International Journal of Science and Research (IJSR) ISSN: 2319-7064

ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

The Effect of a Vitamin D3 Supplement (Supracal HD Tablet) in the Acceleration of Orthodontic Tooth Movement - A Clinical Comparative and Observational Study

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Abstract: Time factor in orthodontics is the major concern of most of the patients undergoing orthodontic treatment. Every patient seeking orthodontic treatment for malaligned teeth wants the best possible treatment in the least time possible. To promote this, the term accelerated orthodontics came into existence. Corticotomy, inspite of being the best modality of treatment to accelerate tooth movement, posed limitations majorly due to the surgical exposure and a traumatic experience for the patient due to invasive techniques. Hence the aim of this clinical studywas to benefit the patient by accelerating the movement of teeth within the dense bone, but this time in the least invasive way possible, i.e. just by administering a vitamin D3 supplement tablet named Supracal HD to the patient that will hasten the process of tooth movement and will thus decrease the span of orthodontic treatment without causing any pain, discomfort or trauma. This work presents the effects of drugs and systemic factors capable of affecting bone metabolism and influencing the speed of orthodontic tooth movement.

1. Introduction

Researchers have demonstrated that bone remodeling activity can be regulated either by local factors such as applied forces, or by systemic factors such as drugs, hormones and vitamins. Orthodontic tooth movement is induced by the prolonged application of controlled mechanical forces to a tooth. Such forces cause pressure and tension zones in the PDL and alveolar bone, subsequently remodeling tooth socket and enabling tooth movement. The prerequisite for bone remodeling and tooth movement is occurrence of an inflammatory process involving osteoclasts, osteoblasts, neuropeptides, cytokines and changes in innervation and local vascularization. In this approach of clinical study we showed that doses of vitamin D3 supplement called Supracal HD actually accelerated the movement of teeth in orthodontics. A sample of 100 patients requiring orthodontic treatment were allocated using simple random sampling from the opd at Smile and Shine dental clinic, pune and were matched against a control group of 100 patients who also required orthodontic treatment. The drug was administered to the study group with the patients informed consent and compared with the control group in which treatment was carried out without the administration of the vitamin D3 supplement. Thus the main aim of the study was to enable professional orthodontists to consider all the factors related to orthodontic treatment and to select the best therapeutic strategy for accelerated orthodontics

2. About Supracal HD

What is SupracalHd?

SupracalHD tablet is used for low blood calcium levels, vitamin d deficiency, normal functioning of heart, normal functioning of nerves, normal functioning of bones, acne, age related vision loss, normal functioning of muscles, diarrhoea, wilson's disease and other conditions. supracalhd tablet may also be used for purposes not listed in this medication guide.

Supracal HD tablet contains calcium citrate, magnesium, vitamin d3 and zinc as active ingredients. SupracalHD tablet works by preventing or treating the low blood calcium levels; increasing absorption of calcium and phosphorus required for strong bones; regulating the intestinal fluid transport, mucosal integrity, immunity, gene expression and oxidative stress; relaxing the muscles and nerves during stress

SupracalHd Tablet Uses

SupracalHd Tablet is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Low blood calcium levels
- Vitamin d deficiency
- Normal functioning of heart
- Normal functioning of nerves
- Normal functioning of bones
- Acne
- · Age related vision loss

Volume 8 Issue 6, June 2019

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Paper ID: ART20198544 10.21275/ART20198544 539

International Journal of Science and Research (IJSR) ISSN: 2319-7064

ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

- Normal functioning of muscles
- Diarrhea
- Wilson's disease
- Anemia
- Anorexia
- Attention-deficit/hyperactivity disorder
- Low amounts of magnesium in the blood
- Normal functioning of cells

Supracal HD Tablet - Composition and Active Ingredients

Supracal HD Tablet is composed of the following active ingredients (salts)

- Calcium Citrate
- Vitamin D3
- Zinc
- Magnesium

Please note that this medicine may be available in various strengths for each active ingredient listed above.

Supracal HD Tablet - Side-effects

The following is a list of possible side-effects that may occur from all constituting ingredients of SupracalHd Tablet. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Vomit
- Flatulence
- Hypotension
- Headache
- Constipation
- Diarrhea
- Nausea
- Vomiting
- Hypophosphatemia
- Hypomagnesemia
- SupracalHd Tablet may also cause side-effects not listed here.

