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EFFECT OF PULSED ELECTROMAGNETIC FIELD ON THE ALVEOLAR BONE DENSITY AND ITS IMPACT ON THE DENTAL IMPLANT OSSEOINTEGRATION IN OSTEOPOROTIC PATIENTS (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Osteoporosis is a generalized skeletal disease that is considered the fourth most common disease of the elder population, especially women. Osteoporosis is reported to be one of the most common obstacles that may face a successful dental implant treatment due to the low bone quality and density, which affect implant osteointegration adversely.
OBJECTIVES: Evaluation of the effect of pulsed electromagnetic field (PEMF) on alveolar bone density around the implant and its impact on the implant osseointegration compared to the standard implant technique in osteoporotic patients.
MATERIALS AND METHODS: A randomized controlled clinical study with a 5-month follow-up time frame , was conducted on 20 female patients aged from 48 to 60 years were diagnosed with osteoporosis, who have missed tooth/teeth that need to be restored at the premolar\molar area of the mandible. Patients were divided equally into 2 groups. (Study group): 10 patients received a dental implant and then were exposed to PEMF. (Control group): 10 patients treated with only standard implant placement without PEMF exposure. Alveolar bone density was measured by cone beam CT. and implant stability was calculated by osstell.
RESULTS: All patients in both groups experienced a significant increase in alveolar bone density and implant stability. Between the study and control groups, there was a significant difference in the increase of alveolar bone density and implant stability.
CONCLUSION: The study concluded that oral implant treatment is not contraindicated in osteoporotic patients, and PEMF stimulation can effectively increase alveolar bone density and promote dental implant stability.
KEY WORDS: Osteoporosis, Dental implant, Osseointegration, PEMF, Bone density.
RUNNING TITLE: Dental Implant osseointegration in osteoporotic patients.

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INTRODUCTION

The world health organization (WHO) describes osteoporosis as a generalized skeletal condition marked by decreased bone mineralization, mass, and degradation of the microarchitecture of the bony tissue brought on by an increase in marrow voids. This causes the bone tissue to become more brittle and increases the chance of fractures as a result (1).
Additionally, the world health organization (WHO) defines osteoporosis as a generalized skeletal disease characterized by a reduction of 25% in bone mass; while, osteopenia is a term used to describe a physiological decrease in bone mineral density of 10% to 25% from the typical state as an early sign of osteoporosis (2).
Since estrogen controls bone remodeling and the drop of estrogen production causes a bone remodeling imbalance with bone resorption surpassing bone production leading to bone brittleness and increased fracture risk, post-menopausal estrogen insufficiency is the major acknowledged etiology of osteoporosis, even

though it is triggered by numerous factors, such as vitamin D and calcium deficiency, and genetic factor (3).

With a mean survival rate of 94.6% and a mean success rate of 89.7% after more than 10 years, dental implant surgery has recently become a widely used procedure to replace missing teeth. Over time, advancements in design, surface, and surgical protocols have made implants a safe, dependable, and highly predictable procedure (4).

As a long-term viable and acceptable option for the prosthetic rehabilitation of partially and completely edentulous patients, dental implants have been shown to have respectable rates of survival and success in the short, medium, and long range (5).

There is an exhaustive argument about the success rate of oral implant treatment in osteoporotic patients in literature as shown later on.

In 2004, Fini et al. reported that due to an imbalance between the activity of osteoclasts and osteoblasts, bone remodeling and regeneration are compromised by osteoporosis. Consequently, it had been viewed as a potential danger factor for the bone healing process around implants (6, 7).

Moreover, in 2004 Keller et al., showed that due to decreased cancellous bone volume and a reduced rate of bone-to-implant contact (BIC), osteoporosis affects the peri-implant bone and results in inadequate bony tissue support (7, 8).

However, in 2001, Friberg, et al., (9) reported encouraging results of oral implant treatment in patients with osteoporosis. The Presence of peripheral osteoporosis does not affect the success rate of the oral implant treatment as the local bone quality does (7).

In 2009, Tsolaki et al. concluded that there is no evidence to contraindicate and prevent the use of dental implant treatment in osteoporotic patients. To accomplish adequate osseointegration, the surgical procedure may need to be adjusted and planned properly, and a longer healing period before loading may be taken into account. Additionally, extensive prospective studies are required to examine the long-term performance and durability of dental implants in people with osteoporosis (10).

