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Evaluation of a Novel Compule-Based Gingival Retraction System in UK General Dental Practices

Abstract: Twelve members were selected at random from the PREP panel, a group of UK-based dentists who are prepared to carry out research in their practices. A questionnaire was designed to determine the views of the participants, who were asked to use the retraction paste capsules where clinically indicated. They were asked to return the questionnaire after 8 weeks and the information contained therein was collated and presented mainly on visual analogue scales (VAS). A total of 160 impressions were taken using the *Astringent Retraction Paste* (3M ESPE, Seefeld, Germany) plus use in the placement of 25 restorations. Of evaluators, 83% (n = 10) agreed that *Astringent Retraction Paste* was a suitable product for gingival retraction and 75% (n = 9) agreed that it had good haemostatic properties. Overall dispensing and handling of the paste was rated as 4.9 on a VAS scale where 1 = Inconvenient and 5 = Convenient. The viscosity of the paste was rated as 3.6 on a VAS where 1 = too thin and 5 = too thick. Good scores were achieved across all criteria for the product.

Clinical Relevance: Practitioners may wish to be aware of a novel compule-based gingival retraction system.

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Gingival retraction

Retraction of the gingival tissues is a central part of indirect dental restorations to facilitate identification of the restoration margins and to allow the root contour apical to the margins to be replicated to facilitate the achievement of a satisfactory emergence profile with the final restoration.

A number of methods are available to the clinician, including:

- Retraction cords (single or double);

- Electrosurgery;
- Rotary curettage;
- Displacement paste such as kaolin/aluminium chloride (*Expasyl*, Kerr, Peterborough);
- Astringent solutions, such as ferric sulphate or aluminium chloride.

A more general classification for gingival retraction techniques has been suggested by Donovan and Chee, namely mechanical, chemical, surgical and combinations of the three.¹ None of these has gained total acceptance, and there is little consensus regarding their effectiveness.² Some, such as retraction cords, may be considered to have drawbacks, which include:

- Patient discomfort, often local anaesthesia required;
- Potential for epithelial attachment damage;
- Time consuming;
- May be difficult to place;

- Bleeding on removal.

It is not the purpose of this paper to review the advantages and disadvantages of these techniques. For this, readers are referred to the comprehensive literature review by Bennani and colleagues.³

A novel capsule-based gingival retraction system has recently been developed, namely *Astringent Retraction Paste* (3M ESPE). This is composed of:

- 5% Fillers, water, modifiers;
- 15% Aluminum chloride hexahydrate.

It comprises an innovative retraction capsule for use in composite common hand dispensers, having the following features (Figure 1):

- A long slim nozzle with an orientation ring designed to correspond in size and position to the perio probe. The nozzle has a soft-edged capsule tip to allow facilitation of sulcus access and opening;
- Optimized capsule geometry in order to

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Figure 1. The retraction paste capsule.

deliver a high viscous paste through the tip, the highly viscous paste being needed for keeping the sulcus open;

- The unit-dose capsule itself allows for an hygienic procedure with no cross-infection risk.

Practice-based research

The importance of practice-based research has been emphasized by Mandel, who considered that ‘...research is

*not only the silent partner in dental practice, it is the very scaffolding on which we build and sustain a practice.*⁴

The volume of clinical material seen in general dental practice makes dental practice an ideal area for the assessment of new techniques and materials, as success of a material, device or technique could be considered to be its performance in everyday use in a general dentist’s surgery. The assessment of the handling of a new device is therefore of relevance. However, while the performance or handling of a device or technique by one operator is necessarily subjective, when practitioners band together to form a group in order to assess the handling of new devices in dental practice, the results are likely to be more objective and open to generalization. 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 was established in 1993 with six general dental practitioners, and has grown to contain 33 dental practitioners located across the UK, with one in mainland Europe. The group have completed over 60 projects, ‘handling’ evaluations of materials and techniques and, more recently, clinical

evaluations (n = 8) of restorations placed under general dental practice conditions, with the restorations being followed for periods of one year and five years.⁵

The advantages and disadvantages have recently been discussed in a paper celebrating the 20th anniversary of the founding of the PREP Panel,⁵ and are summarized in Table 1.

