# Methodology Used by Task Forces

- Clearly stating the questions and methods
- Using comprehensive search methods to locate relevant studies
- Using explicit methods to determine which articles to include
- Carefully assessing the validity of the primary studies with methods that are reproducible and free from bias
- Analyzing the variation between the findings of relevant studies
- Appropriately combining the findings of the primary studies
- Ensuring that the conclusions are supportable from the data cited

# Evidence-Based Periodontal Treatment. II. Predictable Regeneration Treatment

TASK FORCE GOALS

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*Clinical experience, technical ability, and intuition are indispensable but are no longer sufficient as the sole clinical skills necessary to provide the best outcomes from periodontal and peri-implant regeneration treatment. This article describes a comprehensive and rigorous methodologic framework to assess the available evidence contained within the literature. This assessment tool is referred to as the evidence-based method. The methodology was used by a series of task forces convened to evaluate three common areas of clinical regenerative treatment. The major goals of these task forces were:* (1) *to increase the strength of the inference that practitioners can derive from the base of knowledge contained within the literature,* (2) *to develop algorithms to improve the predictability of regeneration treatment, and* (3) *to determine methods that can be used to predictably transfer the value of therapy to the patient.* (Int J Periodont Rest Dent 1995;15:116–127.)

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In the last 10 years, technologic and biologic advances have hastened the extensive use of regenerative treatment for periodontal, peri-implant, and bone augmentation applications.[1] The body of literature on clinical regenerative treatment documents one of the most important therapeutic approaches in dentistry. Despite reports of clinical success with guided tissue regeneration (GTR), the main dilemma for a majority of practitioners is determining its predictability on an individual patient basis. The systematic incorporation of new knowledge (evidence), together with clinical judgment and personal experience, can improve treatment results. Scientifically valid information can reduce the variation in outcomes and improve the overall effectiveness of clinical practice.[2]

Regeneration of the periodontium has been described in the literature[3] for almost 30 years, but it was not until the development of GTR that its widespread application was incorporated into routine practice. Some of the previously conducted research, significant when published, did not conform

to current methodologic requirements. Currently there is a great opportunity to establish a baseline of evidence, evaluated for accuracy and validity, from which future clinical guidelines, clinical decisions, and research can be developed. At a time when individual patients and third parties require more predictability from therapy, improvements in "traditional" clinical decision-making processes can enhance the opportunity for a successful result.[4-6] Patients' decision making about cost-benefit considerations is refined when they have clear choices and relevant estimates of the predictability of the outcomes (end points) from treatment.[7-9]

In 1992, the authors began a large-scale independent evidence-based evaluation of the literature that supports the validity and predictability of clinical regenerative treatment. The development of the project began with the assistance of an independent meeting organizer (Qi Enterprises) and a sponsor (WL Gore). The project consisted of the formation and meeting of four task forces assigned to evaluate the evidence in four areas of regenerative treatment. The results of their deliberations were planned to be disseminated to communities of interest through an international symposium and by publication in a peer-reviewed journal. Although this project was supported by an educational grant from industry, participants in the process understood that this was a scientific, educational project with no predetermined conclusions. The authors were solely responsible for the scientific content of the project. Three of four task force meetings were informally audited by independent third-party observers.

## Evaluation of the evidence

When scientific evidence and expert guidance are available, the practitioner is obligated to incorporate new information into his or her clinical practice. To perform an adequate assessment of the available information, the evaluation must use objective and reproducible methods. The process outlined in this report has relied heavily on the evidence-based medicine approach developed by the Evidence-Based Medicine Working Group in Ontario, Canada[10-14] and the 1989 World Workshop in Clinical Periodontics.[3] These methods underscore the importance of establishing an explicit, reproducible framework to evaluate the literature. In general, systematic, unbiased, and objective evaluations increase the literature's clinical applicability.[2] *In the absence of the evidence-based approach, the practitioner must be cautious about the interpretation of information derived from clinical experience and intuition, because it can be misleading.*

The *rules of evidence* that have been developed to guide the evaluation are based on the quality and significance of the evidence and on the ability of the information to be applied to clinical periodontal and implant treatment. In general, the guidelines developed by the World Workshop in Clinical Periodontics[3] and the Agency for Health Care Policy and Research[15] were used to determine the type of literature that would qualify as evidence. For example, abstracts were not considered to be acceptable because there is often no way to adequately assess the methods and materials used, and there is usually insufficient detail to permit the kind of evaluation that is necessary.

