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Clinical role of sodium calcium phosphosilicate gel preparations in the prevention of enamel demineralisation in orthodontic treatment

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Enamel demineralisation is a common and complex local problem in orthodontic treatment, this study evaluated the preventive effect of sodium calcium phosphosilicate gel preparations on enamel demineralisation during orthodontic treatment to provide a basis for clinical prevention. 128 patients undergoing orthodontic treatment from The First People's Hospital of Zunyi between January 2021 and January 2023 were divided into CT and CC groups. Both groups were treated with conventional treatment, the CC group was added treatment with sodium calcium phosphosilicate gel preparation. The enamel demineralisation index (EDI), plaque index (PLI), modified bleeding index (mBI), enamel demineralisation chalky lesions and incidence of demineralisation were mainly assessed in both groups. Secondary outcomes included quality of life scores, complications and adverse reactions incidence. After treatment, the indicators of both groups were remarkably different comparing with pre-treatment (P<0.05). The EDI, PLI, mBI, enamel demineralisation chalky lesion condition, the incidence of demineralisation complication and incidence of adverse reactions in the CC group were below the CT group, and the quality of life scores were above the CT group (P<0.05). sodium calcium phosphosilicate gel preparations are effective in preventing the occurrence of enamel demineralisation during orthodontic treatment and improving the quality of life of patients.

Keywords: Sodium calcium phosphosilicate gel, Orthodontic adjuvant therapy, Enamel demineralisation prevention, Demineralisation index, Plaque control, Orthodontic enamel protection

Introduction

Teenage malocclusion, or misalignment, is relatively common in the field of dentistry. With the improvement of living standards and the public's concern for oral health, the problem has received more and more attention[1,2]. Orthodontic treatment is a commonly used method for correcting malocclusion in adolescents[3,4]. The principle is to use orthodontic appliances to apply force and move teeth to align teeth and improve bite[5]. Ceramic brackets enhance orthodontic aesthetics. But it is brittle and prone to breakage, and the price is relatively high[6]. Invisible braces have become a new choice for orthodontics due to their advantages of beauty, comfort, and easy removal, which can reduce oral hygiene risks[7,8]. But the cost of this orthodontic appliance is high and its applicability is limited[9]. Orthognathic surgery is mainly used to correct skeletal jaw deformities in adolescents, such as mandibular protrusion and severe maxillary protrusio[10].

Prevention and treatment of enamel demineralization are crucial in orthodontic treatment[11]. Fluoride preparations can enhance enamel's resistance to acidity, but excessive use can easily lead to dental fluorosis[12]. Calcium phosphate sodium silicate gel preparation is a new type of enamel demineralization prevention product, which can provide calcium phosphate silicon mineral ions[13,14]. Studies have confirmed that sodium calcium phosphate silicate gel can increase the mineral content of enamel and alleviate demineralizatio[15]. Compared with traditional fluoride preparations that are prone to dental fluorosis due to excessive use[16], this gel has more significant safety advantages due to its natural ingredients, good biocompatibility and non-toxic side effects[17].

The purpose of this study was to observe the effect of calcium sodium phosphosilicate gel preparation on preventing enamel demineralization in adolescent orthodontic treatment through clinical control analysis. The study will quantitatively evaluate the improvement effect of the gel on enamel demineralization index and other indicators, analyze its specific impact on plaque index and other indicators, and compare the occurrence of complications, adverse reactions and improvement effect of life quality of the two groups of patients. The results of this study should provide data-driven support

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for the development of orthodontic enamel protection scheme, and clarify the clinical application value of the gel to optimize the oral health management of patients.

Materials and Methods

Study design

The present study was a systematic clinical retrospective study aimed at analysing the clinical role of sodium calcium phosphosilicate gel preparations in the prevention of enamel demineralisation in orthodontic treatment. Patients undergoing orthodontic treatment from The First People's Hospital of Zunyi (The Third Affiliated Hospital of Zunyi Medical University) between January 2021 and January 2023 were divided into CT (Conventional treatment) and CC (Calcium phosphate gel combined with conventional treatment) groups according to treatment modalities. Both groups were treated conventionally (Perform routine acid etching on the surface of teeth, bond straight arch brackets, thoroughly remove residual adhesive around the brackets, and guide patients to clean their teeth and brackets twice a day with an orthodontic toothbrush, with a focus on removing food residue at the edges of the brackets and gums) and the CC group was treated with the addition of calcium sodium phosphosilicate gel preparation. A total of 136 patient's' information was collected, 133 cases were included after exclusion, 5 cases were lost during the follow-up period, and a total of 128 cases were finally analysed. In this study, the therapeutic effect of calcium sodium phosphosilicate gel preparation on enamel demineralisation in orthodontic treatment was comparatively analysed to provide a scientific basis for clinically relevant drug treatment protocols. The flow chart of this study design is illustrated in Fig. 1.

