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Research article

A Six-Month Clinical Study to Evaluate the Effects of Sodium Tripolyphosphate and Tetrapotassium Pyrophosphate Based Calculus Dissolution Oral Rinse in Patients with Zirconium Dioxide and Titanium Dental Implants

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ABSTRACT

Aim: To clinically evaluate the effects of a novel anti-calculus mouth rinse containing sodium tripolyphosphate and tetrapotassium pyrophosphate (Periogen, USA) on development of gingivitis and plaque around dental implants versus control over a period of six months. **Material and methods:** This was a randomized, 6 month, parallel groups, double blind, single center clinical trial. Forty subjects with present dental implants (22 zirconium dioxide and 20 titanium) were randomly assigned to one of two subgroups: control group (regular brushing) and test group (regular brushing followed by using the calculus dissolution based oral rinse). All subjects were assessed with gingival index (GI), plaque index (PI) and Volpe-Manhold calculus index (VMI) after 3 and 6 months. **Results:** Statistical analysis found that test group in both zirconium dioxide and titanium group demonstrated statistically significant lower GI, PI and VMI scores. **Conclusion:** This study demonstrates that calculus dissolution based Periogen® mouthrinse provided clinically significant reduction in calculus formation in subjects with zirconium dioxide and titanium dental implants when used twice daily for 6 months as an adjunct to toothbrushing.

Key words: Dental implant, Oral rinse, Anti-calculus, Peri-implantitis, plaque index, biopolymers, clinical trial

INTRODUCTION

A dental implant is an artificial tooth root that interfaces with the bone of the jaw or skull through dynamic process of osseointergation to hold a replacement tooth or prosthetic bridge. Dental implants are considered to be safe treatment options for missing tooth or teeth subject to proper case selection and placement technique.

Review of literature on peri-implant soft tissue around zirconia showed that zirconia dioxide implants and abutments provide a very good peri-implant soft tissue interface that achieved an irritation-free attachment. Various *in vivo* and *in vitro* investigations of soft tissue response around zirconia revealed comparable or even better healing respsonse, less inflammatory infiltrate and reduced plaque adhesion on zirconium oxide discs compared to conventionally pure titanium.[1-6]

In vitro experimental studies on zirconium showed favorable response in terms of adhesion and proliferation of various cellular components of connective tissue suggesting zirconium as a material of choice for perio-integration.[7] Results of Degidi *et al*. study showed a lower inflammatory response in biopsies from peri-implant soft tissue around zirconium healing caps when compared to titanium.[8]

The greatest biological challenge that affects implants longevity is poor plaque control and deposition of calculus around dental implants leading to host induced inflammatory response. Dental implants and their components act as a scaffold on which bacteria can accumulate and form bacterial biofilm which can lead to peri-implantitis. It is the most common causes of dental implant failure.[9] It has been concluded that zirconia surface accumulate significantly less bacteria when comparable with titanium ones[10-12]

The progress of science and technology leading to new products development that eradicate the reservoir of bacteria i.e. dental calculus seems to be perfect scientific strategy to add longevity to dental implants and their healthy existence in oral cavity.

Calculus dissolution based oral rinse Periogen®, (Periogen Company USA), presents significantly potential oral rinse for suppressing the mineralization of dental plaque into calculus.[14] A six month comparative study by Saini R proved that Periogen® is clinically proven to prevent tartar/calculus build-up 45% more effectively than brushing alone on new supragingival calculus formation.[13]

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In the current literature there is no study of clinical effect of calculus dissolution around dental implants. The aim of this study was to evaluate the efficacy of calculus dissolution based oral rinse (Periogen®) in patients with zirconium dioxide and titanium dental implants placed in lower jaw for long-term effects on prevention of peri-implantitis.

MATERIALS AND METHODS

The present study was performed in the Dental department of Advance Europe Medical Centre, UAE, after approved from the research and ethical committee of Ras al-Khaimah Medical and Health Sciences University (RAKMHSU), UAE, vide no. 3-2014-FD.

