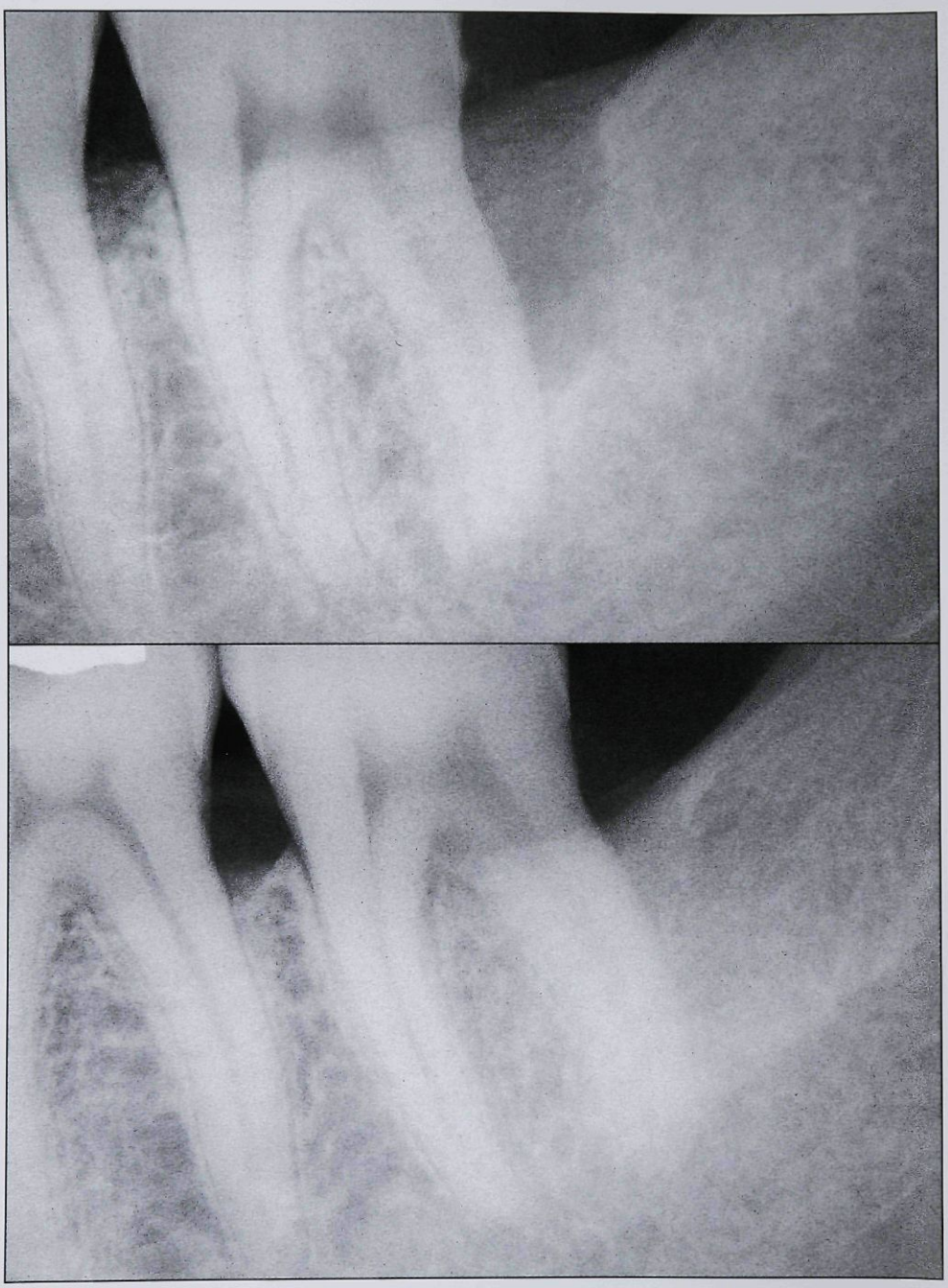

Evidence-Based Periodontal Treatment. I. A Strategy for Clinical Decisions

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This article is first in a series of reports describing an evidence-based approach for evaluating information associated with periodontal treatment. Two main differences distinguish this approach from the traditional one, which is based largely on clinical experience. The evidence-based approach requires that investigators emphasize the importance of unbiased data (evidence) and use specific rules of evidence to quantify their recommendations. Search, evaluate, and rank are the three steps used for gathering information from the literature. The information (evidence) can then be used to formulate new decision pathways, practice guidelines, and treatment recommendations.
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Career demands and economic pressures have made it more difficult for practitioners to keep up with the rapidly changing field of periodontal treatment. New diagnostic aids and therapeutic modalities are being introduced with claims for improved patient care, but their value for individual patients remains unclear. At the same time, managed care and cost-containment efforts are pressuring the clinician to base health-care recommendations on scientific, unbiased information. In the future, the rationale for the choice of a diagnostic or treatment modality may have to include evidence of tangible benefit (outcome) for that particular patient's clinical circumstance for the cost of treatment to be reimbursed.

Many clinical trials designed in the past and proclaiming the efficacy of a particular product or approach to treatment may not meet today's rigorous investigative standards. For example, clinical case studies

demonstrating proof of principle were parlayed into large numbers of consecutive cases and "bigger" studies. The results were often taken as "proof" of the ability of the product of technique to work. What was not and could not be derived from many of those classic dental studies was the determination of the intrinsic value of the product or technique itself or its predictability on an individual patient basis. Exactly how many patients must be treated with a specific procedure before a successful result is obtained or what number of patients must be treated to prevent an adverse event has been an important consideration of the evidence-based approach in medicine.

In the 1950s, the randomized clinical trial (RCT) was introduced to overcome the systematic errors and personal biases of individual proponents of a new therapy. Bias in patient selection and practitioners' opinion were also reduced with this methodology. Today the RCT is the standard of evidence needed to demonstrate the efficacy of drugs, diagnostics, and surgical therapies. The RCT may be performed in a variety of clinical settings, such as private practice or university clinics.