Main materials

Calcium Phosphosilicate SodiumGel, Beijing Daqing Bio- technology Co. Ltd, Approval No.: 2012 No. 2630436, specification: 15g/tube, Current Medical Device Registration No.: Jing Xie Zhu Zhun 20222170393. Fluoride toothpaste, Yunnan Baiyao Group Co. Ltd, batch number: 6901070600890, specification: 65g/tube. Orthodontic Bracket, Zhejiang Xinya Medical Technology Co., Ltd, Medical Device Production License No.: Zhe Yao Xie Sheng Xu 20100135. Bonding agent, Hangzhou Xihu Biomaterials Co., Ltd, Medical Device Registration No.: Zhe Xie Zhu Zhun 20162171003.

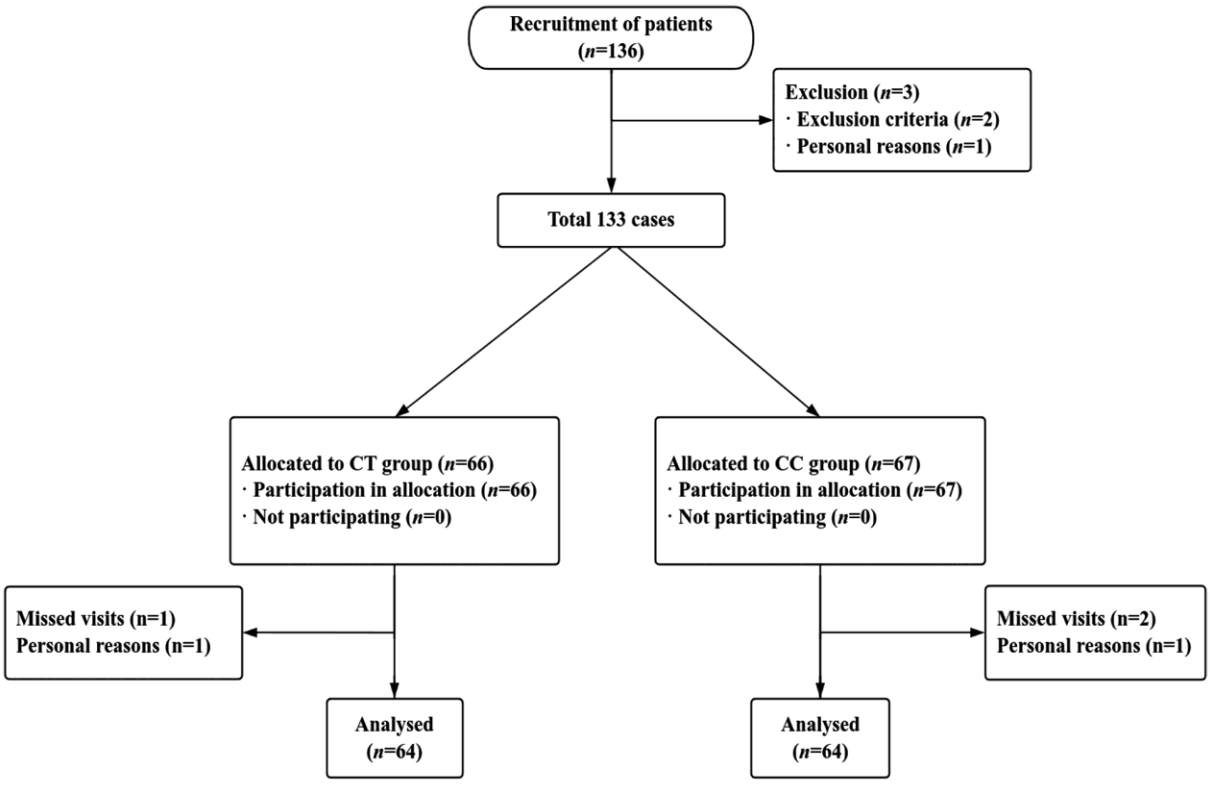

Fig. 1 — Flow chart for screening and inclusion of cases in retrospective studies.

Inclusion and exclusion criteria

Inclusion criteria

1 Patients who underwent orthodontic treatment in our hospital.
2 Age 13 to 25 years old.
3 No recent history of painkiller or desensitising toothpaste application.
4 Patients were treated with fixed orthodontic treatment using the straight arch orthodontic technique.
5 The patients showed good compliance and were willing to cooperate with the treatment plan developed in the study.
6 The patients' overall mental status was good, they were basically healthy, and they could clearly or vividly express their complaints about their symptoms and respond well to relevant questions from the healthcare professionals.
7 Patients who could tolerate the drugs involved in this study.
8 Patients and their family members were informed and agreed to the presented study and signed the patient informed consent form.

Exclusion criteria

1 Patients with enamel hypoplasia, dental fluorosis, and periodontal disease.
2 Patients with dental labial caries, dental implant restorations.
3 Patients who are allergic to fluoride and alcohol.
4 Patients with combined dental caries, enamel defects and other oral diseases;
5 Ultrasonography showing abnormal pulp vitality.
6 Presence of congenital dysplasia of the hard tissues of the teeth.
7 Patients with combined haemorrhagic and coagulation disorders, or with severe liver or renal function defects, severe cardiovascular diseases or other more serious diseases.
8 Combined chronic infectious diseases.
9 Patients who have been involved in clinical drug trials or clinical studies.
10 Requesting to stop treatment or voluntary withdrawal for personal reasons.
11 Other conditions that, in the opinion of the study physician, should not be included.
12 Other circumstances affecting the indicators of follow-up observation.

