Evaluation of the health of the peri-implant tissues around immediately placed dental implants in aggressive periodontitis patients versus periodontally healthy individuals in the maxillary esthetic zone: Controlled clinical trial

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DOI 10.23805/JO.2019.11.03.18

INTRODUCTION

Aggressive periodontitis is a non-symptomatic disease especially in its early stages (1). It is a unique form of periodontal disease characterized by specialized behavior of the immune system against the self-tissues and the inhabiting bacteria. Up till now, there is no definite characteristics that could be determined to describe the onset and behavior of the disease (2, 3). Therefore, it is difficult to be early discovered especially in developing countries with lack of medical insurance and continuous follow up. In 1999, Armitage changed the disease name into aggressive periodontitis (1, 4). In 2018, both terms chronic and aggressive periodontitis were merged into a single term "Periodontitis". The latest classification could not pass over the presence of its unique nature, characters (as progressive periodontal destruction in short periods of time) and its presence in the developing countries. The latest consensus recommended more controlled research to discover its presence and treatment options (3, 5).

As reported in the literature, aggressive periodontitis begins as a silent disease with absence of questionable annoying symptoms during childhood which exhibits great difficulty to collect history from the affected patients. In children, periodontal disease is not a common phenomenon. Marginal inflammation is the first sign that needs meticulous follow up to protect against its progression to periodontitis (3, 6). The incidence of tooth loss is high either it was in the early or late stage during patient’s life (7).

The systematic review conducted by Ramirez et al. (2018) (8) showed that only 15 out of 104 publications provided a definite definition for aggressive periodontitis or in other words, the other publications gave non-specific definitions that could be difficult to be interpreted. Great heterogeneity was identified regarding the diagnostic protocol between the included studies. Finally it was concluded that about 90% of the literature studies were not based on a well-established population and adequate sample size (8).
Furthermore, even in the inactive stages of the disease, the resulted reduced periodontium leads to several events such as increased teeth mobility, teeth migration by the help of tongue and surrounding muscles pressure, parafunctional habits and unbalanced occlusion (7). The insertion of dental implants into fresh extraction sites provided a realistic solution to overcome such problem (9, 10). The most obvious advantages of immediate dental implants are preservation of width and height of the alveolar bone and to counteract the advanced bone resorption following extraction for better placement. It enables perfect three dimensional allocation of the implant and reduction of treatment time and surgical interventions with relevant patients’ satisfaction. On the functional level, better crown to implant ratio could be successfully achieved with improved soft tissue esthetics. Although the advantages of immediate placement, it is generally avoided in aggressive periodontitis (10, 11, 12). According to literature, the implant placement in aggressive periodontitis is not contraindicated. Several researches discussed in details the possible advantages and drawbacks of the delayed placement in aggressive periodontitis patients (13, 14). Short term clinical studies revealed high success and survival rates in the delayed approach (97.4-100%), while long term studies revealed 83.3 to 96% survival rate in the delayed approach (1). Long term studies reported successful results of osseointegrated implants in generalized aggressive periodontitis. No great evidence supports aggressive periodontitis as a risk factor in the survival of dental implants (15).

Only few case reports were conducted to analyze immediate implant placement in aggressive periodontitis patients; up till now, there is no longitudinal study discussing the possibility and safety of this procedure. The aim of the present non-randomized controlled study was primarily to evaluate the health of the immediately placed dental implant in aggressive periodontitis in comparison to healthy individuals along 12 months follow up.

MATERIALS AND METHODS

Research hypothesis
The null hypothesis was that health of the immediately placed dental implants in aggressive periodontitis patients equals periodontally healthy individuals.

Study population, setting and recruitment strategy
The study was conducted in the oral medicine and periodontology department - Cairo University, Egypt. The included sample was recruited from Egyptian patients seeking for implant therapy.

Sample size
A study of independent cases and controls was planned, with 1 control(s) per case. Prior data indicate that the failure rate among controls is 0.55. If the true failure rate for experimental subjects is 0.85, for the study 35 experimental subjects and 35 control subjects were necessary to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. An uncorrected chi-squared statistic was used to evaluate this null hypothesis (16).

Ethical procedures
The study was conducted in accordance with Helsinki declaration (version VI 2002) (16). All procedures were approved the ethical committee of the Faculty of dentistry, Cairo university. The study was registered at clinicaltrials.gov (registration number: NCT03218228). The detailed operation was clearly described to all patients that were selected in this study. Each patient was informed with the study purpose, details of the surgical procedure and the alternative treatments suitable to his/her condition. All patients agreed and provided a signed written and verbal informed consent (17).

