



Overview of the Evidence for Clinical Interventions in Pediatric Dentistry

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Abstract

Purpose: The purpose of this report was to describe the quantity of published literature and types of studies supporting the use of 4 pediatric dentistry procedures: (1) ferric sulfate pulpotomy; (2) stainless steel crowns; (3) space maintainers; and (4) atraumatic restorative technique (ART).

Methods: When available, titles and abstracts of reports written in English and published over a 36-year period (1966-2002) concerning these procedures were retrieved from MEDLINE. They were classified using a modified classification scheme that, in addition to the study designs, also considered the 4 dimensions of measuring dental outcomes.

Results: The quantity of available literature concerning each dental procedure varied considerably. Even though many reports were published on treatments, only a small proportion of the published literature for each procedure was found to evaluate outcomes, regardless of outcome dimension. Besides outcomes evaluations, studies on techniques, material properties, and review articles comprised a large proportion of the literature. Clinical dimension of outcomes was most commonly studied. Case series and case reports were the most frequently used study designs to report outcomes.

Conclusions: The outcomes-related literature to support some of the commonly performed treatments is limited both in quantity and study types. More reports are needed to develop the evidence base to support the commonly performed procedures in pediatric dental practice. Additional analyses reporting of the literature are also needed to assess internal and external validity of the studies. (*Pediatr Dent.* 2005;27:6-11)

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When seeking care, patients often inquire about the treatment choices available to them, the prognoses, and costs associated with treatments. To answer these questions appropriately, the clinician needs to support the treatment plan with sound scientific evidence rather than using only personal clinical observations about prognosis and treatment efficacy. Basing clinical decisions on evidence from the literature is a more recent trend in dentistry, and is known as “evidence-based practice.”¹

Evidence-based practice is based on the principles of clinical epidemiology. These principles hold the evidence from randomized controlled clinical trials to be the “gold standard” for outcomes evaluations. Randomized clinical trials (RCTs) are considered the most valid study design for evaluating outcomes because they minimize bias and confounding, and can most clearly establish efficacy.²

To provide answers to patients’ questions, the clinician searches the scientific literature to find relevant studies that

support his/her treatment plan. This retrieval of literature and its assessment to answer questions (translating the evidence into individual clinical practice or assessing the external validity of the results) has been described as a 3-step process:

1. assessment of evidence availability;
2. assessment of evidence quality;
3. synthesis of the evidence from multiple studies to draw inferences.³

The study types that could potentially be used to draw inferences should report outcomes, which are objective measures of performance.^{4,5} Reports suggest that the pediatric dental literature and dental literature as a whole have very limited outcomes evaluations.^{4,6} To assess the quantity and types of studies that form the evidence base for clinical interventions, it is essential to differentiate between the literature that reports outcomes from that which reports other aspects of treatment procedures.

This study is part of a larger study whose purpose was to evaluate the influence of study design on outcomes—in other words, to compare the outcomes reported by randomized controlled clinical trials to those from comparative observational studies (OS) with concurrent controls. To assess the influence of study design and methodology on outcomes, the published literature was searched for treatment comparisons that were evaluated using both RCT and comparative OS study designs and assessed outcomes in a common dimension. Thus, this report presents results on the availability of literature and types of studies for 4 clinical interventions in pediatric dental practice.

Methods

The published scientific literature on 4 clinical interventions performed exclusively in children was selected for review to assess its quantity and types of studies. The 4 clinical interventions were: (1) ferric sulfate pulpotomy; (2) stainless steel crowns; (3) space maintainers; and (4) atraumatic restorative technique (ART).

These treatments were selected for 2 reasons:

1. These procedures generally are performed exclusively in children.
2. They are either accepted as a “standard of care” or are often compared to treatments accepted as “standard of care” for restoring teeth and function.

The relevant reports were identified through MEDLINE and classified using a modified classification scheme to make an assessment of the quantity and types of studies in the published literature. The literature search and classification used is described in the following sections.

Literature search

To identify the relevant reports published over a 36-year period (1966–2002) indexed on MEDLINE, a combination of appropriate MeSH headings, keywords, and phrases were used (summarized in Table 1). The search was limited to studies written in the English language, utilizing

human subjects less than 13 years of age, and published in dental journals. Unpublished literature, theses, proceedings from consensus conferences, and abstracts from scientific meetings were excluded.

Literature classification

Classification of the reports retrieved was based on review of the titles and abstracts of the identified studies. To classify the types of studies that make up the body of literature, the hierarchical classification suggested by the Canadian Task Force on the Periodic Health Examination⁷ was used as a framework.

In addition, the following literature types were also counted: (1) reviews; (2) systematic reviews and meta-analyses; (3) letters; (4) comments and editorials; (5) in vitro studies; (6) technique articles; (7) practice guidelines and recommendations; and (8) surveys of knowledge, attitudes, and behaviors.