Since the introduction of the RCT in the 1950s, thousands of RCTs have provided unequivocal value in improving human health. The tremendous proliferation of RCTs, studies, data, reports, and hype has resulted in the development of new procedures for clarifying the results. One of these procedures, meta-analysis, is an increasingly popular and stringent statistical method that has received wide acceptance. Results of meta-analyses have been used to allocate resources and set treatment and reimbursement policies. Some authors believe that meta-analyses may ultimately have as profound an effect on setting treatment policy as have randomized trials themselves.[3]

This article is the first in a series of reports describing a new approach and strategy for evaluating information and innovations associated with periodontal treatment. Using the principles and methods described in these reports, clinicians can decide how (if at all) they should modify their practice to provide patients the best treatment based on the quality of available evidence.

There are two fundamental differences between the evidence-based approach and traditional clinical experience and case reports. First, the evidence-based approach places much more importance on the clinician's use of quantitative, unbiased data (evidence) to support specific treatment decisions. Second, the evidence-based approach requires that specific and explicit rules of evidence be used to help quantify the clinician's recommendations to the patient. When scientific evidence is available, the clinician is obligated to incorporate this knowledge into patient care.

The clinical dilemma

A busy dentist in a private practice greets the patient and begins gathering information that will form a large part of the diagnosis and treatment plan. Ms J is a 38-year-old woman who does not routinely take any medications. A careful review of her medical history reveals no medical problems. Ms J has a relatively healthy periodontium with the exception of what appears to be a wide (combination two- and three-walled) intrabony defect distal to the mandibular left second molar (Figs 1a and 1b). Probing pocket depth of this defect is 10 mm, and purulence and bleeding on probing are present. Before any discussion about the clinical findings takes place, the patient inquires about an article she recently read regarding a procedure called guided tissue regeneration and asks whether or not that type of procedure would be indicated in her case.

