Efficacy Study of whitening Toothpaste containing Lemon (Citrus Limon (L) and Salt (Sodium Carbonate)

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Abstract
In recent days teeth hygiene is a social image and physiological strength to the people. People spend the huge amount for the oral hygiene with respect to daily use toothbrush, toothpaste, mouth rinses, etc. Everyone desires to maintain a brighter and whiter tooth with smile, no one interested in the yellowing coloring teeth. Many people use the cosmetic dentistry to maintain the teeth as a brighter white in color and shine. Many teeth whitening gel, paste, rinse off products recommended by the dentist and available in over the counter product. In general hydrogen peroxide, carbamide peroxide and peroxide releasing substances used as a bleaching agent. The present study aimed to estimate the clinical efficacy of Whitening toothpaste containing the Salt and Lemon with respect to the substantiation of product claims like whitening thorough cleansing, intense freshness and removal of yellow stains. At the end of study period almost 76% of people moved or shifted to the ‘Good’ scale and remaining 24% subjects are fall under the ‘Fair’ category. Study results clearly indicate that the salt and lemon help to remove the accumulation of supra gingival debris over six weeks period of usage. Tested whitening toothpaste helps to reduce the stains on the teeth, it clearly indicates significant decrease in CI-S (the value decreased from 1.50-1.09). Study results clearly indicate that the salt and lemon help to remove the accumulation of supra gingival debris minimum six weeks period of usage.

Introduction
In recent days teeth hygiene is a social image and physiological strength to the people. People spend the huge amount for the oral hygiene with respect to daily use toothbrush, toothpaste, mouth rinses, etc. Mainly the teeth discoloration happens by the intake of some foods or drinks like coffee, tea, wines, alcohols, in addition to that continuous intake of some fruits like apples, pineapple, pomegranate and vegetable like potato’s, beetroot cause the coloration of teeth [1,2]. The main reason is, continuous intake of high tannins materials like wines, coffee, soda is deposited in the enamel and cause the yellowish teeth [1-3]. Continuous smoking and usage of tobacco chewing causes the deposition of nicotine in the enamel and cause the discoloration.

Teeth discoloration yellowish also happen by usage of some anti-biotics like Tetracycline or Doxycycline etc. Environmental condition is major causes in teeth discoloration, some of the area ground water containing the higher concentration of fluoride content [4]. Continue usage of excess fluoride water removed the enamel and convert the white layer teeth into the yellow layer teeth. Continuous usage of fluoride tooth paste also causes of the yellowing of teeth. Poor oral hygiene like improper brushing, improper tooth paste also reason for the yellow teeth, discoloration of teeth same is also interlinked with the age factor. In recent days whiter teeth is a social impact and many people spend the huge amount of money to maintain the teeth as white in nature. Many people use the cosmetic dentistry to maintain the teeth as a brighter white in color and shine.

Professional teeth whitening is carried out with help of Dentist; they apply the bleaching agent directly to the teeth and removed the stain. In recent days laser light used for the teeth whitening purpose, many teeth whitening gel, paste, rinse off products recommended by the dentist and available in over the counter product. In general hydrogen peroxide, carbamide peroxide and peroxide releasing substances are used as a bleaching agent [5-7]. Peroxide included gel, paste, rinse off products available in over the counter product, however the harmful effects of chemical affects the enamel; recent days people promote and use the natural teeth whitening agent [8-10]. Natural herbal teeth whitening agent performance equally to the chemical bleach, however the more advantage lead in terms of safety and cost effective [11].

Many scientists proved that chemically treated bleaching agent with respect to the whiteness or teeth bleaching, however the safety is big concern [12]. In recent days many scientists exclusively...
work with the natural teeth whitening ingredients like salt, fruits, vegetable [1,3]. Present study we have aimed to determine the teeth whitening property studied with the combination of sodium-bicarbonate (salt) and lemon extract (Citrus Limon (L)). The present study aimed to estimate the clinical efficacy of Whitening toothpaste containing the Salt and Lemon with respect to the substantiation of product claims like whitening, thorough cleansing, intense freshness and removal of yellow stains.

**Material and Methods**

Main objective of the study was to estimate the clinical efficacy and safety assessment of herbal actives teeth whitening toothpaste. Prepared toothpaste enriched with the lemon extract in Citrus lemon (L) and salt. Prepared toothpaste based on the international regulatory norms and used ingredients are listed in INCI.

**Method of preparation**

Heat the process water up to 50 °C and then add the thickener. Run the cowl and homogenizer for 15 minutes for complete dispersion of the thickener. Actives and flavors to be added at 35 °C, after completion of batch the samples passed the required parameters at quality control lab. Quality control cleared samples submitted for the clinical trial in tubes. Tested toothpaste formulation details summarized in the (Table 1).