It is therefore the aim of this study to evaluate the in-practice ease of the use of *Astringent Retraction Paste* (3M ESPE) by the group of UK-based general dental practitioners who comprise the PREP Panel.

Methods

A questionnaire was designed to determine the views of selected members of the PREP Panel by the co-ordinators of the PREP Panel, along with the sponsors of the project. Twelve members were selected at random from the PREP panel. One was female and the average time since graduation was 24 years, with a range of 9–41 years. Explanatory letters, questionnaires and refill packs containing 25 capsules of the *Astringent Retraction Paste* were distributed to the selected practitioners in June 2012. They were asked to use it for eight weeks and return the questionnaire. The information contained therein was collated.

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 the practitioner’s 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 1. Advantages and disadvantages of practice-based research.

Results

Background information

When the evaluators were asked about the number of impressions which were taken in a typical month, five took 6 to 10, and seven took more than 10. When asked if they took digital impressions, one evaluator replied that he used digital for 90% of the impressions taken.

The evaluators stated that they presently used the following techniques for gingival retraction prior to impressing:

- Nothing 2
 - Double cord 3
 - Single cord 7
 - Paste 5
- (2 Expasyl, 3 Traxodent)

The evaluators were asked to rate the ease of use (where 1 = difficult and 5 = easy) of the gingival retraction system currently used, with the following results:



Evaluation of the *Astringent Retraction Paste* after clinical use

A total of 160 impressions were taken using the *Astringent Retraction Paste*, with one dentist commenting that he also used it in the placement of 25 restorations.

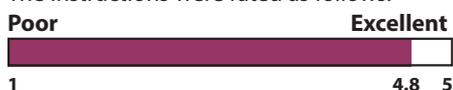
The evaluators rated the layout of the pack as follows:



The ease of use of the capsules were rated as follows:



The instructions were rated as follows:



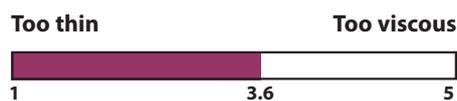
When the evaluators were asked to give their and their dental nurse's overall assessment of the dispensing and handling of the *Astringent Retraction Paste*, the result was as follows:



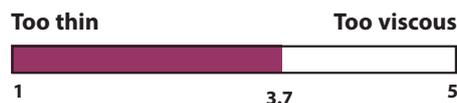
The flow of the retraction paste when pressure was applied to the syringe was rated as follows:



The evaluators rated the viscosity of the materials as follows:



The 'string' of material produced from the syringe tip was rated by the evaluators as follows:



When the evaluators were asked to describe how the new 3M ESPE retraction paste compared with their current retraction system, using a VAS (where 1 = much worse and 5 = much better), the results for various criteria were in Table 2.

The results when the evaluators were asked if they agreed with a range of statements are as follows:

- 83% (n = 10) agreed that 3M ESPE *Astringent Retraction Paste* is a suitable product for gingival retraction;
- 67% (n = 8) agreed that in most cases 3M ESPE *Astringent Retraction Paste* eliminated the need to use cord. The remainder (n = 4) disagreed;
- 75% (n = 9) agreed that 3M ESPE *Astringent Retraction Paste* has good haemostatic properties. Two evaluators offered no opinion;
- 100% agreed that the capsule is well suited to place the retraction paste in the sulcus;
- 83% (n = 10) agreed that the use of 3M ESPE *Astringent Retraction Paste* makes the

retraction procedure more efficient. One evaluator disagreed and one offered no opinion;

- The one user of digital impressing agreed that the use of 3M ESPE *Astringent Retraction Paste* makes the impression scanning more efficient.

When asked if the evaluators considered any changes were essential to the acceptability of the 3M ESPE *Astringent Retraction Paste*, the majority of the evaluators (67%) stated that no changes were needed. However, the remaining two evaluators both mentioned that they found the tips were fragile.

