International Journal of Advanced Scientific Research
ISSN: 2456-0421; Impact Factor: RJIF 5.32
Received: 03-01-2019; Accepted: 07-02-2019
www.allscientificjournal.com
Volume 4; Issue 2; March 2019; Page No. 01-06

Is single stage protocol for placement of dental implants preferable to the conventional two stage protocol? (Original research)

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Abstract
Aim: The aim of the present study was to compare and evaluate failures of implants, prosthetic complications, patients perception of pain and satisfaction levels along with radiologic changes in peri implant bone levels in implants placed with single stage and two stage technique followed by conventional loading of implants
Methodology: A total of 20 implants (10 in each group) were placed in periodontally healthy partially edentulous patients, with one or more teeth missing in mandibular posterior region having adequate amount of bone and keratinized tissue and who were greater than or equal to 18 years of age. They were followed up for a period of 6 months.
Results: The mean of the satisfaction levels was 7.40 in the single stage technique and 5.80 in the two stage technique. The p-value was 0.01.
Crestal bone loss was lower in implants placed with the single stage technique as compared to the two stage technique.
Conclusion: Within the limitations of this study it can be concluded that the single stage approach might be preferable over the two stage approach when placing and restoring dental implants.

Keywords: implant, single stage, two stage, patient satisfaction levels

1. Introduction

Dental implants have emerged as a panacea for the treatment of edentulism, both partial and complete. Quality of life can drastically be improved by replacing missing teeth with dental implants.

The process of replacing missing teeth with dental implants involves a Surgical and Prosthodontic phase [1].

Brånemark *et al* originally suggested that the implant surgery be performed in two stages. During the first stage the implant is placed into the maxilla or mandible and submerged beneath the oral mucosa until osseointegration has been achieved. A second-stage procedure is subsequently performed to uncover the implant and place a healing abutment that remains supra-gingival or nonsubmerged. Submerging the implant during the healing phase avoids infection of the implant, prevents loading, and avoids epithelial downgrowth [1, 2].

However, the prerequisite of submerging implants during the healing phase was not universally accepted. A one- stage (or single stage) procedure was originally developed by the International Team for Implantology (IT I) which showed equally good results when compared with 2 stage implants [1, 3].

Nowadays, clinical research is focusing on shorter and less invasive procedures. Different placement and loading protocols are currently used to shorten treatment times and decrease the amount of surgical interventions, enabling clinicians to choose between a single-stage (non-submerged) and a two-stage (submerged) approach. (4)

Inserting implants in one stage has several advantages. Only one surgical intervention is required, which is convenient for the patient, especially for the medically compromised patient. In addition, there is a considerable cost-benefit advantage. The prosthetic phase can start earlier because there is no wound-healing period involved related to a second surgical procedure. Furthermore, the implants are accessible for clinical monitoring during the osseointegration period [5].

Certain studies [6, 7, 8]. Have also shown a propensity for increased failure rate in implants placed with the single stage technique. The fact that divergent results can be found in the literature merits more randomized clinical trials with a larger number of patients to confirm these preliminary results so that a consensus on the modality of treatment can be arrived at.

Hence the aim of this in vivo study was to evaluate and compare clinical parameters such as implant failures, prosthetic complications, patient's perception of pain and satisfaction levels with the procedure along with radiological parameters such as changes in peri implant

bone levels in implants placed with single stage and two stage technique followed by conventional loading of implants.

Materials and Methods

An in vivo study was conducted in the Departrnent of Prosthodontics, Crown and Bridge and Oral Implantology, H. P Government Dental College and Hospital, Shimla, Himachal Pradesh. A total of 20 implants (10 in each group) were placed in periodontally healthy partially edentulous patients, with one or more teeth missing in mandibular posterior region having adequate amount of bone and keratinized tissue and who were greater than or equal to 18 years of age.

All the patients were informed about the purpose of study and after explaining the purpose and nature of study the informed consent form was signed by the patient.

Presurgical Assessment

A detailed medical and dental history of each subject was obtained along with preoperative photographs and radiographs. All vital signs were checked and a complete hemogram was done to evaluate the fitness of the patient prior to implant placement. The surgical area selected for dental implant placement was evaluated clinically for width and to assess for any deep undercuts. CBCT was used to accurately evaluate the amount of bone and proximity from vital structures for each patient. A complete oral prophylaxis along with prescription of 0.2% chlorhexidine gluconate mouth rinse, twice daily for a period of 15 days before dental implant placement was advised. All subjects were motivated to maintain oral hygiene.

