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RESEARCH ARTICLE

THE INFLUENCE OF IMPLANT NUMBER ON PERI-IMPLANT MARGINAL BONE LEVEL AND IMPLANT FAILURES IN MANDIBULAR IMPLANT OVERDENTURES. A SYSTEMATIC REVIEW WITH META-ANALYSIS.

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Abstract

Purpose: The current systematic review evaluated influence of implant number on peri-implant marginal bone loss (MBL) and number of implant failures in mandibular implant overdentures (MIODs).

Methods: A literature search of electronic databases (PubMed and Cochrane) was performed up to March 2016. The electronic search was complemented by hand search.

Results: nine publications were included for quality assessment and meta-analysis. Pooled data revealed that there is significant difference in the MBL and on number of implant failures when single and 2-implants ODs were compared. On the other hand, there was no significant difference in MBL and number of implant failures when 2 versus 4-implants ODs were compared.

Conclusion: Based on the findings of this meta-analysis, no recommendations could be made with regards of implant number for completely edentulous patients with MIODs. Though single implant was found to be better in terms of MBL and number of implant failures, this result should be interpreted with cautious due to limited number of analysed studies with different loading protocols and limited follow-up period.

Introduction:-

Edentulous patients experience problems with their complete dentures. This is mainly due to lack of retention, stability and decreased chewing ability as their most common complaints. These problems are more frequently encountered with the lower denture.[1] With advent of dental implants used to retain and/or support removable prostheses, the functional deficiencies associated with conventional dentures are greatly improved.[1]

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Guidelines to assist with the selection of the optimal implant number for retaining and/or supporting mandibular implant overdentures (MIODs) are lacking in literature. The McGill consensus held in Montreal, Quebec, Canada on May 2002 was in favor of 2-implant MODs as the first choice of treatment for the edentulous mandible regardless of the attachment system type. Sadowsky suggested increased implant number for mandibular OD when sensitive jaw anatomy, increased occlusal forces, or high retention needs are present or when reduced implant length (<8 mm) or implant width (<3.5mm) are employed [2]. In conclusion of their systematic reviews and consensus statements, Klemetti [3] and Gotfredsen et al. [4] stated that patients' satisfaction, function of the prosthesis and implant survival are not dependent on the number of implants or type of attachment. Roccuzzo et al. [5] concluded that bone loss, patient satisfaction, and complication incidences are not related to the number of implants supporting MOD and recommended the need for well-conducted research to identify the prognostic factors for long-term success. In the same context, there is increased evidence supporting the use of single implant overdenture in case of financial limitation and frail elderly patients with comparable success rate, survival rate and functional improvement to that provided by 2-implants MOD.[6]

The multitude of prosthodontic designs available merits further investigation. The eventual aim of any design is to enhance biomechanical stress distribution, preserve the remaining structures and allow the longevity of the treatment.

Therefore, the aim of the present review is to systematically evaluate the influence of implant number on the peri-implant marginal bone loss and the incidences of implant failure in patients rehabilitated with mandibular implant overdentures opposed by conventional complete denture.

Method of Research:-

The current systematic review was conducted and reported in strict accordance with (PRISMA) guidelines for reporting systematic reviews and meta-analyses.[7] The focused PICO question formulated to summarize the objective of the study was: for completely edentulous patients rehabilitated with mandibular implant overdentures; what is the recommended number of the implants in terms of peri-implant marginal bone loss and the number of implant failures?

To answer this question, two comparisons were included in the meta-analysis: 1) Single implant versus 2-implants MODs, 2) 2-implants versus 4-implants MODs.

The protocol of the present systematic review was registered at PROSPERO International prospective register of systematic reviews, registration number is: CRD42016036603.

Inclusion Criteria:-

Studies were selected if they met the following inclusion criteria: 1) Reports in English up to March 2016; 2) Randomized controlled trials comparing mandibular overdentures with different number of implants 3) Studies including at least 10 subjects; 4) Publications of at least one-year follow-up period.

