

SMART composite (Self-bonding Material for Restorative Treatment) restoration of children's primary molar teeth after minimal caries removal: Class IIa device in a single site, single arm study.

Final Report

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Objectives

Assess percentage restoration failure (complete restoration loss or partial loss exposing dentine or cavity floor) following 1 years placement of SMART composite on minimally prepared cavities in children's teeth.

Safety endpoint: number and type of Serious Adverse Device Effects (SADE) observed at the 6 month and 12 month visit.

Exploratory objective

Patient satisfaction with the placement procedure for the new composite.

Methods

Clinical Investigation of a non UKCA/CE marked product.

Class IIa,

Open label, single site investigation

This single arm trial aimed to recruit 124 children and review them for a year

Inclusion criteria

Children 5 to 9 years of age

At least one primary molar with a carious cavity affecting one or more surfaces (International Caries Detection and Assessment System (ICDAS) score 4,5)

Subject willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment

Exclusion criteria

Unable to give assent/consent

Non-carious anomaly of structure such as amelogenesis imperfecta (this data will be in the patient records).

Patients with significant pain and/or infection who require urgent management (assessed by standard clinical investigations)

Possible teeth for inclusion likely to exfoliate before restoration has been in place for 12 months

Non-vital teeth with draining pus (as per standard care)

Methacrylate allergy

Clinical procedure

Each child had a single molar filled with the new SMART composite.

Standard filling procedures modified to use a minimal caries removal approach were used. If required high speed instruments were used to remove enamel overlying the cavity. Minimal removal of caries using an excavator as per the International Caries Consensus Collaboration recommendations, 2016 was undertaken. This included selective removal to soft dentine aiming to clear the periphery of the cavity. This allowed the margin of the restoration to be on sound enamel/dentine. If required a matrix band was used. Following blot dry with a cotton

pledget, the material was immediately applied. The material was supplied ready-mixed in compules designed for single patient use and ease of placement in the tooth. Following 30s application time to enable composite flow into the enamel / dentine structure, the composite paste was then made to set by 20s of a blue LED light exposure

Recruitment

This single arm trial aimed to recruit 124 children and review them for a year. Children were recruited at the investigation site (Eastman Dental Hospital, UCLH)

Assessment of failures

Restorations were clinically assessed for failure at 6 months (visit 4) and 12 months (visit 5). In addition, following treatment of the first 25 patients, they were contacted by phone/text or email after 3 months to determine if the restoration had remained in place (visit 3). At 6m, interim analysis of the first 50 patients was carried out with a rule to stop the trial if the upper limit of the 95% confidence interval of estimated failure rate was $\geq 40.0\%$.

Statistical analysis

Appropriate descriptive statistics were obtained with mean/median and SD/IQ range or simple counts with percentages to describe the characteristics of patients.

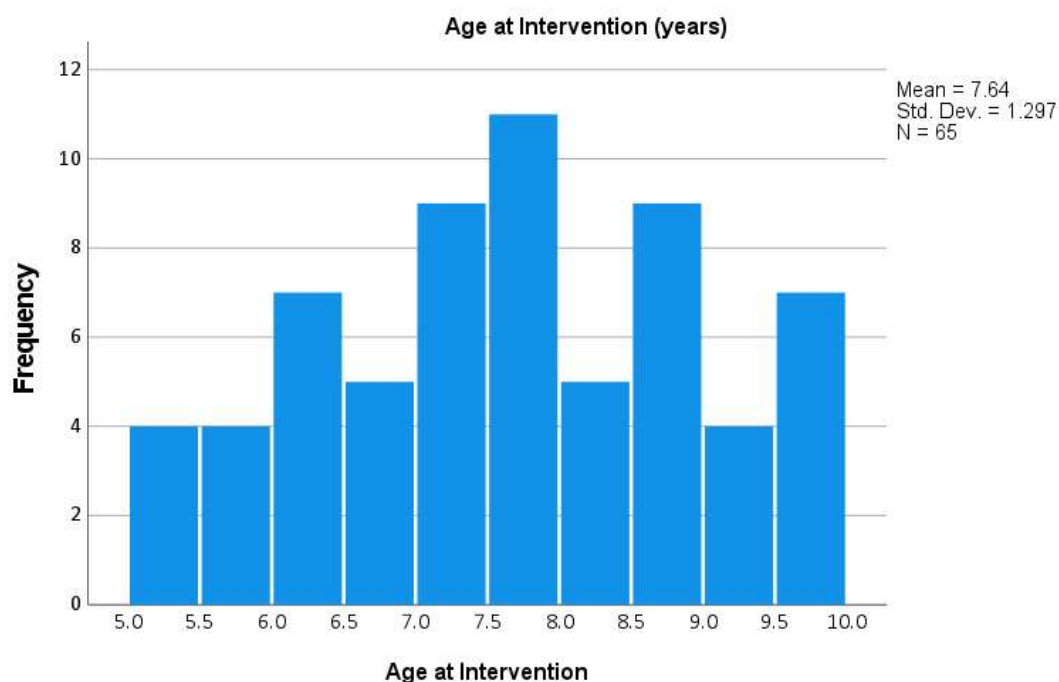
A test was carried out of the hypothesis that failure rates do not exceed 14%, at 12 months. This was intended to demonstrate that the material performed as intended.