Inclusion and exclusion criteria
Patients’ screening procedure continued until the target population was achieved. Screening and examination processes were performed by a periodontist (AR) according to the pre-determined inclusion criteria: patients requiring immediate post-extraction implantation, older than 18 years of age, good oral hygiene defined as a full mouth plaque score and full mouth bleeding score ≤ 25%, presence of failing tooth/teeth in the maxillary esthetic zone, target sites were clinically healthy with no symptomatic periapical radiolucency, absence of acute abscesses or chronic sinus tract, sufficient bone height apical to the target tooth (18), sufficient mesio-distal space for implant placement (≥ 6.5 mm, i.e. 1.5 mm on each side of the 3.5 mm platform), presence of adequate keratinized tissues, psychological health suitable for surgical and restorative procedures (19). As for aggressive periodontitis, all patients had a history of periodontitis but with no active phase during the surgical phases (20). The exclusion criteria included; pregnancy and lactation at the time of inclusion (18), history of uncontrolled systemic condition that may interfere with wound healing (e.g., cardiovascular diseases, diabetes mellitus, osteoporosis, autoimmune diseases, metabolic bone diseases, cancer) (18), history of drugs that affect bone metabolism (bisphosphonate therapy, radiotherapy, chemotherapy, corticosteroids) (18), heavy smokers (≥ 10 cigarettes/day), alcohol and drug abusers (18), non-treated periodontal disease and/or caries, non compliant patients or patients with poor oral hygiene (full mouth plaque score and full mouth bleeding score
Evaluation of immediately placed implants in aggressive periodontitis versus periodontally healthy mucosa

Endodontic condition: A vertical root fracture

Criteria:

- surrounding structures when it met the following
- restorable) with high risk to the adjacent teeth and
- teeth. The tooth was considered hopeless (non-
- Controls: 35 sites of periodontally healthy unrestorable
- were atraumatically extracted and immediately replaced
- end of recall phase, the non-retainable hopeless teeth

Stage 3 limited to three teeth (molars and incisors), Stage 2 limited to two teeth, disease limited to one tooth, Stage 1, a
- results and according to staging mentioned in the latest

Patients’ grouping

The enrolled patients were divided into equal groups with 35 implants per each. Control group (A): immediate implant placement in periodontally healthy individuals. Test group (B): immediate implant placement in aggressive periodontitis patients. Periodontally compromised patients: 35 sites underwent periodontal treatment at the department of periodontology-postgraduate clinic, faculty of dentistry, Cairo University (Egypt). The diagnosis was based upon both the American Academy of Periodontology (4) and its latest modification in 2018 (3). The enrolled periodontally affected patients revealed localized or generalized clinical attachment loss (>3 mm) at more than 3 sites including incisors and/or first molars. Prior to surgery, the enrolled patients followed a 2 months recall system including instructions, motivation, education and professional oral hygiene control. For appropriate results and according to staging mentioned in the latest consensus (3), patients were classified into Stage 1, a disease limited to one tooth, Stage 2 limited to two teeth, Stage 3 limited to three teeth (molars and incisors), Stage 4 the classic Löe and Brown definition of disease. At the end of recall phase, the non-retainable hopeless teeth were atraumatically extracted and immediately replaced with dental implants.

Controls: 35 sites of periodontally healthy unrestorable teeth. The tooth was considered hopeless (non-
- retrievable hopeless teeth were atraumatically extracted and immediately replaced with dental implants.

Clinical parameters

According to Misch et al. (2008) (21), evaluation of the health and survival of the immediately placed dental implants depends mainly on assessment of pain and tenderness during function, clinical mobility, radiographic bone loss following implant placement and exudates. The Health scale (descriptive scale) is chosen to describe the primary outcome for dental implants. It depends on the assessment of 5 parameters that evaluate the implants’ health; 1, pain and tenderness upon function; 2, clinical mobility; 3, radiographic bone loss following the initial surgery; 4, probing depth; 5, exudates. The resultant information was then categorized into 4 classes: success (optimum health), satisfactory survival, compromised survival and failure (clinical or absolute failure) (21). Higher scores of peri-implant probing depth do not indicate the presence of disease. In successful implants, 2-6 mm pocket depths could be reported. Deeper probing depths were associated with implants rather than teeth in partially edentulous patients. Probing depth is only indicator for compromised survival condition (16, 21).

