

# What's new for the clinician?

## Summaries of and excerpts from recently published papers

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Compiled and edited by V Yengopal

### 1. A Randomised Controlled Trial (RCT) of complete denture impression materials.

Hyde TP, Craddock HL, Gray JC, Pavitt SH, Hulme C, Godfrey M<sup>1</sup>

Published studies from many different parts of the world have shown that the majority of dentists report the use of alginate as the material of choice for the definitive secondary impression material for complete dentures. This contrasts with the position both practised and taught in many dental schools which recommend the use of silicone impressions for secondary/final impressions.<sup>1</sup>

Hyde and colleagues (2014)<sup>1</sup> reported on a RCT that sought to primarily establish whether there is a patient preference for dentures produced from alginate or silicone impressions. The secondary objectives were:

1. To assess the impact of dentures produced from alginate and silicone impressions on oral health related quality of life;
2. To assess comfort, stability and chewing efficiency for dentures produced from alginate or silicone impressions; and
3. To assess patients' experience of having impressions made using alginate and silicone impression materials.

#### METHODS

This was a single centre, double-blind, randomised, controlled crossover clinical trial of alginate and silicone impressions for complete dentures. Edentulous adult patients who required new complete dentures, were available for follow up and were able and willing to complete the informed consent process were included. Patients were excluded if they had an oral tumour, required an obturator, had extreme xerostomia, had a known hypersensitivity to silicone or alginate or would benefit from selective pressure impressions. A sample size calculation revealed that 76 patients would have 80% power to detect a difference in preference rates of 30% between the two dentures (30% versus 60%) at a significance level of 5%, assuming that 10% of patients express no preference. A total of 85 patients were recruited overall to allow for a dropout rate of 10%.

Baseline OHIP-EDENT questionnaires were completed by the patients prior to denture construction.

#### ACRONYMS

OHIP-EDENT:	oral health impact profile in edentulous patients
RCT:	randomized clinical trial

All 85 patients received two sets of dentures, one set of dentures made from impressions taken with silicone, the other set made from alginate impressions.

Two sets of acrylic, spaced, and customised impression trays with stub handles and acrylic "stops" were constructed for each patient (Tray A or B). During impression taking, the trays which were used first (A or B) and the impression material which was used first (alginate or silicone) were randomised. The trays to be used for the alginate impression were border moulded with green stick impression compound (Kerr) and the alginate impressions taken (Xantalgin, Heraeus). The trays used for silicone impressions were border moulded in silicone, using heavy bodied for the upper (Extrude, Kerr) and regular bodied for the lower (Express, 3M ESPE) and the impressions were taken with light bodied silicone (Express, 3M ESPE). The quality of the impressions was assessed by the clinician and by a second independent inspector. If either the clinician or the second independent assessor felt an impression was below an acceptable standard, the clinician re-took the impression.

The master casts were poured in the dental laboratory and the casts cleaned to remove all traces of impression material. The casts were allocated a number (blind to the clinician) which allowed the later identification of the dentures. At all subsequent stages of denture construction the clinician was blind to the impression material used.

The completed unadjusted dentures were labelled by random allocation with blue and red dots. Half the red dot dentures were from alginate impressions and half from silicone; similarly for the blue dot dentures. Patients were given both sets of unadjusted dentures and asked to follow a structured programme of alternate wearing of the dentures, starting with the red dentures, for a two-week 'Habitation Period' which allowed patients to become accustomed

to the new dentures and assess their preference for the unadjusted dentures (primary outcome).

Following the initial assessment of the dentures (primary outcome) the dentures were relabelled by green or yellow coloured dots by randomised allocation. Patients then wore the newly coded dentures sequentially in two periods of eight weeks each ('Adjustment Period'), during which time the patients returned to the clinic for any adjustments they required. All necessary adjustments were made by a second independent, blind clinician who was blind to the denture group. The 1:1 randomisation coded by the yellow or green dots established the order of testing during the 'Adjustment Periods'. The patients and the clinical team were blind to these allocations. Finally, patients took both sets of dentures for a final two week period ('Confirmation Period') at the end of which they returned for the final assessment.

The primary outcome assessed was the patients' preference for the unadjusted dentures following the two weeks 'Habituation Period'. Secondary outcome assessments were:

1. Patient perception of denture comfort, stability and chewing efficiency of the dentures using 5-point Likert scales;
2. Patients' preference for the adjusted dentures following the two week 'Confirmation Period';
3. OHIP-EDENT questionnaires assessing the patient oral health related quality of life following each Adjustment Period;:
4. Patient perception of comfort and taste of each impression material using 5-point Likert scale at the impression stage;
5. and Patient preference for the impression materials at the impression stage.