**Table 1: Teeth whitening toothpaste ingredients list.**

| Ingredients                        |
|-----------------------------------|
| Water/Aqua                        |
| Thickener / Sodium carboxy methyl cellulose |
| Glycerine IP grade                |
| Sorbitol-IP grade                 |
| Saccharin Sodium IP               |
| Sodium Benzoate IP                |
| Methyl Paraben IP                 |
| Citric acid-IP                    |
| Sodium laurel sulphate            |
| Tri sodium Pyro phosphate         |
| Lemon juice Citrus lemon (L)      |
| Sodium bicarbonate                |
| Flavour                           |
| Herbal extracts (Salvador Persico extract) (Papain enzymes) |
| Precipitated Silica / Abrasive silica |

**Clinical Study**

Clinical study was carried out in presence of Dentist at M/s. Savitha Dental College and Hospitals, 162, Poonamallee High Road, Chennai-6000077, India during the period of July 2018. The primary objective of the study is to evaluate the clinical efficacy of Whitening toothpaste containing the natural whitening agent like Lemon and Salt. Efficacy was tested and measured in terms of Whitening, Thorough Cleansing, Intense Freshness, Remove Yellow stains. Secondary objective of the study is estimating the adverse effect of the tested product. Tested sample was placed in the home and monitor the results in 6 weeks in periodical interval. The potential subjects were screened as per the inclusion and exclusion criteria only after obtaining written informed consent from the subjects.

Around 50 subjects were screened at initial stage and signed the informed consent document for the study. Out of these 50 subjects, 25 subjects are selected based on inclusion, exclusion criteria. Subjects are selected the age group between 18 and 45 years and average age of subject is 26 years. Each subject tested only one product for the 6 weeks period. The product was place at the household, to enable performance basis usage experience and to avoid the personal bias. User instruction provided to the subjects for the proper usage the test product. Subjects are requested to stop using the other branded tooth paste during the study period and insist to the usage of tested product. Similarly, each subject was tested at 3rd week and 6th week respectively after the commencement of treatment.

Safety evaluation and adverse event (AE) monitoring, were carried out at each visit by the dentists being the study Investigators’. Measurements on safety parameters were done, graded on 0-3 scale to assess: Drying of oral tissues in the mouth, Oral ulceration, Pain, Bleeding, Swelling, burning sensation, Tooth sensitivity, altered taste and Altered oral sensations (if any). Universal accepted ‘Simplified Oral Hygiene Index’ or OHIS used for the assessment of oral hygiene condition and records in qualitative manner. The same attribute used to estimate the test product. The amount of debris measured based on the OHIS method, the criteria are; 0-1.2: Good; 1.3-3: Fair and 3.1-6 Poor.

**Results and Discussion**

Subjects were tested the test tooth paste during the study period of 6 weeks and noticed that there is reduction on debris deposits on using test toothpaste samples with salt and lemon extracts. All the subjects were fall under the grade of ‘Fair’ before sing the test products, during the usage of test product around 40% of the subjects are shifted to ‘good’ scale grade and noticed by the investigator. At the end of study period almost 76% of people move or shifted to the ‘Good’ scale as per investigator observations and remaining 24 % subjects are fall under the ‘Fair’ category. Study results clearly indicate that the salt and lemon help to remove the accumulation of supra gingival debris over six weeks period of usage and furnished in the (Table 2).

Dental calculus, both supra and sub gingival occurs in most adults worldwide. Dental calculus is calcified dental plaque, composed primarily of calcium phosphate mineral salts deposited between and within remnants of formerly viable microorganisms. A viable dental plaque covers mineralized calculus deposits. Levels of calculus and location of formation are population specific and are affected by oral hygiene habits, access to professional care, diet, age, ethnic, origin, time since the last dental cleaning systemic disease and the use of prescription medications. We have also estimated the Oral Hygiene index for calculus (CI-S) was assessed and the results are detailed in the (Table 2).
Figure 1: Effect of Whitening tooth paste – Salt and Lemon on OHI for Debris over a period of six weeks.