Ethical statement

This study was conducted in accordance with the Declaration of Helsinki and the ethical guidelines of the hospital and was approved by the hospital ethics committee.

Intervention

All patients were given a straight arch fixed orthodontic treatment in which the straight arch brackets were glued in place after routine acid etching of the tooth surfaces and the adhesive around the brackets was thoroughly removed. The patients were instructed to clean the teeth and brackets every morning and evening using orthodontic toothbrushes and toothpaste, and to pay attention to cleaning the brackets and food debris attached between the gingiva and so on during cleaning. Follow-up appointments were made every 3 to 4 weeks.

CT group patients: brushing with fluoride toothpaste for 3 min 3 times a day. The treatment cycle was 12 weeks.

CC group patients: use a cotton swab dipped in calcium phosphate gel after brushing with fluoride toothpaste and apply it to the tooth surface around the brackets for 2 min at a time. Care should be taken not to rinse or eat for the following 2 h. The treatment cycle was 12 weeks.

Observation indicators

Main indicators

Enamel demineralisation index

The enamel demineralisation index (EDI) value was calculated based on the presence or absence of chalky discolouration on the tooth surfaces of the eight upper teeth[18]. The tooth surfaces were divided into four regions centred on the crown, gingival, symphyseal, proximal-medial and distal-medial, and the degree of demineralisation was classified into four levels. The absence of chalky discolouration on the enamel surface was noted as degree 0, enamel surface discolouration <50% as degree 1, enamel surface discolouration >50% as degree 2, and surface discolouration occupying the area where it is located or the presence of caries as degree 3. The demineralization performance of each level is calibrated based on clinical photos of representative patients' teeth (Supplementary Fig. 1), clarifying the criteria for determining each level. EDI value = the sum of demineralisation scores of each part of the observed tooth as a percentage of the area of the observed tooth.

Plaque index

After drying the tooth surface, the plaque index (PLI) was calculated by direct visual observation of

the amount of plaque on the tooth surface near the gingival margin in conjunction with probing[19]. A score of 0 indicates no plaque near the gingival margin, 1 indicates that plaque is visible only when a probe is used to cross it, 2 indicates a moderate amount of plaque on the gingival margin or tooth surface, and 3 indicates a large amount of plaque in the gingival sulcus or gingival margin area and tooth surface.

Modified bleeding index

The periodontal condition of the patients was probed using a periodontal probe and the modified bleeding index (mBI) was scored [20]. The presence of spontaneous bleeding or heavy bleeding of the patient was scored as 3. The presence of bleeding in the patient, presenting as linear bleeding in the gingival sulcus was scored as 2. The presence of bleeding in the patient, presenting as isolated spot bleeding was scored as 1. The absence of bleeding was scored as 0.

Enamel demineralisation chalky lesions

To check for enamel demineralisation chalky lesions after treatment, the patient was seated in a special cranial fixture chair, and a digital camera was placed perpendicular to the surface of the patient's enamel demineralisation chalky lesions, and standardised intra-oral images were taken, and chalky lesions were scored according to the area of the patient's enamel demineralisation chalky lesions, using the Image J software. The total score ranged from 0 to 100, with a score of 0 for a chalky enamel surface and a score of 100 for a smooth, clear, chalk-free enamel surface. The lower the score, the more severe the chalky enamel demineralisation.

Incidence of demineralisation

The incidence of demineralisation after treatment in both groups was counted, enamel demineralisation rate = number of demineralised teeth/total number of teeth × 100%.

Secondary indicators

Quality of life

It was assessed at 1 year after the treatment by using the Cohort of Oral Health Impact Scale for Adolescents (COHIP)[21]. The scale consists of five items, including oral health, functional health, and self-image, with a total score of 136. The score was positively correlated with patients' quality of life.

Complications

The occurrence of complications in both groups was recorded, including decreased bracket adhesion, worsening enamel demineralisation, formation or increase of white spots, gingival redness and swelling, gingival bleeding, oral odour, pharyngitis, and so on.

Incidence of adverse reactions

The occurrence of adverse reactions during treatment in both groups was recorded, including itching, rash, redness and swelling of the oral mucosa, dentin sensitivity, abnormal salivary secretion, gingivitis, and abnormal taste sensation in the gingiva.

Follow-Up Visits

This study was primarily scheduled for a 12-month post-treatment follow-up to assess the durability of the effects and to address any potential adverse reactions or problems.

Sample size calculation

Power analysis was performed to calculate the sample size according to the G*Power 3.1.9.7 computer software to determine the sample size required to detect a statistically significant difference. Based on the primary outcome of clinical efficacy, taking into account an alpha level of 0.05 and 85% efficacy, we calculated that a sample size of 59 patients was required for each group. Considering the potential uncertainties, a sample size of 64 cases per group was chosen for this study, and we believe that the sample size of this study allows for reliable conclusions to be drawn.

