

Conference Paper

Indirect Pulp Therapy and Stepwise Excavation

Lars Bjørndal, DDS, PhD

Abstract: Various treatment concepts have been suggested to solve the deep carious lesion dilemma. Recent systematic reviews are presented. Their conclusions are based on very few studies, and the main message is that optimal randomized clinical studies are lacking. Observational studies on indirect pulp treatment and stepwise excavation demonstrate that these treatments avoid pulp exposures, but it cannot be said which approach is best. A less invasive modified stepwise excavation approach is described, focusing on changing an active lesion into an arrested lesion even without performing an excavation close to the pulp. In Denmark and Sweden a randomized clinical multi-center trial is currently taking place, the Caries and Pulp (CAP) trial. This trial is investigating the effects of stepwise excavation over 2 visits versus 1 complete excavation of deep caries in permanent teeth. Guidelines for treatment are presented. (*Pediatr Dent* 2008;30:225-9)

KEYWORDS: CARIES, DENTIN, INDIRECT PULP TREATMENT, PULP, RANDOMIZED CLINICAL TRIAL, STEPWISE EXCAVATION, TERTIARY DENTIN

Introducing Thoughts about Level of Evidence in Clinical Research

A demanding trend in clinical research is to perform a randomized clinical trial (RCT) to compare 2 interventions. Why is RCT so important, or in particular the randomization? The level of evidence is the short answer to that question. Expert opinion is allocated to the lowest level of evidence, with the next level being observational studies. At the top of the hierarchy is the systematic review of high-quality RCTs. A more extended answer deals with the largest problem in studies that are non-randomized, which is that of confounding variables. Many factors cannot be controlled for if a simple comparison is made between 2 studies in which the same treatment has been provided. The distribution of prognostic factors might differ between the 2 studies. Are the 2 studies, in fact, treating the very same stage of diseases? With regard to caries, how deep are the lesions? Finally, we cannot exclude the psychological phenomenon that investigators tend to see what they want to see. The perceived effect might in reality differ between the 2 studies.

There is a great deal of difference between RCTs and observational studies, but this does not mean that the thousands of clinical studies that have been carried out with a non-RCT design do not indicate relevance, but they simply do not have the highest level of evidence.

The following is a list of factors that characterize a high-quality RCT:

1. the presence of well-defined inclusion and exclusion criteria;
2. prognostic factors are equally distributed between the 2 interventions that are going to be compared;
3. the number of treatments needed to show a difference between control and experimental groups is calculated;
4. adequate allocation sequences: for example, the randomization of patients to control or experimental groups is generated by a computer;
5. adequate allocation concealment: the randomization is carried out with a central independent unit;
6. follow-up examination is done by an investigator(s) who is blinded as to the patient's group assignment;
7. ideally, the RCT should be carried out in a number of trial centers.

The Latest Systematic Reviews from the Cochrane Collaboration Regarding Caries Treatment and the Pulp

The Cochrane Collaboration carries out systematic reviews of high-quality clinical studies. The recent reviews of caries and pulp treatments all indicate the lack of RCTs.^{1,2} The Cochrane Collaboration has found fewer than 10 studies that could be compared, and they are not all high-quality RCTs.

Within the concept of maintaining pulp vitality, treatment modalities that included indirect pulp treatment (IPT) showed no differences in symptoms at 12 months among studies using Life, Dycal, and Cavitec formulations of calcium hydroxide.²

Dr. Bjørndal is associate professor, Department of Cariology and Endodontics, School of Dentistry, Faculty of Health Sciences, University of Copenhagen, Denmark. Correspond with Dr Bjørndal at lb@odont.ku.dk

In relation to partial caries removal, the following points were addressed in the review¹:

1. Partial caries removal in symptomless primary or permanent teeth reduces the risk of pulpal exposure;
2. No pulpal symptoms were found;
3. Partial caries removal appeared preferable in deep lesions to reduce the risk of carious exposure of the pulp;
4. There is insufficient evidence to show whether it is necessary to re-enter and excavate further in the stepwise excavation technique, but studies that did not re-enter reported no adverse consequences.