Table 2: Effect of Whitening Toothpaste-Salt and Lemon on Calculus index (CI-S).

| OHI for Calculus- CI-S | Baseline Visit | 3rd Week | 6th Week |
|------------------------|---------------|----------|----------|
|                        | Mean | SD      | Mean | SD | Mean | SD |
| Baseline               | 1.5  | 0.19    | 1.25 | 0.18 | 1.09 | 0.16 |

Study results clearly indicates that, the significantly decrease in CI-S value observed. The calculus index value started in 1.50 before starting the treatment, i.e. base line and the value fall on 1.09 during the six weeks treatment period. It indicates that the food declaims the mean calculus index values inter that the tested toothpaste improved the oral hygiene. Many scientists proved that peroxide-based bleach is unsafe and affect the teeth enamel [11,13] Recent days many scientists exclusively work on the natural/herbal teeth whitening properties with various herbal materials [1,12] Lemon extracts containing the higher amount of citric acid and help to bleach some extents of yellow teeth naturally, similar kind of observations noticed by [14]. The acidic material also helps to improve the oral hygiene [15]. Among the natural product, salt and lemon are familiar in teeth whitening, many scientists exclusively worked on the same; salt (backing soda) mixed with small amount of lemon/acidic solution make an acidic foam and it helps to remove the stain from the teeth [5]. exclusively studied the effects of vinegar on the teeth whitening in in-vitro level and they confirmed that, the vinegar/acidic solution act crucial role in the teeth whitening.

Conclusion

The tested whitening active toothpaste is safe to use and does not cause any adverse effect during the usage of six weeks study period. Tested tooth whitening paste helps to reduce the stain on the teeth, it clearly indicates that significantly decrease in CI-S. The value decreased from 1.50-1.09, i.e. significantly reduced. Study results clearly indicate that the salt and lemon help to reduce the accumulation of supra gingival debris over six weeks period of usage. The tested toothpaste is immense useful to get rid-off from the chemical treatment for the teeth whitening.

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Conflict of Interest

No conflict of interest.

References

1. Malini Murali, Sai Krishna P, Mukesh Raj LS, Kannan I, Jai Santhosh Manikandan, et al. (2018) Effect-teeth-whitening-produced-various-natural-food-substances-vitro-study. International Journal of Current Research 10(10): 74405-74407.
2. Mithra HN, Krishna SR, Shishir S (2012) Overview of in office bleaching of vital teeth. International research Journal of Pharmacy 3(11): 12-16.
3. Zamani M, Sharifi Tehrani A, Ali Abadi AA (2007) Evaluation of antifungal activity of carbonate and bicarbonate salts alone or in combination with biocontrol agents in control of citrus green mold. Commun Agric Appl BiolSci 72(4): 773-777.
4. Chandrashekar J, Anuradha KP (2004) Prevalence of dental fluorosis in rural areas of Davanagere India. Int Dent J 54(5): 235-239.
5. Zandim DL, Correia FO, Sampaio JE, Rossa Júnior C (2004) The influence of vinegars on exposure of dentinal tubules: A SEM evaluation. Braz Oral Res 18(1): 63-68.
6. Miglani R, Karibaapapa GN, Dodamani AS, Mallana GB, Rajeshwari K (2012) Comparative assessment of sodium chloride, sodium bicarbonate dissolved in vinegar and hydrogen peroxide as bleaching agents to reduce intrinsic dental stains: In vitro study Indian J OralSci 3: 151-155.
7. Attin T, Hennig C, Wiegand A, Attin R (2004) Effect of bleaching on restorative materials and restorations a systematic review. Dent Mater 20(9): 852-861.
8. Kleber CJ, PuttMS, Nelson BJ (1997) In vitro tooth whitening by a sodium bicarbonate/peroxide dentifrice. J Clin Dent 9(1): 16-21.
9. Kleber CJ, Moore MH, Nelson BJ (1998) Laboratory assessment of tooth whitening by sodium bicarbonate dentifrices. J Clin Dent 9(3): 72-75.
10. Joiner A (2004) Tooth color: a review of the literature. J Dent 32 Suppl 1:3-12.

11. Brinda B, Kumar MPD, Janaid, M (2015) Effect of an indigenously available herbal tooth whitening system on human enamel microhardness and micromorphology-an invitro study. Sch J Dent Sci 2(3A): 254-258.

12. Yeh ST, Su Y, Lu YC, Lee SY (2005) Surface changes and acid dissolution of enamel after carbamide peroxide bleach treatment. Operative Dentistry 30(4): 507-515.

13. Craig BJ, Supeene L (1999) Tooth Whitening: Efficacy Effects and Biological safety. Probe Scientific Journal 33(6): 169-174.

14. Penniston KL, Nakada SY, Holmes RP, Assimos DG (2008) Quantitative Assessment of Citric Acid in Lemon Juice, Lime Juice, and Commercially Available Fruit Juice Products. J Endourol 22(3): 567-570.

15. Watts A, Addy M (2001) Tooth discoloration and staining: a review of the literature. Br Dent J 190(6): 309-316.