Fabrication of Study Models and Surgical Stent

Preliminary alginate impressions were made and study models fabricated prior to surgery. A diagnostic wax-up of the involved tooth was made and a surgical stent was fabricated based on the wax-up to facilitate implant placement.

Fabrication of the Vinyl Polysiloxane Jig

A Polysiloxane putty jig was fabricated to standardize the radiographic film holder (Rinn XCP) for each subject, in terms of, angulations and position of the film relative to the X-ray beam. Vinyl Polysiloxane Putty was mixed and attached to film holder. The film holder was seated into subject's mouth at a correct angulation and subject was instructed to bite on putty to get indentation of maxillary teeth. Then, this occlusal jig was used to take radiographs at subsequent visits during the follow-up visits to measure/assess bone level changes [17].

Surgical Preparation

The patients were pre-medicated with antibiotics (Amoxicillin 2g) 1 hour prior to surgery. They were asked to rinse the mouth with Chlorhexidine 0.2% prior to administration of local anaesthesia using Lignocaine with adrenaline in the ratio of 1:100000.

Implant Placement with Single Stage Procedure

Crestal incision was given for full thickness flap reflection, to expose the implant site.

Surgical stent was then placed over the crest to mark the implant site. The implant size and diameter was kept the same when comparing both the techniques. The implant site was penetrated with the help of a pilot drill which was used to create a bleeding point and site of initial osteotomy when the surgical stent was still in place. After marking the implant site by surgical stent, the surgical stent was removed and pilot drill was used to complete depth , followed by subsequent drills of increasing diameter to create an osteotomy site of required dimensions for each patient. A paralleling pin was used during osteotomy preparation to assess the drilling orientation. The implants were then inserted into this osteotomy site with the help of a torque wrench.

Healing abutments were then screwed to the implants immediately after implant placement to close the opened implant site. Once the healing abutments were placed the surgical site was thoroughly irrigated and flap was sutured using non- resorbable 3-0 silk sutures to achieve water-tight closure. The patients were prescribed with antibiotics and analgesics for I week, post-operatively.

Implant Placement with Two Stage Procedure

Crestal incision was given for full thickness flap reflection, to expose the implant site.

Surgical stent was then placed over the crest to mark the implant site. The implant site was penetrated with the help of a pilot drill which was used to create a bleeding point and site of initial osteotomy when the surgical stent was still in place. After marking the implant site by surgical stent, the surgical stent was removed and pilot drill was used to complete depth , followed by subsequent drills of increasing diameter to create an osteotomy site of required dimensions for each patient. A paralleling pin was used during osteotomy preparation to assess the drilling orientation. The implants were then inserted into this osteotomy site with the help of a torque wrench.

Cover screws were then screwed onto the implants and after thorough irrigation the implant site sutured with non- resorb able 3-0 silk sutures to achieve water-tight closure. The patients were prescribed with antibiotics and analgesics for 1 week, post-operatively.

The second stage surgery was carried out 10 weeks after implant placement in which the cover screw was replaced with a healing abutment. The patients were again prescribed with antibiotics and analgesics for 1 week, post-operatively.

Impression making and prosthesis fabrication

After abutment placement, the transfer cap was placed on the abutment and the impression was made by polyvinylsiloxane material using indirect impression technique. After applying gingival mask, Impression was then poured in die stone to fabricate the cast.. Final prosthesis was fabricated and cemented with the help of Type I Glass Iononer Cement (Luting).

Follow up

Any implant that was removed or failed to osseointegrate was designated as a failed implant. Prosthetic complications such as abutment screw loosening were noted.

Patient’s perception of pain in implants placed with single stage and two stage technique was evaluated evaluated using a 0 to 10 numbered scale,0 corresponding to no pain at all, and 10 as the maximum pain imaginable. Patients entire experience with the procedure was also evaluated by a numbered scale after loading.

The patient was then recalled for follow up for radiographic evaluation which was made at 3 months and 6 months of implant placement for evaluation of crestal bone changes with help of radiographs.

The measurements were recorded at: Immediate post-operative .3 months following dental implant placement ,6 months following dental implant placement

The standardized periapical radiographs were obtained were digitized using Digimizer Image analysis. The known implant length was used to calibrate the images in the computer software.

To measure radiologic changes in per implant bone level, a fixed reference point had to be selected. The shoulder of the implant was taken as the reference point in the study. The distance from the point to the crest of the bone where it contacted the implant on mesial and distal sides was measured. The first point was selected on the shoulder of the implant. The second point was measured on the crest of the bone where it contacted the bone. The distance between the points was displayed. On each recall the distance was measured and changes in crestal bone levels were analysed.