Let us add some comments, which in the future might bring these conclusions further up the hierarchy of evidence. One problem has been the definition of the penetration depth of the deep caries lesion. This point has in many studies been defined as a lesion in which one would expect a pulpal exposure if all caries was removed. Among the 4 included studies on which the above conclusions are based, the lesions differed between deep lesions and those extending to half the thickness of the dentin. In 2 of the studies, a stepwise excavation approach was used with lesions defined as deep, whereas the other 2 studies did not re-enter the lesion. The problem in comparing these studies is confounding factors. One of the studies treated less progressed lesions, which might be important when trying to compare the 2 interventions.

We need high-quality RCTs to compare IPT and stepwise excavation. I will return to this later.

How Deep Is a “Deep” Caries Lesion?

The definition of deep caries lesions points toward the potential exposure of the pulp.³ When do clinicians expect that a potential pulp exposure is close? In a practice-based observational study, general dentists were asked to judge the penetration depth of caries lesions that would pose a risk for pulpal exposure.⁴ The majority of dentists selected lesions that penetrated to within three fourths of the entire dentin thickness or more as evaluated on x-rays. This judgment was made in one case in which only half of the dentin was demineralized, indicating that this definition varies substantially among practitioners.

Let us adopt the same clinical concern for potential exposures as did the majority of these general practitioners. A deep caries lesion is present when the penetration depth is in the range of three fourths of the entire thickness of the dentin or more when evaluated on an x-ray.

The Biologic Dilemma

On the first day of this symposium, we discussed the understanding of caries, and that the treatment of deep caries lesions has been placed in what one could call “no mans land,” with different schools of opinions as classically given by Tomes⁵ and Black.⁶ Another aspect is that we do not have any reliable or accurate clinical diagnostic device for monitoring the degree of pulpal inflammation. The case selection for a given treatment, whether or not we want to avoid an exposure of the pulp, is still based on indirect diagnostic procedures. We might try to

divide a few clinical stages of vital pulp problems, depending on the results from our clinical as well as paraclinical diagnostic procedures, as described in detail by Reit et al.⁷ The diagnostic data should be collected from the following 3 areas: (i) the patient’s description of subjective symptoms, (ii) pulp sensibility testing, and (iii) paraclinical examinations (radiographs for exclusion of apical pathosis).

Attempts to divide degrees of pulp pathology seem ambitious, because we do not always know in what direction the pulpal inflammation will turn. It has not been possible to devise an overall applied classification system on this issue. For some practitioners, the clinical diagnosis of the pulp is centered on subjective symptomatic factors, ie, symptomatic or nonsymptomatic pulpitis,⁸ whereas for others the use of *reversible* and *irreversible* pulpitis is applied.⁹ Within the latter diagnostic dichotomy, the treatments are guided toward either invasive pulp therapy or procedures aiming to maintain the pulp integrity. Thus, the words irreversible and reversible cannot solely be interpreted as the gold standard expression for the actual state of the pulp, but rather they represent our best clinical judgment.

The Dentist Must Handle the Biologic Dilemma!

The clinical use of the irreversible pulpitis diagnosis as well as symptomatic pulpitis is essentially the same; the tooth will be managed with an invasive pulp treatment.⁹ However, the deep carious lesion might also be a potential reversible pulpitis case, with confirmed pulpal sensibility but with no objective signs of apical pathology or subjective symptoms before start of the treatment. Even though the absence of clinical symptoms is not a sign of absence of pulp pathology, this approach provides one more chance to maintain the pulp’s integrity, until the opposite is proved. An important point after treatment of such cases must be the maintenance of pulp sensibility, because the finding of “no clinical symptoms” could be the result of a silently developing pulp necrosis.

A Brief Historical Focus on Excavations Methods in Asymptomatic Deep Caries Lesions

Many pulps have probably been exposed through the years on the basis of the concept that deep caries lesions are always associated with inflammation, and diagnoses such as asymptomatic pulpitis or chronic pulpitis have been made. Various excavation methods have been proposed, such as IPT¹⁰ and the two-stage excavation procedure or stepwise excavation.¹¹ In recent articles and reviews the expression “partial excavation”¹ has emerged to refer to various treatment modalities, but in reality the term has not led to consensus, because it can mean anything from almost no excavation to excavation very close to the pulp. The differences between the 2 methods mentioned above are that the IPT procedure involves almost complete removal of the affected dentin, leaving a thin layer of demineralized dentin. Re-entry is not attempted. In contrast, the stepwise excavation technique involves re-entry at varying intervals. What did these early clinical articles prescribe in terms of clinical procedure?

