

ORIGINAL RESEARCH

Clinical and Radiological Evaluation of Two Stage Implant in A Single Stage Procedure and Two Stage Procedure – A Comparative Study.

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Abstract: The aim of this study was to estimate and compare the marginal bone loss, pocket formation and stability of two stage implant in single stage procedure and two stage procedure. Sixteen patients with twenty edentulous sites participated in this study. After randomization, 10 edentulous sites received two stage implant with standard protocol of delayed loading and 10 edentulous sites received two stage implant in which immediate abutment is placed. Loading was done for immediate group within 2 days with temporary resin crown. After 3 months, permanent crowns were fabricated for both the groups. A standardized clinical and radiographic evaluation was performed immediately after prosthesis placement and after 6, 12 and 18 months. One implant of the 2-stage group was lost after 3 months. The mean bone loss after 18 months for two stage group was 1.11 ± 0.60 mesially and 0.88 ± 0.48 distally where as for single stage group was 1.05 ± 0.49 mesially and 0.70 ± 0.34 distally. All implants were stable with no clinical mobility and pocket depth was comparable for the groups. The results of this study suggest that dental implants designed for a submerged implantation procedure inserted in the partially edentulous ridge in a one-stage approach appears to be at least as predictable as the conventional two-stage technique, suggesting that a two-stage implant system can be safely used for implant insertion in a single stage procedure.

Keywords: Two Stage implant, Single Stage implant, Immediate loading, Delayed loading, Bone loss.

Introduction

The success of osseointegrated dental implants has revolutionized dentistry. Branemark and co-workers recommended a period of stress free unloaded healing to ensure the osseointegration of endosseous implants^{1, 2}. High success rates for two stage implant protocol have been documented³. But taking into account the prosthetic phase, patient frequently had to wait up to one year for a lost tooth to be replaced. But the result of advances in research on implant design, materials and techniques, made it possible to shorten this edentulous period because of which the use of these devices has increased dramatically in the past 10 years and is expected to expand further in the future⁴. In a 2 – stage approach, the implant is submerged during the first surgical procedure and then after osseointegration abutment is connected; the microgap at the junction between implant and abutment is generally situated at bone crestal level. Where as in a single stage procedure with one stage implant there is no microgap between

abutment and implant, which is considered to be better for success of implant. This is because it has been suggested that the microflora colonizing the microgap causes peri implant marginal bone loss in 2-stage procedure⁵. Techniques have their own advantages, so both are taken into consideration in this study and hence we have used 2-stage implant as a two stage procedure and two stage implant as a single stage procedure. Immediate loading is done only in cases where we got immediate stability with insertion torque above 40 Ncm, otherwise standard two stage protocol was followed. By using this method we can decide intraoperatively, after placement of the implant whether to go for single stage or two stage procedure. The surgeon can anytime during osseointegration period switch from nonsubmerged implant to a submerged implant. The aims of the study were to estimate and compare the marginal bone loss, pocket formation and stability of two stage implant in single stage procedure and two stage procedure.

Materials and methods

The present comparative clinical study was conducted as an open, prospective, interdisciplinary trial in the department of oral and maxillofacial surgery, Sharad Pawar Dental College Wardha. All the patients requiring replacement of single missing tooth in upper or lower jaw were considered for this study irrespective of their sex, caste, religion under the auspices of an informed consent document. The random sample of 16 patients with 20 single tooth missing was included in the study based on following inclusion and exclusion criteria. The study was approved by the institutional ethical committee.

INCLUSION CRITERIA: -

1. Patients above 16 years old age.
2. Patient's had to be free of periodontal diseases
3. Patient with partial edentulous ridge preferably with missing mandibular lower first molars.
4. Sufficient amount of residual alveolar ridge should be present.

EXCLUSION CRITERIA: -

1. Patient's with debilitating disease.
2. Patients who were pregnant, lactating or having habits such as smoking & tobacco chewing.
3. Patients with severe bruxism & uncontrolled periodontal disease.
4. Patient's using any drug which compromising osseointegration.

