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Evaluation of Topical Application of Nigella Sativa (Black Seeds) on Delayed Dental Implant

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ABSTRACT

Purpose: The present study was conducted to evaluate the effect of topically applied Nigella Sativa (Black Seeds) on osseointegration of delayed dental implant in an effort to improve outcomes of dental implants. **Subjects and Methods**: The current study was performed on twelve (12) healthy patients that were divided randomly into two groups: Group 1 (Test group) included six (6) patients with delayed implant insertion with the topical use of nigella sativa; Group 2 (Control group) included six (6) patients with delayed implant insertion without the use of nigella sativa. **Results:** A non-statistically significant difference was recorded in clinical parameters after three and six months follow up in both groups. Test group showed a highly significant increase in its bone density after six months in comparison with control group. **Conclusion**: The topical use of nigella sativa in delayed dental implant showed an improvement in peri-implant tissues.

KEYWORDS

Dental implants, Nigella Sativa, Modified gingival index

INTRODUCTION

Dental implant is a valuable management approach in complete or partially edentulous patients, playing an important role in orofacial anatomic contour reconstruction, health, function, and esthetic [1,2].

A paper extracted from Master Thesis titled "Evaluation of Topical Application of Nigella Sativa (Black Seeds) on Delayed Dental Implant"

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About 450,000 osseointegrated dental implants are being placed annually, with high success rate reach 95% specially in case of solitary tooth replacement with an implant supported crown [3].

The original purpose of the dental implant treatment and to guarantee implant success is to produce and maintain a firm connection between bone and dental implant. This idea has been explained as composed of highly distinguishable tissue making" a direct structural and functional connection between prepared, existing bone and the surface of a load carrying implant"[4].

Bone quality is one of the main factors that have an effect on osseointegration of dental implant, reduced bone quality and/or quantity, believed as one of the most significant causes of implant failure as it leading to unfortunate anchorage and stability. Bone mass relays on the level of bone density there. Bone quality can progress in the region of a functional osseointegrated dental implant as a result of the positive bone stimulation, the extra bone that is present by the side of an implant place, the enhanced chance for implant success [5] .

Implant surface alteration has been considered and used to enhance natural surface properties helping osseointegration [6]. The main issue in implant osseointegration is surface irregularity, that demonstrated to raise osteoblast action in contrast to a smooth surface [7] . Surface roughness of the implant has been improved via different means as machining, plasma spray coating, grit blasting, acid etching, sandblasted and acid etching (SLA), anodizing, and biomimetic coating [8,9] .

With the purpose of encourage wound healing and attain an optimized osseointegration , systemic and local administration of drugs , plus growth and differentiation factors and / or implant drug based surface alterations have been engaged [10,11]. In the older years, the text concerning the local interferences become highly developed [11].

World is rising attention to treat different diseases by using medicinal herbs or plants due to their therapeutic potential and less side effects [12] .

One of the most classified as evidence based herbal medicine is Nigella Sativa (NS) [13,14] . Nigella Sativa is a flower plant within the family Ranunculaceae resident to the south and southwest Asia, and is developed in numerous countries within the Mediterranean area as South Europe, Syria, Turkey and Saudi Arabia. Nigella Sativa also recognized as black seed, black cumin, the seed of bleesing or Habbatul Barakah [15,16] .

The black seed has a religious and spiritual energy for the Muslims, as its therapeutic use was started after the arrival of Islam since **prophet Mohammed (peace and pray upon him)** talk about its therapeutic value and likely of cure, when said that" there is cure for every disease in black seed except death " [17]. This give explanation why NS is broadly used by many Muslims all over the world [18] .

The pharmacological action of the NS expose a broad spectrum of activity including antidiabetic[19,20], antihypertensive, anticancer, immunomodulator[20], antimicrobial, anti-inflammatory, analgesic, antihistaminic, bronchodialator, liver protection, kidney protection, spasmolytic and antioxidant qualities [21].

On the topic of implant dentistry, in an invivo study, the black seed oil extract was utilized to inspect its outcome on the bone implant interface's (mechanical and histological properties). Inside this experimental study, 12 New Zealand rabbits take delivery of 4 screw-shaped implants in the tibiae bone, the implant were separated into 2 groups; coated and uncoated with black seed oil extract, over a period of time. the end results demonstrated that, mechanically the coated implants had considerably superior torque resistance than that of uncoated implants, and histologically revealed early osseointegration with an osteophilic surface, besides, no undesirable tissue reaction [22] .

CBCT applied in implant dentistry to estimate the bone quality and quantity and to identify any bone diseases at implant site [23,24] and it was used in this study to estimate bone density changes before and after implant insertion.