The studies that evaluated outcomes were also subclassified in the 4 dimensions of oral health care outcomes: (1) biological; (2) clinical; (3) psychosocial; and (4) economic.⁶

The following definitions were employed to classify the studies:

1. *Biological dimension*: includes outcomes associated with physiological and microbiological conditions and processes. Physiological status outcomes include considerations such as salivary or crevicular flow and demineralization. Microbiological status outcomes focus on presence or concentration of pathogens. Sensory status outcomes deal with pain and paraesthesia.
2. *Clinical dimension*: includes survival status, characteristics of restorations, and functional states. Survival status addresses longevity and loss of teeth, tooth surfaces, restorations, and devitalization. Mechanical status addresses characteristics of restorations. Diagnostic status outcomes are presence of pathology, caries, and periodontal disease. Functional status outcomes address patient-level behaviors dependent on speaking and chewing.
3. *Psychosocial dimension*: includes assessments of satisfaction, perceptions, and preferences of oral health status. The concepts included in this dimension range from satisfaction with treatment to perception of and satisfaction with esthetics and with oral health status preferences for various health states or health events and assessments of oral health-related quality of life.
4. *Economic dimension*: includes assessments of financial and nonfinancial costs of treatment to the patient, provider and insurer in terms of out-of-pocket costs, and costs for treatment and retreatment. Also included are forgone wages or other opportunity costs (eg, transportation costs) that are considered indirect costs.
5. *Randomized controlled trials*: experimental studies comparing groups that have been randomized to the treatment they receive.
6. *Nonrandomized controlled trials*: experimental studies comparing groups that have not been randomized to the treatment they receive.

Table 1. Keywords and MeSH Headings Used to Identify Studies

Stainless steel crowns	Preformed crowns, stainless steel crowns, ion-chrome crowns, pre-formed crown, stainless steel crown
Ferric sulfate pulpotomy	Ferric sulfate, ferric sulphate, pulpotomy, pulp therapy
Space maintainers	Space maintainer(s), space management, space control, deciduous tooth loss, premature loss
Atraumatic restorative technique (ART)	Atraumatic restorative technique, ART, glass ionomer cement

7. *Cohort studies*: observational studies assembling a group of people (a cohort), none of whom has experienced the outcome of interest, but all of whom could experience it. Retrospective chart reviews were classified as cohort studies.
8. *Case control studies*: observational studies where the cases and controls are compared after they have had the “exposure.”
9. *Cross sectional study*: studies that report findings at one point in time.
10. *Case series*: studies of larger groups of patients with a particular condition with the absence of a comparison group.
11. *Case reports*: detailed presentations of a single case or several cases.

Reviews and expert opinions were classified separately from systematic reviews and meta-analyses. Studies that used the materials or techniques for alternate procedures or non-traditional uses of the material were classified as “other uses” and not classified using the classification scheme. Studies that reported on practices and policies of use and did not report outcomes were classified under surveys. Such studies usually report numbers of restorations placed but do not report on outcomes. This category also included studies on knowledge, attitudes and behaviors of providers, and attitudes of patients toward treatments. Surveys of oral health-related assessments of quality of life were included in the psychosocial dimension and not classified under surveys. Letters and comments include letters to the editor, responses to outcomes or methodology reported in previously published studies, or concerns about outcomes.

One author classified the studies using the title and abstract. Each study was counted only once.

Results

There was a wide range in the numbers of reports found for the different topics. Overall, there were few randomized controlled trials. Reviews, expert opinions, and studies on techniques were very common. Outcomes evaluations for clinical interventions reviewed here were relatively limited, and the clinical dimensions of outcomes were the most commonly studied. Economic, psychosocial, and biological dimensions of outcomes were seldom studied. A large proportion of the literature was found to be discussions of techniques of use, reviews, and expert opinion. Specific

results on the types of studies on each procedure are presented in the following sections and in Tables 2 to 5.

Ferric sulfate pulpotomy

Even though numerous reports exist regarding techniques and outcomes for pulpotomy, only 6 were found on MEDLINE that report on uses of ferric sulfate as a pulpotomy agent. This

was the smallest number of studies identified for any treatment considered here. All 6 reports evaluated the clinical dimension of outcomes. By study design, the 6 reports were: (1) 2 RCTs; (2) 1 non-RCT; (3) 2 cohort studies; and (4) 1 review of literature.

Stainless steel crowns

A total of 122 articles were identified on stainless steel crown restorations in children. Of the 122 articles, 45 evaluated clinical outcomes, 4 evaluated biological outcomes, 2 evaluated psychosocial outcomes, and 1 evaluated economic outcomes. All 45 articles that evaluated clinical outcomes employed observational study designs. Sixteen of the 45 reports on clinical outcomes were cohort studies, 2 were case-control studies, 1 was a cross-sectional study, 5 were case series, and 21 were case reports. Biological outcomes were studied by case control (2 studies) and case series (2 studies). Psychosocial outcomes were studied by case control (1 study) and case series (1 study). Economic outcomes were studied by case control study design.