Patient confirming to the inclusion criteria and willing to provide informed consent were enrolled. Sixteen patients required twenty single tooth implant were divided into two groups randomly, after placement of 2-stage implant intraoperatively.

Group A: - Patients received 2-stage implant with a 2-stage procedure.

Group B: - Patients received 2-stage implant with single stage procedure.

For all patients included in the study Diagnostic cast, blood investigations & x-ray were made preoperatively. In the present study, the Adin implant system (Adin Dental Implant Systems Ltd., Israel) was used. The surface of the implant is SLA Aluminum oxide blasted, with a slightly tapered design and are double thread 2 x 0.6 mm self tapping. Its unique design allows extremely accurate

positioning for improved esthetics and load distribution. Implant length, implant diameter were recorded for every case. For all patients preoperatively planning was done for two stage implant surgery and patients were randomly selected for placement of abutment immediately and making it a single stage surgery provided that immediate initial implant stability is above 40 Ncm. All patients were informed prior regarding the procedure and if possible immediate loading will be done. The surgeries in this study were performed by one surgeon. The patients were prescribed chlorhexidine 0.2% mouth rinse two days prior. Standard surgical protocol was followed for two stage procedure.

After placement of the implant, cases were randomly selected as Group B patients. In these patients immediately abutment was placed and surgical site was closed with non resorbable Mersilk 3-0. After 7 days suture removal was done for control group i.e. Group A and patient was recalled after 3 months for second stage procedure. But for Group B patients in test group, after 2 days of implant placement, patients were recalled for impression and temporary crown made of white acrylic resin replacing missing tooth. Then patient were recalled after 3 months for permanent crown fabrication.

Three months after implant placement, second stage surgery for the connection of titanium prosthetic abutment and final restoration was performed in the Group A patients whereas temporary crowns replaced with final restoration in group B patients. Radiographs and clinical examination was done for both the groups to assess bone loss, periodontal pocket and clinical mobility in both the groups. Then patients were recalled at 6 months, 1 year and 1.5 year of interval postoperatively for further follow up for probing pocket depth, mobility and bone loss.

Results and observation

A total of 16 patients (20 sites) were evaluated in the study and divided in two groups. There were 5 male (50%) and 5 female (50%) patients in two stage group and there were 3 male (30%) & 7 female (70%) patients in single stage group. The age of the patient ranged from a minimum of 22 years to a maximum of 52 years, median age of the sample being 37 years. There were 5 patients (50%) in two stage group and 6 patients (60%) in single stage group in age up to 30

years, 5 patients (50%) in two stage group and 4 patients (40%) in single stage group in age more than 30 years. So pt's age and site was almost same for both the procedures as shown in Table 1.

		Two stage	Single stage
Sex	Male	5 (50.0%)	3 (30.0%)
	Female	5 (50.0%)	7 (70.0%)
Age	Up to 30	5 (50.0%)	6 (60.0%)
	More than 30	5 (50.0%)	4 (40.0%)
Site	Maxillary	2 (20%)	3 (30%)
	Mandibular	8 (80%)	7 (70%)

For both the group total 10 sites were included in each. The results of all the three parameters for both the groups are shown in table 2. All implants were stable in two stage group at end of 1.5 year span except 1 which lost after 3 months. Bone loss mesially was 1.11 ± 0.60 and distally was 0.88 ± 0.48 at the end of 1.5 year. Periodontal pocket depth recorded was 1.16 ± 0.17 after 1.5 year. All implants were stable in single stage group at end of 1.5 year with no clinical mobility. Bone loss mesially was 1.05 ± 0.49 and distally was 0.70 ± 0.34 at the

	Bone Loss				Pocket Depth		Clinical Mobility	
	Two Stage Group		Single Stage Group		Two Stage Group	Single Stage Group	Two Stage Group	Single Stage Group
	Mesial	Distal	Mesial	Distal				
6 months	0.55±0.68	0.33±0.50	0.65±0.57	0.20±0.34	1.08±0.18	1.05±0.10	No	No
1 year	0.94±0.52	0.66±0.35	1.0±0.52	0.70±0.34	1.08±0.18	1.05±0.10	No	No
1.5 year	1.11±0.60	0.88±0.48	1.05±0.49	0.70±0.34	1.10±0.17	1.05±0.10	No	No

end of 1.5 year. Periodontal pocket depth recorded was 1.05 ± 0.10 after 1.5 year. According to these results there is no significant statistical difference in both the groups at the end of 1.5 year, so two stage implants may be as predictable as single stage implants when loading immediately. Further to analyze both the groups critically at any period of time various following test has been done, which gave accurate differences between both the groups at any period of evaluation time.

