Restoration of primary teeth: Clinical criteria for assessment of the literature

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Abstract.

Aim: To establish a system of clinically based criteria for the assessment of papers published in peer reviewed journals concerning the use of restorative techniques in primary teeth. **Background:** Various publications that consider the approaches to be taken in setting up assessment criteria within the dental/medical literature were reviewed. These included the so called 'Cochrane criteria'. On the basis of this review a set of clinically based criteria were drawn up that were then used to produce a list of criteria to be used in a series of systematic reviews of the literature concerning the various restorative techniques, materials and medicaments for pulp therapy and the restoration of primary teeth. **Results:** There were 25 criteria that were felt to be appropriate of which all criteria were deemed to be appropriate for pulp therapy and 23 for restorative techniques and materials. **Conclusion:** A set of clinically based criteria is suggested for the systematic review of publications on restorative techniques, materials and medicaments where used for pulp therapy, as used for primary teeth.

Background

Because there is a growing requirement to be sure that each and every technique and material that we use for the dental care of children has some validity, various methods have been devised in order to assess the published literature. The aim is to determine if the supporting information on a technique or material is sufficient to justify that a particular technique and/or material should continue to be used. This need is growing as, particularly in the case of Paediatric Dentistry, those government or other bodies that fund dentistry require evidence of validity.

Early methods of setting criteria for assessing restorations focused on the clinical evaluation of restorations. Thus in 1971 Cvar and Ryge published a set of criteria for the clinical evaluation of dental restorative materials. But these criteria were for individual studies and not to assess all of the literature on a particular fact of dental restorations.

Systematic reviews or meta-analyses. There are a number of processes of systematically locating, appraising and synthesizing evidence from scientific studies in order to obtain a reliable overview, becoming invaluable with the wealth of information that is available today. Dentistry is dealing with huge amounts of information on a regular basis and in order to utilise the salient literature produced, systematic reviews and meta-analyses are appearing more often [Ismail and Bandekar, 1999]. In particular these reviews are useful for providing guidance on which clinical techniques or materials are supported by reliable evidence from the literature.

Mulrow, [1994], reported on the rationale for systematic reviews by exploring the use of reviews as an efficient scientific technique, avoiding the cost and time expenditure needed and providing guidelines and policies for evidence-based practice. Where meta-analyses are carried out, they may provide increased power and precision of an estimate. It is in this area that we are interested here in this special issue of the European Archives of Paediatric Dentistry. As clinicians we need to know which techniques and materials are the currently most appropriate for the restoration of primary teeth, which includes pulp therapy.

Cochrane criteria. The "Cochrane Collaboration" and its associated library are the premiere source for data on clinical effectiveness of healthcare interventions. There are six databases and the Cochrane Database of Systematic Reviews, [CDSR], holds the full text of reviews carried out by the Cochrane Collaboration. The Database of Abstracts of

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Reviews of Effectiveness, [DARE], hold abstracts and comments on reviews carried out by other establishments. Other sources of systematic reviews may be found in a variety of sources such as MEDLINE, EMBASE, NICE, etc. With this data availability in mind, the structure of the question for consideration of the clinical effectiveness of restorative techniques in primary teeth would be pertinent. It was therefore thought beneficial for readers to have access to a series of papers looking at the evidence for using a number of restorative techniques, medicaments and/or materials. A decision was made at this juncture to confine the assessment to only primary teeth in order that the large amount of material available from the literature could be adequately handled. In addition, the main readership of this journal is specialist paediatric dentists whose interest lies in the primary and mixed dentitions.

Methods of Assessment

There are several approaches to devising a method of assessment. One way is to search through the literature for all studies on a subject and then decide which are adequate and which are not. Today that approach would not be considered sufficient.

A second approach is to set up a list of criteria and see which of the studies from the literature meet those criteria. Thus, studies may meet most of the criteria, sometimes referred to as alpha or beta studies, perhaps meeting more than 90% of criteria. Others may meet most of the criteria, say 75%, in which case they may be B or, studies. However, this latter category may be further broken down into those that meet most B1 (75%) and those that meet many B2 (say 50%). That often leaves a large number of studies that are determined to be inadequate as reported and listed as C studies. These C studies are usually not kept in the final assessment but may be for completeness of reporting the assessment results.