Site-specificity is a feature of osteoporosis, and fortunately there is an evidence to suggest that osteoporotic patient's jawbone is not one of the most prevalent skeletal sites affected by osteoporosis (11).

Over time, the belief that considers using oral implant treatment with osteoporotic patients is contraindicated has steadily changed. Owing to numerous publications demonstrating that people with osteoporosis can benefit from dental implants, and that the outcomes for these patients are the same as those for patients without osteoporosis (7).

In 2017, Li et al. reported that four decades of increasing evidence point to the possibility that pulsed electromagnetic fields (PEMF) therapy can successfully cure a number of bone ailments, including osteoarthritis, osteoporosis, fresh and nonunion fractures, and bone abnormalities. Furthermore, multiple studies have shown that PEMF can considerably raise bone mineral density and encourage osteogenesis (12).

At light of the results of animal and human investigations, numerous in vitro studies also reveal that PEMF stimulation dramatically boosted osteoblast proliferation and mineralization while inhibiting the maturation and function of osteoclasts. Given the high cost or unfavorable side effects of presently available anti-osteoporosis medications (e.g., hormones and bisphosphonates) and nutrients (e.g., calcium and vitamin D), PEMF therapy might become a more hopeful substitute treatment for fending off osteoporosis due to its affordable, secure, and noninvasive nature (13).

Also, Pulsed electromagnetic fields have been reported to accelerate the healing of fractures of the long bones as well as the mandible (14).

Stemming from the above, and due to the controversy in the literature surrounding the reliability of oral implant treatment in osteoporotic patients, given also the stimuating effect of PEMF on the osteogenesis and bone healing mechanism which may enhance the bone quality and density around the placed oral implants and hence improves implant stability, the objective of this study was to assess the efficacy of a pulsed electromagnetic field on the alveolar bone density and its impact on the osseointegration of dental implants compared to the standard implant technique in osteoporotic patients.

MATERIALS AND METHODS

A randomized controlled clinical trial was performed after receiving the approval of the Research Ethics Committee in the Faculty of Dentistry, Alexandria University. An informed consent form was given and signed by all patients before the surgical procedure to ensure and affirm that they understood the procedure's potential outcomes as well as any risks involved. All patients were recalled for the final prosthetic phase.

Patients

All patients enrolled in this study were twenty female patients aged from 48 to 60 years old, diagnosed with bone density problems (osteopenia or osteoporosis), and planning for having dental implants for single or multiple teeth restorations. Patients were selected from patients attending the outpatient clinic of the orthopaedic department, Faculty of Medicine, Alexandria University, each of the patients has been diagnosed as an osteoporotic patient by his orthopaedic specialist according to clinical symptoms and radio graphical measurements of bone mineral density (BMD), which determines bone density, each patient has been identified by his orthopaedic specialist as an osteoporotic patient. Dual-energy X-ray

absorptiometry (DXA) is the most commonly used validated technique for determining BMD (15-19)

Patient inclusion criteria

Female patients aged from 48 to 60 years (menopause age) diagnosed with osteopenia or osteoporosis (20), did not receive any anti-osteoporotic drugs as bisphosphonates (Bps) yet (21), with missed tooth\teeth need to be restored at the posterior region of the lower arch (premolar\molar area of the mandible), and with good oral hygiene (22).

Patient exclusion criteria

Patients with inadequate horizontal or vertical space for prosthesis, with any local lesion in the jaws (cyst or tumor), or any anatomical barriers for dental implant placement according to pre-surgical radio graphical examination (23). Patients with any systemic chronic debilitating diseases that may affect the oral implant treatment outcome adversely (24), and not undergoing chemotherapy or radiation therapy to the head and neck region (25).

Patients that fulfilled all the criteria for the study were informed of all the surgical procedures and accepted the planned treatment plan with all of the follow-up procedures

Patients randomly are divided into 2 groups (26)

Group A (study group): consisted of 10 patients. All patients involved in this group were treated with placement of dental implants and were exposed to PEMF for (40 minutes) daily for 3 days starting from the next day of the surgery according to manufacturer recommendations (27, 28).

Group B (the control group): consisted of 10 patients. All patients involved in this group were treated with only standard implant placement without exposure to PEMF.

