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Tooth Whitening Efficacy of a Dentifrice Containing Papain and Bromelain Extracts: An In Vivo Clinical Study.

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ABSTRACT

To study the effectiveness of a new dentifrice containing papain and bromelain extracts at whitening the tooth shade over a period of 3 weeks.A randomized, single center, pilot clinical study was designed to evaluate the effectiveness of a new dentifrice at whitening the tooth shade over a 3 week period .Thirty five subjects were included in the study.Each subject was assigned to the toothpaste. Subjects were instructed to brush twice daily with the supplied toothpaste & tooth brush. The subjects were recalled after 1 week, 2 weeks and 3 weeks and the tooth shade was examined using a Vita shade guide.Thirty four subjects completed the study. One subject did not complete the study because of personal or medical reasons unrelated to use of study toothpaste. The below tables indicates that the test dentifrice resulted in whitening the tooth shade over a period of 3 weeks.The test dentifrice showed significant whitening of tooth shade which could be attributed to the role of proteolytic enzymes in the test dentifrice.

INTRODUCTION

The color of the teeth is influenced by a combination of their intrinsic color and the presence of any extrinsic stains that may form on the tooth surface [1,2]. Intrinsic tooth color is greatly influenced by the light absorption and scattering properties of the enamel and dentin, with dentin playing a significant role in determining the overall tooth color [3,4].

Extrinsic color is linked with the adsorption of materials into the acquired pellicle on the surface of enamel, which ultimately cause staining [5]. Factors that influence extrinsic stain formation include poor tooth brushing technique, smoking, dietary intake of colored foods , subject age and the use of certain cationic agents such as chlorhexidine or metal salts like tin and iron [1,5,6,7,8].

Consumers and patients alike have always had a strong desire for white teeth and many individuals are dissatisfied with their current tooth color as indicated in a number of recent studies [9,10,11].

The desire for whiter teeth has given rise to a growing trend in the increased use of tooth whitening products [12,13]. Manufacturers of oral care products are constantly developing improvements and new approaches for tooth whitening in order to meet the demanding expectations of patients and consumers. Thus, today there is a huge range of product types and technologies addressing the problem of tooth discoloration available on the market. Recently an in-vitro study reported that a papain and

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bromelain (proteolytic enzymes) containing dentifrice was more effective in removing stains than the control dentifrice [10].

Hence the present study aimed to evaluate the tooth whitening efficacy of a novel commercially available dentifrice containing papain and bromelain (Glodent tooth paste, Group Pharmaceuticals Ltd, Mumbai, India)

MATERIALS AND METHODS

A randomized, single center, pilot clinical study was designed to evaluate the effectiveness of a new dentifrice at, whitening the tooth shade over a 3 week period.

Thirty five subjects were included in the study, who have minimum of 20 teeth present. For inclusion in the study, the subjects were required to have visible stains on atleast four teeth without restorations or untreated caries. These subjects were periodontally healthy without fixed or removable orthodontic appliances or removable prostheses.

Each subject was assigned to the toothpaste. Subjects were instructed to brush twice daily with the supplied toothpaste & tooth brush. The subjects were recalled after 1 week, 2 weeks and 3 weeks and the tooth shade was examined using a Vita shade guide, statistical analysis was done using Fischers exact test .

Statistical Analysis of Shades

The grades at different time intervals are given below:

Shade at Baseline

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	A1	1	2.9	2.9	2.9
	A2	2	5.9	5.9	8.8
	A3	4	11.8	11.8	20.6
	A3.5	4	11.8	11.8	32.4
	B2	3	8.8	8.8	41.2
	B3	7	20.6	20.6	61.8
	C2	2	5.9	5.9	67.6
	C3	1	2.9	2.9	70.6
	D2	2	5.9	5.9	76.5
	D3	5	14.7	14.7	91.2
	D4	3	8.8	8.8	100.0
	Total	34	100.0	100.0	

This table shows the patients with different shades and their frequency of occurrence at the start of the study. Called the base line group

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Shade at Week 1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		2	5.9	5.9	5.9
	A1	1	2.9	2.9	8.8
	A2	4	11.8	11.8	20.6
	A3	4	11.8	11.8	32.4
	B1	3	8.8	8.8	41.2
	B2	7	20.6	20.6	61.8
	B2	1	2.9	2.9	64.7
	C1	1	2.9	2.9	67.6
	C2	2	5.9	5.9	73.5
	C3	1	2.9	2.9	76.5
	D1	4	11.8	11.8	88.2
	D2	1	2.9	2.9	91.2
	D3	3	8.8	8.8	100.0
	Total	34	100.0	100.0	

This table shows the frequency of occurrence of the shades in the same group of patients after one week use of the paste.

This table shows the frequency of occurrence of the shades in the same group of patients after two week use of the paste

Shade at Week 3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	2.9	2.9	2.9
	A1	12	35.3	35.3	38.2
	A2	17	50.0	50.0	88.2
	A3	4	11.8	11.8	100.0
	Total	34	100.0	100.0	

This table shows the frequency of occurrence of the shades in the same group of patients after three week use of the paste

Comparison of shades at Baseline and Week 1:

The comparison is carried out using Fisher's exact test.

Shade	Baseline	Week 1	P-Value
A1	1	1	1.00
A2	2	4	0.671
A3	4	4	1.00
A3.5	4	0	0.112
B2	3	7	0.299
B3	7	0	0.011
C2	2	2	1.00
C3	1	1	1.00
D2	2	1	1.00
D3	5	3	0.706
D4	3	0	0.237

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We see that there is no significant difference in the change of shades at Baseline and Week 1 for all shades (P>0.05).

There is slight change in the shades moving towards the lighter shade (A shades) but statistically not significant

Comparison of shades at Baseline and Week 2:

The comparison is carried out using Fisher's exact test.

