Abstract

Outcomes encompass multiple factors, not just success and failure. They include other considerations such as being workable and profitable to the dentist and safe and acceptable to the patient. The more biological outcomes are most frequently measured. These measurements are on a scale from least to most predictable outcomes of treatment by the dentist, as shown on the evidence pyramid. Impact trauma is an example of a general scarcity of high-level evidence with treatment because of the nature and individuality of the injuries and the difficulty (or impossibility) of designing controlled clinical trials in humans. Much of the evidence is cohort (retrospective or observational studies), case reports, animal studies, and “expert” opinion. Thus, guidelines are largely based on lower levels of evidence. Nonetheless, the current guidelines provide the clinician with the best evidence that is available. The best opportunity for randomized controlled trials is in prevention. Specifically, mouthguard design and usage can be subjected to higher levels of controlled research. Revitalization and regeneration are relatively new procedures. To date, there is a lack of high levels of evidence to be able to substantiate whether these are clinically feasible to become a routine in practice. (J Endod 2013;39:563–566)

Key Words

Evidence-base, evidence pyramid, outcomes

Isn’t it all about outcomes? What is meant by outcomes? According to Webster’s dictionary, the definition is “end result; consequence; aftermath.” In the 2012 American Association of Endodontists Glossary of Terms, the term outcomes is described in clinical terms of healing, healed, nonhealed, and functional.

This article is intended to examine the clinical significance of outcomes, particularly as related to trauma. These outcomes have many facets from both clinical and research perspectives. This review will not delve into outcomes for specific treatments; these will be included in other publications and presentations that are a part of the proceedings of this Endodontic/Pediatric Dentistry Trauma Symposium. Rather, this review provides a general critique of trauma outcomes research, what is the basis of that research, and ultimately how decisions are reached (or should be reached) regarding treatment choices by the individual dentist. Incorporated will be some examples of related research as to validity, usefulness, and predictability. These will be taken from some of the topics included in the Symposium.

As professionals, we tend to equate outcomes on our clinically obtained metrics, which lead to conclusions such as success/failure or survival/non survival. However, there are 2 major sets of outcomes in arriving at any particular conclusion:

1. Those measured by the dentist.
2. Those reported by the patient.

When evaluating the result of a procedure, the dentist consciously or subconsciously evaluates many factors (outcomes) such as efficiency of the treatment, familiarity with the procedure, profit, personal satisfaction, interest, ease of performance, patient comfort, and functionality. These are in addition to the biological factors such as success or survival.

The patients have their own set of outcome criteria. These may or may not include those of the dentist but instead likely consist of factors such as comfort, speed, cost, pain during and after appointment, function and speech, esthetics, number of appointments, and so on. In many ways these varied factors impact on the global assessment of the impact of the dental treatment on the quality of their life.

An obvious goal of any treatment procedure is that it satisfies the needs, both real and perceived, of both the dentist and the patient. This includes several outcomes. Virtually all research, both biological and clinical, is designed to measure somewhat limited objectives of treatment.

An example of a limited research objective is comparing various transport media after avulsion. These experiments generally ask which transport medium (independent variable) is superior for some outcome measure reflecting root resorption (dependent variable) after replantation. The amount of resorption over different time periods after replantation has been measured both histologically and radiographically (1). However, is this a direct indicator of survival or even of success? Another uncertain aspect of avulsion research is the use of extraction in animal models. After removal with forceps (accompany with various variables such as time to air dry), the tooth is replanted. However, the use of forceps extraction may not fully mimic the conditions that occur when a tooth is forcibly avulsed by a severe traumatic event. Therefore, the results from studies by using this extraction technique may not be representative of the clinical reality of how to best manage avulsion/replantation. Although preclinical extraction models are more controlled than the heterogeneous nature of trauma in humans, the results are generally not considered sufficient in developing evidence-based recommendations.