Materials and equipment

1. EM-probe solo PEMF mini fisioline device (Fisioline® srl Borgata Molino, 29 - 12060 VERDUNO (CN)- ITALY). (Fig. 1)
2. Two-piece dental implants Dentium (Dentium Co Ltd: #214, 105, Gwanggyo-ro, Yeoungtong-gu, Suwon-si, Gyeonggi-do, Korea).
3. Implant Motor (Aseptico, advanced dental technology. P.O. Box 1548 Woodinville, WA 98072 8333 216th Street S.E. Woodinville, WA 98072 (425) 487-3157).
4. Osstell (Osstell AB org. nr: 556612-4938 Address: Stampgatan 14, 411 01 Gothenburg Sweden).
5. Cone beam C.T. X-ray machine (J. MORITA MFG. CORP. 680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan).
6. Mepecaine-L 2% (1.8 ml) with mepevacaine HCL 36mg\1.8ml + levonoderfin HCL 0.108mg\1.8ml (Alexandria co. for pharmaceuticals & chemical industries ,Alexandria, Egypt).
7. GMS Silk 3\0 suture material (ghatwary medical supply (GMS), Alexandria, Egypt.

Figure (1): EM-probe solo (PEMF mini fisioline device).

Methods

1. Preoperative phase

All patients had thorough history-taking, which included gathering information on their names, ages, genders, occupations, and medical and dental histories.

To assess the status of the remaining teeth in each patient, an intraoral examination was performed, with edentulous areas receiving the greatest attention.

Radiographic Examination

Pre-surgical cone beam computed topographies (CBCTs) were taken to - exclude any hidden pathologic lesion, identify the nearby vital structures such as the mental nerve and inferior alveolar nerve, evaluate bone volume and quality of bone in the area where the implant will be inserted, and determine the proper site, size, and angulation of the implant in the alveolar bone (29).

Surgical stent fabrication (surgical aids)

An alginate impression was taken for each of the maxillary and mandibular arches; study casts were fabricated and mounted. This was followed by the fabrication of an acrylic vacuum-formed stent on the study cast for accurate positioning of the implant "Surgical stent". In the proposed implant site, a hole 2 mm in diameter was made to accommodate the first drill. The stent was made to fit accurately inside the patient's mouth during the surgical operation.

2. Surgical phase

1. **Selection of the implant:** Proper size (width and length), and angulation of the implant was determined and selected according to the pre-surgical cone beam computed tomography findings.
2. **Anesthesia:** Area will be anesthetized using (inferior alveolar nerve block and infiltration for long buccal nerve if needed) with 2% mepecaine-L anesthetic agent. (Fig. 2A)

3. **Flap design:** A pericrestal incision was initiated over the lingual aspect of the ridge crest; two curvilinear vertical releasing incisions that extended onto the buccal aspect of the alveolar ridge were made at the mesial and distal ends of the pericrestal incision without including the interdental papilla (periodontal type). This was followed by a reflection of the buccal full-thickness mucoperiosteal flap using the mucoperiosteal elevator to expose the entire ridge crest and to provide access for implant instrumentation. (Fig. 2B)
4. **Preparation of the implant site:** The prefabricated surgical stent was placed securely in the oral cavity; it was used to guide the first drill during the drilling of the pilot hole. Drilling was done with light intermittent finger pressure by the use of a surgical implant motor (medium torque 45 NCM, low speed 800 RPM) equipped with internal irrigation using sterile saline solution. (Fig. 2C). The sequence of drilling was performed as per the manufacturer' instructions. The diameter of the final drill was o.3mm less than the implant diameter. Each drill was having laser markers at 8, 10, 11, 13.5, and 16 mm lengths for proper recognition of the desired length. (Fig. 2D)
5. **Paralleling guides:** The desired implant angulations were checked intermittently after each drilling using paralleling pins. (Fig. 2E)
6. **Implant placement:** The vial container of the dentium superline S.L.A. Surface™ implants was removed from the non-sterile outer packing after the implant site was prepared. After that, the implant was drawn out of the inner vial by the selection stopper and forced with finger pressure into the ready socket. Then, the implant driver was positioned in the internal hex and the implant was threaded in place using low torque (25 Ncm) low speed (45 Rpm) implant motor (Fig. 2F), and directed into the final position using the ratchet.

Once the implant has been seated, the implant driver was removed and the Osstell smartPeg was screwed into the implant fixture with a uniform torque for all cases (15 Ncm) to calculate the primary stability of the implant (baseline readings of implant stability) in osstell ISQ (implant stability quotient) unit (30-32). (Fig. 3A)

The smartPeg was removed and the cover screw was threaded into the implant with the driver.