Statistical methods

SPSS 28.0 statistical software was used for data analysis. Lucidchart was used to draw flow charts. The data in this study were tested for normal distribution. Baseline characteristics were described as number of persons and variables (expressed as $\bar{x}\pm s$). The results of EDI, PLI, mBI, and COHIP scores in the results are expressed as $\bar{x}\pm s$. Enamel demineralisation chalky lesions were scored using using Image J software and results are expressed in $\bar{x}\pm s$. Comparison between both groups was tested using independent samples *t*-test. The incidence of demineralisation, complications and adverse effects in the results were expressed as proportions (%). Comparison between both groups was analysed using x^2 test. All statistical tests were two-sided and $P<0.05$ indicated statistically significant differences.

Results

Basic information

A total of 128 patients undergoing orthodontic treatment at The First People's Hospital of Zunyi

(The Third Affiliated Hospital of Zunyi Medical University) between January 2021 and January 2023 were included in this study. They were divided into CT group (n=64) and CC group (n=64) with the aim of evaluating the clinical efficacy of sodium calcium phosphosilicate gel formulation in preventing enamel demineralisation in orthodontic treatment. Prior to inclusion in the study, baseline demographic characteristics, such as age and gender; and baseline clinical characteristics, covering key information such as oral hygiene practices and initial periodontal health status, were collected and recorded in detail for both groups. In the statistical analysis stage, independent samples t-test was used for continuous variables (e.g., age), and chi-square test was applied for categorical variables (e.g., gender). After rigorous statistical processing, the results (Table 1) clearly showed that none of the baseline characteristics differed statistically between the CT and CC groups (P>0.05). As a result, demographic factors and other clinical confounding factors were effectively controlled during the course of this study, thus minimising their interference with the results, and effectively guaranteeing the scientific and clinical guidance value of the study conclusions.

EDI

The EDI scores of CT and CC groups at different time points were analysed, and the results (Fig. 2) showed that the EDI scores in CT group and CC group before treatment, and there was no significant difference in both groups (P>0.05), which indicated that the two groups of patients had a good comparability at baseline. After treatment, the EDI scores of both groups decreased over time, showing a trend of reduced demineralisation, but the difference between the groups was remarkable. The EDI scores of the CC group were remarkably below the CT group at all time points after treatment (P<0.05), suggesting that the intervention in the CC group was more

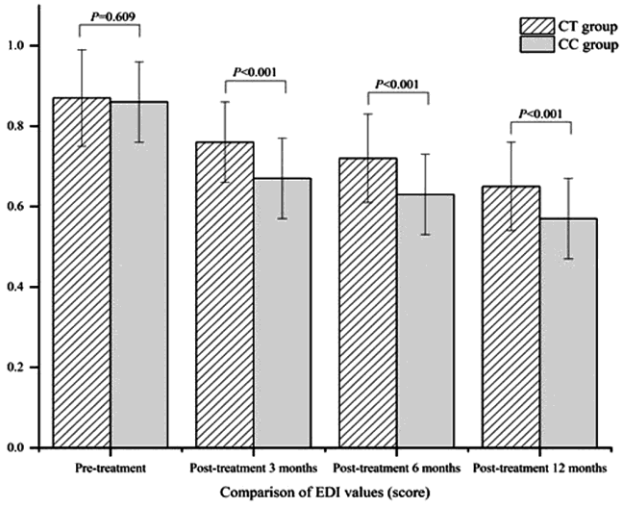

Fig. 2 — Comparison of EDI values (score).

Table 1 — Patient demographics and baseline disease characteristics

Parameter	CT group (n=64)	CC group (n=64)	t/x^2	P
Age (year)	17.28±2.03	17.03±2.19	-0.670	0.504
Sex (male/female)	30/34	32/32	0.180	0.671
Height (cm)	150.62±4.39	150.18±3.67	-0.615	0.540
Weight (kg)	63.83±4.38	63.81±5.43	-0.023	0.982
Body mass index (kg/m^2)	21.56±2.29	21.37±1.91	-0.510	0.611
Ethnicity (Han/Minority)	60/4	58/6	0.649	0.421
Regular consumption of sweets (Yes/no)	50/14	49/15	0.029	0.866
Total teeth (pcs)	1358	1361	-	-
PLI (score)	1.61±0.46	1.63±0.54	0.226	0.822
Saliva flow rate (mL/min)	0.84±0.20	0.83±0.24	-0.256	0.798
History of fluoride application (Yes/no)	22/42	21/43	0.022	0.881
Estimated treatment period (months)	18.70±2.71	18.49±3.14	-0.405	0.686
Extractions (Yes/no)	28/36	30/34	0.181	0.670
Bracket bonding position (maxillary anterior/ mandibular anterior)	52/12	50/14	0.276	0.599
Fluoride toothpaste use (Yes/no)	64/0	64/0	-	-
History of systemic diseases (Yes/no)	0/64	0/64	-	-
Temperature (℃)	36.53±0.41	36.46±0.40	-0.978	0.330
Respiration (breaths/min)	17.54±1.21	17.40±1.04	-0.702	0.484
Heart rate (beat/min)	74.44±4.87	74.59±5.46	0.164	0.870
Systolic blood pressure (mmHg)	118.97±3.45	118.81±4.37	-0.230	0.819
Diastolic blood pressure (mmHg)	75.55±3.79	75.13±3.90	-0.618	0.538