In a perfect clinical research world, the predicted outcome, which is management of avulsions and other dental traumas in this case, would be evidence-based. It is now widely accepted, and in fact it is a position by the American Medical Association and by
the American Dental Association, that practitioners should include current best evidence in making treatment decisions. However, there is no legal obligation and no means of enforcement. There is no question that evidence-based care is more predictable as to desirable outcomes. Incorporating evidence-based care is superior to intuition-based or experience-based care. The dentist has the opportunity to apply the best relevant research to patient care and must know the levels of research relevance.

Figure 1 is the so-called evidence pyramid. This figure illustrates the concept that moving toward the top provides a higher level of evidence. This translates into increased confidence in predicting the clinical outcome (depending on what is to be measured) of a procedure. Conversely, the lower the level of evidence is, the less predictable the outcome. In the ideal dental world, 3 factors would be present and in effect:

1. All procedures would have high level evidence-based guidelines.
2. All dentists would have knowledge of each guideline.
3. Each dentist would apply the guidelines when performing the procedure.

Of course, the consideration of evidence-based knowledge must be combined with the dentist’s skill and judgment and patient preferences in making treatment recommendations.

However, our dental world is far from perfect.

1. There are many treatment approaches and relatively few evidence-based guidelines. This is particularly true with management of trauma, for compelling reasons.
2. Dentists are busy and often overwhelmed by trying to manage a practice, while still enjoying their personal lives. Many will not have the incentive or appreciate the value (both monetary and/or treatment outcomes) of investigating and applying best-quality evidence. Also, the clinical research article base is expanding rapidly; searching for certain topics would be a daunting task. Finally, these levels of evidence may be in conflict with the experienced dentist who has a long history of performing certain procedures a certain way and with presumed success. Organizations such as the American Dental Association (www.ebd.ada.org) and the American Association of Endodontists (www.aae.org/dentalpro/evidencebasedendodontics) have established very useful and accessible websites that provide synopses of systematic reviews. Brief descriptions of other websites and search engines are included in the excellent article by Niederman et al. Other good sites are www.evidencebasedendo.com and http://guides.library.vcu.edu/ebd, as well as Cochrane Reviews (www.ohg.cochrane.org/index).
3. A dentist may have several disincentives for not performing best-evidence procedures. They may lack training. Also, the practitioner may not have the required instrumentation or materials, have insufficient time, perceive the procedure to be unprofitable, refuse to refer, not want to change, or perceive that the patient may prefer another approach. Thus, there are a myriad of reasons that the individual dentist may elect to continue with “what has worked before.”

From the American Dental Association Center for Evidence-Based Dentistry: “Evidence-based dentistry (EBD) is based on three important domains: the best available scientific evidence, a dentist’s clinical skill and judgment, and each individual patient’s needs and preferences. Only when all three are given due consideration in individual patient care is EBD actually being practiced. The first domain, evidence, is there to inform dentists and patients, but never to mandate a specific course of treatment.”
Despite these concerns, experts have addressed the needs of clinicians by integrating available information into consensus guidelines for managing dental trauma in the 2012 “International Association of Dental Trauma Guidelines” (7–9). By necessity, it should be realized that these guidelines are derived by experts but are based primarily on relatively low levels of evidence, for the reasons stated above. This is not to say that the Guidelines are invalid. They are designed on the best available evidence, which is a combination of lower levels of research, opinions of experts, case reports, controlled animal studies, uncontrolled human cohort clinical trials, and retrospective reports. Interestingly, there is some evidence, at least in the medical literature, that outcomes from observational (which includes cohort, retrospective, cross-sectional, and non-randomized trials) versus randomized controlled trials did not differ significantly (10). This study was somewhat limited in the interventions examined but does provide some support of general validity for this approach. Unfortunately, similar investigations could not be found in the dental literature. It is uncertain whether lower levels of evidence could replicate controlled trials in dentistry, but the possibility may very well exist. If so, this gives more credibility and validity to Guidelines, which are based on best-available evidence.

High-level determinations from meta-analysis or systematic reviews are a problem. An example is the review by Hinkfuss and Messer (11) on splinting duration after avulsion and replantation. Definitive data and recommendations that are based on high-level data were not possible and therefore lacking. The authors concluded: “dentists should continue to use currently-recommended splinting periods when replanting avulsed permanent teeth.”