In addition to outcomes evaluations, 70 reports discussed other aspects of the treatment. Of the 70 reports, 12 were reviews or expert opinions, 1 was a systematic review, 5 were in vitro studies, 13 were reports of surveys of practices and use of stainless steel crowns, 21 were articles on techniques of tooth preparation and crown cementation, 2 were practice guidelines, 7 were letters or editorials, and 9 were studies that discussed uses of stainless steel crowns other than restorations of primary molars.

Space maintainers

Ninety-nine reports were retrieved on space maintainers, 26 of which evaluated clinical outcomes and 1 of which evaluated economic outcomes. Reports on outcomes evaluations were mainly case reports, case series and cohort studies. In addition to the reports on outcomes, 42 studies addressed techniques of fabrication or considerations and indications for space maintainers.

ART

Thirty-seven ART reports were identified—22 of which evaluated the clinical dimension of outcomes. Ten of these studies used the cohort study design, 9 were case-control studies, and 1 was a randomized controlled trial. One study evaluated economic outcomes using a cohort study design.

Table 2. Classification of Literature on Ferric Sulfate Pulpotomy (N=6)

	Outcomes evaluations				Other studies	
	Biological	Clinical	Psychosocial	Economic	Review/expert opinion	
RCT	-	2	-	-	Systematic review/meta-analysis	-
Non-RCT	-	1	-	-	Practice guidelines	-
Cohort	-	2	-	-	Letter, editorial, abstracts	-
Case control	-	-	-	-	Survey	-
Cross-sectional	-	-	-	-	Technique	-
Case series	-	-	-	-	In vitro studies	-
Case report	-	-	-	-	Other uses	-
Subtotal	0	5	0	0		1
Total						6

Table 3. Classification of Literature for Stainless Steel Crowns (N=122)

	Outcomes evaluations				Other studies	
	Biological	Clinical	Psychosocial	Economic	Review/expert opinion	
RCT	-	-	-	-	Systematic review/meta-analysis	1
Non-RCT	-	-	-	-	Practice guidelines	2
Cohort	-	16	1	-	Letter, editorial, abstracts	7
Case control	2	2	-	1	Survey	13
Cross-sectional	-	1	-	-	Technique	21
Case series	2	5	1	-	In vitro studies	5
Case report	-	21	-	-	Other uses	9
Subtotal	4	45	2	1		70
Total						122

Of the other 14, 7 were reviews and expert opinions, 3 were reports on practices of use, and 2 were in vitro studies. Most of the studies that reported ART outcomes were field trials.

Discussion

Four clinical interventions were selected for review so the available literature could be assessed in detail for the available types of evidence. This can provide a better understanding of what types of studies are published in the pediatric dental literature. This evaluation of the published pediatric dental literature is unique in that it describes the proportion of outcome-related literature from the overall literature published concerning the 4 materials considered.

There was substantial variation in numbers of studies per topic, ranging from 6 on ferric sulfate pulpotomy to 122 on stainless steel crowns. Only a modest proportion of studies on each topic evaluated outcomes. The clinical dimension of outcomes was most commonly studied. The research designs most often utilized to study the treatments were case series and case reports. Also, most of the studies on outcomes that were found were case series and case reports. The next most numerous were reviews and expert opinions, which is

in line with a study by Nainar reporting that level III (case series and case reports) is the most common category of study designs used in the pediatric dental literature.⁴

Careful evaluations of the dental practice outcomes in all domains—not only in the clinical domain, but also including biological, psychosocial, and economic aspects—are required to provide the information needed to continue to improve the quality of care and demonstrate the value of dental treatments to dentists, patients, and payers.⁸ Providing the research to allow dentists to transition from an empiric-based to an evidence-based practice is a challenging but worthwhile goal.

Several studies in the dental literature have reported on the paucity of outcomes-related dental literature. A systematic review by Patton et al⁹ was intended to compare the occurrence of complications for 7 dental procedures in HIV-positive and healthy patients. The dental procedures of interest were: (1) orthognathic surgery; (2) periodontal therapy; (3) dental implants; (4) prophylaxis or scaling and root planning; (5) endodontic therapy; and (6) extractions. The authors reported that they did not find any published literature on complications for orthognathic surgery, periodontal therapy, dental

Table 4. Classification of Literature on Space Maintainers (n=99)