Exclusion Criteria:-

Studies were excluded if they: 1) compared implant overdentures to complete dentures or to fixed prosthesis; 2) were non-randomized, retrospective, cross sectional and case series studies; 4) did not clearly define the opposing arch 5) did not clearly define the peri-implant marginal bone loss and /or implant failures.

Search Strategy:-

A comprehensive literature search of the following database was done: PubMed and the Cochrane database to identify relevant articles. The search was conducted up to March 2016 and included the following key words (overdenture, dental implants, implant number, single implant, two implants, three implants, four implants). Two authors (Elawady DE and Alqutaibi AY) performed the search independently, screened the titles and abstracts for relevance. Then, three authors (Elawady DE, Osman RB and Alqutaibi AY) screened the full text of the selected relevant RCTs based on inclusion criteria and any disagreement was solved by consensus and in case of missing data, the corresponding authors were contacted for clarification.

Bibliographies of eligible RCTs were scrutinized for further useful publications. In addition a manual search of the following journals was conducted: Clinical Implant Dentistry and Related Research, Clinical Oral Implants

Research, European Journal of Oral Implantology, Implant Dentistry, Journal of Clinical Periodontology, Journal of Dental Research, Journal of Oral and Maxillofacial Implants, Journal of Periodontology, and The International Journal of Periodontics & Restorative Dentistry, Egyptian Dental Journal, Journal of Advanced Prosthodontics and Journal of Prosthodontic Research. Moreover, online databases providing information about clinical trials in progress were checked (www.clinicaltrials.gov; www.centerwatch.com/clinicaltrials; www.clinicalconnection.com).

Data Collection:-
A data extraction form was used to collect the following study information: 1) title; 2) authors 3) year of publication; 4) number of subjects and number of subjects per group; 5) subjects analyzed 6) age of subject (mean); 7) number of implants placed and number of implants placed per subject; 8) implant system and type 9) loading protocols; 10) the type of attachment used; 11) the follow-up period (months); 12) number of patients with failed implants and 13) peri-implant marginal bone loss (MBL).

Quality Assessment:-
Elawady DE, Kaddah AF and Osman RB assessed individually the risk of bias of selected randomized controlled studies according to endorsements of Cochrane collaboration's tool.[8] The risk of bias was classified as either "Low risk of bias," "High risk of bias," or "Unclear risk of bias" in each domain of assessment, according to guidelines from the Cochrane Handbook, (Cochrane Handbook for Systematic Reviews of Interventions). [8]

Data Synthesis:-
The meta-analysis was conducted using the software program; Review Manager (RevMan, Version 5.3 Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) to pool individual outcomes and produce the forest plots. A fixed-effects model was used in the absence of a statistically significant heterogeneity, whereas, a random-effects model was used in the case of substantial heterogeneity among the trials. Heterogeneity was assessed using I^2 measurement. Continuous data was summarized using mean difference (MD) and 95% confidence interval (CI). For the dichotomous data, risk ratio (RR) and 95% confidence interval (CI) were used to present effect measures. The pooled effect was significant if P was <0.05. In addition, subgroup analysis was performed for variables, which might affect the outcome.

Results:-
The initial electronic literature search identified 395 titles and an additional 2 studies were identified through hand search. After the removal of duplicate studies 202 records were screened, out of which 174 records were excluded after review of abstracts and key words. From 28 full-text publications evaluated for eligibility, 19 publications were excluded because they failed to meet the inclusion criteria.