One of the earliest articles describing a step-by-step approach is by Sowden.¹² Carious tissue was removed, and a 1-mm layer of calcium hydroxide was placed followed by a temporary restoration. No final excavation was performed within the first visit. Re-entry and final excavation were then made after 2–3 weeks.

A more rigorous approach was addressed in the article by Magnusson and Sundell,¹¹ who emphasized that a thin soft layer of dentin should remain on the pulpal wall. The authors did not describe in detail what was meant by a thin layer. They most likely excavated as close as possible to the pulp, leaving a thin layer of residual caries. Residual caries, as defined by Kerhove et al,¹⁰ means that if you apply additional pressure to the dentin with the excavator, the pulp will be exposed. Magnusson and Sundell¹¹ placed a zinc oxide–eugenol cement temporary restoration and performed the final excavation after 4–6 weeks. This stepwise excavation method has been a very common and widespread approach within the Nordic countries. In 1962, Law and Lewis¹³ accessed all areas of carious dentin and placed calcium hydroxide and an amalgam restoration. Re-entry was made after 6 months.

Eidelman et al,¹⁴ provided details of the excavation procedures. It is stated that all undermining enamel is removed to gain more easy access to the carious dentin along the enamel-dentin junction. At the pulpal wall approximately 1 mm of carious dentin was left behind. The tooth was re-entered after 1 year, and the final excavation was performed.

For reasons discussed earlier, we cannot make detailed comparisons among these older studies, because each represents its own decade, and there is a great deal of variation among them. For example, in the study by Magnusson and Sundell,¹¹ primary teeth were treated, and no follow-up examination was done after treatment was completed.

Note that it is also difficult to determine whether there are any differences between the classic IPT and the first excavation step as performed in the study by Magnusson and Sundell.¹¹ Thus, the potential risk of creating pulpal exposures following either IPT or during the first step of stepwise excavation might very well be the same.

Observational Data about Indirect Pulp Treatment

In a retrospective study AL-Zayer et al,¹⁵ found that IPT in primary posterior teeth is a successful technique and should be considered as an alternative pulp therapy. Recently, Gruythuysen et al,¹⁶ also reported that the IPT technique produces clinical success. Concerning the more detailed treatment procedures, the Cochrane review indicated that variation in base materials did not produce any differences.² Also, Marchi et al,¹⁷ concluded

that IPT in primary teeth arrests the progression of the underlying caries, regardless of the material used as a liner.

Use the Knowledge from Caries Pathology to Design an Excavation Approach

The optimal focus on avoiding a pulpal exposure and using caries pathology might be demonstrated by the concept of a less invasive or modified stepwise excavation (Fig. 1).^{18,19} The primary aim of the first excavation is to change the caries environment and not to remove as much carious dentin, eventually reaching the residual level close to the dentin-pulp interface. Microbiologic and clinical studies have shown that it is possible to decrease the number of bacteria and arrest the caries process during a treatment interval.^{19,20} The active, soft, yellowish demineralized dentin becomes a darker, harder, and drier demineralized dentin, resembling a slowly progressing lesion. More detailed microbiologic observations also indicate that during a treatment interval the flora becomes a type associated with slow lesion progress in root caries.²¹ These findings have gained additional support.²² Whether the presence of such flora can remain “inactive” beneath a permanent restoration in a deep cavity needs further investigation.