SUBJECTS AND METHODS

Study design

The current study was a randomized clinical trial on 12 patients selected from the out-patient Clinic of Oral Medicine & Periodontology Department, Faculty of Dental Medicine for Girls, Al-Azhar University.

Sample Size:

Sample size calculations achieved using http://biomath.info/power according to the study (Clinical and Radiographic Evaluation of Immediate Loaded Dental Implants with Local Application of Melatonin: A Preliminary Randomized Controlled Clinical Trial)[25] . A total sample size of 12 patients (6 patients in each group) was sufficient to identify the difference. Total numbers of patients were divided randomly in to two groups;

Group 1 (Test group): 6 patients with delayed implant placement with the topicl use of nigella sativa.

Group 2 (Control group)**:** 6 patients with delayed implant placement without using nigella sativa

The patients were selected according to selected criteria (completely healed surgical site, presences of proper inter arch space for the placement of the implant prosthetic part, bone density ranging from D2 to D3, non-smoker and non-pregnant women). The selected patients signed an informed consent explaining all the procedures to the patients including all benefits and side effects in simple and easy way.

Surgical protocol:

After local anesthesia administration, crestal incision at the edentulous site with sulcular incisions around mesial and distal natural tooth were performed. Full thickness flap was elevated using mucoperiosteal elevator. Osteotomy site preparation through sequential drilling followed the protocol described by the implant company surgical kit (Dentium super line implant system (Emergo Europe, Seoul, Korea)) until reaching the desired diameter of the implant under copious saline irrigation, then the implant screwed in clockwise manner until complete seating of the implant to its final insertion depth. Flap was returned to its position covering the implant and sutured with 4-0 polypropylene (vicryl, absorpable) suture material.

Regarding test group (group1), the same steps were followed but, after preparation of osteotomy site and before implant placement, Nigella Sativa gel was applied inside the prepared site until the gel fill the whole osteotomy site. Augmentin 1g tablet antibiotic was prescribed twice per day for at least 5 days after surgery, Ibuprofen 400 mg tablet was given twice daily for 3 or 5days as analgesic and anti-inflamatory, Chlorhexidine 0.12% mouthwash was prescribed twice daily for one week after surgery.

Sutures were removed 10 days postoperatively. Two months after surgery, the cover screw of the implant was removed and gingival former was placed.

Nigella Sativa gel preparation: the gel prepared under complete aseptic condition according to this paper [26].

Clinical evaluation:

Modified Gingival index (MGI) was recorded for each patient at 3-months and 6- months after implant placement.

Probing depth (PD): It was obtained by measuring the probing pocket per site around the implant. Probing depth is measured from the gingival margin to the base of the sulcus. Probing depth was recorded at 3 and 6 months for each patient around the healing abutment.

Radiographic Assessment:

Cone beam computed tomography (CBCT) was used twice before fixture placement and at the end of the study (after 6 months) to record bone density.

Bone density was taken for the sagittal and coronal view. For each view, two lines were drawn along the total length of the implant fixture (mesial and distal aspect of the sagittal view, buccal and palatal of coronal view) and then each line splitted into three parts, corresponding the coronal, middle and apical thirds. Measurements were obtained from around approximately 1 mm in a parallel manner away from the implant fixture to avoid titanium artifact at the bone implant interface. Then these six readings were divided by six to get the mean value of bone density around each implant in each view. The readings were recorded in Hounsfield Units (HU) [27] .

STATISTICAL ANALYSIS

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges while qualitative variables were presented as number and percentages.

RESULTS

Clinical evaluation results:

Modified Gingival Index: at 3 months, test group showed a lower MGI mean (0.04 ± 0.10) than control group (0.13 ± 0.21), however this difference was statistically insignificant (P=0.401). At 6 months, test group showed a lower MGI mean (0.08 ± 0.20) than control group (0.21 ± 0.29), however this difference was statistically insignificant (P=0.411) (table 1).

Probing Depth: at 3 months, test group showed a lower PD mean (0.96±0.68) than that of control group (1.83±0.70), however this difference was statistically insignificant (P=0.053). At 6 months, test group showed a lower PD mean (0.63±0.16) than control group (1.44±1.05), however this difference was statistically insignificant (P=0.090) (table 1).