7. **Flap closure:** Thorough irrigation of the surgical field was done using a sterile saline solution. The mucoperiosteal flap was repositioned to cover the implant and sutured with interrupted silk sutures.

Post-operative care

- **Post-Operative Radiographs**

Immediate postoperative cone beam C.T. was taken for each case to calculate the actual baseline readings of alveolar bone density around the dental implant after drilling (as the use of drilling technique causes a significant reduction in bone density post-operatively compared to the pre-operative bone density values), and to evaluate the direction, parallelism, and site of the implant inside the alveolar bone (29,30). (Fig. 4A)

- Bone density values represented in Hounsfield units (HU) after application of {Y= 0.628(X) _161} equation where Y = bone mineral density and X = CBCT gray value (31).

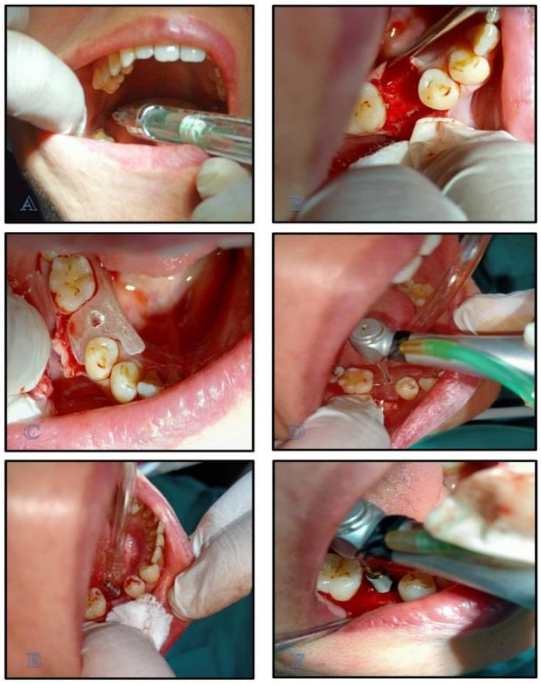

Figure (2): Implant Surgical procedures. A) Anaethesia. B) Flap design. C) Surgical stent placement. D) Preparation of the implant site (pilot drill). E) Paralleling guides. F) Implant placement.

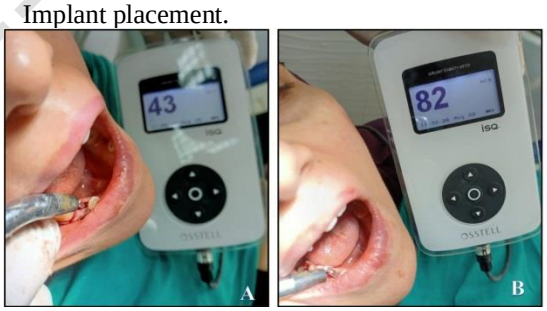

Figure (3): Osstell readings for implant stability. A) Osstell baseline reading immediately after surgery. B) Osstell final reading 5 months later.

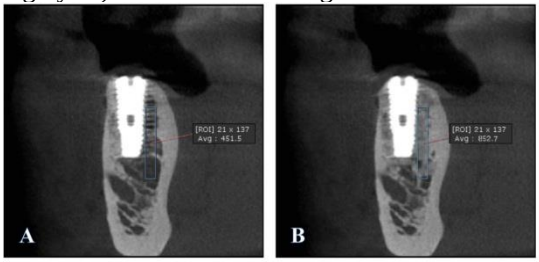

Figure (4): Cone beam C.T readings for bone density. A) bone density baseline reading

immediately after surgery. B) bone density final reading 5 months later.

- **Post-operative instructions**.

Patients were informed to avoid mouth rinsing, hot food or drinks for 24 hours after surgery. Using of cold packs immediately for 8 hours with 20 minutes application and 20 minutes off. Soft diet was advised for the first week.

- **Post_operative medication**

– Antibiotic (Amoxicillin with clavulanic acid) 1000 mg every 12 hours for 7 days.(Augmentin- Galaxosmithkline Australia).
– Non-steroidal anti-inflammatory drugs (Diclofenac potassium 50 mg) every eight hours for 5 days.(Cataflam.Novartis pharma,AG, Basel, Switzerland).
– Chlorohexidine 0.2 %mouthwash was prescribed thrice per day starting the second day after the surgery and to be continued for 2 weeks (Hexitol. The Arab drug Co. Cairo, Egypt).