effective in reducing the degree of enamel demineralisation. Meanwhile, the EDI scores of both groups at all time points after treatment were remarkably different from the pre-treatment ($P<0.05$). This indicates that both intervention measures can effectively improve enamel demineralization, with the CC group showing a more prominent improvement effect.

PLI

The PLI scores of the CT group and CC group at different time points were carefully observed and analysed, and the results are shown in Fig. 3. The dental photos of both groups of patients are shown in Supplementary Fig. 2. Before treatment, and no remarkable difference in PLI scores was observed in both groups ($P>0.05$). As the treatment progressed, both groups showed a significant downward trend in PLI scores, and there was a significant difference in the magnitude of PLI score reduction between the two groups ($P<0.05$). Further comparison of both groups at each time point showed that the PLI scores of the CC group were remarkably below the CT group at 3, 6 and 12 months after treatment ($P<0.05$). This fully demonstrated that the interventions used in the CC group were more effective in suppressing plaque accumulation compared to the CT group.

mBI

The results of dynamic monitoring and comparative analysis of the modified bleeding index (mBI) of the CT group and CC group at different time points are presented in Fig. 4. The dental photos of both groups of patients are shown in Supplementary Fig. 3. Pre-treatment, the mBI score in the CT group and the CC group, and there was no remarkable discrepancy among both groups ($P>0.05$). After treatment, the mBI scores of both groups decreased remarkably over time, suggesting that the degree of gingival inflammation was gradually relieved, but there was a remarkable difference in the magnitude of improvement between the groups. The mBI scores of the CC group were remarkably below the CT group at 3, 6 and 12 months after treatment ($P<0.05$), confirming that the intervention in the CC group was more effective in reducing gingival inflammation and lowering the risk of bleeding. In addition, the mBI scores of both groups at all time points after treatment were remarkably different compared with the pre-treatment ($P<0.05$). Both intervention methods can effectively improve gum health, with the CC group showing a stronger advantage.

Enamel demineralisation chalky lesions

The results of the longitudinal comparative analysis of enamel demineralisation chalky lesion scores before and after treatment in the CT and CC groups are presented in Fig. 5. Before treatment, the mean value of the scores in the CT group and the CC group, and the difference between both groups was not statistically significant ($P>0.05$). The data at each time point after treatment showed that the scores of both groups decreased remarkably over time, suggesting that the degree of enamel demineralisation chalky lesions continued to improve, but the rate and magnitude of improvement in the CC group was remarkably superior to the CT group. The scores of the CC group were remarkably below the CT group at 3, 6 and 12 months after treatment ($P<0.05$),

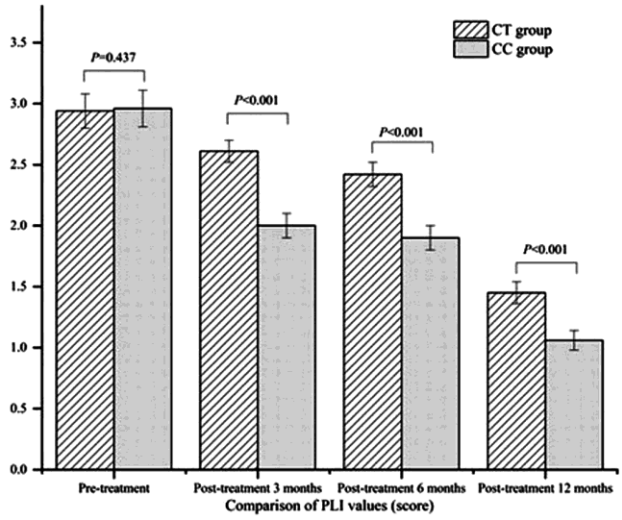

Fig. 3 — Comparison of PLI values (score).