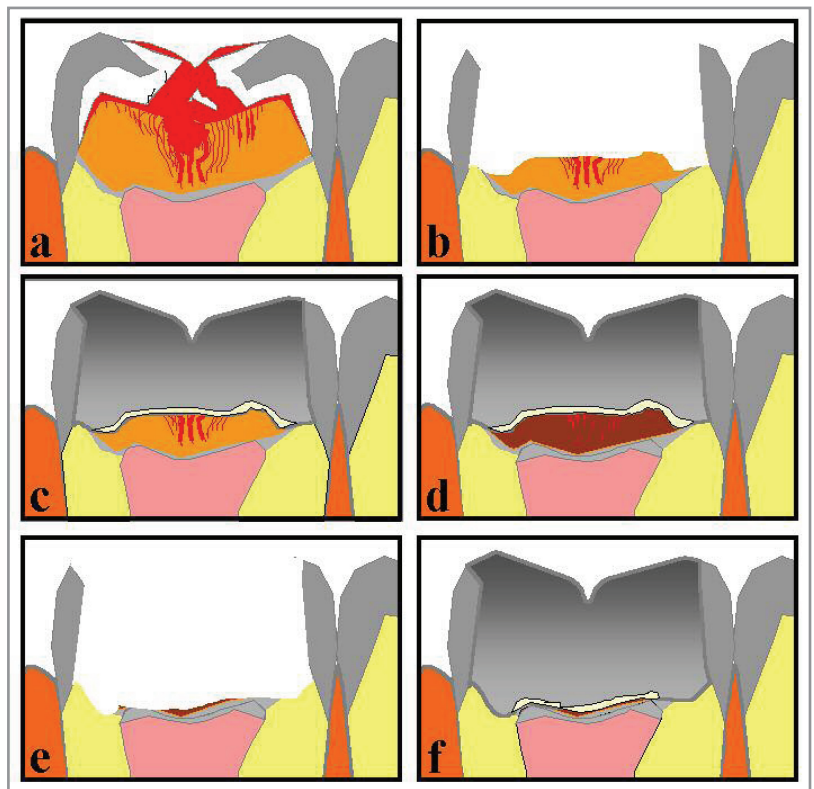


Figure 1. Diagrams demonstrating the less invasive stepwise excavation procedure. A closed lesion environment before and after first excavation (a, b) followed by a calcium hydroxide-containing base material and a provisional restoration. During the treatment interval the retained demineralized dentin has clinically changed into signs of slow lesion progress, evidenced by a darker demineralized dentin (c, d). After final excavation (e) the permanent restoration is made (f). Red zones indicate plaque. Reprinted with permission from Blackwell Munksgaard from Bjørndal L. Dentin and pulp reactions to caries and operative treatment: biological variables affecting treatment outcome. *Endodontic Topics* 2002;2:10–23.²⁷

This aspect of using our knowledge of caries pathology as an integrated part of caries removal is also reinforced in a new textbook chapter.²³

Is A Two-step Excavation Necessary?

As shown from a recent survey, 18% of respondents would partially remove caries in a deep lesion in which one would expect that complete caries removal would lead to pulpal exposure.²⁴ I interpret this technique as the IPT with no re-entry. In the United States IPT has been carried out for years, whereas we in the Scandinavian countries traditionally have applied a stepwise excavation approach. It is difficult to state which treatment approach is better, because no high-quality RCTs have yet been performed to give us the answer.

The clinician's intention is to avoid a pulpal exposure on the basis of the best possible indications. The main concern is that when excavating to a level close to the pulp, a number of pulpal complications might arise, as indicated within the various stepwise excavation approaches. Clinically, the changes in dentin appearance during the excavation provide the clinician with information regarding the changes in caries activity. This is also true in cases in which the changes in color of the carious dentin are not as clear. The final excavation is safer, because it is easier to remove the remaining dry carious dentin.

The final step of stepwise excavation is 2-fold: (1) to assess the tooth's reaction and (2) to remove the slowly progressing lesion in slightly infected discolored demineralized dentin before carrying out the final restoration.

A Two-step Approach Might Be the First Way of Changing Clinical Habits

The vast majority of respondents to the aforementioned survey selected an invasive approach in relation to the deep caries case because they presumably did not believe in leaving carious dentin behind.²⁴ If the operator leaves infected dentin, it might stimulate obliteration of the root canals, making future endodontic treatment more difficult. It is important to say that such a hypothesis is relevant, but it has not been proved. In reality, this would favor a second visit. Remember the second aim, which is to remove the slowly progressing caries in slightly infected discolored demineralized dentin before carrying out the final restoration.

However, it is not easy to change a clinical habit from one of removing all carious dentin to one of leaving caries permanently. One way to accomplish this would be to experience the strategy of "changing the local caries environment" by performing a 2-step procedure next time a deep caries lesion presents in your practice.

A High-quality RCT Concerning Deep Caries Treatment: The Caries and Pulp (CAP) Trial

The aim of the CAP trial has been to investigate the beneficial and harmful effects of stepwise excavation of symptomatic and asymptomatic permanent teeth during 2 visits versus complete excavation of deep caries in 1 visit. The CAP trial is being performed as a multi-center RCT, and the status of inclusion has recently been reported, which means that the enrollment of patients has been discontinued, and the results are about to be

analyzed.²⁵ Preliminary data on the outcome pulp exposure favor the use of stepwise excavation.