The establishment of standard objectives was fundamental to achieving objectivity and consistency throughout the task force process. *The use of explicit rules represents one of the most significant differences between the evidence-based approach and traditional reviews of the literature.* A major goal of evidence-based periodontal treatment[2] was to demonstrate the feasibility of applying the rules of evidence to the literature on regenerative treatment. Several objectives were used to guide task force proceedings.

*Clearly stating the questions and methods*

A clear statement of the question focuses the target of the literature search and permits clinicians to use appropriate guides to assess the validity of the articles. Each task force was provided with a comprehensive and detailed workbook containing explicit instructions. Tables, charts, and decision trees (algorithms) for each chosen focus area were included by the organizers as a starting point for further development by the task force.

*Using explicit methods to determine which articles to include*

Articles that discussed the strategy, methods, and background for evidence retrieval and analysis were provided to the task force participants, with permission, from the Agency for Health Care Policy and Research,[15] the Division of Health Care Services of the Institute of Medicine,[16] and the National Library of Medicine Collection Access Section,[17] as well as individual authors.

*Using comprehensive search methods to locate relevant studies*

A comprehensive electronic search of the world literature on a particular facet of regeneration was conducted by the reviewer.[18–19] The Proceedings of the World Workshop in Clinical Periodontics[3] and the United States Air Force's review of the literature on regeneration[20] were provided to all participants as an adjunct to the review. Task force participants also provided additional references.

*Carefully assessing the validity of the primary studies with methods that are reproducible and free from bias*

Using the explicitly stated goal(s) of the study as a framework for evaluation, the task force was asked to determine if the measures that were used to assess the outcome were appropriate. A citation evaluation form was used as a guide (Fig 1). For example, if a study used probing pocket depth as the sole measure of success in a trial where connective tissue reattachment was the primary goal of treatment, could the authors justify claims of successful regeneration? Were the primary and secondary measurements of the study's outcome accurate and complete, and were there adequate safeguards to ensure that study participation itself did not alter the end results of the study?[21,22]

*Carefully analyzing the variation between the findings of the relevant studies*

To accurately evaluate the variation and/or differences between different studies of regeneration, the clinician must ensure that accurate and appropriate analytical techniques were used.[14,23,24] Differences between clinical and statistical significance must be explicitly analyzed. It is here that many studies often confuse "proof of principle," or ability to demonstrate success, with scientific evidence. McGuire and Newman[2] have suggested that clinical interpretation by gifted clinicians cannot substitute for controlled, unbiased data for the purpose of treatment predictability. The randomized clinical trial is the gold standard of evidence, but there are relatively few randomized clinical trials in the literature on regeneration. Consecutive controlled case studies are good evidence for demonstrating clinical success (not predictability), and case reports establish proof of principle that a technique has the potential to achieve the desired goal. Results from case reports and reports on a series of patients, however, do allow weak inferences about the treatment. In regenerative treatment, many variables, some of which are not a direct part of the treatment itself, influence the outcome. These confounding variables include bias, chance events, systemic influences, psychological factors, diet, materials, patient and site preparation, and others.[25–31]

## Citation Evaluation Form*

(Use for each citation)

Citation

_____

_____

_____

_____

Rank* _____

*Relevant study

*Possibly relevant

*Irrelevant study

Bibliography style: Int J Periodont Rest Dent

Classify by study design: The following list is in rank order, with the most important at the top of the list:

_____ Randomized, blinded longitudinal clinical trials with histology

_____ Randomized, blinded longitudinal clinical trials without histology

_____ Cohort or longitudinal studies

_____ Case-controlled studies

_____ Noncontrolled case studies

_____ Descriptive studies

_____ Indirect evidence—Animal studies

_____ Indirect evidence—Laboratory studies

Identify design flaws and biases:

_____ Sample size

_____ Patient/defect selection bias

_____ Selection of control group

_____ Clear acceptable definition of the outcome measures

_____ Validity of conclusions

_____ Statistical power sufficient

_____ Adequate inclusion criteria

_____ Randomization methods

_____ Other_____

Determine the generalizability of conclusions:

_____ Representative study population

_____ Reproducibility in private practice setting

Other evaluation criteria (use additional pages as necessary): _____

_____

_____

_____

_____

***Fig 1*** *Citation evaluation form for assessing the validity of the primary studies.*

*Appropriately combining the findings of the primary studies*

Results from many adequately performed and analyzed studies were combined by explicit semiquantitative methods (described later). In one task force, meta-analysis was used to evaluate the evidence.[32] Throughout the discussion about the evidence, the participants used the information contained in the evaluation form (see Fig 1) as a guide to group the citations into three general categories: relevant, possibly relevant, or irrelevant. This evaluation was used to develop the listing of supportive evidence.

*Insuring that the conclusions are supportable from the data cited*

This phase of evaluation of the evidence was clearly the most demanding and difficult to achieve. In almost all cases, acceptance of an article as pivotal evidence required justification, according to the rules of evidence, by the individual participant citing the study. Debate about the relevance of specific articles was transformed into confidential voting via anonymous electronic technology (OptionFinder, described later). A composite net value rating was entered as the level of evidence for a particular therapy to achieve the designated outcome. The summary report from each task force documented the final outcome of the evidence evaluation process.[32–35]

## The evidence-based process

Therapy should be based on reproducible scientific data. Whenever possible, the only variability in success rates should be attributed to clinical judgment and experience or known patient differences. Scientists and experienced clinicians must be able to formulate evidence-based clinical guidelines that can be used to predictably improve outcomes. For an overview of the evidence-based process in periodontal therapy, see the article by McGuire and Newman.[2]

*Areas of evaluation*

Because there are some factors that are common to all regenerative procedures and other factors that might be significant only in certain areas of regeneration, it was decided that the problem of predictability would be best evaluated by focusing on three common applications of GTR: Class II furcations, intrabony defects, and bone defects associated with implants. A fourth area, critical to successful outcomes, was based on the identification of those factors that could enhance the transfer of information to the patient in ways that would improve the patient's desire for, acceptance of, motivation of, and compliance with regenerative therapy.

*General principles*

The general guiding principles and sequence of tasks were similar to those used for conflict resolution: *(1)* the overall goal was divided into specific relevant and manageable focus areas; *(2)* specific components of variability or uncertainty were identified; *(3)* consensus or disensus was reached on each component by use of unbiased rules and anonymous expression of opinion so that each voter had an equal vote; *(4)* the influence of the dominant opinion on the final outcome was minimized; and *(5)* the results of deliberations and evaluations were placed into a specific framework, and, for reasons of accountability and dissemination, the proceedings were documented.

*Reaching consensus: Use of OptionFinder Technology*

OptionFinder (OptionFinder Technologies) is a computer based audience-input system that allows groups of participants to give their opinions quickly and anonymously on specific questions posed to them via a computer and displayed on a screen (Fig 2). Questions sought to determine the strength of agreement or disagreement about a variety of issues, including the efficacy, value, predictability, and validity of inferences, statements, and recommendations. All participants operated a hand-held keypad that permitted them to send their

vote by pressing a number on the keypad. The vote was transmitted via radio signal to a receiver, where all responses were collated, tabulated, and displayed for the group to interpret and discuss.

OptionFinder technology has several advantages over traditional face-to-face group decision-making methods, because each person's response is anonymous, and traditional strong or dominant personalities and their opinions are mitigated. Because all votes are given simultaneously, group pressure has no influence. The quantitative tabulation and display of the voting permits the group to determine the nature and strength of disensus and allows for dissenting opinions and minority reports.[36,37]

### *Task force membership*

To examine the evidence associated with a particular focus area, the four task forces, or expert panels, were convened during a period from March to June 1994. Each task force was made up of 10 to 13 experts, a professional facilitator familiar with OptionFinder technology, and a support team. A chairperson and a reviewer were chosen based on their international recognition as experts.