From the 19 excluded articles; two articles [9, 10] were excluded as they were not comparing mandibular overdentures with different number of implants. Further, related outcomes could not be extracted from nine articles [11-19], one article compared different implant systems and opposing dentition was not reported [20] . In one article [21] maxillary overdentures were included, another five articles were not RCTs [22-25] and one article [26] did not clarify whether maxilla or mandible was restored

Thus, nine full text articles [6, 27-34] were selected and considered eligible for inclusion as shown in the flow chart (Fig. Characteristics of included studies are shown in Table 1. In case of long term RCTs, only last results were reported. Meijer et al. [27] corresponding to (Visser et al. [35]), Batenburg et al. [28], and de Jong et al. [29]). Stoker et al. [30] corresponding to (Wismeijer et al. [36], and Wismeijer et al. [37]). kronstrom et al. [34] corresponding to (Kronstrom et al. [38]). Bryant et al. [33] corresponding to (Walton et al. [39])

Characteristics of included Studies:-
The selected nine studies [6, 27-34] were RCTs and were published between 1998 to 2016. The observation period ranged from 12 months to 10 years. A total of 444 participants received 1048 implants. The number of participants available at the end of follow–up period was 365 participants. All of the studies were conducted in a university setting; four trials were conducted in Netherlands [27-30], two studies in Canada [33, 34] two studies in Egypt [31, 32] and one in Germany [6]. Six studies reported delayed loading protocol [27-32] while the other three studies [6, 33, 34] followed an early/immediate loading protocol. In early loading protocol, the dentures were inserted 42 days after implant placement [33] whereas in immediate loading protocol the denture were inserted at time of surgical implant placement

[34]. In one study [6], soft liner material was used in the first 6 weeks after surgery and the authors described it as a progressive or an early loading protocol.
Data on the peri-implant marginal bone level changes was reported in six studies [6, 27, 28, 30-32], whereas the number of implant failures was extracted from all of the included studies [6, 27-34].

The peri-implant marginal bone level changes were assessed in three studies [27, 28, 30] comparing 2 versus 4-implants MODs and in another three studies [6, 31, 32] comparing single versus 2-implants MODs.

The assessment of marginal bone level changes around implants in included studies was based on digital radiographic techniques. [6, 27, 28, 30-32]. Batenburg et al. [28], Meijer et al. [27] , Stoker et al. [30] and Tavakolizadeh et al. [6] used a standardized intraoral long cone radiographic technique and a digital sliding gauge for the bone level evaluation. Whereas, Elawady et al. [32] used digital panoramic radiographs and analysis was performed using the Digora software system. In the last study Talawy et al. [31], cone beam CT was used and image analysis was done using OnDemand3D, CD Viewer. In five of included studies, the measurements were limited to the vertical extent of marginal bone resorption [6, 27, 28, 30-32], except in one study [32] bone density was also measured.

The number of implant failures was extracted from all of the included studies [6, 27-34]. Five studies [6, 31-34] evaluated marginal bone loss when comparing single versus 2-implants MODs and 4 studies [27-30] when comparing 2 versus 4-implants ODs. Five studies [6, 27, 28, 31, 32] used criteria published by Albrektsson et al. [40] to determine the implant success rate, whereas one study [30] defined implant success according to the criteria of Buser et al. [41] and the other three studies [29, 33, 34] did not report the success criteria used for the evaluation.

Meijer et al. [27] evaluated the marginal bone level alterations of 27 and 25 participants in 2 and 4-implants OD groups respectively. Three implants failed in two patients in the 2-implant OD group. At 10-year follow-up period, the radiographic examination revealed marginal bone loss of 1.4 ± 1.4 mm and 1.0±1.4 mm for 2 and 4-implants MOD groups respectively. The difference between the two groups was considered non-significant.

Stoker et al. [30] assessed peri-implant marginal bone level in a population of 110 participants. At a follow-up period of 99 months, the mean MBL of 0.95±0.99 and 1.73±1.93 mm for 2 and 4-implants MODs respectively were reported. One implant was lost in one patient in 4-implants OD group compared to no failures in the other group.

Batenburg et al. [28] revealed MBL of 0.7 ±1.1 mm for 2-implants MOD group compared to 0.4 ± 0.8 mm for 4-implants counterpart in 58 participants followed up for a period of 12 months and no implant failures in any group. In the same context, while comparing 2 and 4-implants ODs, de Jong [29] reported implant failures in 2 patients in 2-implant MODs compared to no failures in 4-implant MODs in a follow-up period of 120 months in a population of 41 participants.

