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What's new for the clinician – summaries of recently published papers (June 2023)

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1. Caries-preventive effectiveness of two different fluoride varnishes: A randomised clinical trial in patients with multibracketed fixed orthodontic appliances

There has been a huge increase in the number of adolescents and young adults on fixed orthodontic treatment for periods longer than 1 year. Often the desired outcome of having a perfectly aligned set of teeth has been marred by the significant increase in the presence of white spot lesions (WSLs). These lesions are commonly observed on the labial surfaces of the maxillary incisors adjacent to the brackets, thus jeopardising the final aesthetic result of the treatment and having limited chances of improvement even after the orthodontic appliances are removed.[1] The incidence and prevalence of WSLs during multibracketed fixed orthodontic treatment are relatively high with a wide range, and the problem is quite alarming for the orthodontists and patients.[1] Patients with multibracketed fixed orthodontic appliances have been considered to be at moderate to high risk for caries and various preventive strategies have been examined to prevent the development of WSLs, among which topical fluorides have been studied widely and found to be efficacious in reducing the incidence of WSLs around the brackets.[1] Among the various forms of topical fluorides studied, varnishes are deemed critical for preventing the WSL formation. The efficacy of topical fluoride varnishes has been established through multiple systematic reviews[1] with a preventive fraction of about 43% and 37% in permanent and primary dentitions respectively, compared with that in the placebo or no treatment.

Among the fluoride varnishes available commercially, Duraphat® varnish (Colgate-Palmolive) containing 5% sodium fluoride (NaF) (2.2% fluoride) is one of the most commonly used varnishes and has been reported to exhibit a substantial caries-inhibiting effect in both primary and permanent dentitions.[1] Clinpro™ white varnish (3M ESPE), another professionally applied topical fluoride agent commercially available, contains tricalcium phosphate (TCP) in addition to NaF and allows a higher concentration of calcium phosphate available for deposition on the enamel surface. It also contains a protective fumaric acid barrier to facilitate the coexistence of the ions of calcium and fluoride during storage, which breaks upon contacting with saliva, thus releasing the ions for effective remineralisation of the tooth.

Sardana and colleagues (2023)[1] reported on a randomised clinical trial that sought to compare the effectiveness of a traditional NaF varnish [Duraphat®] versus an advanced novel NaF varnish containing TCP [Clinpro™] in preventing WSLs among patients undergoing multibracketed fixed orthodontic treatment. The null hypothesis tested was that there is no difference between NaF varnish containing TCP and conventional NaF varnish in preventing WSLs during multibracketed fixed orthodontic treatment compared with standard oral hygiene instructions.

MATERIALS AND METHODS

The trial was conducted in Hong Kong where the communal drinking water is fluoridated at a concentration of 0.5ppm. Subjects about to undergo fixed orthodontic treatment were invited to participate in this study. Only those participants from whom informed written consent was obtained directly from the participants or their parents (if the participants were younger than 18 years) were included in the study. Participants were excluded if they had: history of fixed orthodontic treatment, any developmental defects of enamel on labial surfaces of teeth, any dental anomalies or direct/indirect labial restorations on teeth, history of long-term antibiotic usage, untreated cavitated lesions and/or plaque levels >25%.

The sample size required for this trial was calculated to be 90 (30 per group) but the final sample size was inflated to 99 to compensate for any dropouts.

This study was a single-centre equivalence randomised controlled trial with three parallel arms in which individual participants, not parts of the mouth, served as the unit of randomisation. Ninety-nine participants were randomly allocated into the following intervention groups:

Group A – control receiving standard oral hygiene instructions (OHI) every 3 months (n=33);

Group B – Intervention 1 received standard OHI along with the application of topical fluoride varnish containing 5% NaF (Duraphat® varnish) every 3 months (n=33); and

Group C – Intervention 2 received standard OHI along with the application of topical fluoride varnish containing 5% NaF + TCP (Clinpro™ white varnish) every 3 months (n=33).