Clinical mobility is a term that describes the tooth or implant movement upon function. In osseointegrated implants, lack of vertical and horizontal clinical mobility is a characteristic phenomenon. Ideally, dental implants could move in a range less than 75µm. In case of clinical mobility, the implant is considered as being failed (21).

The radiographic assessment along the study period includes: rate of interproximal crestal bone loss (the distance reflects the number of the exposed threads in relation to implants). The measurement of radiographic bone level in relation to implant length and threads is an ideal method rather than the standardized parallel technique in order to avoid vertical distortion. Radiographs were evaluated by single examiner (16, 22). During the first year, the average marginal bone loss in relation to dental implants usually ranges between 0-0.2 mm. According to (21) Misch et al .(2008), the amount of radiographic bone loss is a clinical criterion that determines the implant success, survival or failure. Records were measured at 1, 3 and 6 months post-operatively. The radiographic bone resorption throughout the follow up period was measured by calculating the mean of the pre-loading period (6 months) and the mean of the post-operative period.

Surgical procedure

Using a pilot drill with copious saline irrigation, an initial osteotomy was created on the palatal wall and apical to the socket base in order to achieve maximum engagement of the remaining alveolar bone and protection of the thin labial walls. Sequential drilling was then performed according to the manufacturer’s protocol to complete the osteotomy. The implant

≥25%) (18), severe parafunctional habits as bruxism and clenching (18), patients during active orthodontic treatment, psychiatric disorders with psychiatric drugs administration, acute infection (with the presence of pus or fistula) around the failing tooth (18), failure to achieve a stabilizing insertion torque of at least 25 Ncm, and failure to maintain integrity of the bony socket during the extraction, the need for prior augmentation of the implant site (18)

- Remaining supragingival sound coronal tooth structure. Loss of tooth structure deep into the root dentin/canals and/or furcation involvement (19).
- Endodontic condition: A vertical root fracture or a tooth that has been retreated several times endodontically and/or surgically without resolution. Occlusal plane and tooth: A tooth so far super-erupted or tilted out of the occlusal plane that it cannot be restored into correct position/function, or would interfere with the restoration of that arch or the restoration of the opposing arch (19).

After 6 months, all patients underwent implant exposure with placement of healing abutment for 4 weeks. Fortunately, all patients displayed good compliance along the study period (12 months).
(Biomate implant system, Biomate Medical Devices Technology Co., Ltd, Taiwan) was then inserted and screwed manually using a multi-setting torque wrench till resistance was achieved. In order to ensure primary stability, the positioned implants had to be placed at least 3-4 mm apical to the most apical point of the socket reaching a final insertion torque 25-35 N/cm. In an apico-coronal direction, the implants' platforms were placed at least 1.5-2 mm apical to the labial alveolar bone crest. Following placement, implant cover screw was placed (12, 18, 22). The flap was adapted into its original position using 4/0-5/0 polypropylene interrupted sutures ensuring primary closure.

Statistical analysis
The statistical analysis was performed with software program (Minitab). The mean values, standard deviation and p-value were determined for each group of patients. The paired t-test was used to compare between the clinical values of the placed implants in both groups and verification of the statistical significance.

RESULTS
Periodontitis was the main reason behind the need of tooth replacement. Of the 35 implants placed in patients with history of periodontitis, all implants were successfully osseointegrated (Fig. 1). Fortunately, no drop outs were detected. About 90% of the patients were females and the total number of patients was non-smokers. Mobility (50%) was the main cause behind the need for teeth replacement in the test group. While dental

FIG. 1 Implant-supported rehabilitation procedure in patients with localized aggressive periodontitis.
caries (35.7%) followed by root fracture (8.57%) and iatrogenic perforation (5.17%) were the main causes in the control group.

In the test group, according to Armitage classification, 14 (20%) implants were placed in patients with the localized form, while 21 (30%) implants were placed in patients with the generalized form. But according to the latest classification, all sites of the test group (50%) were categorized as stage 4 (including more than 3 teeth).

Health scale for dental implants is a descriptive scale describing tested implants as successful, survived or failed. The scale categorized the implants into: successful, satisfactory survival, compromised survival or failure (clinical and absolute failure). All the placed implants were successfully osseointegrated up to the end of the 12 months of follow up period. The health scale recorded 97.17% success in the test group and 100% success in the control group (Fig. 2). Only one implant (2.85%) in the test group showed satisfactory survival due to the presence of peri-implant mucositis.