Clinical Guidelines Based on an Observational Study and a High-quality RCT

Observational studies from dental practice environments have demonstrated the effectiveness of treating deep carious lesions by using a less invasive or modified stepwise excavation. Long-term recall (3.5–4.5 years) has demonstrated a high success rate (92%), indicating that the method can be carried out in clinical practice.²⁶ The placement of high-quality temporary and final restorative materials must be stressed, because failures are most often associated with inadequate restorations.⁴ Therefore, a 2-step excavation procedure will add to the cost of the treatment. Because of the possibility of asymptomatic development of irreversible pulp degeneration over time, follow-up examinations are required with regard to pulp sensibility and apical conditions. Because readers are already familiar with the guidelines of the IPT, the following presents the stepwise excavation technique²⁷:

1. Deep lesion considered likely to result in pulp exposure if treated by a single and terminal excavation. Evaluated by x-ray, the dentinal lesion involves three fourths or more of the dentin thickness.
2. No history of pretreatment symptoms such as spontaneous pain and provoked pulpal pain. However, mild to moderate pain on thermal stimulation is accepted.
3. Positive pulp sensibility tested by an electric pulp tester, thermal stimulation, or test cavity.
4. Pretreatment radiographs that rule out apical pathosis.
5. Finish the peripheral excavation of the cavity followed by a central excavation removing the outermost necrotic and infected demineralized dentin, in order that a provisional restoration can be properly placed.
6. Do not excavate as closely as possible during the first step, thereby reducing the risk of pulp exposure.
7. Select a provisional restorative material on the basis of the length of the treatment interval, ranging between 6 and 8 months.
8. The final excavation is often less invasive than expected, as a result of the altered dentinal changes gained during the treatment interval.

Recognize that the procedure appears very similar to the IPT, except for the less invasive first step. This requires the clinician to decide before reaching the pulp whether to perform a stepwise excavation approach before all carious dentin has been removed. Otherwise, the clinician will not promote local changes in the cariogenic environment.

It Is Not Just a Matter of Selecting a Proper Clinical Treatment Concept

We do not yet have noninvasive tools for the measurement of the severity of pulpal inflammation. Thus, the discussion of reversible or irreversible development of pulpitis is controversial in relation to the actual state of the pulp. When treating the deep carious lesion, we are forced to make a choice on the basis of indirect diagnostic methods. Consequently, different schools

of thought exist. Future high-quality RCTs might reduce this problem. The understanding of clinical treatment concepts also includes knowledge of its limitations. The control and prevention of further pulpal and periapical damage in relation to the restored tooth will, besides a sufficient restoration, include proper oral hygiene procedures for the removal of cariogenic biofilms, which tend to accumulate where the problem began—in the areas of the restored tooth surfaces. In addition, follow-up examinations are mandatory for the evaluation of pulp sensibility and the possible presence of apical pathosis.²⁸