Tavakolizadeh et al. [6] placed 30 implants in 20 patients who received either single or 2-implants MODs. A provisional/early loading protocol was followed and the dentures were delivered with a soft liner material for the first 6 weeks after surgery. Radiographic marginal bone resorption values of 0.6±0.67 mm and 0.6±0.51 mm were reported in single and 2-implant OD groups respectively over a follow-up period of 12 month. No implant failures were revealed for either group. However, the authors warned in interpreting the results because of the limited follow-up period.

On the other hand, Talawy et al. [31] found decreased MBL of 0.96±0.32 mm in single implant OD compared to 1.21±0.41 mm in 2-implant group in a population of 18 participants followed up to a period of 24 months when a delayed loading protocol was used. Further, the authors reported the failure of four implants in two patients in 2-implants MOD group.

Similarly, Elawady et al. [32] followed a delayed loading protocol and evaluated the peri-implant MBL and number of implant failures in single and 2-implant ODs in a population of 28 patients, followed for up to12 months. The authors reported mean MBL values of 0.53±0.1mm and 0.807±0.1 mm for both groups respectively and no implant failures in either group. However, The authors recommended the need for more studies with a longer follow-up period to confirm the results.

Kronstrom et al. [34] compared the number of implant failures between single and 2-implants MODs. The dentures were immediately delivered after surgery, and implants were followed up for a period of 36 months. Three implants failed in 3 patients in single implant OD group compared to 7 implants in 6 patients in 2-implant OD. However, when an early loading protocol was followed, Bryant et al. [33] found no implant failures in either the single or 2-implant OD group in a population of 62 participants followed up for a period of 60 months

Methodologic Quality:-

By using Cochrane tool for critical appraisal of randomized control studies, the nine included studies were evaluated for the risk of bias. Seven categories were used to evaluate the quality of each selected study as shown in figures 2 and 3. For each included study each category was rated either to provide high, low or an unclear risk of bias. Results of quality evaluation are summarized in figures 2 and 3. Two studies [6, 34] were rated to provide a high risk of bias, 6 studies [27-32] provided an unclear risk of bias and one study [33] showed a low risk of bias. The overall quality of the included studies was rated to provide an unclear risk of bias. Randomization was performed differently in the selected studies [6, 27-34] through the use of sealed opaque envelopes [32], a predefined randomization table [33], random generated number [31], random sampling system [34], randomization lot [27-29], and computerized random allocation procedure [30]. Nonetheless, one study [6] did not report the randomization method. Allocation concealment was performed in 4 studies [30, 32-34] and was considered unclear in the other 5 studies [6, 27-29, 31]. Strategies to minimize potential source of detection bias were not described in five of the included studies [6, 27, 29, 30, 32] but four [28, 31, 33, 34] where the use of masked outcome assessors was reported. Data reporting in three of studies [6, 29, 34] was incomplete. However, Selective reporting was not detected in any study.

Meta-Analysis:-

A meta-analysis was performed for the studies having same comparison groups. The results of the meta-analysis showed that there is a significant difference in the peri-implant marginal bone loss (MD: 0.27, 95% CI: 0.20, 0.34, P <0.0001, I^2 = 0%) (Fig. 4) and on number of implant failures (RR: 3.26, 95% CI: (1.18, 8.97), P = 0.02; I^2 = 0%) (Fig. 5) when the single and 2-implant MODs were compared favouring single implant group. On the other hand, there was no significant difference in the marginal bone level changes (MD: -0.01, 95% CI: -0.7, 0.69, P = 0.98, I^2 = 70%) (Fig. 6 and 7) and number of implant failures (RR: 2.01, 95% CI: 0.45, 9.02) P = 0.36; I^2 = 0%) (Figure 8) when 2 versus 4-implants MODs were compared.