The results obtained were subjected to statistical analysis using Student's(Unpaired) t-test.

Results and discussion

The original protocol for implant surgery as suggested by Branemark *et al* required it to be performed in 2 stages. During the first stage the implant is placed into the maxilla or mandible and submerged beneath the oral mucosa until osseointegration has been achieved. A second-stage procedure is subsequently performed to uncover the implant and place a healing abutment that remains supra-gingival or no submerged. Submerging the implant during the healing phase avoids infection of the implant, prevents loading, and avoids epithelial down growth [1, 2].

However, the prerequisite of submerging implants during the healing phase was not universally accepted. A one- stage (or single stage) procedure was originally developed by the International Team for Implant ology (IT I) which showed equally good results when compared with 2 stage implants.

The major disadvantage of the two stage procedure was the need for a 2nd surgical intervention which not only increased treatment time but was also uncomfortable for the patient.

Although there have been multiple previous studies which have compared the single stage approach with the two stage approach with respect to changes in peri implant bone levels, there has been no study to our knowledge which has compared the patient's perception of pain as well as the patient's satisfaction levels with each procedure.

As the patient is the centre of everything that we as clinicians and researchers do, it was the aim of this study to determine, among other parameters, the perception of pain the patient felt with each procedure as well as the satisfaction level of the patient with the procedure.

The aim of the present study was to compare and evaluate failures of implants, prosthetic complications, patients perception of pain and satisfaction levels along with radiologic changes in peri implant bone levels in implants placed with single stage and two stage technique followed by conventional loading of implants.

The present study showed that there were no implant failures or prosthetic complications in either group.

When comparing patient's perception of pain and satisfaction levels with the procedure, the present study showed that the mean of the patients perception of pain for the single stage procedure was 2.47 while the mean of the patients perception of pain for the two stage procedure was 3.20. The p-value was 0.059 which is considered to be not significant . Although insignificant, the patients perception of pain was lesser in the single stage technique as compared with the two stage technique.

The mean of the satisfaction levels was 7.40 in the single stage technique and 5.80 in the two stage technique. The p-value was 0.01 which is considered to be significant **.** This shows that the satisfaction levels of the patients with the single stage approach was significantly higher than that of the two stage technique.

Present study also aimed to compare the radiologic changes in peri implant bone level in implants placed with the single stage and two stage technique. The mean of the mesial crestal bone loss at 3 months for the single stage technique was 0.40 mm while it was 0.46 for the two stage technique. The p-value was 0.018 which is considered to be significant**.**

The mean of the mesial crestal bone loss at 6 months for the single stage technique was 0.58 mm while it was 0.64 for the two stage technique. The p-value was 0.082 which is considered to be insignificant.

The mean of the distal crestal bone loss at 3 months for the single stage technique was 0.40 mm while it was 0.46 for the two stage technique. The p-value was 0.012 which is considered to be significant.

The mean of the distal crestal bone loss at 6 months for the single stage technique was 0.40 mm while it was 0.46 for the two stage technique. The p-value was 0.013 which is considered to be significant.

Thus the present study shows that there was also a significant decrease in crestal bone loss in implants placed with the single stage technique and that the single stage technique can actually be preferred over the two stage technique.

The results of this study are in accordance with studies done by Barber (1996) [1] in which a total of 20 implants were placed in 5 patients in which osseointegration and soft tissue healing of a traditional two-stage implant system placed in one stage and two stage procedures in the posterior edentulous mandible were compared and they and demonstrated no significant difference between the experimental and control groups.

They are also in accordance with studies conducted by Cecchinato [9, 10] in 2004 and 2008 who after evaluating 324 implants placed in 84 patients concluded that Peri implant bone-level change during function seemed to be unrelated to whether the implant installation had occurred by the single stage or two stage approach.

Apart from the above mentioned studies, other studies [11-17] done in the past have suggested that the one stage technique can be as predictable as two stage technique, a result that is in accordance with the present study .In fact, the results of this study suggest that the one stage approach can actually be preferred over the two stage approach, a result that is supported by a study conducted by Park *et al* (2009) [18] who placed 97 implants (62 one-stage and 35 two-stage) and stated that Bone resorption due to the difference in placement method (one-stage surgery, two-stage surgery) showed a statistically significant difference 1 year after

prostheses placement, with the one-stage surgery exhibiting less resorption.

The results of this study though are not in accordance with other studies conducted in the past by Roynesdal (1999),Fenlon (2002) and Bector 2007 which have concluded that the two stage approach is better than the single stage approach as the single stage approach has shown an increased propensity for implant failures [6, 7, 8].