Post-operatively, the clinical parameters were measured after 6 and 12 months. The amount of the interproximal bone loss and the survival rate were measured. The 70 inserted implants ranged in average implant dimensions between 3.5x 10-13 mm. In total, the implants were successfully osseointegrated along the study period with no dropouts. No signs of peri-implant infection, mobility, pain or increased probing depths were detected.

During six months post-surgically, no peri-implant soft tissue dehiscence, edema, suppuration, pain or mobility was reported in both study groups. The peri-implant probing depth ranged between 0-3 mm in both groups, which indicated the absence of active disease or peri-implant destruction. In the control group, peri-implant bone defects could not be determined. While in the test group, the range of bone level was between 0-1 mm (between the implant collar and first thread), no peri-implantitis with severe bone loss was reported. About 20% of the placed implants were covered by bone on surgical exposure. Six implants (8.57%) were covered with bone in the test group while 8 implants (11.4%) were recorded in the control group.

**DISCUSSION**

Aggressive periodontitis is one of the most common forms of periodontal disease that affect individuals in developing countries, inducing problems such as increased tooth mobility, severe alveolar bone loss, and rapid attachment loss. Unfortunately, the disease sets on at earlier stages of life, when the esthetic demands of patients is increased. Furthermore, the patients suffer from masticatory, phonetic, social and psychological problems.

Recently, there has been a controversial discussion on whether the replacement of lost teeth with dental implants using delayed placement protocol is indicated in periodontally compromised patients in general and more specifically in patients suffering with aggressive periodontitis (14).

In the early 1990s, Mengel and his colleagues (13, 14, 16, 23-28) initiated a series of long-term prospective studies (between 1996-2017) that aimed to evaluate the efficacy of placing osseointegrated implants using the two-staged (delayed) technique in aggressive periodontitis patients 6 months after teeth removal. The concept aimed to reduce the overall bacterial load in the site of implant placement and so the incidence of future peri-implant disease. Moreover, objective
evidence of clinical, histological studies and systematic reviews have shown that immediate placement protocol in periodontally compromised fresh extraction sockets provided successful clinical outcomes. Reduction of the overall treatment duration, shortening of the healing period and appropriate implant position are the main advantages of the immediate approach. The ongoing controversy focuses on immediate implant placement in aggressive periodontitis patients and the risk of infecting implants by inserting them in direct contact to deep infected pockets (reservoirs for bacterial colonies) and the uncontrolled progressive bone loss (29).

Based on the previously mentioned data, the present study was conducted to evaluate and compare the health status of the immediately placed dental implants in aggressive periodontitis patients versus implants placed in healthy individuals along 6 months after loading. In both groups, 70 immediate implants were inserted in both study groups (35 implants per each group). Along the study period, no dropouts were recorded in both groups because the patients strictly adhered to the treatment protocol.

According to Albandar (2014) (30), the age of aggressive periodontitis onset usually reported is before the age of 25 years, that coincides with our results. Low socio-economic status, incautiousness or poor educational level may lay behind the delay of the affected patients to discover the disease. Although the disease begins in early childhood, patients usually ask for treatment in adolescence and post-adolescence ages when teeth loss begins. The same observations were noticed by Mengel et al. (2005) (13) and Li et al. (2017) (31), who reported the same age range as in the present study. On the other hand, Mengel et al. (2001) (32) enrolled patients who were diagnosed and treated for aggressive periodontitis at an older age range (31-44 years old). It was found that 46 (65.7%) out of the 70 selected sites were in females while only 24 (34.2%) were in males. Higher frequency of female affection (74.2%) was reported in aggressive periodontitis patients. The latter observation reflected either the increased female affection or their overcare for aesthetic problems. These results agree with studies conducted in other developing countries. In Egypt, only one single cross-sectional study was conducted by Khattab in 2009 (33), who reported a female: male ratio of 2.5: 1; in Jordan, in 2012, Ababneh et al. (34) recorded a ratio of 1.6:1 (F:M), and in India, Almadi et al. (35) reported a ratio of 2:1 (F:M) in 2018.