Forty patients present with one or more dental implant in posterior part of lower jaw were analyzed in this study. Twenty patients were treated with zirconium dioxide dental implants (Axis Biodental, Switzerland), polyetherketoneketone (PEKK) abutments and full ceramic single crowns on them (Group A), Figure 1-2 and twenty with titanium implants (Starumann, Switzerland), titanium abutments and porcelain -fused to metal single crowns (Group B), Figure 4-5.

The inclusion and exclusion criterion for the subject selection in the study is illustrated in table 1. On the beginning of study patients were asked to understand study protocol and accepted subjects signed the consent form to participate in the study.

Clinical Evaluation

The subjects were asked to participate for evaluation of following clinical parameters on baseline, 3 and 6 months.

Gingival index (GI)

Plaque index (PI)

Volpe-Manhold calculus index (VMI)

Gingival index (GI) (Mombelli)

In the order to assess the severity of peri-implant soft tissue, the gingival index was used. The peri-implant tissue was divided in four analyzed unites (disto-facial papilla, facial gingival margin, mesio-facial papilla & lingual gingival margin). A score ranging from 0 to 3 was given to each surface using the periodontal probe. Score of the all unites were summed and divided by four yielded the individual implant score. Totaling all the scores per implant and dividing by implants number was used for calculation of GI per person.

Plaque index (PI) (Mombelli)

Plaque was assessed on the four peri-implant surfaces (mesial, distal, buccal and lingual) with score between 0to3. Plaque score for each implant was obtained by totaling the score for each implant and individual score was calculated.

Table 1: Inclusion and Exclusion Criteria for the Subjects

Inclusion criteria:
• Age-group between 18 and 65
• ASA I or II group patient
• Patients with present one or more dental implants (zirconium dioxide or titanium) in lower jaw with single crown restoration.
Exclusion criteria:
• Presence of any neurological disorders
• Patient who received antibiotics or NSAIDS in the past 9 to 11 weeks
• Pregnant and lactating mothers
• Patients with clinically mobile implants
• Heavy smokers
• The oral hygiene is inadequate

Table 2: Distribution of mean and standard deviation (SD) values of clinical parameters in Group A (Test and Control)

Clinical Parameters	Base Level Mean ± SD	3 months Mean ± SD	6 months Mean ± SD	Percentage Decrease
		Test Group		
GI	0.49 ± 0.13	0.37 ± 0.10	0.18 ± 0.08	63 %
PI	0.98 ± 0.39	0.72 ± 0.18	0.49 ± 0.11	50%
VMI	1.93 ± 0.69	1.42 ± 0.72	0.93 ± 0.91	51%
		Control Group		
GI	0.57 ± 0.27	0.50 ± 0.19	0.42 ± 0.16	26%
PI	1.01 ± 0.42	0.97 ± 0.39	0.89 ± 0.41	11%
VMI	2.03 ± 0.91	1.87 ± 0.63	1.78 ± 0.45	12%

Table 3: Distribution of mean and standard deviation (SD) values of clinical parameters in Group B (Test and Control)

Clinical Parameters	Base Level Mean ± SD	3 months Mean ± SD	6 months Mean ± SD	Percentage Decrease
		Test Group		
GI	0.91 ± 0.31	0.73 ± 0.47	0.44 ± 0.27	51%
PI	1.3 ± 0.51	0.87 ± 0.67	0.63 ± 0.31	51%
VMI	2.91 ± 1.1	1.79 ± 0.83	1.53 ± 0.97	47%
		Control Group		
GI	1.01 ± 0.47	0.97 ± 0.4	0.87 ± 0.51	14%
PI	1.19 ± 0.43	1.12 ± 0.51	1.02 ± 0.42	6%
VMI	3.18 ± 1.11	2.78 ± 0.92	2.63 ± 0.89	17%