## RESULTS

Of the 85 patients recruited, 59 (69.4%) were female and 77 (90.6%) were white, with a mean age of 69.4 (SD 10.87). Seventy eight (91.8%) patients completed the primary assessment. 53 (67.9%) patients preferred dentures made from silicone impressions while 14 (17.9%) preferred alginate impressions. Four (5.1%) patients found both dentures equally satisfactory and seven (9.0%) found both equally unsatisfactory. There was a 50% difference in preference rates (in favour of silicone) (95% CI 32.7–67.3%,  $p < 0.0001$ )

After the 'Habituation Period' (i.e. before substantial denture adjustment), the patient assessments of the 'Comfort', 'Stability' and 'Chewing Efficiency' of the dentures showed significant evidence that unadjusted dentures made from silicone impressions were rated as more comfortable ( $p=0.0039$ ), more stable ( $p=0.0047$ ) and more efficient for chewing ( $p < 0.0001$ ) than unadjusted dentures made from alginate impressions.

After the confirmation period there was a 33.8% difference in preference rates for the adjusted dentures (in favour of silicone) (95% CI 14.3–53.3%,  $p=0.0016$ ). After the 'Confirmation' period, the patient reported assessments of the 'Comfort', 'Stability' and 'Chewing Efficiency' of the dentures showed there was no evidence of a difference in comfort rating between silicone and alginate impression materials ( $p=0.5417$ ). However, there was significant evidence that dentures made from silicone impressions were rated as more stable ( $p=0.0066$ ) and more efficient ( $p = 0.0010$ ) than dentures made from alginate impressions after adjustment.

Data gathered after the patients had been wearing the dentures for the two eight week Adjustment Periods, there was significant evidence that the OHIP-EDENT score was lower (better oral health related quality of life) after wearing dentures made with silicone impressions materials with a median reduction in score of 5.5 units ( $p=0.0014$ ). There was significant evidence from the patient reported Likert scores that silicone impressions were more comfortable than alginate impressions ( $p=0.0021$ ) but no evidence of a difference in taste between the two impression materials ( $p=0.1128$ ). An additional *post hoc* statistical analysis using McNemar's test showed there was a 28.9% difference in patient preference rates for having impressions taken in silicone (95% CI 11.1–46.8%,  $p=0.0027$ ).

## CONCLUSIONS

Dentures made from silicone impressions were preferred by patients over dentures constructed from alginate impressions, both before and after the dentures were adjusted. Overall, patients preferred the experience of having impressions taken in silicone, finding them more comfortable; however there was no preference for the taste of either material. Patients' oral health related quality of life was better after wearing dentures made from silicone impressions. Unadjusted dentures made from silicone impressions were more comfortable, stable and efficient for chewing. After adjustment, the dentures made from silicone impressions remained more stable and efficient for chewing. However, after the dentures had been adjusted there was no detectable difference in comfort between the dentures.

## IMPLICATIONS FOR CLINICAL PRACTICE

This high quality RCT provides strong evidence that dentists should consider replacing alginate with silicone as the material of choice for secondary impressions for complete dentures.

### Reference

1. Hyde TP, Craddock HL, Gray JC, Pavitt SH, Hulme C, Godfrey M, et al. A Randomised Controlled Trial (RCT) of complete denture impression materials. *J of Dent.* 2014; 42: 895-901.

## 2. The efficacy of two treatments for removing fluorosis stains: A RCT.

Castro KS, de Araújo Ferreira AC, Duarte RM, Sampaio FC, Meireles SS<sup>1</sup>

In the era of a heightened awareness of aesthetics by patients seeking that perfect smile, tooth appearance has been reported to have psychosocial and oral health quality

### ACRONYMS

BL:	bleaching
MAB:	microabrasion
VAS:	visual analogue scale

of life effects on patients. This has been shown to be the case among patients who have dental fluorosis.

The choice of treatment depends on the severity of the disease. For less severe cases, more conservative methods such as enamel microabrasion, tooth bleaching or a combination of these techniques have been used for removing and/or reducing superficial enamel opacity.<sup>1</sup> The microabrasion technique uses an abrasive paste composed of 37% phosphoric acid and pumice that is applied to the affected enamel.

Tooth bleaching techniques have also been used to reduce the contrast between white spotted lesions and the remaining tooth surface. This may be done at home or in the dental office usually using 30% hydrogen peroxide (for in-office) or home bleaching (15% carbamide peroxide). Castro and colleagues (2014)<sup>1</sup> undertook a parallel group randomized clinical trial (RCT) that sought to evaluate the acceptability, efficacy and safety of enamel microabrasion and the association of this technique with at-home tooth bleaching on the removal fluorosis stains.