- **Group A: (PEMF application)**

Patients of this group were given follow-up appointments on daily basis for the first consecutive 3 days after the day of the surgery according to the recommendation of the PEMF device manufacturer for enhancing bone density and healing in osteoporotic patients (27, 28).

The device applicators were positioned on the part to be treated (the mandible) with the assistance of the elastic Velcro straps provided with the device.

The device applicators were placed with the same orientation (the label in the same direction) to link the magnetic flux on the zone to treat. (Fig. 5)

The device setting was selected according to the manufacturer's recommendation for the treatment of osteoporosis with frequency 70 HZ, and intensity 40 GAUSS.

The recommended time of application by the manufacturer for the treatment of osteoporosis was 120 minutes, divided into three sessions (40 minutes for each) for the three consecutive days after the day of the surgery (27, 28).

- Sutures were removed 7 days after the surgery.
- Then the following assessment appointment was 1, 2 and 3 months postoperatively for - *the clinical evaluation of the implant site* (clinical failure signs)

Infection, swelling (hyperplastic soft tissues), fistulas, suppuration, colour changes of the marginal peri-implant tissues, and early/late mucosal dehiscence can occur and may point to implant failure - **Clinically marked mobility,** mobility of implants is the key sign of their failure. There are several various types of mobility, including rotational, vertical, and horizontal movement. The reverse-torque test was suggested to discover mobile implants (32).

- The radiographical evaluation (Radiographic signs of failure)

One of the primary methods for identifying failed implants in clinical practice is the radiographic evaluation. Standardized periapical radiographs should be taken at regular follow-up intervals to detect **peri-implant radiolucency** and/or progressive **marginal bone loss.** At this point, the peri-implant radiolucency proposes the absence of direct bone-implant contact and possibly a loss of stability, whereas in the case of increased marginal bone loss, the implant can be stable (32). (Fig. 6)

- Then, the final appointment was 5 months postoperatively to take the final cone beam C.T. for determination of the final reading of alveolar bone density in HU (29). (Fig. 4B) at the identical regions of the bone around the implant and assessment of implant osseointegration and stability using osstell ISQ with the Osstell smartPeg threaded into the implant with the same torque (15 Ncm) (33-35). (Fig. 3B)

- ***Group B:*** Sutures were removed 7 days after the surgery

Patients of this group were given follow-up appointments on 1, 2, and 3 months postoperatively for clinical and radiographical evaluation as in the study group.

The final appointment was 5 months postoperatively to take the final cone beam C.T. for determination of the final reading of alveolar bone density in HU at the same areas around the implant and assessment of implant osseointegration and stabilit using osstell ISQ with the Osstell smartPeg threaded into the implant with the same torque (15 Ncm).

- Final prosthesis insertion will be done five months after the surgery. (Fig. 6C)

Figure (5): PEMF device application.

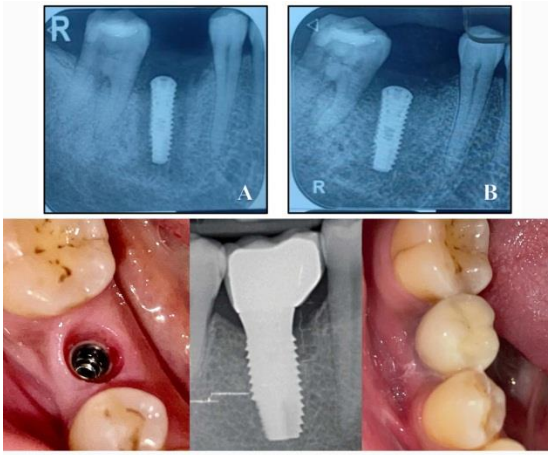

Figure (6): Follow up P.A. X-rays show the bone quality improvement. A) P.a. x-ray immediately after surgery. B) P.a. x-ray 1 month after surgery. C) Clinical and radiographic pictures after loading the final restoration.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. **(**Armonk, NY: IBM Corp**)**. To confirm the distribution's normality, the Shapiro-Wilk test was utilized. The range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR) were used to characterize quantitative data. The 5% level was judged to determine the significance of the obtained data.