When the fixed effects model was used (Fig. 6), heterogeneity (I^2 = 70%) was detected in the studies comparing 2 versus 4-implants ODs [27, 28, 30] in terms of MBL. However, repeated analysis with random effect model (Fig. 7) revealed the same result indicating that heterogeneity did not influence the initial outcome and no significant difference was detected in the marginal bone level changes (MD: -0.01, 95% CI: -0.7, 0.69, P = 0.98, I^2 = 70%).

Subgroup Analyses:-

The possible source of heterogeneity and its influence on the evaluated outcomes in the included studies was assessed by subgroup analyses. A comparison was made based on loading protocol between two different groups; a conventional and an immediate/early loading protocol.

With regard to the peri implant marginal bone loss, the subgroup analysis demonstrated no significant difference between the immediately loaded single and 2-implant ODs (MD: 0.0001, 95% CI: -0.52, 0.52, P = 1). However, the difference was significant when a delayed loading protocol was followed (MD: 0.28, 95% CI: 0.20, 0.35, P < 0.0001; I^2 = 0%). However, the overall effect of all studies showed a significant difference between single and 2-implant ODs in the peri-implant marginal bone loss (MD: 0.27, 95% CI: 0.20, 0.34, P <0.0001, I^2 = 0%) (Fig. 4) favouring single implant group

When the implant failure rate was considered, there was no significant difference between the single and 2-implant ODs when both the immediate (RR: 2.75, 95% CI: 0.97, 7.8; P = 0.06) and delayed loading protocols (RR: 6.11, 95% CI: 0.33, 111.7; P = 0.22) were used. However, the overall effect of all studies showed a significant difference in number of implant failures (RR: 3.26, 95% CI: (1.18, 8.97), P = 0.02; I^2 = 0%) (Fig. 5) when the single and 2-implant ODs were compared favouring single implant group.

Discussion:-

This systematic review and meta-analysis followed the recent guidelines of PRISMA [6] and the Cochrane collaboration methods[7] to evaluate the best available evidence as regards to the effect of the implant number on the

marginal bone level changes and the number of the implant failures in completely edentulous patients rehabilitated with mandibular implant overdentures opposed by conventional maxillary denture.

This review presented a focused PICO question related to mandibular IODs. This ensured the homogeneity of the studies including a unified single clinical parameter to be investigated. Only RCTs with restricted minimum follow-up period of 24 months were included. Three independent authors reviewed the included studies to assess their conformity with the inclusion criteria. The aim with all of this was to provide reliable evidence-based conclusions related to the overall treatment outcome. The review was supplemented with meta-analysis to increase the validity of the findings while employing both fixed and random effect models as heterogeneity was detected in some of the comparisons. Limitations of this review should also be acknowledged and include the limited number of studies included with small sample size and different follow-up periods. Comparative analysis of marginal bone loss among the included studies should be performed with cautious due to the lack of the standardization in methods used for the evaluation. However, the inclusion of the number of implant failures as one of the outcome measures enabled better understanding and evaluation of the findings.

The overall treatment effect of the five studies that compared single implant with two implant ODs demonstrated significant difference in number of implant failures ($P = 0.02$) and marginal bone loss ($P < 0.00001$) between the two groups. Single IODs showed reduced incidence of implant failures and less MBL compared to the 2-implant MODs. On contrary to the common belief that with a single IOD there is increased axial and lateral forces generated on implant/abutment complex, low stress values were reported in abutments and bone around single implants [42]. In the case of single IOD, the denture can rotate freely and the overdenture stability is dependent to a large extent on mucosal support from the alveolar ridge [43]. With the increase in supporting effect in the case of increased implant number, more loading forces will be applied on implant/abutment complex and less on the mucosal area. The forces will be distributed through fulcrum line passing through the implants resulting in increased stress/strain values in the bone around the implants [42].

