CONFIDENTIAL

PREP PANEL RATINGS:

PROMPT L-POP – 5 STARS

HYTAC – 4 STARS

THE CLINICAL EVALUATION OF PROMPT L-POP & HYTAC BY THE PREP PANEL

F J T BURKE & R J CRISP

Dental Primary Care

University of Glasgow Dental School

378 Sauchiehall Street

Glasgow G2 3JZ

Tel & Fax 0141 211 9778

INTRODUCTION

Product:	**1. Prompt L-Pop**
	2. Hytac
Description:	**1. Compomer adhesive system**
	2. Compomer restorative material
Manufacturer:	**ESPE, Seefeld, Germany**
Sponsor:	**ESPE UK Ltd, Haig Court**
	Haig Road, Knutsford
	Cheshire, WA16 6XZ
	Telephone: 01565 755408
	Fax: 01565 654949

INSTRUCTIONS TO EVALUATORS

Explanatory letters, questionnaires and packs of Prompt L-Pop and Hytac were distributed in mid-1999. The practitioners were asked to use the packs and complete and return the questionnaire as soon as possible. The questionnaire is reproduced in Appendix 1.

THE EVALUATORS

15 practitioners were selected at random from the PREP panel, of which 2 were female. The average time since graduation was 20 years, with a range of 6 to 35 years.

EVALUATION OF PROMPT L-POP

BACKGROUND INFORMATION

REPLIES TO SECTION 1

The response was 100% with 80% (n=12) of the evaluators stating that they used compomer materials. Of these evaluators, nine (75%) used Dyract and three (25%) used F2000.

The principal reasons for the choice of these materials were ease of use and aesthetics. Other reasons stated were F^- release, good flow, and good results in a previous PREP panel evaluation.

The ease of use of the currently used compomer material was rated as follows:

The number of compomer restorations placed in a typical week was as follows:

Number of restorations	Number of respondents
<10	4
16-20	3
16-21	1
>20	5

The mean time taken for the currently used compomer/composite bonding sequence was 1minute 45 seconds (range 40 seconds to 5 minutes).

EVALUATION OF PACK AND MATERIALS AFTER FAMILIARISATION – REPLIES TO SECTION II.

The evaluators rated the presentation of the ‘lollipop’ as follows:

Excellent Poor

Suggestions made to improve the presentation included:

" Number sequence as well for colour blind surgery assistants"

" Colours strange but presumably to mimic traffic lights"

" Pack took up a lot of storage space"

The evaluators rated the instructions as follows:

Excellent Poor

The only additional comment made was:

" Perhaps stress that no light curing is needed"

73% (n=11) of the evaluators stated that the Prompt dispenser handle worked in the anticipated way. Comments from the remainder included:

"It didn't look as though it would work but it did!"

"Needed a smaller head for tiny cavities"

"Dental nurse unsure about it"

With regard to the Prompt liquid:

a) 93% (n=14) of the evaluators stated that the dispenser worked satisfactorily. The remaining evaluator stated that it was difficult to know if the reservoirs were empty. Two evaluators commented that the nurse found it 'fiddly' to use at first.

b) All 100% of the evaluators found the sponge tip easy to remove from the dispenser.

c) 93% (n=14) of the evaluators stated that the Prompt liquid was easily applied to the tooth surface. The remaining evaluator experienced some difficulty with lingual and palatal areas.

d) When asked for other comments regarding the Prompt liquid the following comments were made:

" Smells odd" (4)

" Brilliant system – idiot proof to suit me" (2)

" Needs 50% more volume for large cavities"

When asked to compare the application of Prompt liquid with the application of other previously used resins, 73% (n=11) stated it was less messy and 60% (n=9) stated it was better. Comments made included:

" It didn't spread to the gingivae"

" Less evaporation"

80% (n=12) of the evaluators stated that the dental nurse did not experience difficulties in operating the Prompt L-Pop. Comments made included:

" She really liked the system – clean and fast"

" A problem occurred only once in breaking the capsule seal"

80% (n=12) of the evaluators stated they would purchase Prompt L-Pop if it was available for average cost.

Comments made by the evaluators when asked if there were any changes essential to the acceptability of Prompt L-Pop included:

" The names a bit 'off the wall' – why not PLP – it sounds more technical and high value"

" Very good system which is simple and practical" (3)

" Wasteful for a single restoration"

" Don't know how well the liquids have mixed and the instructions stated that incomplete mixing affects bond depth"

" Smaller packs please"

The mean time taken for the bonding sequence with Prompt L-Pop was 62 seconds (range 25 seconds to 180 seconds).

CONCLUSIONS

The Prompt L-Pop compomer bonding system has been subjected to an extensive evaluation by 15 members of the PREP panel. Based on this evaluation the following comments can be made:

a) The 'lollipop' scored highly for presentation and instructions (4.7 on a visual analogue scale where 5 = excellent and 1 = poor).
b) The majority of the evaluators (93%) found that the dispenser worked satisfactorily.
c) The application of the Prompt liquid was found by the majority of the evaluators to be better (60%) and less messy (73%) than other resins.
d) Four evaluators (27%) did comment on the smell of the Prompt liquid.

There was found to be a significant reduction in the mean time taken for the bonding sequence, from 105 seconds with the previously used system, to 62 seconds with the Prompt L-Pop system. It was also noted that the majority (80%) of the dental nurses, who are the most likely to operate the dispenser, did not experience any difficulty with the Prompt L-Pop.

That 80% of the evaluators would purchase the Prompt L-Pop system, if available at average cost, indicates how well received the product was.