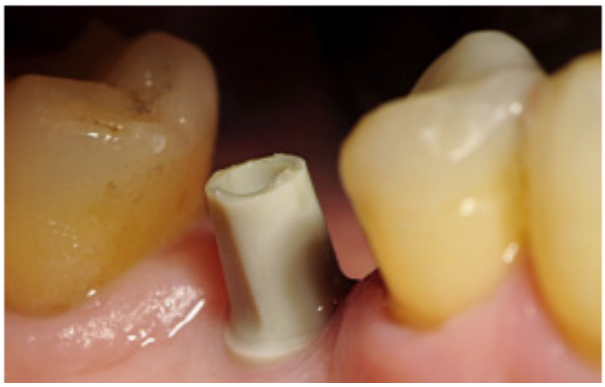


Figure 1: Group A - PEKK abutment on zirconium dioxide dental implants

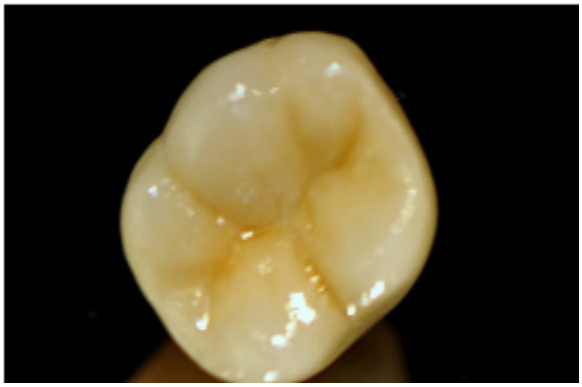


Figure 2: Group A - Full ceramic crown

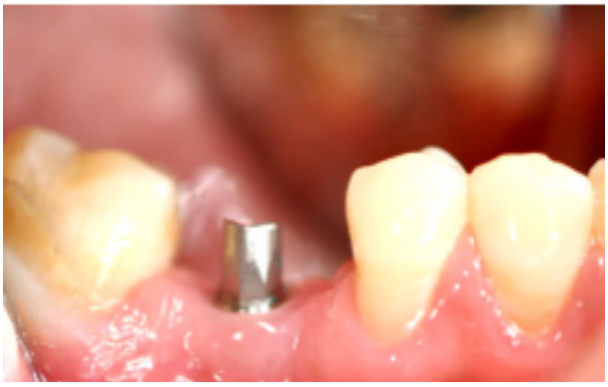


Figure 3: Group B - Titanium abutment on titanium implant

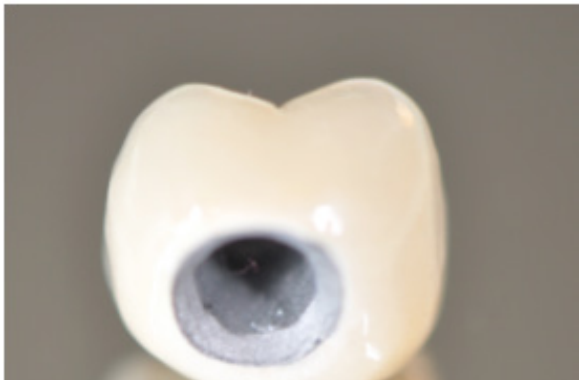


Figure 4: Group B - Porcelain fused on metal crown

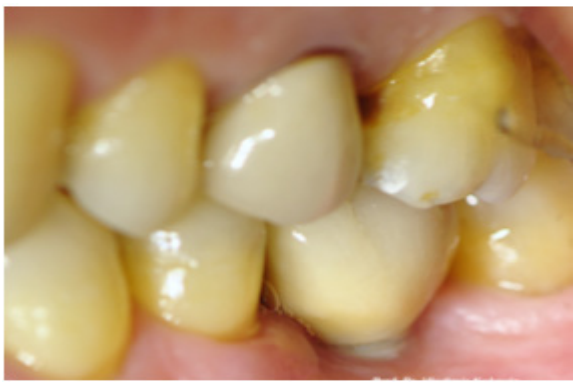


Figure 5: Group A - check point at 6 months.