The used tests were

1- **Paired t-test** for normally distributed quantitative variables, to compare between two periods
2- **Mann Whitney test** for abnormally distributed quantitative variables, to compare between two studied groups

RESULTS

This study was conducted on 20 female patients aged from 48 to 60 years old, diagnosed with bone density problems (osteopenia or osteoporosis), and planning for having dental implants for single or multiple teeth restorations at premolar\molar area of the mandible. Patients were divided into two equal groups;

Study group: contained ten patients with baseline readings of alveolar bone density around the placed implant (immediately after implant placement) ranged from 112.9 HU (minimum) to 511.3 HU (maximum) with Mean ± standard deviation SD. = 300.4 ± 123.9 and median (Inter quartile range IQR) = 286.8(224.4 – 399.2), while the final readings of alveolar bone density at the same regions around the placed implants (five months post-operatively) were ranged from 387.3 HU (min.) to 852.7 HU (max.) with Mean ± SD. = 543.4 ± 162.2 and Median (IQR) = 496.3(407.7 – 666.8), and the paired t-test - for the comparison between the two studied periods according to bone density - (T) value was = 5.514 with p-value <0.001 (Statistically significant at $p \leq 0.05$).

Baseline readings of implant stability of study group patients immediately after implant placement (with Osstell smartPeg was screwed into the implant fixture with a uniform torque for all cases *15 Ncm*) ranged from 24.0 ISQ (min.) to 51.0 ISQ (max.) with Mean ± SD. = 35.60 ± 9.52 and Median (IQR) = 33.50(27.0 – 43.0), while the final readings of implant stability - five months post-operatively - (with the same torque of smartpeg *15 Ncm*) were ranged from 53.0 ISQ (min.) to 82.0 ISQ (max.) with Mean ± SD. = 63.20 ± 9.92 and Median (IQR) = 60.0(56.0 – 68.0), and the paired t-test - for the comparison between the two studied periods according to implant stability - (T) value was = 7.654 with p-value <0.001 (Statistically significant at $p \leq 0.05$).

Control group: contained ten patients with baseline readings of alveolar bone density around the placed implant (immediately after implant placement) ranged from 106.8 HU(min.) to 612.4 HU (max.) with Mean ± SD. = 300.2 ± 138.9 and Median (IQR) = 301.1(203.3 – 343.2), while the final readings of alveolar bone density at the same regions around the placed implants (five months post-operatively) were ranged from 219.3 HU (min.) to 723.3 HU (max.) with Mean ± SD. = 379.4 ± 153.5 and Median (IQR) = 382.0(251.3 – 442.8), and the paired t-test- for the comparison between the two studied periods according to bone density - (T) value was = 7.280 with p-value <0.001 (Statistically significant at $p \leq 0.05$).

Baseline readings of implant stability of control group patients -immediately after implant placement- (with Osstell smartPeg was screwed into the implant fixture with a uniform torque for all cases *15 Ncm*) ranged from 22.0 ISQ (min.) to 55.0 ISQ (max.) with Mean ± SD. = 36.0 ± 9.53 and Median (IQR) = 35.0(32.0 – 37.0), while the final readings of implant stability - five months post-operatively - (with the same torque of smartpeg *15 Ncm*) were ranged from 39.0 ISQ (min.) to 66.0 ISQ (max.) with Mean ± SD. = 48.60 ± 9.65 and Median (IQR) = 46.0(41.0 – 56.0), and the paired t-test - for the comparison between the two studied periods according to implant stability - (T) value was = 4.776 with p-value <0.001 (Statistically significant at $p \leq 0.05$).

In the study group the recorded increase of bone density ranged from 95.0 HU (min.) to 519.4 HU (max.) with Mean ± SD. = 243.0 ± 139.4 and Median = 187.8, while in the control group the recorded increase of bone density ranged from 5.10 HU (min.) to 112.5 HU (max.) with Mean ± SD. = 79.2 ± 34.41 and Median = 88.50, and Mann Whitney test – for the comparison between the two studied groups according to increase of bone density – (U) value

was = 4.0 with p-value <0.001 (Statistically significant at $p \leq 0.05$).

Finally, in the study group the recorded increase of implant stability ranged from 12.0 ISQ (min.) to 41.0 ISQ (max.) with Mean ± SD. = 27.60 ± 11.40 and Median = 29.50, while in the control group the recorded increase of implant stability ranged from 3.0 ISQ (min.) to 29.0 ISQ (max.) with Mean ± SD. = 12.60 ± 8.34 and Median = 10.0, and Mann Whitney test – for the comparison between the two studied groups according to increase of implant stability – (U) value was = 12.0 with p-value =0.003 (Statistically significant at $p \leq 0.05$).

