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Twenty Years of Handling Evaluations and Practice-based Research by the PREP Panel

Abstract: Abstract: Dental materials which are user friendly make clinicians' lives simpler by facilitating their placement in patients' teeth: accordingly, the handling of materials is of relevance to the clinician. This paper traces the history of product handling evaluations and practice-based research by the PREP Panel, a group of practice-based researchers based in the UK.

Clinical Relevance: The ease of handling of dental materials is important in dental practice, given that practitioners may find that a material which is difficult to handle leads to suboptimal clinical results.

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The first issue of *Dental Update* contained a paper on the handling of a fibre-optic unit. It is the aim of this paper, 40 years on, to provide reasons why handling evaluations remain fundamental to clinical practice and to demonstrate the progress which has been made in dental practice-based research.

Handling of dental materials

Readers will remember materials which they have purchased, used once and confined to the back of the practice storage cupboard. Reasons for discarding a material may include the following handling, or other, problems:

- Excessive stickiness (sticking to instruments rather than to the cavity);
- Suboptimal viscosity (considered to be important by evaluators, especially for dentine-bonding agents);
- Excessive/long setting time (UK dental practitioners are notorious in their demands for fast setting materials);
- Dispensing and handling of the material not being to the liking of the dental clinician and/or dental nurse;
- Insufficient shades for a material intended for use in the aesthetic zone;
- Poor aesthetics (amalgam being an extreme example which will be rejected by practitioners who seek to enhance the aesthetic aspect of their practice);
- Not doing what it says on the product profile (one material in the late 90s was advertised as having F and OH ion release when the pH dropped below 4.5 but required the preparation of an undercut cavity and was found to perform suboptimally clinically);¹
- Too expensive (not cost-effective);
- Poor packaging or bottle dispenser difficult to use.

It may therefore be considered that the assessment of the handling of a

material is of importance. Additionally, it has been considered that ease of use of a material enhances clinical effectiveness,² so it is the responsibility of manufacturers to strive to develop materials which are straightforward and easy to use, with these aspects of the material having been thoroughly tested, along with physical properties, before the product launch.

The performance or handling of a restorative material by one operator is necessarily subjective, but when practitioners band together to form a group in order to assess the handling of new materials in dental practice, the results are likely to be more objective and general. All of this is possible when practitioner-based research groups are teamed with the expertise available in academic institutions. A UK-based group of practice-based researchers is the PREP (Product Research and Evaluation by Practitioners) Panel. This group, which is co-ordinated by the authors, was established in 1993 with six general dental practitioners, and has grown to contain 35 dental practitioners located across the UK, with one in mainland Europe. The group has completed over

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70 projects, 'handling' evaluations of materials and techniques. By carrying out the work in general dental practice, it is possible to place large numbers of restorations (for example, 875 in a recent evaluation of *Scotchbond Universal* (3M ESPE, Seefeld, Germany)) during the evaluations, ensuring a comprehensive assessment of the material under scrutiny. In the majority of the evaluations, the views of the participating dentists are collated and presented in the form of Visual Analogue Scales (generally 0–5, where 5 = ideal), with satisfaction with the material under evaluation being compared with the practitioner's previous material (Figure 1). Over the years, only two materials have achieved a maximum score of 5 for ease of use, these being *G-Bond* (GC, Leuven, Belgium) in 2006 and *Beautibond* (Shofu, Tonbridge, UK) in 2012. One of the authors (FJTB) also helps co-ordinate, with Dr Dominic Stewardson, a practice-based research group local to the West Midlands known as BRIDGE (Birmingham Research in Dental General PracticE). Readers may have noted their recent work on Class V restorations which gave insight into the restorative materials which performed best in Class V cavities, with the results indicating optimum performance when resin-modified glass ionomer was used.³

A US-based group specializing in handling evaluations is the **Clinical Research Associates** (CRA) founded by Gordon Christensen in Utah, USA over 30 years ago. This organization carries out practice-based evaluations of a wide range of dental materials in 250 dental practices worldwide and is funded by the sales from its monthly publication, *Clinicians Report* (previously known as *CRA Newsletter*).

The PREP Panel has carried out over 70 handling evaluations in its 20-year history, and it may be considered to be of interest to examine the generic types of product for which handling assessments

have been commissioned. These are presented in Table 1, with details of the manufacturers who have commissioned these evaluations being presented in Table 2.

