Short-term evaluation of dental implants in a diabetic population: an *in vivo* study

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PURPOSE. The study was conducted to evaluate the efficacy of implant supported tooth replacement in diabetic patients. **MATERIALS AND METHODS.** The study involved placement of implants (UNITI implants, Equinox Medical Technologies, Zeist, Holland, diameter of 3.7 mm and length 13 mm) in five diabetic patients (three females and two males) of age ranging from 35-65 years with acceptable metabolic control of plasma glucose. All patients included in the study were indicated for single tooth maxillary central incisor replacement, with the adjacent teeth intact. The survival of the restored implants was assessed for a period of three months by measurement of crestal bone heights, bleeding on probing and micro flora predominance. Paired t-test was done to find out the difference in the microbial colonization, bleeding on probing and crestal bone loss. *P* values of less than 0.05 were taken to indicate statistical significance. **RESULTS.** Results indicated that there was a significant reduction in bleeding on probing and colonization at the end of three months and the bone loss was not statistically significant. **CONCLUSION.** The study explores the hypothesis that patients with diabetes are appropriate candidates for implants and justifies the continued evaluation of the impact of diabetes on implant success and complications. **[J Adv Prosthodont 2012;4:134-8]**

KEY WORDS: Diabetes mellitus; Dental implants; Gingival bleeding on probing; Osseointegration; Implant prosthesis

INTRODUCTION

In the past two decades, dental implants have become increasingly popular as a procedure to restore missing teeth. A number of patient and procedure related parameters determine the success of the implant treatment.

Diabetes Mellitus (DM) is the most common systemic disease which is generally considered as a relative and not an absolute contraindication for implant therapy.¹

Among men and women over 55 years of age, where the rates of edentulism are higher, about 18.4 percent of individuals have some form of diabetes affecting the whole body.²

Since tooth loss is greater in diabetic than in non-diabetic individuals, the validity of dental implant treatment options for these patients has to be realized.³ The metabolism of phosphorus and calcium is essential for bone mineralization & remodeling and is affected by hyperglycemia, which alters the response of the parathyroid hormone. Diabetes mellitus also inhibits osteoblastic differentiation.⁴ The success of replacing lost teeth by dental implants in diabetic patients was evaluated in a study in 1999 by Balshi and Wolfinger.² The study found a success rate of 94.3% with 227 Brånemark implants for a follow up period of two years, and concluded that the success rates of dental implants are higher in controlled diabetics.² In 2003 Peled *et al.* evaluated the clinical outcome of dental implants in a group of controlled diabetics over a five year period and they reported an overall success rate of 97.3%.⁵

Further a study done in 2003 by Al Jabbari *et al.*, showed that diabetic geriatric patients with acceptable glucose control demonstrated a 92.7% success rate, 1 year after first stage surgery.⁶

The above literature indicates that diabetic patients are eligible candidates for implant therapy provided their plasma glucose level is under metabolic control.

The aim of the study was to evaluate the efficacy of implant as tooth replacement in diabetic patients with acceptable metabolic control with early non-functional loading protocol evaluated at periodic time intervals for three months. Survival of the implants is evaluated by radiographic evaluation to measure the crestal bone heights, clinical assessment by bleeding on probing and microbiological colonization around the implants.

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CLINICAL REPORT

- The study group consisted of five patients (three females and two males) of age ranging from 35-65 years attending the outpatient clinic of Department of Prosthodontics, Faculty of Dental Sciences, Sri Ramachandra university, Chennai, India.
- The patients were diagnosed as diabetic and were on a modified diet or receiving oral medication, insulin or combination therapies and with good metabolic control as evaluated by laboratory investigation. Efforts were made to meet the plasma glucose levels recommended by the American Diabetes Association (fasting plasma glucose-of 140 ml/dl and 2- hour post prandial glucose of 200 ml/dl).⁵ All cases were indicated for single tooth maxillary central incisor replacement (Fig. 1) with adjacent teeth intact or restored with functionally and aesthetically acceptable restorations.
- The exclusion criteria were patients with a history of smoking habit, alcohol or drug abuse, health conditions not permitting surgical procedures, history of bone grafting at the implant site, patients who had previously failing implants in the selected implant locations and patients who had evidence of oral pathology such as tumour, chronic bone disease or previous irradiation.

MATERIALS AND METHODS

Blood glucose levels were monitored one week prior to surgery. The patients signed an informed consent and were explained about all the procedures that would be done during the study. The approval for this clinical study was obtained from the Institutional Review Board of Sri Ramachandra university. Under local, anesthesia, a crestal incision was made and a full thickness muco-periosteal flap was raised. Sequential osteotomy was performed following manufacturer's instructions. Single stage screw tapered, self threaded Implants (UNITI implants, Equinox Medical Technologies, Zeist, Holland) with a diameter of 3.7 mm and length 13 mm were placed with an insertion torque of 45 Ncm (Fig. 2) and an early non-functional loading protocol was followed.