Membership in each of the four task forces was based on two major factors: *(1)* familiarity with literature in the specific area of focus, and *(2)* broad-based experience to allow for representation of opinion and insight across a wide spectrum of periodontal care. Individuals from France, Germany, Israel, Italy, Sweden, and the United States provided diversity of opinion and experience. The clinicians who participated were primarily periodontists, except for the task force on translating clinical outcomes to patient value. In that task force, multidisciplinary input was received from general dentists, dental hygienists, and office administrators. Clinicians experienced with regenerative treatment were chosen to give a grassroots "reality check." Academicians participated because they were familiar with codifying, standardizing, and blending art and science so that information could be transferred in a manner that incorporated sound principles of education. Researchers provided a resource of knowledge and familiarity with objective evaluation of new technology. The support team consisted of a literature search expert and staff.

## Consensus development (Fig 2)

### *Step 1: Review of the evidence*

Prior to convening the task force, the reviewer was asked to critically evaluate the relevant evidence using the methods described above. From this evaluation, a summary report was *drafted*. Together with individual copies of all of the major citations, the report was sent to each task force participant for his or her own individual review and evaluation. Each task force chairperson and reviewer met with the program cochairs prior to the actual review process to determine the scope of the review.

### *Step 2: Convening of task force*

The four individual task forces met for approximately 2 days each during the period from March to June 1994.[32-35] The task forces were supported by a library of applicable literature, on-line literature retrieval capability, an electronic voting system, and audiovisual equipment. The structural layout of the meeting room maximized group interaction. Rules of conduct, confidentiality, conflicts of interest, and disclosure were made part of the operating procedures. Of importance was the explicit opportunity for "minority" or dissenting reports by anyone at any time during the proceedings.

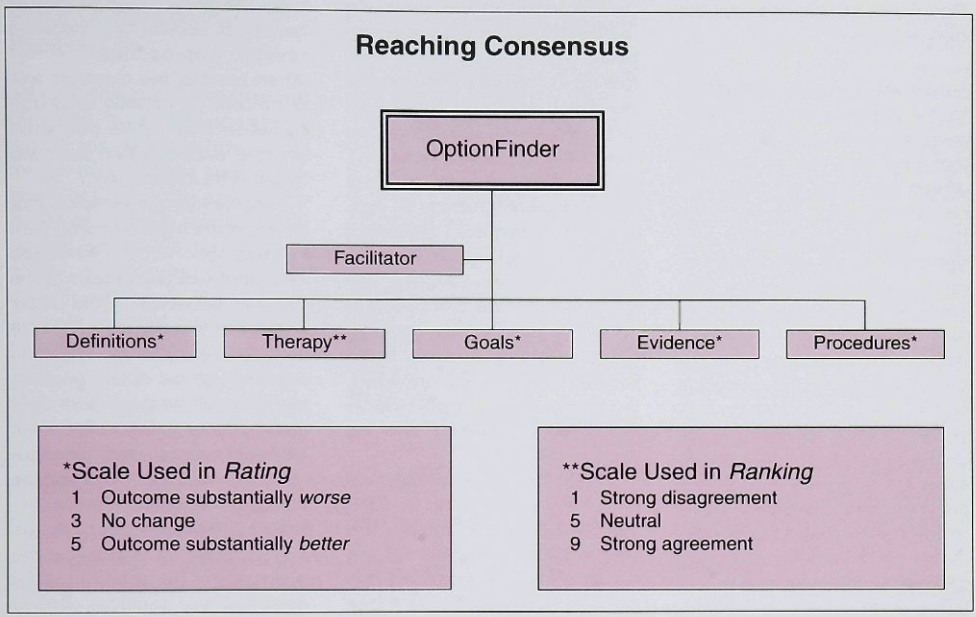


**Fig 2** *Methodology for reaching consensus.*

*Step 3: Definition of success*

In an effort to focus the task force process, consensus was sought on exactly what constituted the desired outcomes of treatment (success). Previously, some clinicians referred to this as *endpoints of therapy*. Each task force was asked to clearly define *(1)* the clinical problem (ie, Class II furcation defect), *(2)* regeneration, *(3)* treatment success, *(4)* the goals of treatment, and *(5)* the methods used to measure them.