It is clear that resin-based materials predominate, perhaps not a surprise since these are the materials which have seen much development in recent decades, especially dentine-bonding agents which have seen steady improvement. While the report of the handling evaluation is for the commissioning company's eyes only, the majority of the reports go on to be published (in journals such as *The Dentist*), albeit in less detail than the manufacturers' reports. This then enables practising dentists to learn the views of a group of general dentists on a particular material.

Table 2 also provides information on the companies who value this type of research, and who presumably place importance upon the view of practising dentists on how easily (or otherwise) a product handles. In this regard, over the years, the feedback from the PREP Panel has led to changes in product packaging (for example, a bottle which can be stood upside down without leaking) and handling, the latter including a suggested change in the setting time of an impression material which was considered to set too slowly. The manufacturers then produced, for the UK market, a version of their impression material which set faster!

Practice-based research

The logical development of a group which carries out handling evaluations, such as the PREP Panel, is to evaluate the performance of the restorations which were placed during the handling evaluation over a period of time. As a result, the PREP Panel today also carries out clinical trials, as well as

handling evaluations, with ten such trials having been completed to date, with its first clinical evaluation being a one-year evaluation of a compomer, published in 1998.⁴ While one-year evaluations are not sufficient to predict the longer-term performance of a restoration in a patient's mouth, these may be useful to assess the potential for short term catastrophic failure of a material, with this being of particular value if the material is a newly-developed one, such as compomers were at the time of the PREP Panel study. Longer term evaluations provide added value for the clinician, patient and/or third party funder, but the number of cohort clinical studies (especially from a general practice base) which extend beyond five years is small. However, among the recent evaluations carried out by the PREP Panel are the five-year evaluation of 42 *Lava* (3M ESPE, Seefeld, Germany) and three-unit, zirconia-based, all-ceramic bridges, with the results indicating excellent performance of the zirconia core and only one failure, that being due to an unaesthetic chipping fracture of the veneering ceramic on a central incisor tooth.⁵ Another five-year study, that of the low shrinkage-stress composite *Filtek Silorane* (3M ESPE, Seefeld, Germany) will be completed when the restorations are assessed in the summer of 2013, with the results of the three-year evaluation indicating good performance, with very low incidence of post-operative sensitivity in comparison to publications on conventional composites placed in posterior teeth.⁶ This may be considered to be a particular advantage for the use of this material. Studies are ongoing which will examine the effect, at three years, of selective enamel etching on marginal integrity of resin-based composite restorations.

Practice-based research – advantages and disadvantages

The types of research appropriate to general dental practice have been considered to be:⁷

- Clinical trials of materials;
- Assessment of materials and techniques;
- Assessment of treatment patterns;
- Assessment of behaviour and attitudes (of patients and of dentists);

When the evaluators were asked to rate the ease of use of the Scotchbond Universal, the result was as follows:

Difficult to use 1  5 Easy to use
4.9

Figure 1. An example of the VAS scale used in PREP Panel handling evaluations.

Type of Product	Number of Evaluations
Composite restorative materials	22
Bonding agents	19
Glass ionomer restorative materials	4
Compomer restorative materials	2
Impression materials	7
Gloves	2
Desensitizing agents	3
Resin luting materials	5
Temporary crown and bridge materials	2
Others*	11
TOTAL	77

Table 1. Number of evaluations, by material type. *Comprised: bur evaluation, automix impression machine, fibre post system, impression tray system, lip and cheek retractor, restoration sculpting hand instrument system, restoration matrix system, bioactive dentine substitute, composite polishing system, retraction paste compule and a composite veneer system.

Manufacturer	Number of Evaluations
3M ESPE	21
Ansell	2
Apex Dental Materials	1
BJM Laboratories	2
Chameleon Dental	1
ColteneWhaledent	7
Dentsply	7
GC	2
Heraeus Kulzer	6
Ivoclar Vivadent	6
Kerr	1
Kuraray	2
SDI	1
Septodont	2
Shofu	4
Tokuyama	2
Voco	9
Zhermack	1
TOTAL	77

Table 2. Number of evaluations, by commissioning company (in alphabetical order).

■ Surveys of patient satisfaction.