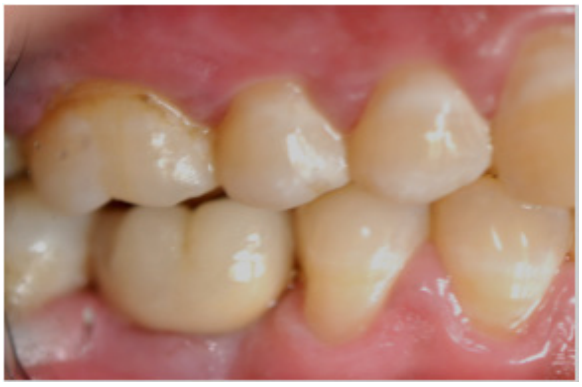
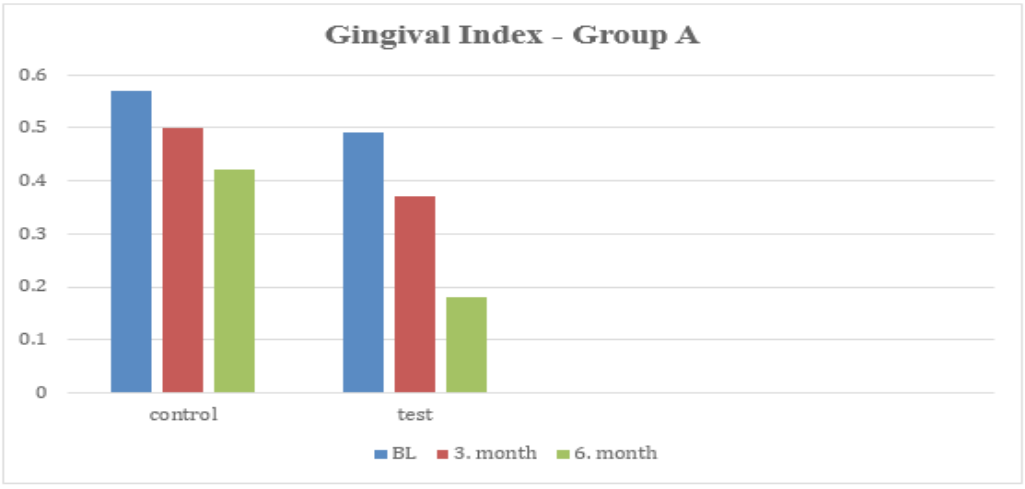
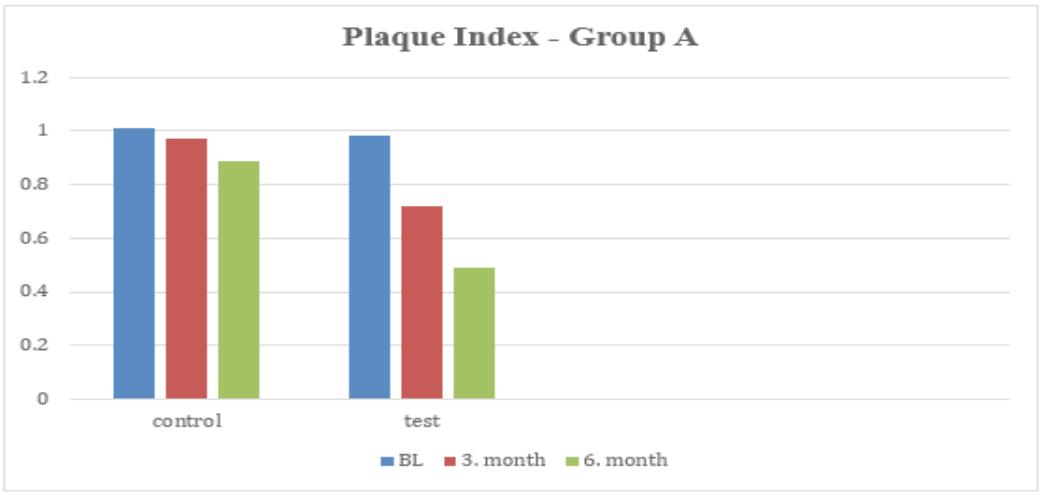