Patients were recalled after an interval of 4 days from the day of surgery, for evaluation of the implant and for cementation of the provisional restoration. Abutments were placed with a torque of 15 Ncm. The provisional restoration was fabricated using heat cure acrylic resin and cemented with non-eugenol zinc oxide cement (3M ESPE). The restoration was relieved from all centric and eccentric contacts. Sutures were removed after a period of one week.

Data collection

Three parameters were selected for each patient to evaluate the survival of implants; radiographic evaluation, microbiological assessment and clinical assessment.

Radiographic evaluation

The examinations were done at periodic intervals on the 4^{th} , 20^{th} , 40^{th} , 60^{th} and 90^{th} day after the surgical procedure.

Radiographic examination was carried out with Radiovisuography (RVG) taken with RINN X ray holders (RINN Corp. Com., Dentsply, Elgin, IL, USA) using a paralleling long cone technique.

The implant shoulder and the alveolar crest were used as reference points. The distance between the 2 references points was measured digitally, using SOPRO digital imaging software. Measurements were made at the proximal site; the values were calculated and recorded. Original implant length was used as a standard to calculate distortion of radiographs.



Fig. 1. Preoperative facial view of single missing maxillary central incisor.



Fig. 2. UNITI implant (Equinox Medical Technologies, Zeist, Holland) with a diameter of 3.7 mm and length 13 mm placed.

Microbiological assessment was done to identify microorganisms located subgingivally along the implant site. The micro flora was examined for their predominance of aerobic organisms and represented by means of colony forming units (CFU). All patients were instructed to brush twice daily and rinse the mouth after every meal.

On the fourth day, the provisional restoration was removed and the abutment was isolated with sterile gauze at the palatal and buccal sites. Specimens were collected using sterile swab which were inserted into the depth of peri-implant site and kept for 15-20 seconds (Fig. 3). The swab was transferred to a test tube (Fig. 4) and handed over to the Microbiology laboratory for investigations.

All the samples were plated in 5% Blood agar (Fig. 5a), Chocolate agar (Fig. 5b) and MacConkey agar (Fig. 5c) using streak culture (surface plating) method. Plates were then analysed and quantified by semi quantitative method. Colonies were identified by Gram stain, growth was reported



Fig. 3. Specimen collection using sterile swab to identify microorganisms located subgingivally along the implant site.

for, Cocci, Bacilli, Gram positive (Staphlylocoocus aureus, Streptococcus species) and Gram negative (Pseudomonas species) pathogens. The number of colonies of each sub cultured isolate was related to the total colony count (CFU) to obtain the relative proportion.

This sampling procedure was also repeated at regular intervals of 4^{h} , 20^{h} , 40^{h} , 60^{h} day and at the end of three months. Since the restoration was cemented using a temporary cement, it could be removed easily without causing damage to the soft tissues around the implant.

Clinical assessment

Bleeding on probing (BOP) is a widely used clinical indicator to detect the presence of inflammation. By clinical observation of bleeding on probing using calibrated manual periodontal probe, the peri-implant tissue was assessed around the implant.

The Mombelli *et al.*⁷ scores were used as the standard (Table 1).



Fig. 4. Transfer of samples to vials.



Fig. 5. A: Blood agar medium demonstrating colonization of fastidious organisms, B: Chocolate agar medium showing largest proportion of microorganisms obtained from the samples. This is a non-selective medium that showed colonies of respiratory bacteria, anaerobic organisms and gram positive cocci, C: MacConkey agar medium showing colonization. Colonies of Gram negative bacteria were seen.

Table 1. Mombelli et a	<i>al.</i> ⁷ scores	tistical significance.
Score	Finding	The differences in the crestal bone measurements were
0	No bleeding	investigated using paired t-tests (Table 2). P value (probability
1	Isolated bleeding spots	value) between the 4^{th} day and the end of three months was less
2	Confluent red margin	than 0.05 to indicate statistical significance
3	Heavy or profuse bleeding	The Mombelli <i>et al.</i> ⁷ scores indicate that there was a defi-

RESULTS

Statistical analysis

The microbial colonization, bleeding on probing and crestal bone loss data was transferred onto a spreadsheet programme. The data were analyzed using statistical packages (SPSS for Windows) for statistical analysis. Initially the mean, the standard deviations and ranges were calculated for the quantitative data. Paired t-test was done to calculate the difference in the microbial colonization, bleeding on probing and crestal bone loss data. P values of less than 0.05 were taken to indicate sta-

nite amount of inflammation present in all patients after implant placement, especially till the 20th day. By the end of three months there was significant reduction in bleeding on probing, indicating healthy tissues surrounding the implant. Statistical values describing gingival bleeding scores are presented in Table 3.