Bone resorption is known to take place mainly during the first year after prosthesis placement, decreasing considerably after the prosthesis is stabilized [19]. There is no precise known cause for initial bone resorption around the implant, but some studies suggested that it could be caused by the interruption of blood circulation due to the external injury made during surgery [20, 21].

It is well known that vascularization of the underlying bone is determined by three essential sources: major supra-periosteum vessels, vascular plexus of the periodontal ligament, and the vessels of the alveolar bone. With the absence of a tooth, the plexus of the ligament disappears, leaving the vascularization to the two other sources. Under these conditions, flap reflection entails a loss of the blood supply of the supraperiosteum vessels so the bone vascularization depends upon its own vessels which is a poor blood source, especially in the case of cortical bone. This will imply a certain level of bone resorption during healing in cases in which a mucoperiosteal flap is raised especially in cases where a mucoperiosteal flap is raised twice such as when implants are placed using a two-stage approach [22]. Since the patients were carefully selected, and the surgery was performed by the same operator under standard conditions, the higher bone loss around implants installed through two-stage approach can be attributed to the histological process of bone repair after trauma and the surgical procedure done for submerge fixtures in which the tissue had to be manipulated twice.

As the patient is the raison d'etre for all clinicians, emphasis must be placed on the satisfaction levels of the patient. The decreased satisfaction levels of patients in whom implants were placed with the two stage approach can be attributed to the fact that they had to undergo two separate surgical procedures. The two separate surgical procedures not only increased the chances of patient morbidity but also led to the patient having to suffer the psychological trauma of a surgical procedure twice. It also led to increased cost for the patient as it led to a potential loss in work hours for the patient, not to mention the fact that they had to follow post-operative instructions as well as consume the same course of medicines twice.

The drawbacks of this study included the fact that in this study, intra-oral radiography was used to evaluate the radiologic changes in peri implant bone level, which is quite a sensitive method. However, it should be noted that this technique could only record bone level in two dimensions (mesial and distal). Therefore, it is highly likely that some information (bone loss in the buccal and lingual dimensions) might be missing, although enough data can be recorded for clinical follow up and diagnostic procedures. Currently, new diagnostic radiographic methods such as cone beam computed tomography (CBCT) are more reliable for scientific studies and evaluations, but due to lack of patient co-operation and absence of relevant infrastructure we had to use intraoral radiography.

Although this study shows that the single stage approach can actually be preferred over the conventional two stage approach, However, there might be situations, for instance when an implant has not obtained an optimal primary stability or when barriers are used for guided tissue regeneration, or when it is expected that removable temporary prostheses could transmit excessive forces on the penetrating abutments especially in fully edentulous patients, where a 2-stage submerged approach might be still preferable [23].

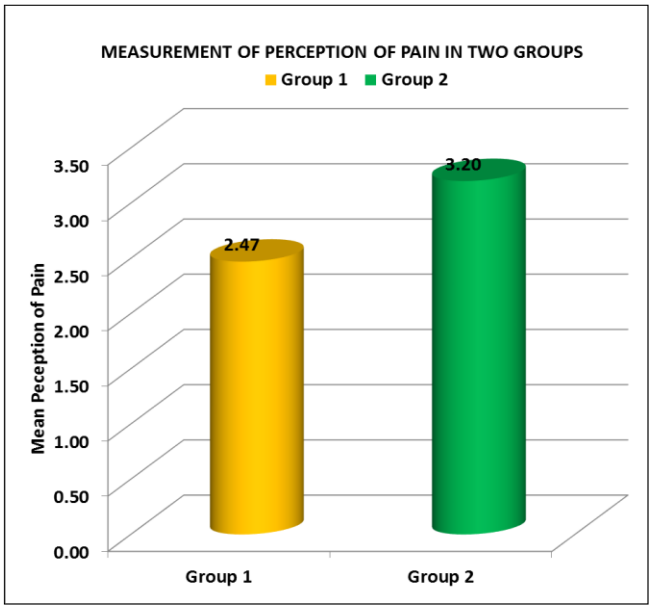


Fig 1: Perception of pain in Implants Placed with Single Stage Protocol (Group 1) and Two Stage Protocol (Group 2)