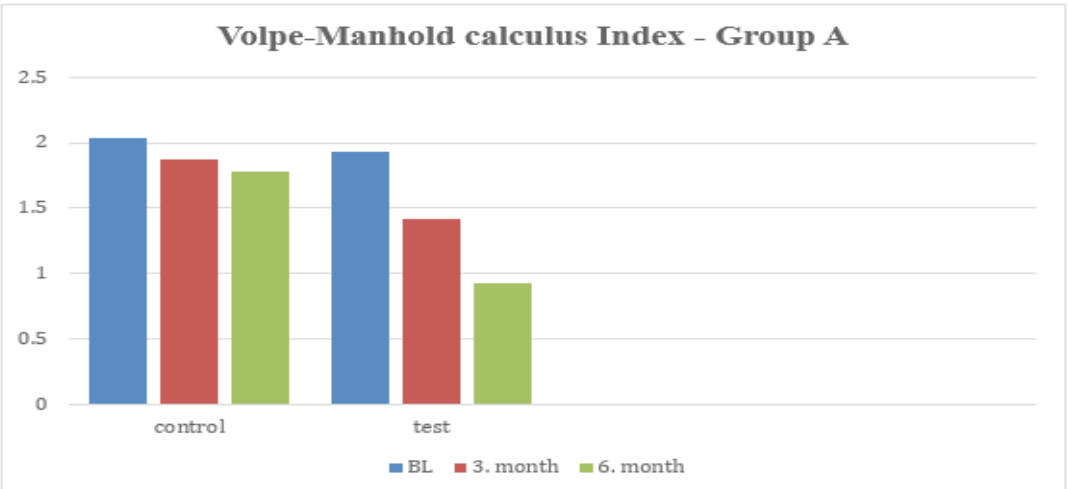
Figure 6: Group B - check point at 6 months.



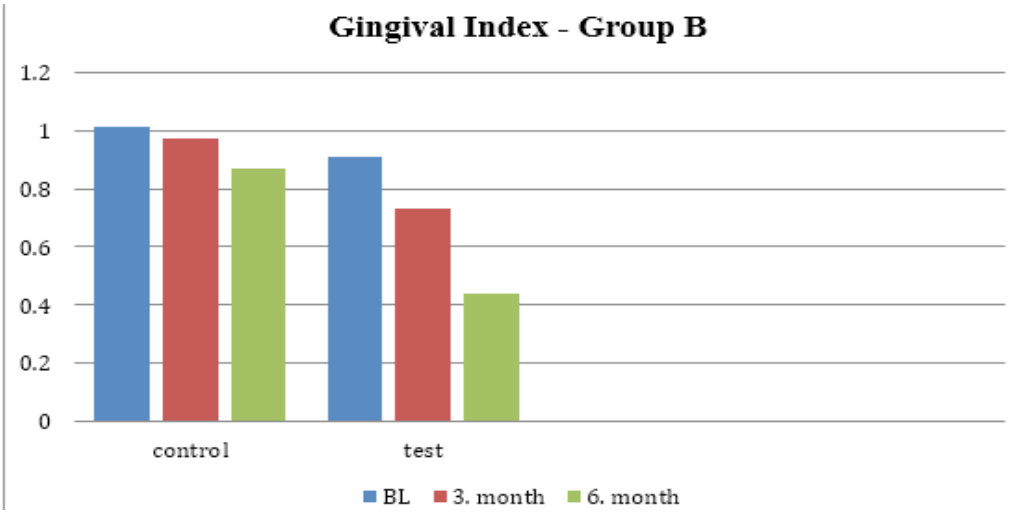
Graph 1: Gingival index – Differences between control and test subgroups in zirconium dioxide implants group.