If you notice other side-effects not listed above, contact your doctor for medical advice. You may also report side-effects to your local food and drug administration authority.

Supracal HD Tablet Working, Mechanism of Action and Pharmacology

SupracalHd Tablet improves the patient's condition by performing the following functions:

- Preventing or treating the low blood calcium levels.
- Increasing absorption of calcium and phosphorus required for strong bones.
- Regulating the intestinal fluid transport, mucosal integrity, immunity, gene expression and oxidative stress.
- Relaxing the muscles and nerves during stress

Supracal HD Tablet - Drug Interactions

If you use other drugs or over the counter products at the same time, the effects of SupracalHd Tablet may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the

drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. SupracalHd Tablet may interact with the following drugs and products:

- Actinomycin
- Alendronate
- Barbiturates
- Calcium Gluconate
- Calcium acetate
- Chlorpropamide
- Cholestyramine
- Ciprofloxacin
- Diflunisal
- Digoxin

Supracal HD Tablet - Contraindications

Hypersensitivity to Supracal HD Tablet is a contraindication. In addition, SupracalHd Tablet should not be used if you have the following conditions:

- Allergic reactions
- High blood calcium level
- High calcium levels
- Hypersensitivity
- Kidney disease
- Kidney stone
- Sarcoid

Aims

To compare the rate of acceleration of tooth movement with and without the intake of tablet supracalld

Objectives

- 1) To assess whether if the given drug actually promoted acceleration in orthodontic tooth movement.
- 2) To promote acceleration in orthodontic tooth movement by noninvasive means.
- 3) To increase the rate of tooth movement and decrease the orthodontic treatment span.

Inclusion Criteria:-

- 1) Orthodontic treatment patients
- 2) male patients
- 3) Age group:- 15-40 years
- 4) Initial alignment before retraction phase.
- 5) Same age of study and control patients.
- 6) All 4 1st premolar extraction cases

Exclusion Criteria

- 1) Older age patients
- 2) Young females
- 3) Allergic patients
- 4) Periodontally compromised patients
- 5) Pregnant females
- 6) Patients with bone deformities
- 7) Medically compromised patients
- 8) Non extraction cases.

3. Materials and Methods

To analyse the positive effects of supracalld, a sample size of 200 patients were collected from the opd of smile and shine orthodontic care, pune. The sample was collected by

Volume 8 Issue 6, June 2019

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International Journal of Science and Research (IJSR)

ISSN: 2319-7064 ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

simple random sampling method by taking into consideration the inclusion and exclusion criteria enlisted above. Out of 200 patients 100 were given the drug and 100 were the control group. The study included only all the patients with all 4 1st premolars extracted before the commencement of retraction phase. The patients were given a consent form which was to be signed before the

commencement of the interventional study. The purpose of giving thesupracally tablet was also explained to them verbally and only after the patients consent, the tablet was administered and treatment started.

Sample Participant Consent Form

Consent to Participate in a Research Study Smile and shine Orthodontic Care, pune

Title of Stud	"The effect of a vitamin d3 supplement(supracalhd tablet) in the acceleration of orthodontic tooth movement"				
Investigators:					
1 st :-	Dr. BhushanJawale	Phone:	9850299277		
2 nd :-	Dr. Lishoy Rodrigues	Phone:	9975444631		

Introduction

- You are being asked to be in a research study of a drug named supracalled which is studied for its effectiveness in acceleration of orthodontic tooth movement
- You were selected as a possible participant because of your need to complete orthodontic treatment in the least possible time duration.
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study

- The purpose of the study is to accelerate the rate of tooth movement and to complete the orthodontic treatment in the shortest possible time span by advocating a drug named supracalhd.
- Ultimately, this research may be published as a part of a journal or presented as a paper.

Description of the Study Procedures

If you agree to be in this study, you will be asked to do the following things:

- A tablet named supracalHD will be advocated to you after the completion of the leveling and alignment phase and before the commencement of the orthodontic tooth retraction phase.
- After a period of 3 months the amount of retraction is compared between the study group and the control group

Risks/Discomforts of Being in this Study

 There are no reasonable foreseeable (or expected) risks as the dose of supracallyd given in this study is intended for the purpose of tooth movement acceleration only. There may be unknown risks.

