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Exploratory Trial to Evaluate the Hydroxyapatite Layer Formed by a New Dental Treatment System

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Abstract

Objective: A powder jet deposition (PJD) process can be used to create a thick hydroxyapatite (HA) layer on the human tooth surface. The purpose of this exploratory trial was to evaluate the safety and efficacy of the hydroxyapatite layer formed by a new dental treatment system for cases of caries, dentin hypersensitivity, or discolored teeth. Methods: A single facility, non-blinded study comparing before and after treatment interventions, without a comparative control, was conducted. A rubber dam was attached to the teeth followed by the application of Vaseline to the gingival margins. Extra- and intra-oral vacuums and a saliva discharge tube were used to spray HA powder over the target site with the PJD equipment. Results: The formation of an HA layer tended to reduce pain on exposure to cold water and air in the cases with caries, and increase brightness and satisfaction in the cases with tooth discoloration. The pain on exposure to air was significantly reduced in the cases with dentin hypersensitivity. PJD was not observed to cause any inflammation of the surrounding gingiva or pulpal symptoms. Conclusions: HA is anticipated to reduce the need for repeat treatment by offering superior compatibility with the tooth substance when compared with other dental materials.

Keywords

Exploratory Trial, Hydroxyapatite Layer, Powder Jet Deposition

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1. Introduction

Treatment of dental caries generally involves carious tissue removal, followed by filling the cavity with a dental restorative material. However, dental caries is known to recur when the dentin and adhesion layer deteriorate over time, resulting in ill-fitting restorations, thereby leading to the entry of bacteria that could cause caries within the gaps between the restorative material and dentin. Resin fillings generally require re-treatments after 5.2 years on average [1]. Dentin hypersensitivity affects approximately 30% of the Japanese population. Although various treatments have been used to control dentin hypersensitivity, the results have proven to be unreliable so far [2]. In recent years, there has been an increased demand for the treatment of discolored teeth due to esthetic reasons [3]. Treatments such as tooth bleaching, ceramic crowns, and porcelain laminate veneer restoration are being performed. However, dentin hypersensitivity may develop due to these treatment methods, making it necessary to perform additional invasive procedures on the tooth [4].

In our previous report, the possibility of applying a hydroxyapatite (HA) layer as a new restorative material with compositional and mechanical properties corresponding to the tooth substance was presented [4]-[6]. Powder jet deposition (PJD) is a coating process in which ultra-fine particles are accelerated up to several hundred meters per second by a jet flow of a carrier gas. The PJD is performed at room temperature and atmospheric pressure, enabling its use with HA particles in the creation of a HA layer on human teeth. The micro-Vickers hardness of the HA layer was equal to that of enamel, and its bonding strength was almost equal to that of composite resin [4] [5]. On human tooth dentin, HA particles were deposited onto the dentin and solidly into the dentin tubules by PJD. After application of the HA layer, the permeability of dentin was greatly reduced and a potential clinical application of PJD in desensitizing dentin hypersensitivity was demonstrated [6]. The HA layers created in this study maintained their excellent microstructure and mechanical properties even after the application of thermal stress. In a preclinical trial, the PJD process and created HA layers showed biocompatibility and safety.

The purpose of this exploratory trial was to evaluate the safety and efficacy of the hydroxyapatite layer formed by a new dental treatment system for caries, dentin hypersensitivity, or discolored teeth.

2. Materials and Methods

2.1. Study Design

A single facility, non-blinded study comparing before and after treatment interventions, without a comparative control, was conducted. Before implementing the trial, approval was obtained from the clinical trial ethical review committee based on ethical, scientific, and medical considerations. **Table 1** shows the criteria used for subject selection in the present study. A total of 30 cases (10 cases each for caries, dentin hypersensitivity, and discolored teeth) were included and researched from November 2014 to February 2015.

Table 1. Criteria used for subject selection.

Key inclusion criteria
1. 20 years old or more at the time of informed consent.
2. Agreement with written informed consent.
3. Capable of visiting the hospital regularly
4. Agreement with mixing investigational treatment and existing treatment
5. Agreement with selecting one tooth per disease
6. Following selection criterion
・Caries: dentin caries
・Dental hypersensitivity: pain induced by daily life
・Discolored teeth: desire for whitening
Key exclusion criteria
1. Patients with oral mucosal diseases
2. Past medical history of adverse effects of local anesthetic
3. Pregnancy or possibility of pregnancy
4. Participants of other clinical trials
5. Taking painkillers
6. Patients judged inadequate for this trial by the investigators