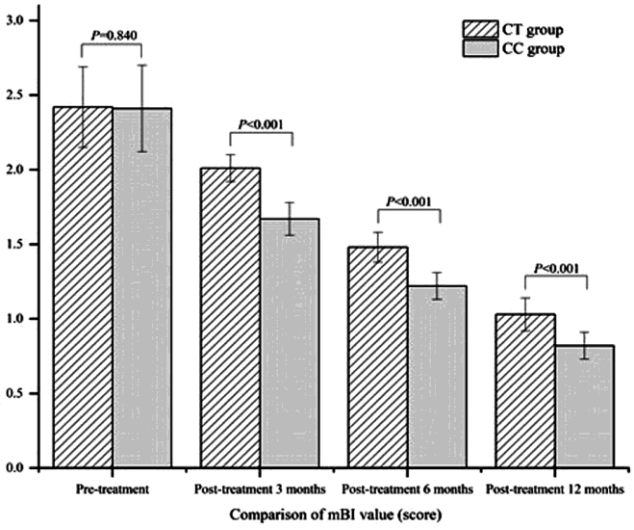

Fig. 4 — Comparison of mBI value (score).

confirming that the intervention in the CC group was more effective in inhibiting enamel demineralisation chalk plaque formation and promoting lesion repair. In addition, there were remarkable differences in the post-treatment scores of both groups at all times compared with the pre-treatment scores (P<0.05). Both intervention methods can effectively alleviate enamel demineralization and chalky lesions, with CC group showing better relief effect.

Incidence of demineralisation

The dynamic tracking and comparative analysis of the incidence of enamel demineralisation before and after treatment in the CT group and the CC group was carried out, and the results are presented in Table 2. Before treatment, the incidence of demineralisation in the CT group and the CC group, with no remarkable difference in both groups (P>0.05). The data at each time point after treatment showed that the incidence of demineralisation in both groups showed a decreasing trend over time, but the decrease in the CC group was remarkably superior to the CT group. It shows that there is a remarkable difference between both groups in the demineralisation prevention and control effect. Comparison between the groups showed that the incidence of demineralisation in the CC group was remarkably below the CT group at 3, 6 and 12 months after treatment (P<0.05), confirming that the intervention in the CC group was more effective in reducing the risk of enamel demineralisation.

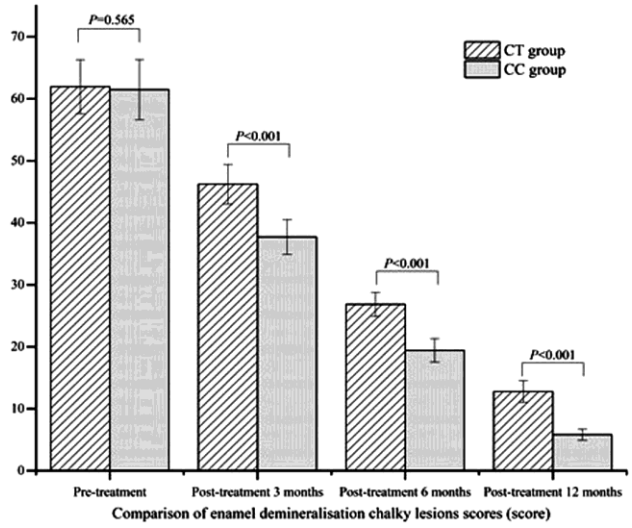

Fig. 5 — Comparison of Enamel demineralisation chalky lesions scores (score).

Quality of life

The post-treatment quality of life scale scores of both groups were analysed and the results are presented in Table 3. There was a significant difference in the scores between the two groups (P<0.05). This indicates that the CC group intervention measures are more effective in improving patients' oral health-related quality of life.

Complications

The occurrence of complications in both groups, including decreased bracket adhesion, was demonstrated in Table 4. No marked difference was observed between both groups when compared to the groups of patients who developed complications (P>0.05). The total complication rate of patients in the CC group was 7.81% (5/64) remarkably below that of 18.75% (12/64) in the CT group (P<0.05). It indicates that the treatment modality in the CC group can effectively reduce the incidence of complications.

Incidence of adverse reactions

Patients in both groups experienced adverse reactions of varying degrees such as gingival itching during treatment as indicated in Table 5. No remarkable discrepancy was found in the comparison

Table 2 — Incidence of demineralisation [n(%)]

Group	Total teeth	Pre-treatment	Post-treatment 3 months	Post-treatment 6 months	Post-treatment 12 months
CT group	1358	978 (72.02)	815 (60.01)	597 (43.96)	76 (5.60)
CC group	1361	981 (72.08)	435 (31.96)	217 (15.94)	0 (0)
t		0.000	15.781	18.667	6.186
P		1.000	<0.001	<0.001	<0.05

Table 3 — Quality of life ($\bar{x}$±s, score)

	CT group	CC group	t	P
Oral health	26.97±4.07	31.59±4.01	6.469	<0.001
Functional health	22.03±2.62	26.05±1.87	9.991	<0.001
Self-image	13.72±3.38	16.81±2.93	5.526	<0.001
Social-emotional health	25.79±2.48	30.01±3.15	8.421	<0.001
School environment	14.95±1.60	17.35±1.35	9.171	<0.001

Table 4 — Complications [*n*(%)]

	CT group	CC group	x^2	*P*
Decreased bonding of brackets	1 (1.56)	0 (0.00)	2.020	0.155
Increased enamel demineralisation	2 (3.13)	1 (1.56)	0.205	0.651
Formation or increase of white spots	2 (3.13)	1 (1.56)	0.205	0.651
Redness and swelling of the gums	2 (3.13)	1 (1.56)	0.205	0.651
Bleeding gums	2 (3.13)	1 (1.56)	0.205	0.651
Oral odour	2 (3.13)	1 (1.56)	0.205	0.651
Pharyngitis	1 (1.56)	0 (0.00)	2.020	0.155
Total incidence	12 (18.75)	5 (7.81)	5.181	<0.05