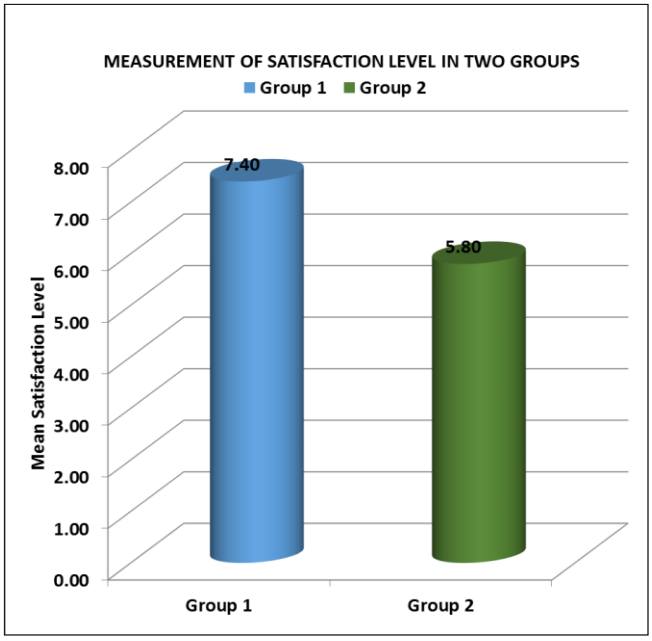


Fig 2: Measurement of Satisfaction Level in Implants Placed with Single Stage Protocol (Group 1) and Two Stage Protocol (Group 2)

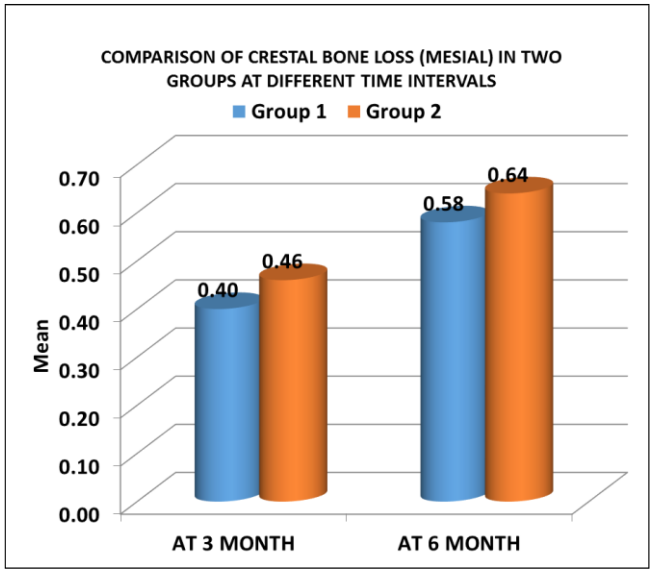
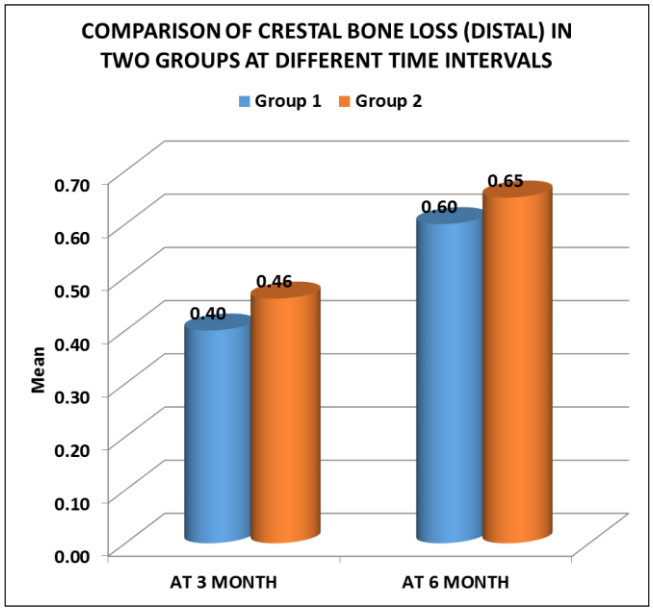


Fig 3: Comparison of Crestal Bone Loss (Mesial) in Implants Placed with Single Stage Protocol (Group 1) and Two Stage Protocol (Group 2)



Graph 4: Comparison of Crestal Bone Loss (Distal) in Implants Placed with Single Stage Protocol (Group 1) and Two Stage Protocol (Group 2)

Conclusion

Within the limitations of this study it can be concluded that the single stage approach might be preferable over the two stage approach when placing and restoring dental implants. However, there might be situations, for instance when an implant has not obtained an optimal primary stability or when barriers are used for guided tissue regeneration, or when it is expected that removable temporary prostheses could transmit excessive forces on the penetrating abutments especially in fully edentulous patients, where a 2-stage submerged approach might be still preferable.

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