Results

Recruitment was stopped in September 2024 due to the Chief Investigator being diagnosed with a serious illness. At this point 65 patients had been recruited. The decision was made to pause recruitment, the remaining 65 patients were reviewed by T Malkiel.

Demographics of sample

Age at intervention



Gender

		Frequency	Percent
Valid	Female	35	53.8
	Male	30	46.2
	Total	65	100.0

Tooth and tooth site frequencies where SMART filling was placed

	Smart Filling status at visits 3, 4 and 5		
Filling status	Visit 3	Visit 4	Visit 5
Intact	12 (75%)	31 (84%)	28 (56%)
Not intact	4 (25%)	6 (16%)	22 (44%)
Total attendance	16	37	50

	Total	Class I	Class II
First primary molar			
URD	1	3	4
ULD	1	1	2
LLD	1	6	7
LRD	3	4	7
Second primary molar			
URE	4	7	11
ULE	4	5	9
LLE	8	5	13
LRE	7	5	12
Total	29	36	65

Attendance and intact status at in person follow up visits

Visit 4

37 patients attended. Of these 31 (84%) had intact fillings, 6 (16%) the fillings were no longer present

16 patients responded, of these 12 (75%) reported the restoration as being intact

Visit 5

Due to investigator illness the study was not completed. 50 patients were reviewed at visit 5. The remaining patients (n=15) had either failed previously or been withdrawn. Of these 28 (56%) had intact fillings, in 22 (44%) the fillings were no longer intact

This failure rate of 44% at 12 months meant that the hypothesis that the material performed as intended was rejected.

Adverse events

No serious adverse events were reported during this trial. 5 teeth experienced fractures of buccal or palatal walls. This was not judged to be related to the restoration.

Report on laboratory assessments

None of the exfoliated teeth were returned so these could not be carried out

Report of Questionnaire data

Handed out visit 2 and Visit 5.

Frequency analysis due to simplicity of data

Visit 2

Questions for the Parent

Were there any unusual or unexpected reactions?

	Frequency
No	19
Total	19

How did it compare to fillings you have had before?

	Frequency
Easier	15
Not sure	4
Total	19

Do you have any other comments?

Only one response

“Worked well for my daughter. She was less scared”

Questions for the patient

What did you think about the filling placement? If you have had a filling the normal way, did this seem easier than normal filling/more difficult?

	Frequency
Easier	11
No different	1
Not sure	7
Total	19

What did you think about the look of the filling?

	Frequency
It looks ok	12
Not sure	7
Total	19

How would you describe your feelings about being involved in the research project?

	Frequency
Don't care	1
Don't know	2
Excited	2
Feels good	1
Fine	1
Fine with it	1

Glad to support	1
Good	3
Not sure	3
Nothing	1
Thumbs up	1
Total	19

Did you feel that your views were seen as important in the research project?

	Frequency
Don't know	1
Not sure	9
Yes	4
Total	14

When we were planning this research project we asked young people what they thought. Do you think that was important?

	Frequency
Not sure	5
Yes	14
Total	19

Would you tell other people to get involved in working with researchers?

	Frequency
Not sure	8
Yes	10
Total	18

Visit 5

Questions for the Parent

Unusual or unexpected reactions

	Frequency
No	37
Total	37

Do you have any comments?

“I am really happy with everything”

“It went really well, my daughter is quite nervous and was very relaxed receiving the small filling

“Loved coming to the hospital + overcame fear of dentists coming here”

Questions for the patient

What did you think about the look of the filling?

	Frequency
It looks ok	25
Not sure	12
Total	37

How would you describe your feelings about being involved in the research project?

	Frequency
Don't care	1
Don't know	2

Don't want another filling as it might hurt. I really liked the professor I saw last time	1
Everything was fine	1
Excited because taking part in something that's new	1
Felt a bit Weird	1
Fine	1
Good	5
Great	1
Great so far	1
Great team	1
Happy	1
Happy because I will feel different	1
I didn't like having the filling put in	1
I don't want to	1
I feel calm and happy to be in the project	1
I feel special	1
I felt reassured and confident, as it seemed like the best thing to do	1
Interesting + curious	1
It was really fun. I enjoyed it	1
No	1
Not sure	2
OK	4
positive	1
Preferred it at the hospital then at the normal dentist	1
Very exciting in getting invited in the research	1
very good service	1
Total	29

Would you tell other people to get involved in working with researchers?

	Frequency
No	2
Not sure	9
Yes	26
Total	37

Is there anything else you would like to tell us?

	Frequency
It seems to be safe and a good way to protect teeth for little ones.	1
Now I would like to be dentist when I am older	1

Sometimes the appointments can be stressful to keep	1
Thank you	1
Thank you!	1
The staff have been excellent and very professional	1
Total	6

Summary of Restoration related responses

79% of parents thought it was easier than standard fillings, 21% weren't sure. When the children were asked the same question, 58% felt it was easier than fillings they had had before, 37% weren't sure.

The majority of children were happy with the appearance at visit 2 (63%), this was still the case at visit 5 (68%) with 32% of children unsure.

Summary of PPI related responses

When asked about their feelings with regard to taking part in the research project at visit 5, the majority of children were happy. Only 5 out of 29 (17%) expressed any reservations. Most of the children would advise others to take part in research (70%)