*Step 4: Development of outcomes tables*

The most important outcomes (results) of therapy from both the patient's and clinician's points of view were determined. For each outcome, specific criteria for measuring successful attainment of the goals were listed.[32-35] The basis for this list was a combination of evidence-based criteria, clinical judgment, and common sense. For example, gain in probing attachment level is a desired evidence based outcome, while tooth retention in health and comfort would be derived from common sense. Each and every entry was voted on (with OptionFinder), based on the strength of the available objective evidence. When direct, quotable references were not available, the basis for consensus (or disensus) was clearly quantified and noted. Gaps in the literature were identified and bridged with expert judgment and consensus.

*Step 5: Development of the evidence table*

Armed with the goals of treatment for the specific clinical indication being evaluated, a list of therapies that have been used to treat that clinical condition was proposed. For each therapy, the evidence that supports its efficacy was debated, voted, and listed. The agreed-upon therapies were then evaluated (and voted on) as to how predictably they could achieve each outcome *based on the evidence*.[32-35] The analytical process used in formulating a conclusion (or vote) based on the evidence attempted in all cases to follow the objectivity described in the instructions; however, because of the diversity of data, studies could not always be weighted consistently. This vote related only to the therapy being evaluated. No comparisons *between* therapies were permitted at this time. This was the most difficult and time-consuming phase of the task force proceedings, because each outcome (goal of treatment) had to be backed up by evidence. When evidence was not direct or of the quality needed to justify strong support, the rating for that therapy (as effective in accomplishing the goal) was lower than that of other therapies for which evidence was available. In some instances, the task force decided not to vote on outcome categories because of a lack of evidence. In other task forces, votes were taken, but a notation was made, indicating that it was based on clinical experience, not on evidence.

The rating of the evidence contained within this table was based on a discrete scale of 1 to 5 (see Fig 2). The arithmetic mean of the voting was used as the final rating only after it was determined that a consensus was achieved. This was confirmed by the task force participants through an evaluation of the frequency distribution of votes in graphic form. After discussion and some revoting, any rating with a wide distribution of votes was recorded. An opportunity for recording a minority or dissenting opinion was provided. In some cases, participants abstained from voting, and this was similarly noted.

Once the evidence table was completed with a *rating* for each therapy's ability to achieve the goal in question, a subjective *ranking* of the therapies was performed on a discrete scale of 1 to 9 (see Fig 2). This provided an opportunity for the participants to give a "global" clinical judgment as to which therapy or therapies would most predictably achieve the most outcomes. Ranking appropriate indications for different procedures have been used in medicine in a similar manner with general acceptance.

*Step 6: Development of algorithms (decision trees)*

The findings from the evaluations of the evidence were transferred into algorithms.[32-35] The algorithm has received general acceptance as a format for organizing a process of thinking regarding alternatives while providing visual reinforcement. The method used by the task forces was derived by considering several approaches.[7,15,25,36,37] When possible, the algorithm was annotated to provide a linkage between alternative pathways and the evidence that was used to formulate the choices.

The therapy (or therapies) that received the highest ranking from the evaluation of the evidence evaluation was (were) used as the frame of reference for the development of five algorithms: *(1)* the pretreatment patient selection algorithm, *(2)* the defect selection algorithm, *(3)* the presurgical algorithm, *(4)* the surgery algorithm, and *(5)* the postoperative algorithm. The degree of detail and the strength of recommendations contained within each algorithm varied considerably because of the variability of the strength of the evidence that could be cited to support a specific detail of a particular recommendation. When this occurred, the strength of the evidence, or lack of it, was noted and discussed in the narrative. Some task forces also included a list of clinical guidelines based solely on experience; these guidelines were not considered to be evidence-based but are important nevertheless because they represent common practice.

Where objective data did not exist and clinical experience suggested an area of importance, a list of topics was generated to provide direction for new research.

*Step 7: Compilation of a reference list*

After the task force evaluated the evidence, the individual citations within the bibliography were ranked according to their importance and value. The ranking was based on objective criteria of evaluation, as discussed earlier. This phase of the process allows clinicians the opportunity to personally evaluate selected references and form their own opinions.