The study participants were recruited after orthodontic assessment and screening had been completed for baseline assessment. One calibrated examiner performed the complete clinical examination using a dental mirror and a blunt straight probe. The examiner detected and scored WSLs based on the index proposed by Gorelick et al.[1] for 6 teeth (right maxillary canine, right maxillary lateral incisor, right maxillary central incisor, left maxillary central incisor, left maxillary lateral incisor and left maxillary canine): 0=no lesion; 1=slight lesion (linear shape); 2=severe lesion (band shape); and 3=cavitation.

Following the clinical assessment, standard digital photographs (frontal and lateral views of the teeth) were taken and stored for later comparisons. All the photographs

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were taken by the same digital camera (Nikon D5300 Digital Camera) by the same examiner to ensure that the reflection of the flash on the tooth was absent or minimal to avoid any misdiagnosis of flash as WSLs. The photographs in the JPEG (Joint Photographic Experts Group) format were later randomised and examined in a room with minimal light by two examiners blinded to the group interventions. The three photographs (one frontal view and two lateral views) were paired and evaluated to minimise any further error due to flash, as the three photographs provided different angles. The scoring of the photographs was performed according to the WSL index by Gorelick et al.

The visual examination of the tooth surfaces was followed by assessment using DIAGNOdent Pen 2190 (KaVo). Before any DIAGNOdent reading was taken, the teeth were gently cleaned for visible debris or plaque and dried to avoid false readings. Three readings were taken at the same appointment by a single investigator for the labial surface of each tooth (right maxillary canine, right maxillary lateral incisor, right maxillary central incisor, left maxillary central incisor, left maxillary lateral incisor and left maxillary canine) using tip number 2 of the DIAGNOdent pen, and the value of reliability was calculated. The maximum reading was recorded by tilting the DIAGNOdent probe at various angulations so that all the labial surfaces were covered. Three readings were taken for each tooth to ensure reliability, but the mean of the three readings was considered as the DIAGNOdent value of the tooth. Finally, the mean DIAGNOdent score of the patient was calculated depending on the number of teeth examined, and it was considered to be a final independent variable in the statistical analysis.

All the participants received oral prophylaxis with a rubber cup and fluoride-free pumice paste before the commencement of fixed orthodontic therapy. After the baseline assessment, the mid-buccal enamel of all the teeth was etched, and .022 edgewise orthodontic brackets were bonded. The bonding of the brackets was performed by four different orthodontists who were not involved in other parts of the trial and were masked to the intervention.

Immediately after bonding the brackets, all the participants from Group B received a topical application of Duraphat® varnish (containing 5% NaF) and participants from Group C received a topical application of Clinpro™ white varnish (containing 5% NaF and TCP). The respective topical fluoride varnish was applied on labial and palatal surfaces of all the teeth (including adjacent to the bracket bases) by an independent operator and allowed to dry for 2 min. Clinpro™ white varnish was applied using the brush supplied with the disposable packet for each patient, and Duraphat® varnish was applied using a similar brush as there was no brush provided with the pack. The patients were advised to avoid eating and drinking for 2 hours after the varnish application and after brushing their teeth until the following day. The participants allocated to Group A only received standard OHI. The patients were made aware of the aims and objectives of the study before the start; they were, however, not aware of their respective groups or other groups' allocation. All the interventions were repeated at quarterly intervals for the duration of follow-up and were coordinated with the patients' appointment with the orthodontist.

All the participants also received the diet instructions, standard oral hygiene instructions (OHI), including brushing methods during orthodontic treatment, and advice on toothbrushing twice daily with a fluoride dentifrice. To standardise the use of oral hygiene aids, all the participants received a standard dentifrice containing NaF (with 1500 ppm F) and a toothbrush. The compliance was checked by asking the patients to return the used toothbrushes and dentifrice tubes every 3 months and replace them with the new ones during the quarterly follow-up visits. To reduce the effect of confounding factors, the participants were asked not to use any other oral hygiene aids and fluoride-containing products until the completion of the study. Scaling was provided ad libitum to ensure an optimal periodontal status during orthodontic treatment; the scaling was, however, only limited to other areas of the oral cavity outside the area of interest of the outcome (ie the maxillary anterior area).