In accordance, Talawy et al. [31] have shown better survival rate, reduced marginal bone resorption and functional improvement of single IODs compared to 2-implants MODs. The authors concluded that single implant ODs present a promising treatment alternative to the 2-implant ODs while considering the limitation of the study including the small sample size and limited follow-up period of 2 years. Similarly, Elawady et al. [32] reported that single implant ODs can provide better bone remodeling and less crestal bone resorption than 2-implants ODs.

The results of meta-analysis of the four studies [27-30] that compared the 2 and 4-implants MODs showed no significant differences between the two treatment modalities in terms of MBL ($P = 0.98$) and implant failure rate ($P = 0.08$). In accordance with the findings of this review were the results of several clinical studies that revealed no difference in MBL [27, 28, 36, 37] or implant failure rate [28, 35-37] between 2 and 4-implants ODs. On the contrary, Stoker et al. [30] reported less MBL with 2-implants MODs compared to 4-implants MODs. The mean marginal bone losses were 0.95 ± 0.99 and 1.73 ± 1.93 mm for 2 and 4-implants MODs respectively.

Differences in the findings between the studies can be attributed to variation in the study designs including the differences in the evaluation methods and the different parameters evaluated. Moreover, the accuracy of measurement of peri-implant marginal bone height is always compromised.[44] Distortion of buccal and lingual bone margins may result in overestimation of bone heights. The degree of overestimation is influenced by the buccolingual position of the fixture. Strict parallelism between fixture axes and film plane is essential to obtain valid results using single films. In the present review, the assessment of marginal bone level changes around implants in the included studies was performed using different radiographic techniques. Elawady et al. [32] used digital panoramic radiographs which is controversial when the precession of the measurement is considered in the anterior area.

It is relevant that all studies included in this review, comparing single and 2-implants overdentures used either an immediate/early or delayed loading protocol. In the studies [6, 31, 32] comparing the peri-implant bone loss; one study [6] used an immediate loading protocol while the other two studies [31, 32] used a delayed protocol. Out of the five [6, 31-34] studies that evaluated the implant failures in single versus 2-implants ODs, three studies [6, 33, 34] used an immediate/early loading protocol and two studies [31, 32] used a delayed approach. Therefore, a subgroup analysis was performed to assess the possible source of heterogeneity on the evaluated outcomes.

The results of the subgroup analysis of the two studies that compared the marginal bone loss between single and 2-implants ODs showed significant difference (P<0.00001) when a delayed loading protocol was used. However, no significant difference (P=1.00) was found when an immediate/early loading protocol was employed. Lack of significant differences in the case of immediate/early loading protocol may be attributed to the fact that only one study was analyzed. Therefore, prospective, controlled comparative studies on the outcome between single and 2-implants MODs using an immediate loading protocol are still lacking in the literature.

Scrutinization of different loading protocols in the included studies reveals perplexity and lack of consistency among the multiple definitions usually offered for the same protocol. The precise loading time and the manner of load application with different loading protocols are either ambiguous or loosely defined. Further, the follow-up period of studies comparing single and 2-implants MODs was short and ranged from 12 to 60 months. Hence, comparative studies with similar designs and longer follow-up periods are still required. Further, worth to mention that all the studies were performed in university settings, which are reported to have a bearing on the results. [6, 27-34]

Based on the findings of this meta-analysis no recommendations could be made with regards of implant number for rehabilitation of completely edentulous patients with MIODs. Though single implant ODs were found to be better than increased implant number in terms of MBL and implant failure rate, this result should be interpreted with cautious due to limited number of analyzed studies and the different study designs including different loading protocols, different follow-up periods and different techniques used for the evaluation of clinical outcomes. There is still a need for well-designed RCTs before a recommendation regarding the implant number can be made.

Availability of supporting data

"The data set(s) supporting the results of this article is (are) included within the article (and its additional file(s)"

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Abbreviation:-

MBL marginal bone loss
RD Risk difference
MD Mean difference
OD Overdenture
RCT Randomized Clinical Trial
MIOD Mandibular implant overdenture

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