Comments:

- 'Tips fragile – good for application but break easily';
- 'Tips a bit fragile – otherwise superb – best system I have ever used';
- 'Possibly offer larger-sized capsules for single or multiple preparation use'.

The evaluators were asked to rate the ease of use of the 3M ESPE *Astringent Retraction Paste* system, with the following result:



75% (n = 9) of the evaluators stated that they would purchase the system if available at a cost of £1.60 per application and 83% (n = 10) of the evaluators would recommend the 3M ESPE *Astringent Retraction Paste* to colleagues.

Comments made, when the evaluators were asked if the 3M ESPE *Astringent Retraction Paste* could be improved, were:

- 'Could the paste expand a bit after a few seconds when it is in the gingival crevice?'
- 'Finally – a superb new product! Quick and effective – much easier than *Expasyl* as a result of capsule presentation'.
- 'Nice and easy to use product – should be popular.'
- 'Material and compules excellent.'

Enough material in the compule for several crowns or repeat applications if multiple impressions taken. It worked well for thin biotypes where use of

Criteria	Average score	Range
Ease of use	4.0	2–5
Time saving	4.0	2–5
Deflection of the gingivae	2.9	2–4
Haemostasis	3.3	1–5
Dry and clean field for impression-taking	3.3	1–4
Patient comfort	3.5	2–5
Quality of impression scan	3.5	3–4
Hygiene	3.8	3–5
Occurrence of bleeding when scanning	3.3	2–4
Overall satisfaction	3.9	3–5

Table 2. Comparison of *Astringent Retraction Paste* (3M ESPE) with current retraction system using VAS.

retraction cord can lead to recession. Thin nozzle really good for getting into awkward places. Yes – I liked it very much – it will replace *Expasy!*'

■ 'Perhaps recommend its use prior to preparation of gingival margins as it nicely exposes sites for better visibility and access.'

■ 'It is not the panacea to all gingival retraction problems but a useful addition.'

■ 'Good haemostasis. In patients with no periodontal condition, and tight gingivae, I was unable to get tip into sulcus. If patient has a periodontal condition it is OK.'

■ 'A novel solution would be to have the paste light cured after use to allow it to be peeled away atraumatically from the gingival tissues (analogous to the gingival protection system for in-office bleaching).'

■ 'It is a useful adjunct to cord placement but not a replacement. Excellent for retraction before cementing veneers – it would be easier to use if it could be light-cured post-placement and then lifted out in one or two fragments.'

■ 'Very nice product particularly from the cross-infection control point of view. Generally impressed but I like *Traxodent* so decision on use would come down to cost.'

■ 'Good that it doesn't need another gun. Taste poor – very similar to *Expasy!*'

■ 'End of the tip needs to be narrower but less sharp. Paste needs to have better haemostatic properties. When it gets into concave cavities or line angles it is difficult to wash out.'

Discussion

The 3M ESPE *Astringent Retraction Paste* capsulated system has been subjected to an extensive evaluation in which it was used in the taking of 160 impressions by members of the PREP Panel.

The dispensing and handling of the *Astringent Retraction Paste* scored highly (4.9 on a VAS where 5 = convenient and 1 = inconvenient) and the viscosity of the material was rated close to ideal (3.5 on a VAS where 5 = too viscous and 1 = too thin). When the evaluators were asked to describe how the new system compared with previously used retraction systems, the new system was rated from 'the same' to 'much better' in all criteria, with the best scores for ease of use, hygiene, time-saving and overall satisfaction. Only concerns voiced by more than one evaluator related to cost (always a worry to UK dentists, especially those

practising within the NHS regulations) and the taste of the retraction paste.

The overall rating for ease of use was higher for the new system compared with the previously used retraction method (4.4 vs 3.9 on a VAS where 5 = easy to use and 1 = difficult to use), suggesting that this device may be a useful addition to the clinician's armamentarium during impressioning and in controlling gingival tissues during placement of direct restorations.