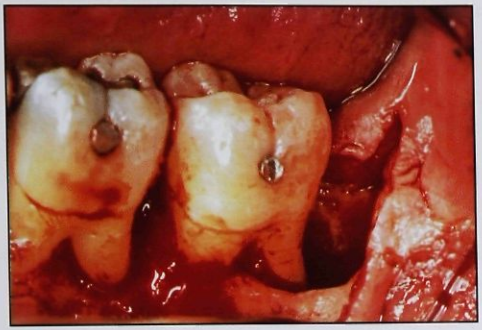

Fig 1a *Intraoperative view of the intrabony defect.*

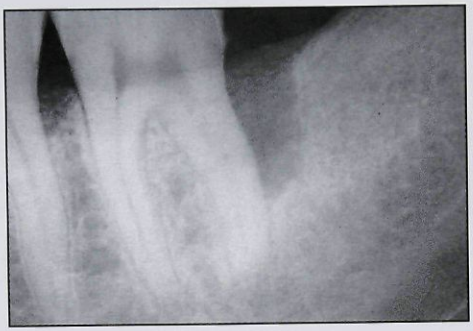

Fig 1b *Preoperative radiograph.*

Typical decision pathway

The dentist in this scenario has some personal experience in regenerative procedures associated with intrabony defects, but is uncertain *how successfully* that procedure would work in this exact situation. The practitioner's limited clinical experience makes an estimation of predictability much more uncertain. Recollection of previous discussions with colleagues provides little guidance, because some clinicians have claimed to have had consistently great success, while others admit that they have had the same problems with predictability. The dentist's feeling of uncertainty is strengthened by the discrepancy between personal experience and the apparently excellent results documented in the literature and reported in continuing education courses. Privately these inconsistencies are disturbing, but based on clinical experience, the dentist explains to the patient that guided tissue regeneration could be attempted to treat the defect behind the mandibular left second molar. The dentist explains that while there have been some reports of success, he personally finds the procedure to be unpredictable. It is still, however, Ms J's best treatment option. The patient leaves the consultation feeling uncertain about how to proceed and wonders if extraction of the tooth, mentioned by another dentist, might not be the best option.

New decision pathway—Based on the evidence

In an effort to answer the patient's questions based on the evidence, the dentist goes to the personal computer, which has access to a medical (and dental) literature database, MEDLINE (National Library of Medicine, Bethesda, Maryland). A literature search is conducted to determine what information is available on Ms J's clinical situation. The dentist realizes the difficulty in keeping up to date with all the latest research and clinical innovations, yet feels a great sense of responsibility to provide the best care available. The literature search is limited to the last 10 years and focuses on specific headings given for the command-driven search (Fig 2).

The search yields 23 articles. The dentist reviews the abstracts that were printed. Fourteen articles are selected that appear to be well done and directly relevant to the patient's problems. These articles are then printed in full, read, and ranked according to recognized rules of evidence.

The search also produces a great deal of indirect evidence in the form of case-controlled and/or case report citations. There are, however, a number of articles that are directly relevant to Ms J's exact problem. Strong direct evidence that was both clinically and statistically significant was found. The information indicates that two- and three-walled intrabony defects distal to terminal mandibular molars should predictably respond to guided tissue regeneration. In fact, the evidence clearly demonstrates that guided tissue regeneration is the type of regenerative therapy that will most predictably achieve the clinical outcome that both the dentist and the patient desire. The dentist in this scenario, therefore, does not have to rely solely on clinical experience when talking to the patient. The information generated in the search permits the patient and the practitioner to have a better understanding and confidence regarding appropriate therapy. The evidence also helps the patient to better understand the ratio of risk to benefit for this procedure. The patient leaves the consultation able to make an informed decision about the use of guided tissue regeneration to treat the problem.

We are not suggesting that a literature search be a part of every clinical decision. In fact, most treatment decisions are easily managed through clinical experience. This new decision pathway should be considered as a supplement to upgrade clinical judgment and experience in areas where the clinician desires access to the most current information.