References

- Ricketts DNJ, Kidd EAM, Innes N, Clarkson J. Complete or ultraconservative removal of decayed tissue in unfilled teeth. *Cochrane Database Syst Rev* 2006;3:CD003808.
- Miyashita H, Worthington HV, Qualtrough A, Plasschaert A. Pulp management for caries in adults: maintaining pulp vitality. *Cochrane Database Syst Rev* 2007;2: CD004484.
- Fitzgerald M, Heys RJ. A clinical histological evaluation of conservative pulpal therapy in human teeth. *Oper Dent* 1991;16:101–12.
- Bjørndal L, Thylstrup A. A practice-based study on stepwise excavation of deep carious lesions in permanent teeth: a 1-year follow-up study. *Community Dent Oral Epidemiol* 1998;26:122–8.
- Tomes J. A system of dental surgery. London: John Churchill, 1859:336.
- Black GV. A work on operative dentistry in two volumes, vol II. 1908: The technical procedures in filling teeth. 2nd ed. Chicago: Medico-Dental Publishing Co,
- Reit C, Petersson K, Molven O. Diagnosis of pulpal and periapical disease. In: Bergenholtz G, Hørsted-Bindslev P, Reit C, eds. *Textbook of endodontology* 2003;Oxford: Blackwell Munksgaard, 2003:9–18.
- Tronstad L. *Clinical endodontics*. 2nd ed. Stuttgart: Thieme, 2003:81.
- Trope M, Sigurdsson A. Clinical manifestation and diagnosis. In: Ørstavik D, Pitt Ford TR, eds. *Essential endodontology: prevention and treatment of apical periodontitis* 1998;Oxford: Blackwell Sci. Ltd, 1998:157–78.
- Kerkhove BC Jr, Herman SC, Klein AI, McDonald RE. A clinical and television densitometric evaluation of the indirect pulp capping technique. *J Dent Child* 1967;34:192–201.
- Magnusson BO, Sundell SO. Stepwise excavation of deep carious lesions in primary molars. *J Int Assoc Dent Child* 1977;8:36–40.
- Sowden JR. A preliminary report on the recalcification of carious dentin. *J Dent Child* 1956;23:187–8.
- Law DB, Lewis TM. The effect of calcium hydroxide on deep carious dentin. *Oral Surg Oral Med Oral Path* 1961;14:1130–7.
- Eidelman E, Finn SB, Koulourides T. Remineralization of carious dentin treated with calcium hydroxide. *J Child Dent* 1965;32:218–25.
- Al-Zayer MA, Straffon LH, Feigal RJ, Welch KB. Indirect pulp treatment of primary posterior teeth: a retrospective study. *Pediatr Dent* 2003;25:29–36.
- Gruythuysen RJM, van Strijp AJP, Gunawan MIM, Ramdas M. Indirect pulp treatment in primary and permanent teeth with deep carious lesions. *Caries Res* 2007;41:269.
- Marchi JJ, de Araujo FB, Fröner AM, Straffon LH, Nör JE. Indirect pulp capping in the primary dentition: a 4 year follow-up study. *J Clin Pediatr Dent* 2006;31:68–71.
- Massler M. Treatment of profound caries to prevent pulpal damage. *J Pedod* 1978;2:99–105.
- Bjørndal L, Larsen T, Thylstrup A. A clinical and microbiological study of deep carious lesions during stepwise excavation using long treatment intervals. *Caries Res* 1997;31:411–7.
- Pinto AS, de Araújo FB, Franzon R, et al. Clinical and microbiological effect of calcium hydroxide protection in indirect pulp capping in primary teeth. *Am J Dent* 2006;19:382–6.
- Bjørndal L, Larsen T. Changes in the cultivable flora in deep carious lesions following a stepwise excavation procedure. *Caries Res* 2000;34:502–8.
- Paddick JS, Brailsford SR, Kidd EAM, Beighton D. Phenotypic and genotypic selection of microbiota surviving under dental restorations. *Appl Environ Microbiol* 2005;71:2467–72.
- Kidd EAM, Bjørndal L, Beighton D, Fejerskov O. Caries removal and the pulpo-dentinal complex. In: Fejerskov O, Kidd EAM, eds. *Dental caries: the disease and its clinical management*. 2nd ed. Oxford: Blackwell Munksgaard, 2008:367–83.
- Oen KT, Thompson VP, Vena D, et al. Attitudes and expectations of treating deep caries: a PEARL network survey. *Gen Dent* 2007;55:197–203.
- Bjørndal L, Bruun G, Markvart M, et al. The CAP-1 randomized trial: stepwise excavation versus one excavation-status of inclusion. *Caries Res* 2007;41:270.
- Bjørndal L. Behandling af profunde carieslæsioner med gradvis ekskivering. En praksis baseret undersøgelse (English summary). *Tandlægebladet* 1999;103:498–506.
- Bjørndal L. Dentin and pulp reactions to caries and operative treatment: biological variables affecting treatment outcome. *Endodontic Topics* 2002;2:10–23.
- Bjørndal L, Mjör IA. Dental caries: characteristics of lesions and pulpal reactions. Mjör IA. *Pulp-dentin biology in restorative dentistry* 2002;Chicago: Quintessence Publishing Co, 2002:55–75.

Conflict of Interest: Lars Bjørndal, DDS, PhD, is a Grant Recipient from the Danish Agency for Science Technology and Innovation.

Copyright © 2008 American Academy of Pediatric Dentistry and American Association of Endodontists.

This article is being published concurrently in *Journal of Endodontics* July 2008;34:7S. The articles are identical. Either citation can be used when citing this article.