A third approach uses a similar one to the second described above but gives points for each criteria that the study meets. On this basis the very best studies, category A as above, will score 90%, or perhaps 95% of the criteria. Studies meeting say 75% or more would be B1 and studies with scores of over 60% would be B2. Using this approach the papers are categorized as:

Grade A: Adequate. Fulfilling nearly all selection criteria,

Grade B1: Relevant and fulfilling all but one or two of the selection criteria

Grade B2: Relevant and fulfilling a majority of the selection criteria

Those papers that fulfilled few of the selection criteria might not be accepted, perhaps discarded and/or recorded as:

C - Rejected.

Clinical trials of restorative techniques and materials.

Reports in the literature on the use of restorative approaches for primary teeth lend themselves very easily to approach number three. By setting up a list of criteria that are met or not met on a Yes or No basis allows points to be given if a study had met the criterion. Thus, ideally a good study would score the maximum number of points. Other studies may be deficient in a few criteria but still score highly and can then be included in the final paradigm. It is this approach that has been suggested to the authors of this series of papers published herein this special issue.

Selection Criteria.

Each paper has to be carefully studied and methodological application of the selection criteria carried out. Retrieved studies can be considered and an updated record maintained of the overall grade for each manuscript using a database. The selection criteria for assessing restorative techniques and materials can be divided into the following categories:

Study Group Characteristics. The following recorded for each paper collected and details completed where possible:

- Comparability of group, if more than one, at baseline and adjustment for confounding factors. Sample stratification or convenience sample was recorded,
- Clear inclusion/exclusion criteria and a record made of dropouts,
- Patient characteristics: - Age group, gender, race and if a special group was recorded.

Intervention characteristic. The following could be collected for each of the intervention characteristics and data relating to the listed facts noted in some detail:

- Duration of follow-up if applicable [minimum of two years required],
- Type of restoration, surfaces involved, clinical conditions used i.e. local analgesia, rubber dam etc.,
- Data collected either daily or weekly,

Outcome characteristics. Data collected according to outcome characteristics:

- Reproducible data of clinical assessment, success or failure of the restoration of pulp treatment, colour changes, defects etc,
- Blind outcome assessment and details of the method of blinding if separate post-operative examiners had been used,
- Method of visual or radiographic recording and whether the teeth were dried, were probes used and if artificial light was the main source of illumination,

- Calibration and training of examiners: Including– intra/inter-examiner reliability, kappa scores, and was this reported in relation to interventions and outcomes.

Other Criteria. The other criteria used could be:

- Power of study/a priori calculation of sample size if carried out,
- Sponsors of trials,
- Publication status (peer reviewed journal),
- Background fluoride/ non-fluoride water levels or use of fluoride,
- Caries level of the subjects before restoration of the teeth,
- Overall outcome of report.

For each of the selection criteria, a statement, relative to the determinant applied, should be recorded. Where data was not recorded this can be shown as not stated (NS) or a simple No, and where not applicable (NA).

Transposing the above to formulate an appropriate checklist would produce one as shown in Table 1. If using this list then an A study would perhaps score at least 22/25 for a pulp therapy study and 20/23 for a restorative technique/materials study. Correspondingly, B1 studies would score 19 and 17 respectively. Quite obviously not everyone will agree on a set of selected clinical criteria, some would add more criteria and others fewer. But as long as the selection criteria are detailed in the review then readers can make their own judgment as to the reliability of the studies reviewed.

Types of studies

There are a number of different types of studies in the literature that can be considered. First of all there is human versus animal and laboratory studies. In the area under discussion it is the human studies that are the most valuable to us. Animal studies are rarely used for restorative materials but can be used for pulp therapy research. However, for the purposes of these reviews only human studies involving children have been considered.

The clinical studies themselves can be

- Randomized trials,
- Non-randomized trials,
- Cohort studies,
- Case control studies,
- Cross-sectional studies,
- Retrospective or prospective,
- Case reports or series,
- Cross-over.

For our purposes the case reports or series of treated children serve little purpose and also retrospective studies carried out by reviewing past clinical treatments are difficult to consider because they are, in most cases, of insufficient design lacking proper inclusion and exclusion criteria, calibration and reproducibility criteria. It is unlikely that retrospective studies would gain an A or B1 rating.

Other authors in attempting similar reviews such as Butani et al. [2005] have also included dimensions such as psychological and financial. In the former assessment satisfaction, perceptions and preferences are included. In the latter the financial and non-financial costs of the restorative treatment to the child, but in reality to their parents, is taken into account. However both of these dimensions are difficult to quantify in a reproducible way. In addition, in many parts of the world, especially in Europe, the majority of children may be cared for under a salaried governmental run or sponsored system. The financial aspects then become impossible to assess.