A. Search strategy

?S (GUIDED()(TISSUE OR BONE)()(REGENERATION OR GENERATION) AND (INTRABONY OR INFRABONY OR INTERPROXIMAL OR 2()WALL OR 3()WALL OR THREE()WALL OR VERTICAL ()DEFECT(2N)DEFECT? ?) AND PY=1984;1994/ENG/HUMAN

B. Detail finding of each term

7695	GUIDED
393663	TISSUE
215125	BONE
30659	REGENERATION
42728	GENERATION
341	GUIDED(W)(TISSUE OR BONE)(W)(REGENERATION OR GENERATION)
133	INTRABONY
93	INFRABONY
460	INTERPROXIMAL
1182932	2
67037	WALL
13	2(W)WALL
814109	TWO
67037	WALL
22	TWO(W)WALL
1101325	3
67037	WALL
20	3(W)WALL
457079	THREE
67037	WALL
34	THREE(W)WALL
14536	VERTICAL
98091	DEFECT? ?
52	VERTICAL(2N)DEFECT? ?
2786025	PY = 1984/ENG : PY=1994/ENG

C. Result of search

S3 23 (GUIDED()(TISSUE OR BONE)()(REGENERATION OR GENERATION)) AND (INTRABONY OR INFRABONY OR INTERPROXIMAL OR 2()WALL OR TWO()WALL OR 3()WALL OR THREE()WALL OR VERITICAL(2N)DEFECT? ?) AND PY =1984:1994/ENG/HUMAN

Fig 2 *Printout of the MEDLINE search used in the clinical scenario. (A) Search strategy. The search terms used (found within the parentheses) are termed concepts. The concepts are grouped and the computer program is told to search the English literature, evaluating human studies from 1984 to 1994. (B) Detailed findings of each term. The number next to the term indicates the number of articles found containing that particular term. For example, 7,695 articles containing the term guided were found in the database. (C) Results of the search. Twenty-three articles (in English) on the utilization of GTR in human intrabony defects were published over the last 10 years.*

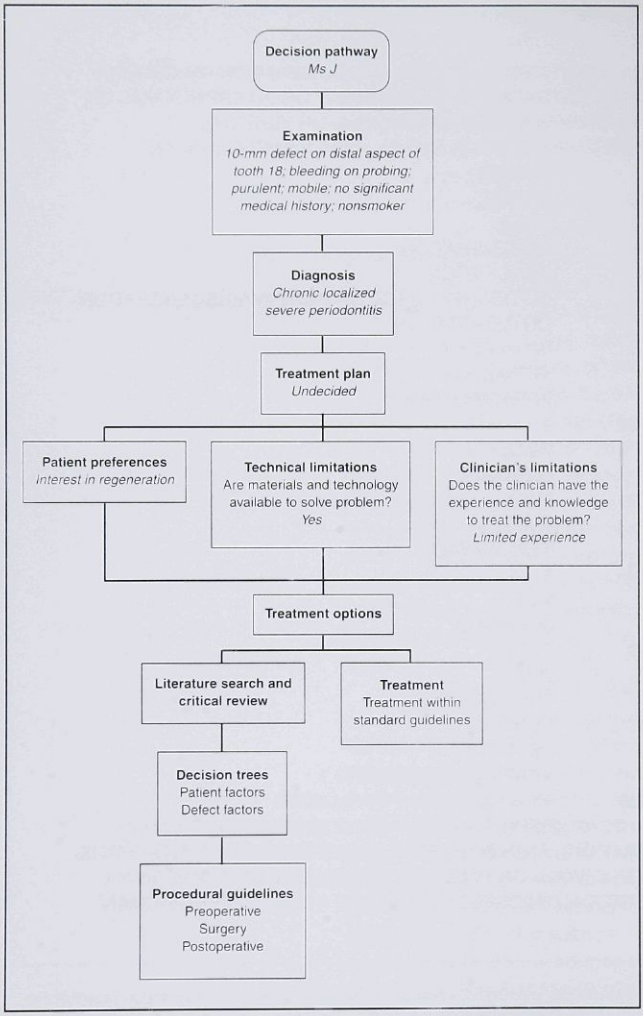

Fig 3 *Decision pathway using the evidence-based approach (the decision pathway for the sample patient Ms J is in italics). Routine* examination, diagnosis, *and* treatment plan, *lead to* treatment options. *If there are uncertainties regarding treatment or further information is desired, then the evidence-based approach is utilized. The* literature search and critical review *are accomplished, yielding appropriate* decision trees *and* procedural guidelines. *When decision support is not required,* treatment *occurs within normal guidelines.*