## METHODS

A hundred and thirty individuals were examined to obtain the calculated sample size of 70 participants who met the inclusion/exclusion criteria. Participants were 15–39 years old, all in good oral and general health. To be included, they had to have at least four maxillary anterior teeth with dental fluorosis ranging from 1 to 7 according to the Thylstrup and Fejerskov (TF) index. Individuals with loss or fracture of some maxillary anterior teeth, with evident malocclusion or with more than 1/6 of their buccal surfaces restored were excluded from this study. Participants under orthodontic treatment, those with previous hypersensitivity or who had nonvital incisors or canines, were smokers, pregnant or lactating women were also excluded.

After the initial examination, the tooth surfaces were cleaned and dried and baseline enamel staining was recorded using a digital camera. The images were loaded into an Image Tool software and two blinded and experienced examiners measured the areas of fluorosis stains ( $\text{mm}^2$ ). These evaluations were carried out after the examiners had undergone calibration training to ensure uniformity in measuring the areas of staining. The examiners achieved interexaminer agreement greater than 70%.

Participants were grouped according to the level of severity of fluorosis and randomized into two treatment groups (n=35): Group I – enamel microabrasion with 37% phosphoric acid and fine-grained pumice; Group II – association of microabrasion and at-home tooth bleaching (10% carbamide peroxide).

Participants from both groups received the microabrasive treatment on maxillary teeth affected by fluorosis stains. Before the start of microabrasion, the mucosa was protected with solid vaseline and isolated using rubber dam. Eyeglasses were also used for eye protection.

For the microabrasive treatment, a layer of microabrasive paste (pumice + 37% phosphoric acid) was applied to the surface using a rubber cup in a slow rotation handpiece for 10 seconds. The excess paste was removed with sterile gauze and the teeth were rinsed for 20 seconds. This procedure was repeated 12 times during each clinical

appointment and was performed in a maximum of two clinical sessions per patient. At the end of the clinical appointment, the microabraded surface was polished with felt discs and polishing paste. Then, after the treated teeth were rinsed and dried, neutral sodium fluoride foam was applied for one min. All the patients received oral and written instructions about dietary restrictions during the course of treatment. Participants also received a toothbrush and a dentifrice without whitening agents (1.500 ppm of fluoride) to standardize the oral hygiene regimen.

A total of 58 clinical sessions of microabrasion were performed for group I (23 patients underwent two clinical sessions of treatment and 12 underwent only one session). For group II, 57 sessions of microabrasion were performed (22 patients underwent two clinical sessions and 13 had only one session of microabrasion).

Two days after the microabrasive treatment, patients in group II had custom trays made for the upper and lower jaws. Patients were instructed to use the bleaching gel simultaneously in both arches for four hours in the evening for two weeks.

Patients were evaluated one month after treatment and the area of fluorosis stains was measured by the same two blinded and experienced examiners following the protocol that was conducted at the baseline evaluations. At the one-month recall, the remaining areas of fluorosis in each patient were compared with the areas at baseline to verify the reduction. The same examiners evaluated dental aesthetic improvement using a visual analogue scale (VAS) ranging from 1 (no improvement in aesthetic appearance or stain not removed at all) to 7 (exceptional improvement in aesthetic appearance or stain totally removed). The same VAS was given to the patients or their parents to assess their opinion about the aesthetic appearance of the teeth after treatment.

Each participant was instructed to record tooth sensitivity and gingival irritation during the treatment and one week after the treatment ended. They used a VAS ranked as follows: 1 (no tooth or gingival sensitivity), 2 (mild sensitivity), 3 (considerable sensitivity) and 5 (severe tooth or gingival sensitivity).

## RESULTS

Forty-eight participants were female (68.6%) and twenty-two male (31.4%) and the mean age was 17.6 (+ 4.0 years). At baseline, treatment groups were balanced with regard to age, gender, education level and TF index. All 70 patients attended the one-month evaluation.

At baseline, means of fluorosis staining areas were  $32.0 \pm 10.1 \text{ mm}^2$  for group I (MAB) and  $31.4 \pm 9.3 \text{ mm}^2$  for group II (MAB + BL) and there was no statistical difference between treatment groups ( $p = 0.8$ ).

At one-month follow-up, both treatment groups showed a significant reduction in stained areas ( $p = 0.0001$ ). However, no significant difference between the groups was observed ( $p = 0.7$ ).