Results of microbiological examination indicate that colonization was significantly reduced by the end of three months and was similar to that of contra lateral tooth. The differences in the colonization, appreciated a gradual decrease in colony forming units. Differences between quantitative variables were tested with Wilcoxon ranked sign test (dependent data, i.e. within-group comparisons), (Table 4). P value (probability value) between the 4th day and the end of three months was less than 0.05 to indicate statistical significance.

Table 2. Comparison of bone loss at base line,	changes over the follow up	p and end of study
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			Paired difference	s				
	Mean		Std. Error	95% Confidence interval of the difference		Т	Df	Sig.
			Ivicali	Lower	Upper			(2-101100)
Pair 1 4th Day - 20th Day	09800	.05630	.02518	16791	02809	-3.892	4	.018
Pair 2 4th Day - 40th Day	22400	.11349	.05075	36492	08308	-4.413	4	.012
Pair 3 4th Day - 60th Day	43000	.23043	.10305	71612	14388	-4.173	4	.014
Pair 4 4th Day - 90th Day	50000	.22192	.09925	77555	22445	-5.038	4	.007

Table 3. Comparison of gingival index scores (t-test) from the base line, over the follow up and at the end of study Paired Samples Test

			Paired difference	es				
	Mean	SD	Std. Error Mean	95% Confidence interval of the difference		Т	Df	Sig.
				Lower	Upper			(2-tailed)
Pair 1 4 th Day - 20 th Day	.40000	.54772	.24495	28009	7.08009	1.633	4	.178
Pair 2 4th Day - 40th Day	.80000	.83666	.37417	23885	1.83885	2.138	4	.099
Pair 3 4th Day - 60th Day	1.40000	.89443	.40000	.28942	2.21058	3.500	4	.025
Pair 4 4th Day - 90th Day	1.60000	.54772	.24495	.91991	2.28009	6.532	4	.003

Table 4. Proportional count of micro-organisms from the base line, over the follow up and at the end of study (Colony forming units) (Wilcoxon signed ranks test) Paired Samples test

	Mean SD		Std. Error Mean	95% Confidence interval of the difference		Т	Df	Sig.
			Ivicali	Lower	Upper			(2-taneu)
Pair 1 4th Day - 20th Day	59400.00	54224.53319	24249.95	-7928.65	126728.7	2.449	4	.070
Pair 2 4th Day - 40th Day	93780.00	5185.74970	2319.138	87341.04	100219.0	40.437	4	.000
Pair 3 4th Day - 60th Day	99360.00	492.95030	220.45408	98747.92	99972.08	450.706	4	.000
Pair 4 4th Day - 90th Day	99720.00	402.49224	180.00000	99220.24	100219.8	554.000	4	.000

DISCUSSION

It is estimated that 15% to 25% of the elderly population suffer from either insulin-dependent or noninsulin-dependent diabetes mellitus.⁸ The influence of diabetes on bone and bone forming cells imposed many speculations about the use of dental implants in diabetics and osteoblast function was shown to improve by glycaemic control.⁹

The present study evaluated the efficacy of implant as tooth replacement in diabetic patients with acceptable metabolic control with early non-functional loading protocol by radiographic evaluation, clinical assessment and microbiological colonization around the implants.

Loading protocol in diabetic patients is an important factor in the success of dental implant treatment. Balshi *et al.* in 2007, identified that an immediate loading protocol in a diabetic patient can lead to successful osseointergration despite the effects that the disease has on the bone remodelling process.¹⁰

In a two year follow up study done by Azza Ezz Ell-Arab in 2000 assessed the durability of single tooth replacement implant in controlled diabetics versus non-diabetics.¹¹ Radiographic evidence of bone intergration was detected in both healthy and diabetic individuals. It is essential to detect early signs of diabetes in the clinical peri-implant evaluation and plan the therapeutic intervention accordingly. Absence of bleeding on probing (BOP) is widely considered as an useful clinical indicator for the absence of inflammation.¹²

In the present study, there was no association found between presence of microorganisms and amount of bone loss. Between 4^{th} day (base line) and at the end of 90^{th} day, statistically different counts were found at the implant surfaces. By the end of 90^{th} day the colonization was similar to that of the contra lateral healthy tooth. Thus, significantly lower bacterial counts of putative pathogens were found at the end of three months.

The findings of the present study were similar to that reported by Salvi *et al.* in 2007.¹²

In the present study, all implants were well intergrated in bone for the duration of the study as evaluated by clinical and radiographic criteria. However, future studies are needed to establish definitive guidelines with objective criteria such as duration, type of diabetes and glycosylated hemoglobin levels. Better study designs, preferably longitudinal randomized clinical trials, are needed to evaluate various determining factors and prove such a statement.

CONCLUSION

The results of this retrospective study show that a growing number of diabetic patients can enjoy the benefits of dental implants provided their diabetes is under control. A high success rate of dental implants is achievable in diabetic patients whose disease is under control.

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