Evidence-based treatment

Ms J selected guided tissue regeneration as treatment for her periodontal problem. The challenge for the clinician now is to translate limited clinical experience into a successful outcome for the patient. To do this, the dentist uses the same evidence-based approach to evaluate guidelines, parameters, decision trees, and algorithms, all of which help the clinician both diagnose the problem and select procedures that result in predictable outcomes (Fig 3). (Decision trees, algorithms, and guidelines for a variety of clinical procedures associated with regeneration will be presented in subsequent articles in this series.)

Following the decision pathway algorithm (Fig 3) the dentist performs an examination, makes a diagnosis, and arrives at the next step—the formulation of a treatment plan. At this point, the dentist evaluates the patient's preferences, the known technical limits of the procedure, and his or her own clinical experience and limitations. If the dentist is satisfied that the therapy is within his or her range of ability, treatment is rendered within standard guidelines. If there are uncertainties, a literature search is performed, and the dentist encounters a series of articles that describe, in the

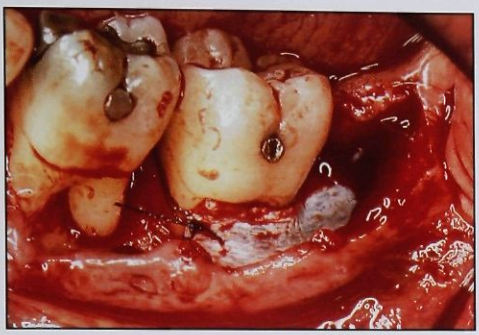

Fig 4a *An e-PTFE membrane in place over the defect in Fig 1a.*

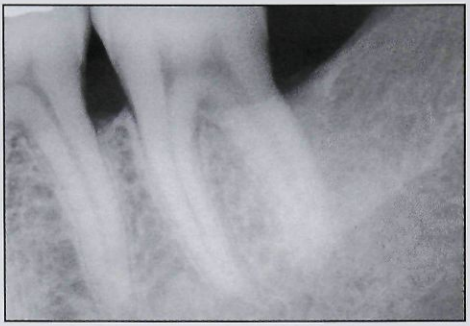

Fig 4b *Six-year postoperative radiograph of the area shown in the preoperative radiograph (Fig 1b), indicating a favorable long-term result has been achieved.*

form of decision trees and annotated algorithms, the latest information about increasing predictability. As the dentist evaluates the *patient selection decision tree* and the *defect selection decision tree*, he or she notes that all of the patient and defect selection variables appear to be in favor of a predictable result for Ms J.

Evidence-based *Preoperative, surgical and postoperative decision tree* guidelines are followed, bolstering the dentist's limited experience. Two weeks later, an uneventful surgical procedure takes place (Fig 4a). The treatment results in a successful and sustainable outcome, measured 6 years later (Fig 4b).

The principles used in the clinical treatment of Ms J can apply equally to discussions between students and teachers and between providers and third-party administrators. Clinical treatment decisions are enhanced by an objective, systematic, and rigorous evaluation of the evidence. The change of emphasis, as seen in Ms J's scenario, is characterized by the absolute requirement that the clinician read and critically "grade" the literature and subsequently use it to guide clinical practice. The critical evaluation may appear to be difficult, but it is the critical evaluation that provides the value.

Traditional strategy for clinical decisions

Dental education provides a framework or model for clinical decision making based on knowledge learned while the dentist was in school, yet the most substantive clinical experiences are gained following dental school and/or postgraduate continuing education. In this traditional education model, decision pathways rely on the unsystematic clinical experience of the clinician or that of another "expert" in the field—the so-called clinical judgment.