EVALUATION OF HYTAC IN CLINICAL USE – REPLIES TO SECTION III.

Thirteen of the evaluators chosen at random for the evaluation of Prompt L-Pop extended the evaluation to include the clinical use of Hytac compomer restorative material. Two of the panel were female and the average time since graduation was 19 years (range 6 to 35 years).

The total number of restorations placed was 306, comprised as follows:

Class V	185
Class III	121

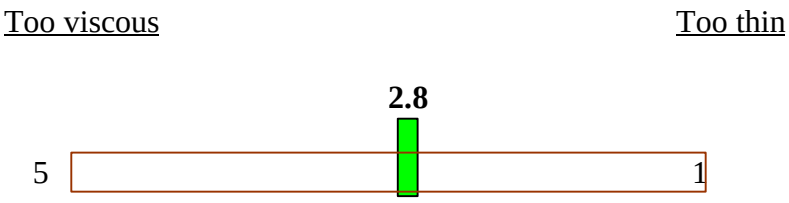
When asked to give details of the placement techniques, the evaluators indicated that a mixture of freehand and matrix techniques were used. However, the replies indicate that the majority of Class V restorations were placed freehand and the majority of Class III restorations were placed using matrices.

When the evaluators were asked to give their, and their DSA's assessment of the dispensing and handling of the Hytac material, the result was as follows:

85% (n=11) of the evaluators did not experience any difficulty with the material sticking to instruments. The remaining evaluators dipped instrument in bond to overcome this.

When the evaluators were asked to rate if the material flowed satisfactorily when pressure was applied to a matrix or placement instrument the result was as follows:

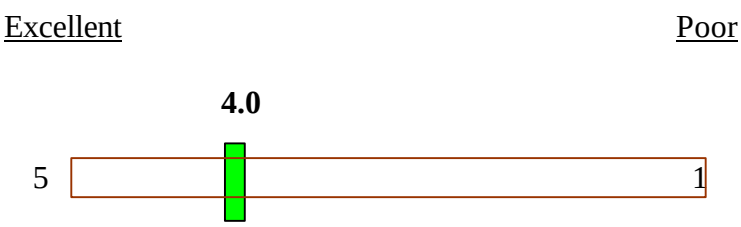
The result when the evaluators were asked to rate the viscosity of the material was as follows:



All the evaluators (100%) stated that the restorations were easily finished and polished using their normal finishing system and 85% (n=11) stated that the material polished to a high gloss. The remaining two evaluators stated that a gloss was obtained but not as good as with a composite restoration.

62% (n=8) of the evaluators stated that sufficient shades of Hytac were provided. The remainder would have liked shades C4, B2 and A4 provided.

When the evaluators were asked to rate the overall aesthetic quality of the Hytac restorations the result was as follows:



Further comments included:

"Very good for a compomer"

"Similar to Dyract"

"A shade change was noted after a few days"

All the evaluators (100%) stated that the restoration margins were generally visually satisfactory.

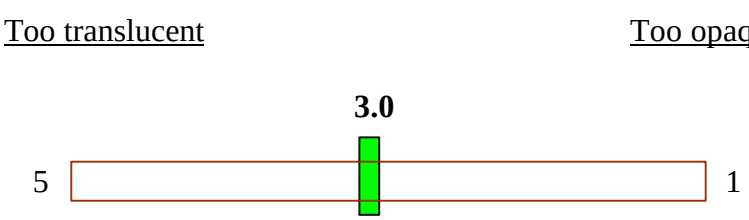
When the evaluators were asked to give details of any difficulties experienced during placement and finishing of restorations made with Hytac, the comments included:

"A little too much flow – had to use in increments in larger cavities" (3)

"Shade shift"

"Overdoses for small cavities"

The evaluators rated the translucency/opacity of the material as follows:



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

Comments made, when the evaluators were asked if there were any changes considered essential to the acceptability of the material, included:

"? Provision of disposable syringe handles? – handle needs autoclaving so not available for next patient"

"Foil wrapping difficult to open with gloved hands"

"Fiddly delivery – would prefer compules and gun"

"Better shade guide"

If the material was available at average cost, 69% (n=9) of the evaluators would purchase Hytac. Of the remainder, one evaluator stated "possibly".

Final comments included:

"Aplitip excellent but too much material in capsule"

"Aplitip difficult at first but innovative and well designed" (2)

"Very user friendly"

"A good quality material and a useful adjunct"

"Not convinced by compomers" (2)

CONCLUSIONS

The Hytac system has been subjected to an extensive evaluation in clinical practice by 13 members of the PREP panel, in which 306 restorations were placed. Based on this the following comments can be made:

a) The material scored highly (4.7 on visual analogue scale where 5 = convenient and 1 = inconvenient) when the evaluators and their DSAs were asked to rate the dispensing and handling of the Hytac material.

b) Ideal ratings were obtained by the material for viscosity (2.8 on a visual analogue scale where 5 = too viscous and 1 = too thin) and translucency/opacity (3.0 on a visual analogue scale where 5 = too translucent and 1 = too opaque).

c) The high rating for ease of use (4.6 on a visual analogue scale where 5 = easy to use and 1 = difficult to use) matched exactly the pre-trial compomer material.

That the material was well received was demonstrated by the 69% (n=9) of evaluators who stated they would purchase the material, if available at average cost. Of the remaining evaluators, two remain unconvinced by the benefits of compomer materials in general and restated their preference for composite and glass-ionomer materials.

ACKNOWLEDGEMNTS

The authors thank the members of the PREP panel who participated in this evaluation and acknowledge the support of ESPE (UK) Ltd.