Table 5 — Adverse reactions [*n*(%)]

	CT group	CC group	x^2	*P*
Itchy gums	2 (3.13)	1 (1.56)	0.205	0.651
Rash	2 (3.13)	0 (0.00)	3.046	0.081
Erythema of the oral mucosa	2 (3.13)	0 (0.00)	3.046	0.081
Dentin sensitivity	1 (1.56)	1 (1.56)	0.000	1.000
Salivary abnormalities	2 (3.13)	1 (1.56)	0.205	0.651
Gingivitis	2 (3.13)	1 (1.56)	0.205	0.651
Taste abnormalities	1 (1.56)	0 (0.00)	2.020	0.155
Total incidence	12 (18.75)	4 (6.25)	7.726	<0.05

of the occurrence of adverse reactions in patients of both groups ($P>0.05$). The total incidence of adverse reactions in patients in the CT group was 18.75% (12/64), which was remarkably greater than the 6.25% (4/64) in patients in the CC group ($P<0.05$), indicating that the therapeutic effect of the treatment method used in patients in the CC group was better and safer.

Discussion

Enamel demineralisation is a major concern in the field of orthodontic treatment for adolescents[22, 23]. Available treatments for enamel demineralisation in adolescent orthodontics are limited and inadequate[24,25]. Although conventional fluoride can reduce enamel demineralisation to a certain extent, its use in large quantities can irritate the gingiva, lead to discolouration of the tooth surface, and even cause dental fluorosis[26,27]. Some remineralisation treatments, such as casein phosphopeptide calcium phosphate remineralisation solution treatment, are effective but slow acting and require multiple operations[28]. As a new type of bioactive material, calcium sodium phosphosilicate gel preparation has shown significant advantages in the medical field in recent years, providing a new way to solve a variety of oral problems[29]. Calcium sodium phosphosilicate, the core component of calcium sodium phosphosilicate gel formulations, has excellent biocompatibility and mineralisation-inducing ability, and it has been widely used in oral mucosal restoration and dentin sensitivity treatment[30,31]. In oral mucosal repair, calcium sodium phosphosilicate gel can accelerate the repair of mucosal damage by releasing calcium, phosphorus, silicon and other active ions to promote the proliferation and differentiation of epithelial cells, and at the same time, its gel matrix can form a physical barrier to isolate external stimuli and alleviate the symptoms of pain[32,33]. In dentin sensitivity treatment, the ions released by this preparation can combine with calcium ions in dentin tubules to form hydroxyapatite-like crystals at the mouth of the tubules, sealing the dentin tubules, effectively blocking the conduction of external stimuli, and alleviating the sensitivity symptoms[34,35]. Therefore, the present study is intended to investigate the clinical effect of sodium calcium phosphosilicate gel preparation in preventing enamel demineralisation in orthodontic treatment, to further evaluate its effectiveness and safety, and to provide a new theoretical basis and practical solution for the prevention and treatment of enamel demineralisation in orthodontic treatment.

The results of this study showed that there was no remarkable difference between the baseline indicators of both groups before treatment, and they were well comparable. After treatment, the CC group showed significantly better improvement than the CT group in EDI, PLI, mBI, demineralised chalky lesion score and incidence of demineralisation, and the difference continued to widen over time ($P<0.05$). This result

suggests that the interventions used in the CC group had a superior combined effect in inhibiting plaque accumulation, reducing gingival inflammation, blocking the progression of enamel demineralisation and promoting lesion repair. It has been demonstrated that sodium calcium phosphosilicate gel preparations can reduce the risk of acid erosion at its source by regulating the oral microenvironment and inhibiting the metabolic activity of caries-causing bacteria such as *Streptococcus pyogenes*[36]. This dual mechanism of 'mineralisation-antimicrobial' has led to a significant difference in the incidence of demineralisation in the CC group at 3 months of treatment, and a zero incidence of demineralisation at 12 months, which is superior to the CT group in terms of long-term prevention and control.

In addition, the CC group also significantly outperformed the CT group in improving the patients' scores on oral health-related quality of life dimensions, suggesting that more effective enamel protection measures may positively affect patients' psychosocial adaptability by improving their oral functional status and appearance. Specifically, the CC group's improved scores on the self-image and socio-emotional health dimensions may be related to their more effective control of chalky white lesions and improvement in dental appearance, whereas the improved scores on the oral health and functional health dimensions directly reflect the optimisation of masticatory function and comfort as a result of the intervention[37]. This finding is consistent with John *et al*. theory of multidimensional interactions on oral health-related quality of life[38], confirming that enamel demineralisation prevention and treatment are not only interventions at the biological level, but also have wide-ranging psychosocial benefits by influencing patients' self-perceptions and social interactions.