Benefits of Being in the Study

 The benefits of participation are that if supracalled has a true orthodontic tooth movement acceleration effect on the participant, it can be used as an orthodontic treatment duration acceleratory medication before every orthodontic treatment.

Confidentiality

- This study is anonymous. We will not be collecting or retaining any information about your identity.
- Your identity will not be disclosed in the material that is published. However, you will be given the opportunity to review and approve any material that is published

Right to Refuse or Withdraw

• The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time without affecting your relationship with the investigators of this study. Your decision will not result in any loss or benefits to which you are otherwise entitled. Youhave the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

Right to Ask Questions and Report Concerns

• You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research .If you like, a summary of the results of the study will be sent to you.

Consent

 Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Subject's Name (print): Subject's Signature:	 Date:	
Investigator's Signature:	 Date:	

Protocol of the Interventional Study

- The protocol of the study was to administer supracalHD to the participant 8weeks before the retraction phase for tooth movement.
- The 200 patients were observed over a period of 6 months during the phase of retraction after initial leveling and alignment
- After the orthodontic treatment was started, all 4 1st premolars were extracted and initial leveling and alignment was started with 0.012, 0.014,0.016, 0.018 inch round NiTiarchwires followed by 0.16x 0.22 and 0.19x0.25 NiTi wires following sequence A of MBT
- Supracal HD was then administered to the participant 8weeks before the retraction phase for tooth movement.
- Use of 0.019/0.025" rectangular NiTi followed by 0.019/0.025" rectangular stainless steel wires for retraction and closure of spaces.

Volume 8 Issue 6, June 2019

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Paper ID: ART20198544 10.21275/ART20198544 541

International Journal of Science and Research (IJSR) ISSN: 2319-7064

ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

 Patients, both of interventional and control group were observed for amount of space closure within a period of 6 months

4. Discussion

- The purpose of giving suprcal HD was because vitamin d3 is the most active hormonal form of vitamin D. It regulatescalcium and phosphate serum levels by promoting theirintestinal absorption and reabsorption in the kidneys.Furthermore, it promotes bone deposition and inhibitsPTH release. It also plays a role in the immuneresponse by promoting immunosuppression.
- D3 deficiency can result from inadequateintake combined with inadequate sunlight exposure, eventually leading to impaired bone mineralization, rickets, and osteoporosis. Furthermore, it can lead toincreased susceptibility to high blood pressure, periodontal disease, affective disorders, and auto-immunediseases.
- Therapy for D3deficiency involvesdiet changes or taking D3 as a supplement. Hypervitaminosis D causes hypocalcemia and might cause anorexia, nausea, polyuria, and eventually renal failure. It can be treated with a lowcalcium dietand corticosteroids.
- The effect vitamin D3 on OTM has been studiedin rats by several authors. Conversely, low supplemental administration does, possibly by upregulation of RANKL (receptor activator fornuclear factorB ligand) expression in osteoblasts, leading ultimately to osteoclast differentiation through the RANK/RANKL system. The effect of supracalled was compared with the control group in context with the amount of retraction achieved in both the groups, ie, the study group and the control group.

5. Results

- Out of the 200 patients studied (100 study group and 100 control group) for amount of tooth retraction achieved during the orthodonticretractionphase, the study group comprising 100 participants showed more amount of space closure than the control group over a period of 6months.
- This indicated that supracally definitely accelerated tooth movement. The results suggested that SupracalHD is sure effective in modulating bone turnover during orthodontic tooth movement, because of its well-balanced effects on bone formation and bone resorption and the accelerated movement of teeth within the dense bones.
- Space closure was accelered in the interventional group by almost 30% faster rate than control group.

6. Conclusion

Supracallid can be effectively used to hasten the rate of teeth movement without posing negatives effects to the patiens treatment protocol. Orthodontistshave long observed that teeth move at different rates and individuals differ in their response to treatment. Some of the differences are caused by change in bone remodeling induced by drugs and systemic factors. All the drugs reviewed have therapeutic effects as well as side effects that influence the cells targeted by orthodontic forces. The value of a thorough medical history

is increasingly significant as young and old alike are exposed to a greater range of therapeutic agents. Therefore, it is imperative that the orthodontists need to pay attention to drug consumption and history of each and every patient, before and during the course of orthodontic treatment, so that the best treatment strategy can be selected for each case. Acetaminophen, which does not have significant influence on the rate of tooth movement, can be recommended for controlling pain during orthodontic treatment.

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