Analysis of variance was carried out to find out the difference between the two groups for periodontal Pocket Depth at different time period. No

statistical difference was observed at any time of assessment ($p > .05$) as shown in table 3.

Pocket depth		Sum of Squares	Df	Mean Square	F	Sig.
PPD (6m)	Between Groups	.169	1	.169	2.107	.165
	Within Groups	1.364	17	.080		
	Total	1.533	18			
PPD (1yr)	Between Groups	.037	1	.037	1.748	.204
	Within Groups	.364	17	.021		
	Total	.401	18			
PPD (1.5yr)	Between Groups	.064	1	.064	3.132	.095
	Within Groups	.350	17	.021		
	Total	.414	18			

No statistical difference was observed for Bone Loss Mesial at any time of assessment ($p > .05$) between two groups as shown in table 4.

Mesial bone loss		Sum of Squares	Df	Mean Square	F	Sig.
Bone Loss Mesial_3m	Between Groups	.313	1	.313	.556	.466
	Within Groups	10.125	18	.563		
	Total	10.438	19			
Bone Loss Mesial_6m	Between Groups	.042	1	.042	.106	.748
	Within Groups	6.747	17	.397		
	Total	6.789	18			
Bone Loss Mesial_1yr	Between Groups	.015	1	.015	.053	.821
	Within Groups	4.722	17	.278		
	Total	4.737	18			
Bone Loss Mesial_1.5yr	Between Groups	.018	1	.018	.059	.811
	Within Groups	5.114	17	.301		
	Total	5.132	18			

No statistical difference was observed for Bone Loss Distal at any time of assessment ($p > .05$) between two groups as shown in table 5.

Distal bone loss		Sum of Squares	df	Mean Square	F	Sig.
Bone Loss Distal_3m	Between Groups	.613	1	.613	2.384	.140
	Within Groups	4.625	18	.257		
	Total	5.238	19			
Bone Loss Distal_6m	Between Groups	.084	1	.084	.462	.506
	Within Groups	3.100	17	.182		
	Total	3.184	18			
Bone Loss Distal_1yr	Between Groups	.005	1	.005	.043	.839
	Within Groups	2.100	17	.124		
	Total	2.105	18			
Bone Loss Distal_1.5yr	Between Groups	.169	1	.169	.961	.341
	Within Groups	2.989	17	.176		
	Total	3.158	18			

Discussion

Teeth can be congenitally missing or lost because of trauma or dental disease. In this study out of 20 edentulous ridges 2 patients were having

congenitally missing tooth (10%) and 2 patients gave a history of trauma (10%) and 16 patients have undergone extraction for caries or attrition (80%). In the present study prevalence of tooth loss was more with caries than trauma and similar findings were observed in other studies⁶.

In the past once the decision has been made for implant supported prosthesis, it was very easy for the surgeon to directly follow the original Branemark protocol to place the implant and do the loading after 6 – 8 months as per the protocol⁷. But with recent advances and research in the field of dental implantology various researchers,^{8,9,10,11} have proved that immediate loading is also a valuable method for implant placement and loading.

Immediate loading of dental implants presents certain advantages, including

1. Elimination of the need for a second surgical procedure.
2. Reduced number of postsurgical visits for prosthesis maintenance.
3. Elimination of the need for relines of the interim removable prosthesis.
4. Increased patient comfort.
5. Immediate restoration of function.
6. Improved esthetics.