When unusual problems occurred, as was often the case, these traditional sources of information provided an array of different suggestions

for patient care. Solutions were further confounded by the fact that dental training, and periodontal training in particular, was often packed with clinical traditions and biases based more on history than on evidence. Although the discipline of periodontology has its history embedded in a foundation of biology and science, periodontists have sometimes segregated into camps—each with a different philosophy, dependent on where the proponents were trained. This almost religious fervor was perpetuated by charismatic leaders in continuing education. The messages and suggestions were often taken on faith based on the reputation of the messenger, and data were used selectively to support a particular position. What was (and is) often missing from this approach were unbiased controlled data, collected and analyzed according to today's standards.

The value to the clinician of rigorous, scientifically collected clinical data is directly correlated to the quality of the data. Although anecdotal reports, case studies, and descriptions of techniques are extremely valuable in the discovery of new information, they are not considered to be the kind of evidence that establishes a basis for the best-quality decision making about the predictability of treatment.[5] The inadequacy of this approach to data collection and decision making is becoming more apparent as clinical demands and external pressures on the dentist increase.

Dangers of uncontrolled observations

In clinical practice, there are usually no control or placebo patients, so efficacy of a particular treatment may be overestimated. Treatment responses are also more likely to be recognized and remembered as favorable in compliant patients.[6] The observations of compliant patients, however, may be incorrect and, more importantly, lead to erroneous conclusions about the true efficacy of a treatment. Compliance itself, rather than the actual experimental treatment, may even account for some of the improved outcomes. Sometimes highly compliant patients in the placebo groups of RCTs have better outcomes than the noncompliant patients in the same placebo group. Because both groups are receiving placebos, it can be concluded that compliance itself, rather than the actual experimental treatment, may account for some of the improved outcomes. In periodontal treatment, clinicians often assume that the beneficial outcome resulting from a particular treatment performed for a highly compliant patient indicated that the treatment is efficacious. Similarly, the particular individualized way in which the dentist performs a specific treatment is often interpreted as the key to success. As stated previously, these observations may not be correct, because the conclusions were derived in an uncontrolled clinical setting—the clinical practice. In this environment, both the placebo effect and the desire of the patient and clinician for success can cause both parties to overestimate efficacy.[6]

The foregoing should not be construed as a recommendation to discard uncontrolled observations made by clinicians. For many procedures in periodontics, randomized clinical trials have not yet been carried out. In many other cases, the overwhelming evidence of efficacy from cohort and consecutive case studies make RCTs unnecessary. The bottom line is to base treatment recommendations and decisions on objective, controlled data whenever possible. If the practitioner accepts this conclusion, he or she will emphasize the importance of critical evaluation of the evidence to help solve each patient's individual periodontal problems.

How may the evidence-based approach affect the clinical practice? Some possibilities include *(1)* the clinician's ability to manage the increase in pressure from third parties to mandate or benefit only those treatments whose efficacy has been demonstrated by evaluation of the evidence; *(2)* less reliance by clinicians on "soft" information, such as nonrefereed journals and advertising, and *(3)* development of *evidence-based* procedural guidelines and parameters of care by professional organizations and commercial companies.

New strategy for clinical decisions

The evidenced-based method of clinical decision making requires that the dentist know how to conduct a literature search for evidence. After information is gathered, the dentist must then apply some specific rules of evidence.[6,7] This process enhances accuracy in interpreting literature on causation, prognosis, diagnosis, and treatment strategy. Evaluation of expert opinions can similarly benefit from this objectivity. In the end, the final treatment decisions will be based on an amalgamation of clinical experience, evidence, expert opinion, and patient preferences. *The approach we are recommending has been used extensively in medicine, and it is based on a large body of literature developed by the Evidence-Based Medicine Working Group.*[8]

In the past, access to large databases and the learning of skills associated with information retrieval were reserved for those investigators and clinicians doing research or writing papers. Today, every clinician must become familiar with this essential ingredient of clinical practice. Access to literature-retrieval services via the personal computer or through reading journals and attending meetings is simple, economical, and essential. Of course clinical experience and intuition should always be relied on to interpret new data and create new knowledge.