Table (1): *Results of MGI and PD changes of both groups through the study period:*

Mean of M.G.I after implant insertion		**Control group**	**Test group**	**Test value**	**P-value**	**Sig.**
		No. = 6	**No. = 6**			
At 3 months	Mean±SD	0.13 ± 0.21	0.04 ± 0.10	0.877	0.401	NS
	Range	0 – 0.5	0 – 0.25			
At 6 months	Mean±SD	0.21 ± 0.29	0.08 ± 0.20	0.859	0.411	NS
	Range	0 – 0.75	0 – 0.5			
Paired t T-test	t	1.000	1.000			
	p-value	0.363 (NS)	0.363 (NS)			
Mean of P.D after implant insertion		**Control group**	**Test group**	**Test value**	**P-value**	**Sig.**
		No. = 6	**No. = 6**			
At 3 months	Mean±SD	1.83 ± 0.70	0.96 ± 0.68	2.197	0.053	NS
	Range	0.75 – 2.5	0.5 – 2.25			
At 6 months	Mean±SD	1.44 ± 1.05	0.63 ± 0.16	1.878	0.090	NS
	Range	0.5 – 3	0.5 – 0.88			
Paired t-test	t	1.290	1.384			
	p-value	0.254 (NS)	0.225 (NS)			

P > 0.05: Non significant , P < 0.05: Significant, P < 0.01: Highly significant

Radiographic assessment results:

Bone density (coronal view): Within test group there was increase in the bone density reading before implant insertion and after 6 months (713.38 ± 124.37 and 969.87 ± 182.13) respectively; with high significant difference (P=0.002) (table 2) .

Bone density (sagittal view): At 6 months after implant insertion; control group and test group readings were 531.18 ± 76.13 and 795.65 ± 127.35 respectively. This demonstrated high statistically significant difference (P=0.001). Within test group there was increase in the bone density reading before implant insertion and after 6 months (627.74 ± 127.53 and 795.65 ± 127.35) respectively; with high statistically significant difference (P=0.005) (table 2) .

Table (2): *Results of bone density (coronal and sagittal view) changes of both groups through the study period .*

Mean of bone density (coronal view)		**Control group**	**Test group**	**Test value**	**P-value**	**Sig.**
		No. = 6	**No. = 6**			
Before implant insertion	Mean±SD	731.88 ± 130.89	713.38 ± 124.37	0.251	0.807	NS
	Range	488.95 – 860.95	506.1 – 820.8			
At 6 **months after implant insertion**	Mean±SD	799.60± 181.29	969.87 ± 182.13	-1.623-	0.136	NS
	Range	641.8 – 1073.95	629.65 – 1181			
Paired t-test	t	0.887	5.886			
	p-value	0.416 (NS)	0.002 (HS)			
Mean of bone density (saggital view)		**Control group**	**Test group**	**Test value**	**P-value**	**Sig.**
		No. = 6	**No. = 6**			
Before implant insertion	Mean±SD	659.44± 87.13	627.74 ± 127.53	0.503	0.626	NS
	Range	557.65– 806.1	441.3 – 752.3			
At 6 **months after** implant insertion	Mean±SD	531.18± 76.13	795.65 ± 127.35	-4.366-	0.001	HS
	Range	443.1– 664.95	596.95 – 924.95			
Paired t-test	t	2.275	4.882			
	p-value	0.072(NS)	0.005 (HS)			

P > 0.05: Non significant , P < 0.05: Significant, P < 0.01: Highly significan

DISCUSSION

Criteria to assess the success and failure of dental implants which involves clinical parameters (Modified Gingival index and probing depth) and radiographic measurement was carried out [28]. As regards Modified gingival index [29], it measured to express disease activity [30]. On the other hand, probing depth index is a critical index for identification of peri-implant disease [31] .

In terms of clinical parameters (MGI and PD) in this study, no significant difference was recorded between both groups at 3 and 6 months postoperative following implant insertion, this could be attributed to adequate patient motivation and proper oral hygiene [32].

Regarding bone density results; Before implant insertion no statistically significant was found between both groups (P=0.626), while, there was

highly statistically significant difference (P=0.001) 6 months after implant insertion.

The consequences of the improved bone around dental implant and enhance bone density in test group, this could be qualified to biological action of NS. Where, NS works as bioactive and bioinductive substance that stimulate and increase speed of bone formation this could be attributed to the existence of its components as Protein and amino acids. NS seed had 22.6% - 26.7% protein and amino acids mainly Glutamic acid, Arginine and Aspartic acid[33]. Moreover, rapid bone formation caused by black seed oil extract could be attributed to the presence of calcium and phosphorous in its chemical constituents which are essential for bone formation[34] .

CONCLUSION

The use of Nigella Sativa gel in delayed dental implants may be able to improve bone quality around dental implants as it increase bone density, thus improving implant osseointegration which leading to good prognosis for a long-term survival.

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