In this study, the CC group not only performed better in terms of efficacy indicators, but also had a significantly lower total complication rate and adverse reaction rate than the CT group, confirming that this intervention has a higher clinical safety. In terms of the mechanism of action, the CC group intervention, as a bioactive glass material, has a biocompatible and low irritation ion release process, which reduces gingival irritation and tooth surface discolouration and other adverse reactions compared with traditional fluoride preparations, which is consistent with the safety advantages of bioactive materials in a similar study by Aggarwal *et al.*[39]. In clinical practice, the CC group intervention demonstrated unique advantages in long-term prevention and control of enamel demineralisation, with the incidence of demineralisation reduced to 0% at 12 months of treatment, suggesting that it may be possible to achieve complete prevention and control of enamel demineralisation in orthodontic treatment[40].

Compared with traditional interventions, the interventions in the CC group ensured the efficacy of treatment while reducing the occurrence of adverse reactions, which is more in line with the concept of individualisation and minimally invasiveness in modern orthodontic treatment. It is worth noting that the differences between both groups in various indicators were gradually significant with the prolongation of the treatment time, indicating that the long-term effects of the CC group interventions were more prominent. El-Damanhoury in his study on calcium silicate-sodium phosphate-fluoride salt with NovaMin bioactive glass in teeth whitening proposed an in vitro enamel remineralisation effect, which allows for a continuous release of reactive ions in saliva, creating a dynamic mineralisation balance, and with prolonged treatment time, this cumulative effect results in increasing enamel resistance to acidity, ultimately leading to the complete inhibition of demineralisation[41]. This is similar to the findings of the present study. This provides an important reference for clinical development of enamel protection programmes for orthodontic patients.

This study still has some limitations. Firstly, the study period was only 12 months, which means that the long-term efficacy of orthodontic treatment, which usually lasts for 2-3 years, needs to be further investigated, especially as the risk of recurrence of demineralisation after cessation of the intervention has not yet been clarified. Secondly, the study population was from a single centre, and the geographical and ethnic representation of the sample may be limited, so caution should be taken when extrapolating the results to other populations. Although several clinical indicators were assessed in this study, an in-depth exploration of the mechanism of action of the intervention, such as the release kinetics of bioactive ions and the specific regulation of oral flora, was lacking, which may limit the judgement on the direction of optimisation of the intervention. In addition, the study did not set up intervention groups with different dosages or

concentrations to determine the optimal intervention programme, and lacked a direct comparison with other novel anti-demineralisation materials (e.g. nanohydroxyapatite), which made it difficult to comprehensively assess their clinical advantages. Finally, although the quality of life assessment covered multiple dimensions, a more specific quality of life scale for orthodontic patients was not used, which may affect the precision of the results. In addition, due to the retrospective nature of this study, the original clinical records focused on recording the occurrence and types of adverse reactions, but did not systematically record whether the same patient experienced multiple adverse reactions simultaneously. This deficiency also reflects the inherent limitations of retrospective data collection in obtaining detailed information on complex adverse reaction patterns, which limits the comprehensiveness of safety analysis. Correspondingly, future research can be conducted through standardized data collection (including detailed records of concurrent adverse reactions) and optimized study designs (such as gradient dose groups, head to head material comparisons, orthodontic specific quality of life scales) for long-term, multicenter prospective studies, which will further enhance the scientific basis and clinical application value of research results.

Conclusion

In this study, we compared and analysed the effects of CT group and CC group in the prevention and treatment of enamel demineralisation in orthodontic treatment, which provided a new reference basis for the clinical optimisation of demineralisation intervention protocols. The results showed that the interventions in the CC group could significantly improve the EDI, PLI, mBI and other indicators, reduce the incidence of demineralisation and the degree of chalky plaque lesions, and at the same time, improve the patients' oral health-related quality of life and reduce the incidence of complications and adverse reactions, which provides a scientific basis for the prevention and treatment of enamel demineralisation in orthodontic treatment. However, the present study has the limitations of having samples from a single centre and a short follow-up period, which failed to comprehensively assess the long-term efficacy and applicability to different populations. Multi-centre clinical studies with large samples and longer follow-up periods can be conducted in the future, and the mechanism of the intervention can be explored in depth to further validate its clinical value and optimize the treatment plan.

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Consent to Publish

The manuscript has neither been previously published nor is under consideration by any other journal. The authors have all approved the content of the paper.

Consent to Participate

We secured a signed informed consent form from every participant.

Ethic Approval

This study was approved by the Ethics Committee of The First People's Hospital of Zunyi (The Third Affiliated Hospital of Zunyi Medical University) (Approval No.: 2025-1-730).

Data Availability Statement

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

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Author Contribution

Meilin Li: Edited and refined the manuscript with a focus on critical intellectual contributions.

Lili Wan, Fang Liu: Participated in collecting, assessing, and interpreting the date. Made significant contributions to date interpretation and manuscript preparation.

Meilin Li, Hongbo Ou: Provided substantial intellectual input during the drafting and revision of the manuscript.

Conflicts of Interest

The authors declare that they have no financial conflicts of interest.

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