The challenge to dental professionals is to apply the results of dental research to clinical practices. Most busy clinicians want to provide effective care but are sharply restricted in time. This is not an article on research methods; it is a framework for using, not doing, research. Knowing how to use the results of an objective evaluation of the clinical literature is essential to providing optimal patient care. Ms J and her dentist benefited from this approach, and it can be assumed that subsequent patients who had similar periodontal problems also benefited.

Sources of clinical information

Clinical useful information comes primarily from two sources: the individual patient and research. To provide the most effective care, the clinician needs both. To collect useful information about the patient, the clinician must take a careful history and conduct a comprehensive examination. Clinically relevant information can also be obtained from the literature.

The literature search

An effective and valuable literature search should include systematic and quantitative overviews, such as meta-analysis, whenever possible and available. Practice guidelines, such as those developed by the American Academy of Periodontology,[9] decision analyses,[10] and economic analysis provide invaluable information. When these types of references are not available or current, the clinician is obligated to do a literature search. For those unfamiliar with the process, a number of resources are available.

The selected topic will point the clinician to the most appropriate database(s) for the search. For example, if the topic lies within the realm of medicine or dentistry, then MEDLINE may be the best database. The policies and procedures of the selection process in any database need careful scrutiny,[11] and the novice searcher is well advised to spend time learning the structure and indexing of the database of choice. He or she should also deliberate over the choice between menu-driven and command language–driven searches to minimize the elimination of important articles. Considerations such as training, ease of use, time, control of results, and complexity would also affect this choice between search modes. Although under most circumstances searches will continue to be done by librarians trained in search techniques, the number of clinicians capable of doing their own searches is steadily increasing.[12]

Evaluating articles on therapy

Search, evaluate, and rank are the three steps of acquisition of evidence. Guidelines and rules have been developed to help the busy clinician evaluate the literature (Fig 5).[13] The first question is usually, "Are the results of the study valid?," and the last is, "Will the results help me in caring for my patients?" After assessing the evidence, clinicians may prefer "yes" or "no" answers to these questions, but easy answers usually lead to inadequate conclusions. Clinical decisions in periodontal treatment are rarely so obvious and clear. To determine the validity of results of a study, the practitioner must first evaluate the study design as well as implementation of the protocol. An inadequate design clearly weakens the results. If design flaws are major, conclusions from the study must be discounted or rejected. Evidence must then be ranked according to its relevance and transferability to human clinical problems.

Levels of evidence

Once the relevant articles are generated through the literature search and reviewed, the clinician's next task is to use an appropriate set of rules of evidence to evaluate the articles for applicability to the individual patient's periodontal problem(s). A number of ways to rank the literature have been suggested.[6,7] In these systems, a particular weight is assigned to each study relative to its strengths and weaknesses. The ranking system allows the clinician to utilize the best available studies to guide decision making. We have modified the approach developed by the Agency for Health Care Policy and Research[14] and the World Workshop in Clinical Periodontics[15] to classify the following levels of

Are the results of the study valid?
Primary guides
- Was the assignment of patients to treatments randomized?
- Were all patients who entered the trial properly accounted for and attributed at its conclusion?
  - Was follow-up complete?
  - Were patients analyzed in the groups to which they were randomized?

Secondary guides
- Were patients, health workers, and study personnel "blind" to treatment?
- Were the groups similar at the start of the trial?
- Aside from the experimental intervention, were the groups treated equally?

What were the results?
- How large was the treatment effect?
- How precise was the treatment effect?

Will the results help me in caring for my patients?
- Can the results be applied to my patient care?
- Were all clinically important outcomes considered?
- Are the likely treatment benefits worth the potential harms and costs?

Fig 5 *User's guide to the medical literature. (From Guyatt et al.[13])*

evidence ranked in order of importance:

1. Randomized, blinded longitudinal clinical trial
2. Cohort and/or consecutive series longitudinal studies
3. Case-controlled studies
4. Noncontrolled case studies
5. Descriptive studies
6. Indirect evidence—animal studies
7. Indirect evidence—laboratory studies.