2.2. Application of PJD Method

All treatments were carried out using PJD equipment and HA powders supplied by Sangi Co., Ltd., Tokyo, Japan. Carious tissues were removed and the tooth surface was cleaned for the treatment of dentin hypersensitivity and tooth discoloration before HA layer formation. A rubber dam was attached to the teeth followed by the application of Vaseline to the gingival margins. Extra- and intra-oral vacuums and a saliva discharge tube were used to spray HA powder over the target site with the PJD equipment. The target sites were sprayed approximately 10 times each under the following conditions: acceleration pressure, 0.5 MPa; supply pressure, 0.5 MPa; powder filling volume, 5 g; and nozzle scan rate, approximately 5 mm/s. The distance between the nozzle spray tip and tooth surface was approximately 3 mm (allowable range: 1 - 5 mm). Single HA particles with a diameter of 3.0 ± 1.0 μm were used for caries and dentin hypersensitivity treatment, and for the treatment of tooth discoloration, TiO_2 was added to the HA particles as a color regulator. After layer formation, caries was treated by applying a primer and bonding agent to the target site before the composite resin restoration. A diamond paste was used to polish the target site for the treatment of dentin hypersensitivity and tooth discoloration.

2.3. Evaluation

The following paragraphs describe the tests that were performed before, immediately after, 1 week after, and 4 weeks after treatment.

Pulpal symptoms including pain on exposure to air, cold water, warm water, vertical percussion, and horizontal percussion and spontaneous pain as evaluated using the Numeric Rating Scale (NRS) with 0 meaning “no pain” and 10 defined as “worst pain imaginable”, and the condition of the restoration including fitting, fracture, and loss or the development of secondary caries were evaluated in the cases requiring caries treatment. Pulpal symptoms including pain on exposure to air, cold water, and warm water, and abrasion pain and spontaneous pain as evaluated using the NRS, and surrounding gingivitis using the Gingival Index (GI) were evaluated in the cases requiring dentin hypersensitivity treatment. Statistical analysis was conducted about NRS and CIE lab measurement. Dunn multiple comparisons test was used for statistical analysis. The statistical significance was chosen to be $p < 0.05$. In the cases requiring treatment of tooth discoloration, evaluation was conducted using the CIE Lab measurement system with a colorimeter for shade changes and visual tone evaluation (VITA classical shade guide). VITA classical shade guide consisted of A1-D4, and B1, A1, B2, D2, A2, C1, C2, D3, A3, D4, B3, A3.5, B4, C3, A4 and C4 were ranked in descending order of brightness. In addition, assessments of surrounding gingivitis according to the GI, material detachment to evaluate the shape (score 0: no detachment; 1: detachment of approximately less than half of the area; 2: detachment of approximately half or more of the area; and 3: almost completely detached), and subject satisfaction (score 0: strongly dissatisfied; 1: somewhat dissatisfied; 2: somewhat satisfied; and 3: strongly satisfied) were also performed.

3. Results

3.1. Caries Treatment

Table 2 shows the mean scores obtained after assessing the pulpal symptoms. Spontaneous pain based on the NRS evaluation was 0 at all time-points. For every evaluation item, no significant difference was observed between all period groups. No ill-fitting resin fillings, fractures, or losses were noted during the 4-week-observation period after the treatment. In addition, there was no onset of secondary caries in any of the cases during the observation period.

Table 2. Mean scores for pulpal symptom evaluation.

	Before treatment	After treatment	1 week	4 weeks
Cold water pain	0.2 ± 0.4	0	0	0
Warm water pain	0.1 ± 0.3	0	0.2 ± 0.4	0
Air pain	0.2 ± 0.4	0	0.1 ± 0.3	0
Vertical percussion pain	0.1 ± 0.3	0	0	0
Horizontal percussion pain	0	0	0	0.1 ± 0.3
Spontaneous pain	-	0	0	0

3.2. Dentin Hypersensitivity Treatment

Table 3 shows the mean scores obtained after evaluating the pulpal symptoms. Comparison of scores before and after treatment revealed significant improvements based on the NRS for abrasion pain.

GI scores were 0 throughout the observation period in nine cases. In one case, GI score was 1 before and after the treatment but subsequently improved to 0.

3.3. Tooth Discoloration Treatment

Table 4 showed the mean values obtained from CIE Lab measurements and showed a tendency to increase the values after the treatment of tooth discoloration while no significant difference was observed between all period groups. **Table 5** illustrates the shade changes in each case; brightness tended to increase after treatment in all cases.

GI evaluation indicated that the scores were 0 for all 10 cases before and after 4 weeks of treatment. **Table 6** shows the mean HA layer detachment scores in the 30 cases. In one case, some detachment (score: 1) was noted after treatment, but no detachment of materials was noted after treatment in any of the remaining nine cases. Subsequently, scores of 1 were noted in approximately half of the cases. **Table 7** shows the mean subject satisfaction scores. Scores rose directly after treatment and were maintained 4 weeks later.

Table 3. Mean scores for pulpal symptom evaluation.