*Step 8: Creation of a summary report for peer review and publication*

Following each task force meeting, the leaders and reviewers took the modified tables and charts, along with the supporting evidence, and developed a summary report to synthesize the consensus and findings of the task force. These reports were submitted for peer review and publication.[32–35]

## Discussion

The process used to assess, debate, rate, and rank the evidence and clinical judgment was semiobjective. It was rigorously applied in its attempt to follow the rules of evidence as presented in the task force proceedings. This framework helped avoid the traditional weaknesses of the narrative review, which often includes lack of objective criteria for determining levels of evidence and potential for bias in article selection. The methods used to weight the quality of evidence in the overall conclusions were set forth. The process also helped to identify gaps in knowledge, the lack of strong evidence, and the existence of diverse opinions in many areas. *However, it was clear that sufficient evidence exists to warrant and support the use of regenerative therapies for the treatment of a variety of indications. Now a basis exists for enhancing the predictability of those treatments based on critical evaluation of the evidence.*

The validity of the evidence-based approach for periodontal and implant therapy has yet to be determined. Validity requires at least three characteristics: reproducibility, appropriateness of the question, and measurement of the intended variable.[38–42] The evidence-based method presented in this report meets these three criteria. The overall quality of the information currently available in the peer-reviewed literature on GTR does not readily permit the determination of quantitative estimates of treatment effect such as the point estimate, calculation of confidence intervals, odds ratios, absolute and relative risk reduction, and other data dependent measures.[10,13,43,44] On the other hand, quantitative statistical conclusions such as cost-utility analysis,[5,6] regression analysis, probability values, and others, do not substitute for clinical relevancy and the powerful influence of individual patient preferences.[4,27,44,45] Success for one patient may not be the same as success for another patient.[47–51]

To further validate the evidence-based approach, long-term randomized clinical trials will be required; their findings can be used by clinicians to make better quality decisions.[8,52,53] A number of short-term studies have confirmed that the evidence-based system can be taught to medical students. These students are more up to date regarding current literature guidelines of medical treatment than are traditionally taught students.[10,12,13] The steps outlined in this report are not the only way in which to evaluate the evidence. In the context of this clinical subject area, however, it represents the most objective approach to date because it emphasizes a comprehensive evaluation of the available empirical *and* quantitative evidence.

Tradeoffs between the specific benefits of regenerative treatment and the cost of alternative treatments, including nonsurgical treatments, are being explored by patients and payers.[54] This is another area in which the evidence-based approach is so important, because it can enhance the clinician's ability to validate the choice of therapy.[5,6,45,46,55–57]

Professional competency and competitiveness depend in part on the ability to provide high quality technologic service. To do this predictably, the clinician must know what factors have been associated with reproducibility and predictability and then determine the best ways to control, use, or integrate them into the actual procedure, as opposed to merely following recommendations based on the uncontrolled clinical

experience of practitioners which may perpetuate the widespread application of treatments that have not been validated.[58,59] Quality-oriented clinicians will benefit from a more precise estimate of predictability. For most practitioners, the magnitude of the beneficial effect from a specific treatment must not only be sufficient to warrant its use but also must provide value based on reasonable expectations of treatment outcomes.

This approach may provide a source of empowerment, allowing practitioners to independently evaluate conflicting recommendations regarding patient care by using evidence as the basis for decisions.[4,30] The results that can be derived from incorporating this system into practice must be of sufficient value to overcome counteractive forces, such as information overload, habitual practice patterns, and economic factors.[16]

## Is the evidence-based approach better?

The evidence-based approach requires a strong commitment of time and resources, and a detailed implementation and dissemination plan to produce information that is truly of value to the constituencies of interest. Evidence-based periodontal treatment complements and supplements a fast-growing body of literature focused on the recognition of risk, prognosis, and treatment predictability factors.[2,25,27,28,43,60] The final proof will be whether or not the predictability of regenerative procedures improves over the current levels. The application of the evidence-based approach to regenerative and other dental treatments has the potential to substantially improve the quality and efficiency of care.

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