Although this system of ranking of the quality of the research is logical, it requires a new mindset for some clinicians. For example, animal studies, although they may be meticulously designed and executed, are ranked near the lowest level of evidence because only indirect or suggestive conclusions can be made from the results. There also must be a *direct* relationship between the level of the evidence and the strength of the recommendation regarding therapy supported by it. Evidence ranked levels 1 and 2 will support a strong recommendation, and levels 3 through 5 will support an array of potential clinical actions.[6] It is apparent that the best way to acquire the most definitive, clinically useful information is through randomized clinical trials. It is also apparent that the dentist may be disappointed in the search and may have to be satisfied with studies of weaker design. By diligently using the process of search, evaluate, and rank, the clinician will discover and elucidate areas of missing information or opportunities for improvement.

Evidence-based clinical guidelines

Clinical guidelines have many potential uses and both the individual clinician and professional organization are beginning to see their value. Guidelines can assist both the clinician and the patient in clinical decision making. Systematically developed, evidence-based guidelines can not only provide an important link in the transfer of information to the patient but they may also play a role in assuring quality of care, thus reducing the risk of liability for negligent care. Concerns about these and other issues are leading to the development of more and better practice guidelines. Sufficient basic, animal, and clinical research evidence exists for a wide variety of periodontal treatments. Combined with clinical judgment, this knowledge base can produce clinically valid recommendations for appropriate care.

Clinical algorithms

Clinical algorithms, as defined by Hadorn et al,[16] are "written guides to stepwise evaluation and management strategies that require observations to be made, decisions to be considered, and actions to be taken." They serve to organize thought in a visible way.[16] Algorithms for periodontal treatment have appeared in the literature for many years.[17] They are very helpful for clinicians because they permit a logical flow of information and resulting actions to be organized into a conceptual flow chart. Most important, they provide a framework for thinking about clinical problems. By using an algorithmic approach, the practitioner can facilitate the identification of clinical, biological, psychological, and environmental factors that contribute to treatment predictability.[18] To be effective, algorithms must incorporate a degree of clinical flexibility and they must be linked to the literature to maximize clinical validity.[16] The major difference between previous versions that have appeared in the dental literature and the evidence-based algorithm suggested here is the explicitness of the documentation used to justify a decision or recommendation along the algorithm's pathway. Often, evidence of the quality desired is not sufficient for each branch of the algorithm. When this occurs, the best available information is used, and the basis for choosing the evidence is annotated at the specific location where the evidence is used.

The algorithm pathway provides for several clinically important and valid alternatives that can be chosen for a particular patient's situation and preferences. As long as these alternatives are supported by sufficient evidence, the algorithm fulfills its role of being a flexible guide for enhancing patient outcomes.

Clinical guidelines and their associated algorithms can assist the clinician in his or her efforts to inform and educate patients. Most dentists agree that good dental care requires shared decision making by practitioners and patients. Patient preferences are a fundamental part of determining the goals of treatment, and these preferences will be used to measure success.[16,18] Ultimately, general guidelines with their associated algorithms could be used to improve patient information brochures and informed consent procedures.

The evidenced-based approach and the various formats that are used to convey information do not diminish the necessity and value of clinical experience and instincts—so-called clinical judgment.[8]

Because the practice of clinical periodontics involves a complex interplay of innumerable variables, many sides of patient care elude thorough scientific examination. Clinical judgment sharpened by unbiased observation is and always will be an essential ingredient in the successful treatment of periodontal disease.

While the evidenced-based approach may sound cumbersome and unnecessary, it is both necessary and better than the approaches used in the past. Many clinicians already implicitly follow this approach each time they administer therapy. By making the process explicit and by applying guidelines to help assess the strength of evidence, dentists will improve patient care.

Advances in periodontal treatment and the incorporation of these advances into widespread clinician application will, undoubtedly, continue to create an exponentially increasing volume of literature and new technologies as well as renewed attentiveness to rising costs vis-a-vis benefits and outcomes. *Evidence-based periodontal treatment* will help clinicians to manage these pressures by encouraging them to move beyond clinical experience. Evidenced-based periodontal treatment will give the profession a new set of rules to change the future. Care that is based on the best available evidence will yield the highest quality and the most cost-effective periodontal treatment.

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