As was shown in the distribution of hopeless teeth, maxillary incisors were the most commonly extracted ones, generally in both groups and specifically in the test group, followed by maxillary premolars and maxillary canines. These findings were in accordance with the typical characteristics of aggressive periodontitis. It also reflects the minimal resistance of the incisor region to disease progression compared to other regions. Moreover, mobility dominates as cause of tooth loss, followed by caries, root fracture and iatrogenic perforation. There was no attempt to save questionable teeth adjacent to the placed implants to reduce the risk of implant failure in the present study. Pre and post-surgical systemically administered antimicrobials might play a crucial role in management and stability of aggressive periodontitis patients according to previous studies conducted by Xajiigorginu et al. (2006) (36) and Griffiths et al. (2011) (37). In the present study, a combination therapy of amoxicillin and metronidazole was preferred to be used 2 days before surgical intervention and continued 6 days after. Meticulous debridement of the sockets and the usage of hexetidine as chemical plaque control were also vital steps to reduce the overall bacterial load.

In the current study, the implant health and success rate was evaluated using the Health scale of dental implants. Among the implants placed in both groups, the study indicated 97.1% success in the test group versus 100% success in the control group. Only one implant was reported as satisfactorily survived in the test group due to the presence of peri-implant mucositis which coincides with the results of Li et al. (2017) (31) and the Mengel's series of publications. The former reported one failed implant in the posterior maxilla, while the latter series of studies reported success rates ranging between 95-100% on the short term and 83.3-96% on the long term follow up. The results of the present study were also in agreement with El Amrousy et al. (2013) (18), who reported a survival rate of 100% with no implant loss or failure. Unlike natural teeth, pain and tenderness is more difficult to be assessed in association with dental implants. According to Misch's consensus, pain was totally absent during the primary healing period in healthy implants when subjected to vertical or horizontal forces. Pain may be arisen from two main sources: either the implant itself when the implant is mobile and/or the surrounding inflamed tissues. In the current study, the pain scores in both groups significantly decreased along the follow up period. All patients showed minimal post-operative swelling, pain, and discomfort with limited needs to analgesics. The reported findings were attributed to the meticulous pre-operative improvement of the oral hygiene status, atraumatic tooth extraction and minimally invasive crestal flap which reduced the soft tissue trauma to the maximum level. Gomez-Roman (2001) (38) reported that the soft tissue manipulation and flap design significantly affect the post-operative complications during implant placement.

Clinical mobility is a term describing implant movement upon function, indicating lack of osseointegration and failure. In the current study, the clinical implant
stability and the degree of mobility were measured manually using two rigid instruments referring to the proposed grading by Misch (2008). Our results reported complete (100%) absence of mobility (grade zero) in both groups indicating 100% osseointegration. There was no statistically significant difference between the two groups throughout the study period, which is in agreement with Smith et al. (1989) (39), Jovanovic et a. (1993) (40) and Soliman et al. (2014) (41).

In the present study, both groups obtained satisfactory outcomes regarding PI, BI and PPD along the study period. During phase I therapy, aggressive periodontitis patients showed higher plaque index which could be attributable to the severe attachment loss resulting in exposure of more roots with inaccessible cleaning. Both plaque and bleeding indices were kept between 10-15% with non-statistically significant differences between the mean scores in both groups. The results of the present study showed absence of inflammation due to the meticulous personal and professional oral hygiene maintenance. Due to the different nature between the surrounding tissues to teeth and implants, probing depth assessment required a lighter pressure with special probes (41). In the current study, PPD scores were recorded at baseline, 3 and 6 months. No statistically significant differences were reported in the mean values throughout the evaluation period, although there was increased probing records of the test group compared to natural teeth. This does not indicate the presence of disease as mentioned by Misch et al., 2008 (21) and Swierkot et al., 2012 (16). There was a statistically significant decrease in the PPD results throughout the study period that may be attributed to the successful adaptation of the peri-implant sulcular epithelium to the implant surface as reported by Soliman et al. (2014) (42).

In the current study, the radiographic interpretation of the alveolar bone level showed promising results. In the test group, the peri-implant interproximal bone loss was minimal, <0.5 mm along the study period (12 months), and there were no statistically significant differences between both groups.

CONCLUSION

In conclusion, our study yielded nearly equal survival rates of immediately placed implants in periodontally compromised and healthy patients with no reported complications. Adequate phase I therapy with strict oral hygiene instructions prior to implant placement was the most important factor behind success. Implant insertion in the resting phase of the disease is one of the main success criteria. The quantity and quality of the formed bone is patient relevant. It also may be due to the severity of the disease.

Disclaimer
This study was not funded by any company or any research institute.
Conflict of interest: no conflict exists. All authors declares that they have no conflict of interest. The research involved human subjects and all procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the Helsinki declaration and its later amendments or comparable ethical standards.
A written informed consent was obtained from all individual participants included in the study.

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