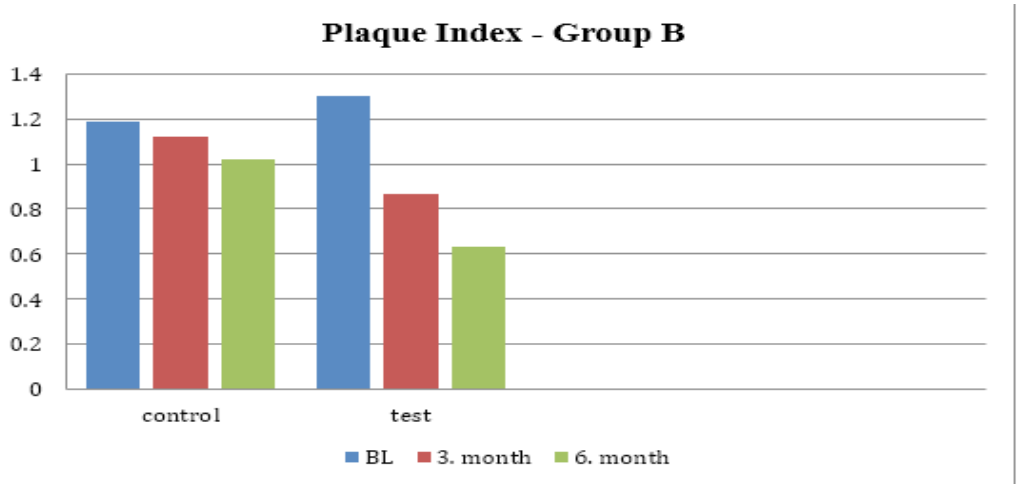
Graph 2: Plaque index – Differences between control and test subgroups in zirconium dioxide implants group.



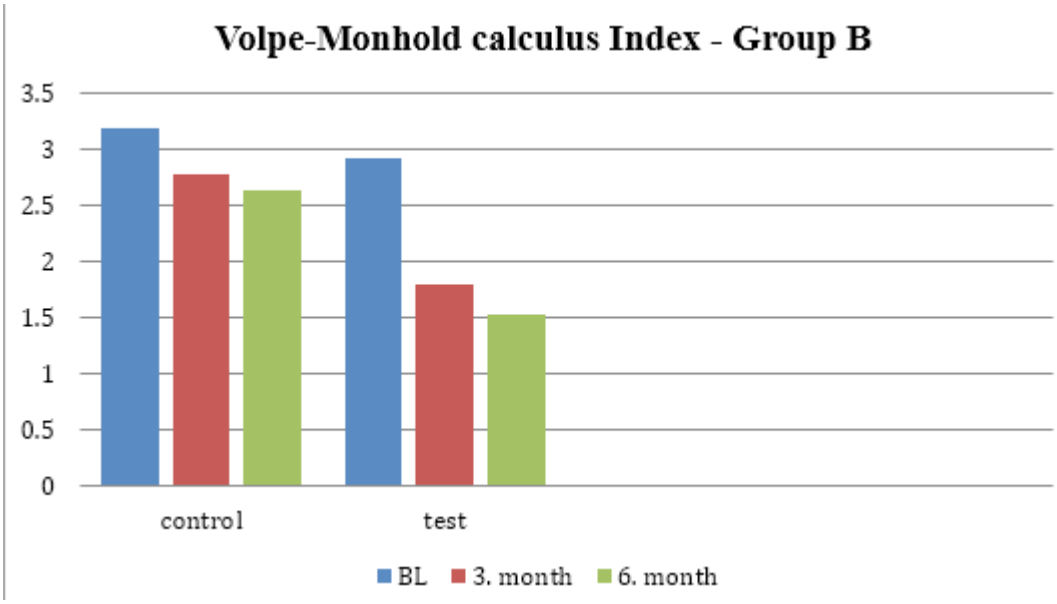
Graph. 3: Volpe-Manhold calculus index – differences between control and test subgroups in zirconium dioxide implants group.