Shade	Baseline	Week 2	P-Value
A1	1	3	0.612
A2	2	9	0.042
A3	4	8	0.333
A3.5	4	1	0.353
B2	3	0	0.237
B3	7	0	0.011*
C2	2	8	0.08
C3	1	0	1.00
D2	2	0	0.492
D3	5	0	0.052
D4	3	0	0.237

We see that there is a significant difference in shade B3 from Baseline to Week2 (P<0.05). There is no significant change in the other shades (P>0.05).

Here the number of patients who fell in the B3 shade in the baseline has shifted to the lighter shade that is A- shades were you can see the increase in the number of patients at the end of week two. This shift is significant statistically

Comparison of shades at Baseline and Week 3:

The comparison is carried out using Fisher's exact test.

Shade	Baseline	Week 3	P-Value
A1	1	12	0.001*
A2	2	17	<0.001*
A3	4	4	1.00
A3.5	4	0	0.112
B2	3	0	0.237
B3	7	0	0.011*
C2	2	0	0.492
C3	1	0	1.00
D2	2	0	0.492
D3	5	0	0.052
D4	3	0	0.237

We see that there is a significant change in shades A1 and B3 (P<0.05). Also there is a significant difference in the change in shade A2 (P<0.001). There is no significant change in the other shades (P>0.05).

In the final week as most of the darker shades have become lighter there is more number of patients falling in the A1and A2 shades and no one falling in the shade B3 which was 7 patients to start

with. This increase in number of patients in the lighter shade (A1 & A2) is statistically significant to tell there is shift of the shades from darker shades to lighter shades after continuous use of the paste for three weeks

There is 35% increase in the A1 shade

There is 45% increase in the A2 shade in the same group of patients by the end of study.

RESULTS

There is no significant difference in the change of shades at Baseline and Week 1 for all shades (P>0.05). There is slight change in the shades moving towards the lighter shade (A shades) but statistically not significant.

There is a significant difference in shade B3 from Baseline to Week2 (P<0.05). There is no significant change in the other shades (P>0.05).

Here the number of patients who fell in the B3 shade in the baseline has shifted to the lighter shade that is A- shades were you can see the increase in the number of patients at the end of week two.This shift is significant statistically .

There is a significant change in shades A1 and B3 (P<0.05). Also there is a significant difference in the change in shade A2 (P<0.001). There is no significant change in the other shades (P>0.05).

In the final week as most of the darker shades have become lighter there is more number of patients falling in the A1and A2 shades and no one falling in the shade B3 which was 7 patients to start with. This increase in number of patients in the lighter shade (A1 & A2) is statistically significant to tell there is shift of the shades from darker shades to lighter shades after continuous use of the paste for three weeks

There is 35% increase in the A1 shade

There is 45% increase in the A2 shade in the same group of patients by the end of study.

DISCUSSION

The current study evaluated the tooth whitening efficacy of a novel dentifrice containing papain and bromelain. Today there is a huge range of product types and technologies addressing the problem of tooth discoloration available on the market. The majority of these products work in one of two ways, either by bleaching of the teeth, or by the removal and control of extrinsic stain. Tooth bleaching typically involves the application of hydrogen peroxide or carbamide peroxide containing gels to the teeth through various formats, including a mouth guard or strip or even painting directly on. The peroxide causes decolorisation or bleaching of the colored materials found within the tooth giving rise to whiter teeth [15]. In order to optimise the removal and control of extrinsic stain, specific abrasives and/or chemical agents can be added to toothpaste. These improved stain removal/prevention products are termed whitening toothpastes.

Toothpaste abrasion of dental hard tissues is an important factor in terms of its trade off with cleaning efficacy during the formulation of whitening toothpastes. Hence whitening toothpastes contain additional chemical agents which augment the abrasive cleaning by aiding the removal and/or prevention of extrinsic stains. Ingredients studied previously include surfactants, peroxide, enzymes, citrate, pyrophosphates and hexametaphosphate [5].

Since extrinsic stains are primarily incorporated into the pellicle, it is possible that enzymes such as proteases could help degrade the stained films and potentiate their removal. Early clinical evidence demonstrated that a highly proteolytic mixture of enzymes of fungal origin formulated into toothpaste were effective at reducing extrinsic stain levels as compared to a negative control toothpaste after 6 months of use[16]. Clinical studies have demonstrated the stain removal efficacy of dentifrice containing papain, alumina and sodium citrate [17, 18, 19].

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In the present study, the tooth whitening efficacy was assessed in terms of change in shade values only. The pretreatment shade was assessed and the patients were instructed to use the test dentifrice for 3 weeks. Change in shade was assessed at intervals of 1, 2 and 3 weeks by using vita shade guide.

There was a significant difference in shade B3 from Baseline to Week 2.

The number of patients who fell in the B3 shade in the baseline had shifted to the lighter shade that is A- shades. There was a significant change in shades A1 and B3. Also there was a significant difference in the change in shade A2.

In the final week as most of the darker shades had become lighter there were more number of patients falling in the A1and A2 shades and no one falling in the shade B3 which was 7 patients to start with. This increase in number of patients in the lighter shade (A1 & A2) is statistically significant to tell there is shift of the shades from darker shades to lighter shades after continuous use of the paste for three weeks.

The test dentifrice in the present study contained extracts of papain and bromelain, which are proteolytic enzymes. They disrupt and or remove the protein portion of the pellicle or plaque layer that forms on the surface of teeth over time, thus removing the stains that are bound to these proteins. Hence the tooth whitening efficacy of the test dentifrice can be partly attributed to these enzymes. Further clinical trials are needed to asses the tooth whitening efficacy of this novel dentifrice.

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