In addition, while audit may not be considered as research, the examination of a variety of procedures, followed by changes, as necessary, is an important aspect of clinical practice, with these audits

sometimes being the 'springboard' to a research project.

The advantages and disadvantages have previously been discussed,⁷ but are summarized in Table 3.

From Table 3, it should be noted that the uncontrolled nature of

practice-based research may be considered as both a disadvantage and an advantage, depending on how the research is viewed. However, the advantage is that the work includes practitioners from different backgrounds (undergraduate and postgraduate), and a variety of patients, all of which contribute to the potentially uncontrolled variations that are seen in general dental practice. In this regard, practice-based research is real world.

It is apparent that increasing numbers of dentists are becoming interested in practice-based research, particularly in the USA, where a \$70million grant was awarded by the National Institute of Dental and Craniofacial Research in 2003. This has facilitated the establishment of a number of practice-based research networks that have completed a variety of projects.^{8,9} In this regard, Mjör and colleagues wrote:⁸ 'Hopefully this announcement will harbinger a fundamental shift towards recognising the major role that practice-based dental research can have in advancing oral health science worldwide'. While this level of funding makes UK-based counterparts green with envy, practice-based research continues to prosper in the UK and Europe and has led to the establishment of a Network for Practice-Based Research within the auspices of the International Association of Dental Research (IADR).

Along with the authors of the present paper, Ivar Mjör and Nairn Wilson have been staunch supporters of practice-based research, making a number of well made statements, for example:¹⁰ 'Real world, practice-based data from general dental practice are needed to qualify and supplement the findings of experimental investigations'. They have also suggested that work from the field of general dental practice can be used to illustrate the discrepancies between research data and clinical practice. In this respect, it is the view of the authors of the present paper that, since the majority of dental treatment, worldwide, is carried out in the general practice setting, it is appropriate that this is also the setting for the majority of research into, for example, restoration longevity to be carried out.

It has been suggested that clinicians join a research network to have the opportunity to answer questions relating to the routing of dental care.⁹ For

Advantages	Disadvantages
Practitioner involvement – real world, real pressures, realistic patient base	Cost (funding needs to be obtained to pay for the practitioners' time)
For the dental practitioner – pushing back the comfort zone	Carrying out research takes time (time in practice = money)
Potentially uncontrolled (dentists from differing undergraduate and postgraduate education and a wide variety of patients)	Potentially uncontrolled – lack of calibration
Different 'angle' from academics	Conflicts between practitioners' primary responsibility to patients and the demands of meaningful research
Additional interest for the staff in the practice	Training (practitioners may not be trained in research, but will be able to learn)
Enhanced patient image	Increased paperwork
Dentist interest/involvement outside the normal daily routine	
Increased clinical relevance/external validity	

Table 3. Advantages and disadvantages of practice-based research.

those who are interested in becoming involved, the first decision relates to time available. If this is not an issue, then the next stage could be to form, or join, a practice-based research group with like-minded colleagues. If one or more of them have a background in research, then that is helpful and, if not, then achieving contact with an academic with knowledge of research is essential. The group will never get all the answers, given that a beguiling aspect of research is that answering one research question often leads to another new question! On an individual practice basis, however, if practitioners record the details of the placement of restorations and their subsequent evaluations in sufficient detail, they are then creating a database by which large numbers of restorations may be assessed. Not only is such information of value to the research community, but also to the patients of the practice, who are likely to be interested in the potential outcome for their treatment. In this regard, it may be considered appropriate that research into restoration longevity in dental practice is used as part of the consent process¹¹ before a patient embarks upon a particular type of treatment, since it may be the failure of a restoration to provide what the patient considers to be adequate service which leads that patient to seek the services of a lawyer, something which

is happening increasingly frequently in these chastened economic times (Lewis KJ, Dental Director, Dental Protection Ltd, London: Personal communication).

Finally, the importance of evaluating new materials has been discussed by Merte and colleagues¹ who, while writing about the failure of a material which was designed as an amalgam substitute, stated: '*As long as laboratory methods cannot substitute clinical evaluations, the introduction of new materials should be supported by short term clinical studies*'. This underlines the value of (practice-based) clinical evaluations, whether short or long term, especially of newly developed materials.

Conclusion

Practice-based research has come of age. Starting with product handling evaluations, it has grown to make an increasingly important contribution to dental research, especially in the field of restorative dentistry and assessment of restoration longevity.

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