At one-month follow-up, participants from group II were happier with their dental appearance than were participants from group I ( $p = 0.004$ ). Nineteen (54.3%) participants who received microabrasive treatment and 30 (85.7%) who

received microabrasion and home bleaching reported an improvement in appearance of their teeth from moderate to excellent.

Regarding the visual evaluation carried out by the examiners, 24 (68.6%) participants from group I and 26 (74.3%) from group II showed improvement in the appearance of the teeth from moderate to excellent. However, no significant differences between treatment groups were observed ( $p = 0.8$ ).

There was no statistical difference between the groups for tooth sensitivity ( $p = 1.0$ ) or gingival irritation ( $p = 0.3$ ).

## CONCLUSIONS

Patients who received microabrasion only and those that received microabrasion plus at-home bleaching showed equivalent improvements in appearance of their

teeth. However, patients who used home bleaching after microabrasive treatment reported that they were happier with dental aesthetics without any increase in the incidence of side effects such as tooth sensitivity or gingival irritation.

## IMPLICATIONS FOR PRACTICE

It appears that a combination of in-office treatment (enamel microabrasion) and at-home bleaching results in greater patient satisfaction with tooth appearance than enamel microabrasion alone.

## Reference

1. Castro KS, de Araújo Ferreira AC, Duarte RM, Sampaio FC, Meireles SS. Acceptability, efficacy and safety of two treatment protocols for dental fluorosis: A randomized clinical trial. *J of Dent.* 2014; 42: 938-944.

## 3. A New “Silver-Bullet” to treat caries in children – Nano Silver Fluoride: A randomised clinical trial

dos Santos Jr. VE, Filho AV, Targino AGR, Flores MAP, Galembeck A<sup>1</sup>

Dental caries is one of the most common chronic childhood diseases. In both developed and developing countries, there is a significant caries burden among children that goes untreated. The development of anti-caries agents capable of reducing caries rates in underprivileged populations has represented a challenge for dental researchers and clinicians. A variety of chemotherapeutic agents has been tested for preventing and arresting caries, including antibiotics, metal ions and various types of fluoride agents.<sup>1</sup>

Silver diamine fluoride has been effective in arresting caries after a once-a-year application. However, adverse effects have been reported, such as the staining of carious tissue black, due to the oxidation process of ionic silver in the agent, and reversible slightly painful lesions in oral mucosa caused by accidental contact with SDF solution.<sup>1</sup> Nano Silver Fluoride<sup>®</sup> (NSF), a new experimental formulation containing silver nanoparticles, chitosan and fluoride combines preventive and antimicrobial properties and was developed to be an effective anti-caries agent without the potential of staining the porous dental tissues black, as does silver diamine fluoride and amalgam.

dos Santos Jr. and colleagues (2014)<sup>1</sup> reported on a prospective controlled clinical trial that investigated the effectiveness of a new anti-caries agent for preventing and arresting caries in children. The null hypothesis tested was that there were no differences in the effectiveness of Nano silver fluoride solution and water in arresting dentine caries. Materials and methods: This study was conducted between 2012 and 2013 in a poor community in Brazil where the public water supply is not fluoridated. Each child in the study was provided with a toothbrush, fluoridated toothpaste (1000 ppm F) and oral hygiene and healthy diet instructions before their dental examinations. Children were excluded from the trial if they presented syndromes or were undergoing medical treatment for chronic or acute diseases, to avoid bias for reduced salivary flow.

## ACRONYMS

ICDAS II:	International Caries Detection and Assessment System, code 5 ()
NSF:	Nano Silver Fluoride <sup>®</sup>
SDF:	silver diamine fluoride

The investigation comprised primary teeth with active caries lesions at the dentine level. The cavities had an average shallow depth and no pulpal exposure or fistula, corresponding to the International Caries Detection and Assessment System, code 5 (ICDAS II) for occlusal and smooth surfaces. At baseline, the children did not present caries in their permanent teeth. A single calibrated investigator selected and treated the subjects.

This study design was a randomised, controlled, double-blind trial. One hundred thirty decayed primary teeth were randomly divided into two groups: 63 teeth for the NSF group and 67 for the control group. The number of teeth in each group was not similar because each child had more than one tooth included in the study, and the protocol required the same type of treatment for the same mouth, resulting in no statistically significant differences ( $p > 0.05$ ).

The teeth were clinically treated by one examiner. The follow up examinations were performed by another calibrated examiner who was blind to the type of treatment. The children and guardians were also blind to the type of treatment.

For caries treatment in both techniques, no effort was made to remove the caries or unsupported enamel. For both techniques, cotton rolls were used to isolate the teeth from saliva.