Graph 4: Gingival index – differences between control and test subgroups in titanium implants group.



Graph 5: Plaque index – differences between control and test subgroups in titanium implants group.



Graph 6: Volpe-Monhold calculus index – differences between control and test subgroups in titanium implants group.

Volpe-Manhold calculus index (VMI)

To obtain the VMI score, the three tooth planes (mesial, distal and gingival) on lingual surface were exterminated. The periodontal probe was used to measure supragingival calculus on the implant shoulders. The calculus was measured in increment of 0.5mm from 0 to 5mm. Score of the all three planes were summed and all implants scores were summed for subject's total VMI score. The each of forty patients were consider as the statistic unit, that presents statically minimum value for pilot study.

II Randomization

The randomization was carried out using a lot. The control or test group was randomized using sealed envelopes. Each group (A & B) was divided in to the two subgroups (control & test).

Control group

Patients from control group were advised to brush twice daily 5 minutes;

Test group

Patients from test group were advised to brush twice daily 5 minutes followed by using the calculus dissolution based oral rinse Periogen®, USA, (One spoonful of Periogen was dissolved in 100ml of warm water and was directed to rinse with solution for at least one minute in three 20 seconds interval).

III Statistical Evaluation

All data were first analyzed by descriptive methods (QQ plots, box plots) (SPSS 18.0; SPSS, Austin, TX, USA). The patients were chosen as the unit for statistical analysis. The Wilcoxon signed rank test was used as well as Pearson's coefficient of correlation. The level of significance chosen in all statistical tests was at $P < 0.05$.

RESULTS

40 adult patients (28 females and 12 male) with mean ages 50.37 (SD ± 7.94) were involved in the study. All analyzed implants were tissue-level implants. In group A, 22 two-pieces zirconium dioxide implants (Axis Biodental. Les Bios, Switzerland) with 10 mm length and diameter 4mm were used for single tooth replacement in premolar and molar area of lower jaw. Results of clinical parameters form Group A (zirconium-dioxide dental implant) are presented in Table 1 For all clinical parameters statistical significant differences has been noted between test and control group in the assessment point of 6 months ($P = 0.02$) as illustrated in Figure 5 and Graph 1-3. In group B, 20 titanium SLActive (Straumann, Switzerland) implants length 8mm and 4.1, diameter were used. Results of clinical parameters form Group B (Titanium dental implant) are presented in Table 2. For all clinical parameters statistical significant differences has been noted between test and control group in the check point of 6 months ($P = 0.009$) as illustrated in Figure 6, Graph 4-6.

DISCUSSION

Similar study evaluated the periodontal parameters with zirconium vs titanium abutments. Less bleeding on probing and less plaque accumulation has been noted around zirconium abutment.[15] Kohal *et al*, compared clinical and radio-graphical outcome of one-piece zirconium implants and natural teeth with fixed dental prosthesis. The modified bleeding index (mBI) and modified plaque index (mPI) were significantly lower at implants than at teeth after one year follow up period.[16]

Results of present study is showing statistically significant better peri-implant condition around soft-tissue zirconium dioxide vs titanium implants in group treated with calculus dissolution based oral rinse Periogen® (Periogen Company-USA). During six months follow-up period no side effects were recorded among any group using Periogen mouthrinse. Supplementing toothbrushing by Periogen® mouthrinse will lead to success of peri-implant tissue around zirconium and titanium dental implants with significant amount of plaque and calculus reduction.

CONCLUSION

We conclude that calculus dissolution based Periogen® mouthrinse provided clinically significant reduction in calculus formation in subjects with zirconium dioxide and titanium dental implants when used twice daily for 6 months as an adjunct to toothbrushing.

ACKNOWLEDGMENT

None

CONFLICT OF INTEREST

None

ABBREVIATIONS USED

None

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