The follow-up evaluation of WSLs was performed at baseline (before bonding), post-bonding (after bonding of the maxillary arch) and every 6 months until 18 months using clinical examination, photographic examination and DIAGNOdent assessment. The same examiner performed all the assessments for detecting WSLs by direct visual examination and assessment of the labial surfaces of the teeth with DIAGNOdent pen; two examiners masked to the group interventions, however, evaluated the clinical photographs at the end of the trial.

The primary outcome was the odds of developing WSLs during orthodontic treatment among the participants undergoing multibracketed fixed orthodontic treatment using clinical visual assessment, photographic assessment and changes in the mean DIAGNOdent scores of the patients over 18 months post-bonding of the maxillary teeth. The secondary outcome was the distribution of WSL scores using visual assessment and photographic assessment in all three study groups at an 18-month follow-up.

RESULTS

Eighty-two patients were followed up until 18 months, and the remaining 17 were lost to follow-up due to the impact of the COVID pandemic. The distribution of age, gender, DMFT, WSLs and mean plaque index at baseline was similar across the three groups. It was observed that by the end of 18 months, 80.9% of the examined teeth were free from any WSLs in Group A, 90.7% in Group B and 88.1% in Group C when assessed clinically. The trend was almost similar when the teeth were assessed by photographs, with 81.6% being free of WSL in Group A, 89.5% in Group B and 85.7% in Group C at the end of 18 months. Also, there were a higher number of WSLs (score 2, severe) and cavitation (score 3) in Group A. The results were consistent with DIAGNOdent readings as Duraphat® provided slightly better protection than Clinpro™, followed by standard OHI.

The distribution of mean and median DIAGNOdent scores was also not significantly different across the three groups at various time intervals; the mean DIAGNOdent scores in the three groups, however, increased with the progress of orthodontic treatment. The values of the intra-class coefficient to measure the reliability of the three readings were found to be in the range of 0.66 (moderate) to 0.94 (excellent), depending on the teeth and time point. The values of sensitivity and specificity of DIAGNOdent using

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clinical diagnosis as a standard to detect WSLs at 6, 12 and 18 months were 0.783 and 0.828, respectively (p>0.05).

A logistic regression model with the intervention group, time intervals and intervention* time interaction was used for the evaluation of WSLs by clinical assessment and photographic assessment. Only the effect of time was, however, found to be significant ($p < .001$), whereas there was no significant difference among the three intervention groups ($p=.305$).

When diagnosed clinically, the odds of developing WSLs were reduced by 54% in Group C (odds ratio: 0.456, 95% C.I.: 0.166-1.255, $p=.129$) and 41% in Group B (odds ratio: 0.585, 95% C.I.: 0.180-1.900, $p=.373$), although the results were not statistically significant. Similar results were obtained in photographic evaluation ($p=.599$) among the three groups. The odds of developing WSLs increased significantly over time when evaluated clinically or photographically. There was no significant difference in the presence of WSLs among the three groups.

CONCLUSION

The study failed to demonstrate that the quarterly application of both the study varnishes with OHI provided additional benefits compared with standard OHI alone in preventing WSLs, taking the effect of time of follow-up into consideration. There were higher odds of developing WSLs with an increased duration of orthodontic treatment.

Implications for practice

Patients with multibracketed fixed orthodontic treatment are at an increased risk of developing enamel demineralisation. There are higher odds of developing WSLs with an increased duration of orthodontic treatment. The regular application of sodium fluoride varnish and sodium fluoride varnish containing TCP was found to have no statistically significant additional benefits compared with standard oral hygiene instructions in preventing WSLs over 18 months after the placement of brackets.

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2. Efficacy of two behavioural management techniques during inferior alveolar nerve block administration in pre-school children: a randomised clinical trial

The fear of dental injections among children is a well-known phenomenon in dentistry and often leads to non-cooperative behaviours during dental treatment. The Inferior alveolar nerve block (IANB) injection, frequently used for local anaesthesia in the mandibular jaw, can induce negative behavioural reactions and has been reported to be associated with increased levels of pain perception and dental anxiety in patients.[1]

