 20 lesions.

Perhaps most commonly overlooked by many grading scales is specific identification of the location of lesions. Generally speaking, acne most typically presents as facial or truncal. However, for clarity, the involved site should be specified. This is the final component of the classification system. Possibly involved sites include:

• Forehead
• Cheeks (Right, Left, both)
• Nose
• Chin
• Shoulders
• Chest
• Back

Putting these elements together then, a simple, three-part classification accurately and objectively describes the patient's presentation. There is no room for interpretation or subjectivity. The photos on the previous pages demonstrate:

• *Grade I; Severe; Forehead:* More than 20 comedones on the forehead

• *Grade II/III; Moderate; Chin:* 11-20 papules and pustules on the chin

• *Grade IV; Mild; Left cheek:* Fewer than 10 nodules on the left cheek.

The various combinations are not limited and can be appropriately construed to describe virtually any clinical presentation.

## An Innovative Solution

Recognizing the shortcoming of previous grading systems in the context of investigational trials as well in clinical practice, the FDA has recently highlighted the need for a universally accept-able acne grading system. In documents,[17] the agency notes:

For practitioners and investigators alike, a standardized scale could serve as an objective basis for interpreting published results from individual clinical trials as well as comparing results from different trials.

Attributes of an ideal global scale would include:

• A limited number of levels so as not to be too cumbersome and impractical for use.

• Levels which are sufficiently described so as to limit intra- and inter-observer variability.

• Levels which indicate when treatment is no longer needed or when maintenance therapy is undertaken e.g. "clear" (no acne) or " almost clear."

• Static measures to reflect a point in time.

• Universality for clinical and investigational use.

• A high degree of correlation with lesion counts.

The Grade; Number; Location severity scale is an innovative solution to the acne grading problem that efficiently describes and effectively communicates the nature of the acne presentation. It is suitable for both investigational and clinical use. ■

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