This paper has presented work on a frequently used clinical technique which is necessary to retract and/or displace the fibre-rich periodontal tissues in order to obtain access to the tooth/teeth which have been prepared. Furthermore, the tissues should be displaced sufficiently to permit an adequate bulk of impression material to be placed, so that the impression can be removed from the mouth with no tearing.¹ The material under evaluation in the present study may be classified as a displacement paste. In this regard, the use of an injectable matrix for gingival retraction has been considered to be atraumatic, with no risk of laceration of the gingival tissues and no damage to the junctional epithelium at the base of the sulcus, or to the sulcus walls.³ Ruel and co-workers

evaluated sulcus retraction by cord, copper band and electrosurgery and, although similar wound healing was apparent after 24 days with all three techniques, they considered that retraction by cord involved damage to the sulcular and junctional epithelia and underlying connective tissue.⁶ Accordingly, the use of the injection technique evaluated in this study could be postulated to cause less histological damage than cords and may therefore be more comfortable for the patient.

There is a paucity of data on the clinical effectiveness of the various techniques which are available, and it has been considered, by Jokstad,² that criteria for defining the clinical performance should be established. In his evaluation, using dentists and dental students, knitted retraction cords were ranked better than twined cords and gingival retraction cords containing epinephrine did not appear better than cords containing aluminium sulphate. Jokstad used six criteria to evaluate the clinical performance of the cords which were compared. These were:

- How easily was the cord packed in the gingival sulcus?;
- Did the cord fray during placement?;
- How rapidly did haemostasis occur?;
- How much was the gingival crevice dilated?;
- Was bleeding evident after removal of the cords?;
- Did the gingival sulcus remain dry after removal of the cord?

These are all valid questions and, from examination of the data on the *Astringent Retraction Paste* assessed in the present study, it could be considered that the new capsule-based paste system performed satisfactorily when its performance was based on the above questions.

Finally, Wostmann and colleagues compared the crevicular fluid flow when different retraction techniques were employed.⁷ They used differing retraction techniques (pure retraction cord, cord impregnated with epinephrine, and chemical retraction with *Expasyl*) for 340 prepared teeth and measured crevicular fluid flow. Their results indicated that pure cotton cords led to an increase in flow,

whereas impregnated cords and *Expasyl* significantly reduced it, concluding that the retraction technique had an impact on crevicular fluid flow during impression-taking. The technique under evaluation in the present work has performed well in this regard, but further testing would appear to be indicated.

Conclusion

The good reception of the new 3M ESPE *Astringent Retraction Paste* is highlighted by the scores across all criteria and the number of evaluators stating that they would both purchase the system and recommend it to colleagues.

Manufacturer's comments

The manufacturer thanks the PREP Panel for carrying out this evaluation of a novel product and thanks them for their useful comments. In addition, some further comments have been added.

Indications

3M ESPE *Astringent Retraction Paste* is indicated for the temporary retraction of the marginal gingiva to provide a dry sulcus when the periodontium is healthy, such as:

- Taking impressions (material-based or digital);
- Preparation of temporary casts (impressions with alginates or alginate replacements);
- Preparation of Class II and V fillings;
- The product must not be used in patients suffering from a diseased periodontium, open furcations, exposed bone.

General advantages

- Enables a clean, dry sulcus and long-lasting hemostasis;
- Effectively opens the sulcus.

Features and benefits versus cords

- Easy and time-saving retraction process: up to 50% faster;
- Lower risk of bleeding/haemorrhage after removal;

- Gentle on tissue for increased patient comfort.

Features and benefits versus other pastes

- Easier application into the sulcus and better interproximal access due to capsule's fine tip;
- Hygienic application, avoiding problems caused by cross-contamination (unit-dose);
- Application with common composite dispensers.

Acknowledgments

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CPD ANSWERS May 2014

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|-------------|------------|
| 1. A, B, C | 6. A, B |
| 2. A, B, C, | 7. B, D |
| 3. A, B, D | 8. A, B, C |
| 4. C | 9. A, B |
| 5. B, C, D | 10. C, D |