The NSF solution was left in contact with the tooth surface for 2 min. Each tooth received two drops of NSF with a micro brush, equivalent to a dose of 10 mg of the solution. For the control group, only one drop of water was given. Both treatments were performed only once in 12 months.

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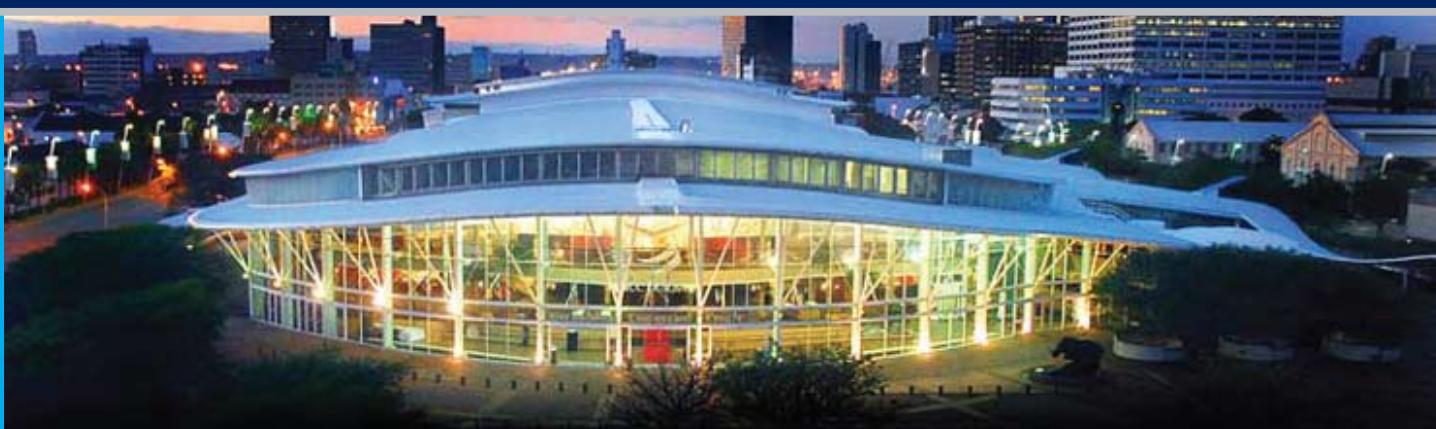
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The teeth were assessed clinically using visual and tactile inspection by a trained blind examiner after a week, and then five months and 12 months later. The ICDAS II criteria were used to classify active caries lesions in both groups. Active caries was recorded when a blunt probe, applied with light force, easily penetrated the dentine, whereas arrested caries was recorded if the dentine could not so be penetrated.

## RESULTS

The sample comprised 60 school children, mean age  $6.31 \pm 0.60$  years; of these, 26 (44.1%) were male, and 33 (55.9%) female ( $p > 0.05$ ). 73% of the treatments were in posterior teeth and 23% were in anterior teeth while 64.6% of the carious lesions involved only one surface and 35.4%, two or more surfaces. The mean dmft (decayed, missing and filled teeth) at baseline was  $4.76 \pm 2.65$  with no statistically significant difference between the two groups ( $p > 0.05$ ).

At one week later, there was no loss of participants or teeth.. At 12 months, and due to exfoliation or extraction, there were 12 losses in the NSF group and 18 in the control group.

After seven days of follow-up, 81% of decayed teeth in the NSF group showed hard arrested dentine, a response which was not observed in the control group ( $p < 0.001$ ). After five months, the NSF group had 72.7% of the teeth showing arrested cavities, and the control group had 27.4% ( $p < 0.001$ ). At 12 months, 66.7% of the lesions in teeth treated with NSF were still arrested, while the control group showed 34.7% ( $p=0.003$ ). The preventative fraction showed that the use of NSF decreased by 81%, 62.5% and 50% the risk of caries remaining active in the intervals of seven days, five months, and 12 months, respectively, when compared with the control group. The number of need to treat (NNT) at five months was two; at 12 months, the number was three.

## CONCLUSION

NSF was demonstrated to be effective in arresting caries in children in poor communities.

## IMPLICATIONS FOR PRACTICE

This intervention holds promise for public health programs to reduce or slow the progression of carious lesions in primary teeth.

### Reference

1. dos Santos Jr. VE, Filho AV, Targino AGR, Flores MAP, Galembeck A, *et al.* A New "Silver-Bullet" to treat caries in children – Nano Silver Fluoride: A randomised clinical trial. *J Dent.* 2014; 42: 945-951.

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