	Before treatment	After treatment	1 week	4 weeks
Cold water pain	2.7 ± 2.1	1.4 ± 1.7	1.1 ± 1.5	0.9 ± 1.3
Warm water pain	1.7 ± 2.6	0.8 ± 1.2	1.0 ± 1.2	1.4 ± 1.7
Air pain	3.3 ± 1.3	1.0 ± 1.2*	0.8 ± 1.0*	1.0 ± 1.2*
Abrasion pain	1.1 ± 1.2	0.4 ± 1.0	0.6 ± 1.3	0.2 ± 0.4
Spontaneous pain	-	0.2 ± 0.4	0	0

*Significantly ($p < 0.05$) different from before treatment.

Table 4. Mean CIE Lab Measurements.

	Before treatment	After treatment	1 week	4 weeks
CIE Lab measurements	29.3 ± 4.5	34.7 ± 6.6	33.8 ± 6.8	33.9 ± 6.5

Table 5. Shade changes for each case.

Registration number	Before treatment	After treatment	1 week	4 weeks
01	A3.5	A3	A3	A3
02	C4	A1	A1	A1
03	A3	A1	A1	A1
04	A3.5	A2	A2	A2
05	A3.5	A2	A3	A3
06	A4	B1	B1	B1
07	B2	A2	A2	A2
08	D3	C3	C3	C3
09	B3	C1	C1	C1
10	B4	C2	C2	C2

Table 6. Mean detachment scores.

Score	After treatment	1 week	4 weeks
0	9	5	6
1	1	5	4
2	0	0	0
3	0	0	0

Table 7. Mean subject satisfaction scores.

	Before treatment	After treatment	1 week	4 weeks
Score	1.1	2.5	2.3	2.3

4. Discussion

The scores relating to evoked pain were generally low before the start of the treatment because of the fact that it was targeted at dentin caries. However, pulpal symptoms disappeared 4 weeks after treatment, with slight improvements in the scores for pain on exposure to cold water and air. No ill-fitting resin fillings, fractures, losses, or secondary caries development were observed during and until the 4-week-observation period. In the present study, we expected the results to be apparent 4 weeks after treatment because it has been previously reported that pulpal symptoms and shape evaluation scores measured 1 week after resin fillings rarely undergo change 1 month and 3 months after treatment [7]. As no cases of resin detachment or secondary caries were observed, it appears that these complications were prevented for a period of at least 4 weeks in this study. *In vitro*, the HA layer adheres very strongly to the dentin; the interface between the dentin and the restoration is considered to be very strong.

The main symptom of pain on exposure to air had improved in terms of dentin hypersensitivity, as the scores were found to be lower 4 weeks after treatment compared with those before treatment. It has been reported that the application of MS coat One F (Sun Medical Co., Ltd., Shiga, Japan), a commonly-used hypersensitivity suppression material, led to the improvement of VAS evaluation scores by approximately 4.9-fold from approximately 6 weeks before treatment to 4 weeks after treatment [8]. Despite different baselines, the results suggest that this material may be more effective in managing dentin hypersensitivity than other over-the-counter hypersensitivity suppression materials. Thus, in the present study, caries and dentin hypersensitivity treatment reduced pulpal symptoms and did not initiate the development of additional pulpal symptoms. Previous *in vitro* study [4] has demonstrated reduced dentin permeability; the results of the present study point towards the same phenomenon, with decreases in pulpal symptoms.

Increased brightness was observed, following the treatment of discolored teeth, with higher satisfaction scores obtained from most cases compared with those before treatment. In most cases, material detachment was not observed directly after treatment; however, some detachment developed later in approximately half of the cases. The application of Beauty Coat (Shofu Inc., Kyoto, Japan), a resin dental coating, as a base directly after treatment has resulted in significant decreases in brightness, fractures, and losses 4 weeks after treatment [3]. Similar trends were noted for the treatment method outlined in the present study.

The conditions involved with HA particle spraying in the present study resulted in the formation of a thicker layer compared with that obtained in previous studies [4]-[6]. However, no worsening in GI scores was noted, and the use of a rubber dam and Vaseline to protect the oral mucosa and teeth other than the target teeth or tooth, did not lead to instances of gingival inflammation or aggravation of pulpal symptoms.

A HA layer, having chemical and mechanical properties corresponding with tooth substance, can be used to generate a novel biomaterial in dental treatment. This study was exploratory trial and the purpose was not to show the superiority as compared to other treatment. We are going to use comparative control on the occasion of next clinical study.

5. Conclusion

In this exploratory study, PJD was applied to cases of caries, dentin hypersensitivity, and tooth discoloration.

The formation of an HA layer tended to reduce pain on exposure to cold water and air in the cases with caries, and increase brightness and satisfaction in the cases with tooth discoloration. The pain on exposure to air was significantly reduced in the cases with dentin hypersensitivity. PJD was not observed to cause any inflammation of the surrounding gingiva or pulpal symptoms. HA is anticipated to reduce the need for repeat treatment by offering superior compatibility with the tooth substance when compared with other dental materials. We plan to conduct a long-term study investigating the HA layer in the future.

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