The August 2009 issue of the Journal of Endodontics is of interest and relevance. This issue is of particular importance because it is devoted to evidence-based endodontics. The guest editorial by Gutmann and Solomon is the foundation and reviews the classification criteria for establishing levels of evidence. This is followed by a series of 14 example articles on clinical endodontic topics. Pages 1160–1162 include 2 articles as related to root surface treatment before replantation of avulsions. Although each of the topics is limited in scope, the articles help form the foundation for future research design.

Similarly, other categories of luxation trauma treatment procedures and their outcomes are somewhat empirical and primarily based on low levels of evidence. Interestingly, prevention of trauma represents one aspect that may have outcomes that are based on higher levels of evidence (12). A good example is mouthguard fabrication and usage. The design is prospective; different materials and thicknesses are selected and compared. Specific sports and usage are examined, and ultimately the incidence and nature of the injuries or other related factors are quantitatively measured (13).

Reovalization and Revascularization

Current and fascinating arenas for treating the traumatized permanent tooth with immature development are reovalization and regeneration (14–16). The concept of restoring the pulp space with vital tissue is not only an admirable goal, it is biological. This is pulp biology at its finest by using anatomy, molecular biology, microbiology, pharmacology, physiology, and so on. Regeneration involves either reestablishment of a blood supply or ingrowth of periapical tissues. This ingrowth has primarily been used in a tooth with a necrotic pulp and an open apex and has been in practice for several years. Regeneration is “rebuidling” a pulp (however, is this really pulp?). Most research is studying different scaffolding materials and stem cells; this research is primarily in its relative infancy and has not yet been shown to be useful or clinically applicable. Companion papers in these proceedings discuss this issue in greater detail.

A central and most important question with either of these asks what about the outcomes? These are perfect examples of examining outcomes for the tooth, the dentist, and the patient and includes both short-term and long-term. Are these practical procedures with predictable outcomes? Are different outcomes feasible to investigate? Is it possible to provide high levels of evidence?

Reovalization

The current evidence is primarily expert opinion and case reports. These are a lower level of evidence as to clinical outcomes. Because the procedure is relatively recent, there are no long-term outcome studies.

Interestingly, there have been reports of discoloration (17); this is unacceptable to patients. Also, there are no data on the satisfaction of the dentist in regard to time, profit, interest, etc.

Controlled clinical trials are lacking that compare reovalization with the alternative technique of apexification (apical barrier formation). These trials would be difficult to perform.

Regeneration

Again, a number of outcomes must be satisfied before this becomes a viable clinical procedure and not just a biologically satisfying exercise. Obviously, new pulp must be grown and survive for long-term. Reovalization should be subjected to controlled trials and compared with other procedures such as root canal treatment and apical barrier formation. It should be practical and profitable for the clinician and acceptable to the patient. Other aspects must also be considered and investigated. Will a newly grown pulp survive crown or cavity preparation, heat, cold, bacterial invasion of tubules, periodontal procedures, or orthodontic forces? In other words, will this new tissue behave similarly to a pulp already in place? These are challenging questions.

Conclusions

Outcomes of treatment of dental traumatic injuries encompass multiple factors, not just success/failure or survival/nonsurvival. They include other considerations such as being workable and profitable to the dentist and safe and acceptable to the patient. The more biological outcomes are most frequently measured. These measurements are on a scale from least to most predictable, as shown on the evidence triangle. Impact trauma is an example of a general scarcity of high-level evidence with treatment because of the nature and individuality of the injuries and the difficulty (or impossibility) of designing controlled clinical trials in humans. Thus, guidelines are largely based on empirical lower but best levels of evidence. Nonetheless, the current guidelines provide the clinician with prevailing evidence and opinions of experts with recommendations for treatment. There are significant barriers to designing and implementing high-level evidence randomized controlled clinical trials. However, our literature contains articles that assist the clinical researcher in designing such trials. These should be consulted and implemented when conditions permit such trials.

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References

6. Statement of Peter Orszag, Director of Congressional Budget Office. The Overuse, Underuse, and Misuse of Health Care: Hearings before the Committee on Finance, United States Senate (July 2008).