Behavioural management techniques are widely used by dentists to alleviate discomfort caused by local anaesthesia injections and have been found to have good efficacy in the management of paediatric pain and distress when using psychological interventions.[1] Distraction techniques can shift the child's attention from perceived disagreeable procedures with strong published evidence in supporting the efficacy of these techniques for the reduction of pain and stress in children requiring treatment measures utilising needles.[1] Some randomised clinical trials have also demonstrated that distraction techniques are effective in managing dental anxiety, negative behaviour and pain in children older than 6 years of age receiving IANBs.[1]

IANBs can be a painful and stressful procedure for children, and a behavioural technique that prevents the patient from seeing the syringe carpule and dental needle by discreetly covering their vision and providing verbal explanations of the procedures can help minimise their anxiety. The current trial sought to use the hands-eyes-mouth distraction technique (HEM-DT) as a distraction technique, with the aim of shifting the patient's focus away from the dental needle puncture and preventing them from seeing the needle by asking them to perform a sequence of game-like movements. Therefore, the aim of this study was to compare the efficacy of the HEM-DT in reducing pain and anxiety levels and improving the behaviour of pre-school children during IANB administration to that of the covering patient's vision technique (CPV-T).

MATERIALS AND METHODS

This randomised clinical trial consisted of parallel groups and complied with the CONSORT regulations. The sample size of 52 (26 in each group) was calculated considering anxiety as the primary outcome.

A total of 63 children aged between 3 and 5 years 11 months were screened by an external researcher who reviewed their medical history and health status and carried out complete extra- and intra-oral examinations using odontograms, any necessary radiographic evaluations, calculation of the Silness-Löe oral hygiene index score and behavioural assessments.

The study included 52 children who spoke/understand Spanish/Valencian and had primary dentition with at least one inferior primary molar exhibiting a deep carious lesion with pulpal involvement requiring treatment under an IANB. Children exhibiting disruptive behaviour, intellectual disabilities, allergy to lidocaine, a history of previous treatment with local anaesthesia and systemic and/or neurological diseases were excluded from this study.

Randomisation was carried out using a sequence of numbers that were put into opaque envelopes and sealed by the external researcher. These envelopes were opened by the operator at the time of anaesthesia administration. Based on this, the study sample was divided into two groups based on the distraction technique used, as follows:

The hands-eyes-mouth distraction technique (HEM-DT) group (G1; n=26 children): In this technique, the operator asked the patient to perform a sequence of game-like movements to divert their attention away from the needle puncture and prevent them from seeing the needle. The sequence consisted of the child putting his hands on his belly, opening his mouth and closing his eyes for 3 sec. Prior to injection of the local anaesthetic, the operator taught the child a "game" for when "the sleepy water" was used, and the sequence was repeated once or twice until the patient had mastered it. Thereafter, the entire sequence was repeated with the same level of calmness and game-like tone of voice during IANB administration. Counting to three, the operator had 3 sec to puncture the area to be anaesthetised by introducing the needle no more than 1mm into the oral mucosa. Then, after number three, the assistant

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removed the light, the patient opened their eyes and the operator immediately began to explain to the patient that the "sleepy water" must be put in very slowly so that it did not bother them and their cheek "fell asleep".

Covering patient's vision technique (CPV-T) group (G2; n = 26 children): In this group, the operator explained to the child in a kind and calming way that "they would make their tooth go to sleep". During administration of IANB, the operator discreetly obscured the child's field of vision with a hand to prevent them from seeing the injection device and the needle, all the time maintaining eye and verbal contact with the patient and explaining that their cheek would "fall asleep".

For dental anxiety levels, the previously validated Facial Image Scale (FIS) comprising a line of five faces with expressions ranging from "very happy" to "very sad" (scores 1 and 5, respectively) was used to self-report dental treatment anxiety. Prior to treatment when the child was still in the waiting room, the external researcher asked them to indicate the face that best represented how they felt at the time. Heart rate (HR), a physiological indicator of anxiety, was recorded using a paediatric finger pulse oximeter on the index finger of their left hand. The child's hand was gently held during measurement to prevent accidental movement and minimise the risk of measurement errors. HR was recorded at baseline (before the injection); 30, 60, 90 and 120 sec into administration of the injection; and 60 sec after administration of the injection.