	Outcomes evaluations				Other studies	
	Biological	Clinical	Psychosocial	Economic	Review/expert opinion	
RCT	-	-	-	-	Systematic review/meta-analysis	1
Non-RCT	-	-	-	-	Practice guidelines	0
Cohort	-	5	-	-	Letter, editorial, abstracts	3
Case control	-	2	-	-	Survey	2
Cross-sectional	-	-	-	-	Technique	42
Case series	-	2	-	1	In vitro studies	-
Case report	-	17	-	-	Other uses	-
Subtotal	0	26	0	1		72
Total						99

Table 5. Classification of Literature on ART (n=37)

	Outcomes evaluations				Other studies	
	Biological	Clinical	Psychosocial	Economic	Review/expert opinion	
RCT	-	1	-	-	Systematic review/meta-analysis	-
Non-RCT	-	1	-	-	Practice guidelines	-
Cohort	-	10	-	1	Letter, editorial, abstracts	2
Case control	-	9	-	-	Survey	3
Cross-sectional	-	1	-	-	Technique	-
Case series	-	-	-	-	In vitro studies	2
Case report	-	-	-	-	Other uses	-
Subtotal	0	22	0	1		14
Total						37

implants, prophylaxis, and scaling and root planning. Only 1 study was found on endodontic therapy, and there were 4 studies on extractions.⁹

Another systematic review of the published scientific literature was undertaken. This was done to determine the strength of the evidence for the efficacy of:

1. professional caries preventive methods applied to high-risk individuals;
2. professionally applied methods to arrest or reverse noncavitated carious lesions.¹⁰

The results of this systematic review did not indicate that the preventive and management methods reviewed are not efficacious; rather, it demonstrated that not enough is known to determine the efficacy of the methods.

Since the quality of evidence (outcomes assessment) currently available to the clinician is not of the highest standards, enhancing its quality in future studies is an important need. One possible step would be data collection in a systematic manner and analyses of outcomes. Dental schools, hospitals, and private practice clinics maintain large patient data records. These collected data present

numerous opportunities for analyses. Ongoing and continuous data collection and analyses could help the clinicians better understand the patterns of success of restorative materials and procedures.¹¹

Another desirable step would be to improve the reporting of the scientific literature with the aim of enhancing the quality of outcomes-related literature. Outcomes evaluation in isolation has limited value, as the results may not extrapolate to an individual clinician and his/her patients. For the outcomes assessment studies to be more meaningful to the clinician, it is important to study outcomes as well as factors that influence them. Therefore, it is essential to integrate the studies' results with the factors that influence them and also assess the influences on outcomes. The outcomes should be adjusted statistically for appropriate influencing factors to improve the study's internal and external validity. The findings of this and other studies that report on the study types and the quantity of the pediatric dental literature indicate that enhancing both the quality and quantity of the literature is imperative.^{2,6,11}

Limitations

For this study, the first step was to retrieve relevant studies using the electronic search engine MEDLINE, the search engine for the National Library of Medicine. Electronic searching of journals is currently the most efficient method of finding relevant studies, but the results of the search can never be held as absolutely comprehensive. One of this study's limitations was that MeSH headings and keywords were used to identify relevant studies on the MEDLINE topics. The MeSH headings and keywords were used in several different combinations to identify as many studies as possible for each material. Indexing of studies under various keywords and MeSH headings, however, is a subjective process. The librarians involved with indexing the studies do not follow a standard indexing method. Only published studies were included in this classification, subject to publication bias. Also, the selection was limited to studies written in the English language in order to facilitate classification. Omission of useful studies written and published in languages other than English likely occurred.

The identified titles and abstracts of studies were classified only once by 1 investigator. The issues of inter- and intra-examiner reliability were, therefore, not addressed. Thus, there is a chance that some studies could have been misclassified.

This study reviewed the published literature on 4 procedures only. These findings may not be representative of the entire pediatric dental restorative literature.

Future directions

If the dental profession is to move toward evidence-based dental practice, then there is an urgent need to collect and report descriptive and analytical outcomes information that will provide the evidence needed.¹² A greater emphasis should be placed on studying oral health outcomes in dental education and research that go beyond the narrow range of outcomes in clinical trials of dental materials.¹³

Conclusions

Based on the results of this report, several conclusions can be reached:

1. Overall, there is a large volume of literature on the procedures studied. Much of it, however, cannot be termed as evidence-based or as having the potential to be the basis for evidence-based practice, because only a limited number of studies evaluated outcomes. A large proportion of the literature on each procedure studied evaluated properties of the materials, techniques, surveys of current practices, practice guidelines, and protocols.
2. Of the 4 dimensions of outcomes, the clinical dimension was most commonly studied.
3. There are very few randomized controlled trials for the widely accepted clinical interventions reviewed for this paper. Current clinical outcomes information is based on observational study designs.

4. There is a need to enhance the quality of outcomes-related studies.
5. Outcomes need to be evaluated, along with assessments of factors influencing outcomes.
6. Along with researchers, the responsibility to develop the evidence base rests with the clinicians in private practice by reporting outcomes from their clinical practice.

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