The psychological aspects are also difficult, if not impossible to quantify. If a restorative material is very successful with a low failure rate, such as pre-formed metal crowns, then repeated restorations are avoided. This means no more local analgesia, rubber dam etc. If a pulp therapy is used which has a very high success rate then there is not likely to be any abscesses and swelling with their associated pain and discomfort and a need for extraction. If dental caries is treated with a once only procedure then subsequent toothaches, sleepless nights, days off school and parent anguish are eliminated. All of these can be recorded but not quantified. Accordingly, in this series of reviews the psychological and financial outcome measure have been excluded, although it is acknowledged that they can be important in some societies.

Discussion

The main criticisms of most of the techniques that we use to manage carious primary teeth are that there is insufficient evidence that what we do has a scientifically proven outcome. For example, the use of pre-formed metal crowns (PMC), often referred to as stainless steel crowns (SSC), has been criticised on the grounds that there have been no controlled studies comparing their outcome with alternative approaches [Milsom et al., 2003]. The meta-analysis of Randall [2002], however, showed that the papers she reviewed indicated a very high success rate for PMC. We all know that the use of PMC has a very low failure rate of well below 10% [Roberts and Sherrif, 1990] but we have to acknowledge that there have been very few prospective clinical trials comparing PMC with, say, three surface amalgam restorations on a contra-lateral tooth.

Table 1 Form used for assessing selection criteria for use in a systematic review of clinical studies in the dental literature on restorative techniques and materials for primary teeth.

Paper Title:.....

.....

Author(s):.....

Journal: .....

1	Published in peer reviewed journal	Yes		No	
2	Prospective study.	Yes		No	
3	Power calculation to determine study size.	Yes		No	
4	Inclusion criteria listed.	Yes		No	
5	Exclusion criteria listed.	Yes		No	
6	Tooth selection criteria given.	Yes		No	
7	Caries status recorded as dmfs/dmft	Yes		No	
8	Mandibular teeth used, for pulp therapy, only.	Yes		No	
9	Criteria for control group given, age, sex, race.	Yes		No	
10	Sample stratification or convenience sample recorded	Yes		No	
11	Details on operators given, number experience.	Yes		No	
12	Training, calibration etc of operators.	Yes		No	
13	Assignment of subjects by an acceptable system.	Yes		No	
14	Pre-op and post-operative radiographs taken by a standardized method.	Yes		No	
15	Outcome measures recorded, after at least two years.	Yes		No	
16	Post-operative assessment criteria listed.	Yes		No	
17	Clinical and radiographic Assessment for pulp therapy only.	Yes		No	
18	Postoperative assessment in a blind manner.	Yes		No	
19	Post-op assessment examiner(s) calibrated.	Yes		No	
20	Kappa scores or equivalent given for post-op examiner(s).	Yes		No	
21	Time to restoration/pulp therapy failure or replacement recorded at intervals up to 2 years	Yes		No	
22	Appropriate statistical tests used.	Yes		No	
23	Sponsors of the trial is reported	Yes		No	
24	Fluoride background, is reported	Yes		No	
25	Outcome report is based on results	Yes		No	
	TOTAL SCORE	.....			
	GRADE	A	B1	B2	C

The papers presented here focus fairly narrowly on restorative techniques. In drawing up a list of areas to be studied, and hence papers to be commissioned, it is acknowledged that the question of prevention cannot be separated from restoration. It is no good providing the most perfect restoration if there continues to be within a child's mouth a highly cariogenic challenge. In addition should fissure sealants be included? The editorial board agreed that, with the constraints of the number of pages that we could publish in a single issue, we should concentrate on restorative techniques at this time. However a further special issue focussing on other materials and prevention techniques has been planned.

One aim of setting up this series of papers has been to show just how many of our clinical techniques can be supported by sound scientific evidence. At the same time it also shows where further research is needed. It is no longer sufficient, in these days of accountability, to say 'such and such works because I have been using it for years without trouble or failures'. Armed with an assessment, as reported here, clinicians caring for children will know that there is more or less scientific evidence to support the techniques they are using. Where evidence is weak then it is to be hoped that the appropriate research will be carried out to rectify these deficiencies fostered by these reviews.

Conclusion

A set of criteria is suggested for the systematic review of publications on restorative techniques, materials and medicaments for pulp therapy to be used for primary teeth.

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