The control session was carried out seven days after administration of IANB, where the dental anxiety levels in groups G1 and G2 were assessed by the external researcher in the waiting room. The Frankl Scale was used to assess the behaviour exhibited by the patient during administration of anaesthesia. The scale is organised into four behavioural categories, as follows: (1) definitely positive, (2) positive, (3) negative and (4) definitely negative.

The Wong-Baker Scale was used to record the level of pain felt by the patient during administration of anaesthesia. This scale consists of a line of six faces with expressions ranging from "very happy" to "very sad" (scores 1 and 6, respectively). The child was asked to select the one that best represented how they felt during administration of the anaesthetic.All dental treatments were provided by the same experienced paediatric dentist (operator) over two sessions [treatment session: baseline/IANB; control session: 7 days after administration of IANB] carried out in the presence of the children's parents.

RESULTS

The study sample included 52 children (38 boys and 24 girls) aged between 3 and 5 years 11 months (mean age: 4.015; standard deviation: 0.809) who were divided into two groups (n = 26 children per group; G1:18 boys and 8 girls; G2: 10 boys and 16 girls). Regarding the distribution of the age groups, 30.76% (n = 16) of the study sample were 3 years old (G1:8; G2:8), 36.53% (n = 19) were 4 years old (G1:10; G2:9) and the remaining 32.69% (n = 17) were 5 years old (G1:8; G2:9). Twenty-four of the 52 IANBs administered were on the right side, while the remaining 28 were on the left side.

Although both groups exhibited low anxiety levels at baseline, the G1 group exhibited significantly higher values compared to the G2 group (G1: 1.38 ± 0.140; G2: 1.00 ± 0.00; p value = 0.01). The mean HR recorded at baseline were within the range considered normal (80-130 beats/min) for the age range of the study sample in both groups, and no significant differences in baseline HR were observed (G1:99.5 ± 11.82; G2:103.81 ± 13.84; p value = 0.233).

A significant increase in HR between the first and last measurements was observed in both groups (p value < 0.001). Moreover, the HR decreased during IANB administration in G1 (HR120 s – baseline HR = – 3.73) and increased in G2 (HR120 – baseline HR = 0.84).

No significant changes in HR were observed in either study group when examining children aged 3 years (p value > 0.05). When examining children in the 4-year age group, no significant changes in HR were observed in the G1 group during the first 60 sec of injection, while the G2 group exhibited a significant increase 30 (p value = 0.037) and 60 sec (p value = 0.019) into IANB administration. Similar findings were observed upon comparison of the baseline and final HRs in children aged 5 years (p value = 0.005). However, regardless of age, the mean HR was significantly lower in the G1 group compared to the G2 group throughout the duration of the procedure [HR30: p value = 0.009, HR60: p value = 0.008, HR90: p value = 0.009 and HR120: p value = 0.033]. No statistically significant differences in mean final HR were observed between the two groups (p value = 0.076). Both groups exhibited low pain levels (G1: 1.31 ± 0.884; G2: 1.46 ± 1.067) and no statistically significant differences were observed (p value = 0.348). Moreover, the patient's behaviours also did not significantly differ between groups G1 and G2 (p value = 0.474).

The mean dental anxiety levels at baseline and after 7 days were low in the G1 group and these values did not differ significantly (p value = 0.798). In the G2 group, the mean dental anxiety levels after 7 days were significantly higher (p value = 0.039) than those observed at baseline. No statistically significant differences in mean dental anxiety levels after 7 days were observed between groups G1 and G2 (p value = 0.936). Assessment of the study sample as a whole as well as by group showed that neither age nor gender were significantly associated with initial or final anxiety levels, self-reported pain or behaviour (p value > 0.05).

CONCLUSION

The findings of this study suggest that the hands-eyes-mouth distraction technique (HEM-DT) was more effective in controlling the anxiety levels of pre-school children during administration of IANB when compared to the Covering patient's vision technique (CPV-T). However, both techniques were equally effective in controlling pain and maintaining cooperative behaviour in the patient.

Implications for practice

While both techniques were equally effective in controlling pain and maintaining cooperative behaviour in the patient, for patients who demonstrate a high level of anxiety, the HEM-DT was superior.

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