Hence, nowadays even after deciding for implant supported prosthesis the task for the surgeon is not finished. He has multiple questions in his mind like, which type of implant is to be used? What type of loading protocol is to be followed? If primary stability is not achieved after placement of one stage implant what would be the fate of that one stage implant? So because of all these questions and doubts surgeons hesitate to use one stage implant even for those patients who can be treated successfully with immediate loading.

The key objective of this randomized controlled prospective study was to evaluate and compare the effect of delayed loading and immediate loading of a single-tooth implant using a two stage implant for both the groups based on implant stability values, radiographic parameters, and clinical pocket depth.

The significance of this microgap between implant components according to studies done^{12, 13, 14, 15, 16} concluded that crestal bone loss occurs even if the microgap is placed 1 mm coronal to the alveolar crest. Furthermore, the alveolar changes occur rapidly and then stabilize. They concluded that one part nonsubmerged implant results in best tissue response. The main disadvantage of two stage implant is if the abutment loosens on the implant placed in the submerged approach, an inflammation ensues and, in some cases, an infection with a fistula is observed. Whereas in some studies^{17, 18} they concluded that dental implants designed for a submerged implantation procedure can also be used in a single-stage procedure and may be as predictable as when the same implants used in a 2-stage procedure or as 1-stage implants. Placement of the microgap at the crestal level in 2-stage implants did not appear to have an adverse effect on the amount of peri-implant bone loss at 1.5 years in this study population. In accordance to these studies we also found similar results in our study that placement of microgap have no adverse effect on bone loss, so two stage implant can be used as single stage implant also by connecting abutment instead of cover screw at the time of implant placement.

In this prospective study total 20 single tooth edentulous sites were included according the inclusion criteria and patients were prepared for surgery and informed that immediate loading will be decided after placement of implant intra-operatively and all patients received two stage implant with the microgap kept at crestal level for all patients. In our study we got primary stability in all 20 implants above 40 Ncm and then patients were randomly divided as for two stage group and one stage group.

The clinical results correspond with those of studies evaluating two-stage implants inserted in the common two-stage approach^{19, 20, 21} and in a one stage procedure^{8, 22 & 10}. In our study we compared three parameters radiographically and clinically i.e. bone loss on mesial and distal sides, periodontal pocket depth and implant stability for both the groups at interval of 3 months, 6 months, 1 year and 1.5 year.

On distal side in two stage group in our results we got bone loss reduced at 6 months than 3months because of the fact that 1 implant was lost of two stage

group after 3 months of time period. Implant was lost because the patient was chronic smoker and he gave the wrong history preoperatively but continued smoking after implant placement. Patient gave this history at the time of failure of the implant. These results are in accordance to the results shown by various authors who compared both the groups^{5,17,23}.

Periodontal pocket depth when compared clinically for both the groups, there was no significant difference found in both the groups ($p > .05$). These results confirmed that clinically also there is no significant difference occurs when two stage implant is loaded immediately^{24,25}.

In our study all 19 implants were stable and there was clinically no mobility seen with any of the 19 implant after span of 1.5 year. 1 implant was lost after 3 months as previously mentioned and rest all implants were stable.

There were as such no complications such as inflammation, pain or altered sensation found with the technique. Healing was good in all the cases and all implants were well osseointegrated. Soft tissue dehiscence was not reported in any of the cases. So according to the Branemark protocol²⁶, Atraumatic surgery and sterile conditions are still the two main factors to be considered at the time of implant placement. Whereas the third factor of two stage protocol to avoid any mechanical or microbiological challenge during the healing period of an implant in the bone may vary according to individual case. In cases where we found acceptable initial stability above 40 Ncm, those implants may be loaded immediately without any complication or compromising osseointegration.

Hence, the outcome of two-stage implants inserted in the partially edentulous ridge in a one-stage approach appears to be at least as predictable as the conventional two-stage technique, suggesting that a two-stage implant system can be safely used for implant insertion in a non-submerged procedure. Complications were not seen with any of the case even though implants were loaded immediately. Microgap was kept at the crest for all the cases and it did not appear to have an adverse effect on the amount of peri-implant bone loss at 1.5 years in this study population.

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