- Cone beam c.t. used to determine alveolar bone density in all patients of both groups in houndsfield units (HU), while osstell used to determine implant stability in implant stability quotient (ISQ).
- No implant clinical and radiographical failure had recorded in all 20 patients based on the implant failure clinical and radiographical parameters.

The increase in the alveolar bone density was significant in both the study and control groups over the study period (five months). **Table (1)**

The increase in the implant stability was significant in both the study and control groups over the study period (five months). **Table (2)**

The recorded difference in the increase of alveolar bone density and implant stability between the study and control groups was significant. **Table (3)**

Table (1): Comparison between the two studied periods according to bone density

Bone density	Baseline	Final	T	p
Study (n = 10)				
Min- Max.	112.9 – 511.3	387.3 – 852.7		
Mean ± SD.	300.4 ± 123.9	543.4 ± 162.2	5.514*	<0.001*
Median (IQR)	286.8 (224.4 – 399.2)	496.3 (407.7 – 666.8)		
Control (n = 10)				
Min- Max.	106.8 – 612.4	219.3 – 723.3		
Mean ± SD.	300.2 ± 138.9	379.4 ± 153.5	7.280	<0.001*
Median (IQR)	301.1 (203.3 – 343.2)	382.0 (251.3 – 442.8)		

IQR: **Inter quartile range** SD: **Standard deviation**
t: Paired t-test
p: p-value for comparing between the studied periods
*: Statistically significant at $p \leq 0.05$

Table (2): Comparison between the two studied periods according to implant stability

Implant stability	Baseline	Final	T	p
Study (n = 10)				
Min. – Max.	24.0 – 51.0	53.0 – 82.0		
Mean ± SD.	35.60 ± 9.52	63.20 ± 9.92	7.654*	<0.001*
Median (IQR)	33.50 (27.0 – 43.0)	60.0 (56.0 – 68.0)		
Control (n = 10)				
Min. – Max.	22.0 – 55.0	39.0 – 66.0		
Mean ± SD.	36.0 ± 9.53	48.60 ± 9.65	4.776*	<0.001*
Median (IQR)	35.0 (32.0 – 37.0)	46.0 (41.0 – 56.0)		

IQR: **Inter quartile range** SD: **Standard deviation**
t: Paired t-test
p: p-value for comparing between the studied periods
*: Statistically significant at $p \leq 0.05$

Table (3): Comparison between the two studied groups according to increase of bone density and implant stability

	Study (n = 10)	Control (n = 10)	U	p
Bone density Increase				
Min. – Max.	95.0 – 519.4	5.10 – 112.5		
Mean ± SD.	243.0 ± 139.4	79.2 ± 34.41	4.0*	<0.001*
Median	187.8	88.50		
Implant stability Increase				
Min. – Max.	12.0 – 41.0	3.0 – 29.0		
Mean ± SD.	27.60 ± 11.40	12.60 ± 8.34	12.0*	0.003*
Median	29.50	10.0		

SD: **Standard deviation** **U: Mann Whitney test**
p: p-value for comparing between the studied groups
*: Statistically significant at $p \leq 0.05$

DISCUSSION

In this study, we tried to determine the effect of PEMF on alveolar bone density around the placed dental implants in the premolar\molar region of the mandible of osteoporotic patients, and by extension the impact on the implant stability which give us a perception of oseointegration.

Our sample was 20 female patients at the menopause age and was diagnosed with osteoporosis; all the patients received a dental implant in the mandible (premolar\molar area), only 10 patients of the study group were exposed to PEMF stimulation sessions after receiving the implants.

The results of our current study highlighted the absence of any implant clinical and radiographical failure (0% clinical failure) in all patients of both groups according to the clinical parameters and signs of the oral implant failure (previously mentioned at method section) with recording a significant increase of alveolar bone density and implant stability in all patients of the two groups (100% success rate) whether with the exposure to the PEMF stimulation or not.

This current study results are highly supported and explained by many older studies from the literature such as, the study of Hohlweg-Majert et al., in 2006 (11), as he concluded that Osteoporosis is a site-specific disease, and fortunately, the jawbone is not one of the common skeletal sites affected by osteoporosis, also, the study of Friberg, et al., in 2001(9), reported that encouraging results of oral implant treatment in patients with osteoporosis, presence of peripheral osteoporosis does not affect the success rate of the oral implant treatment as the local bone quality do (7), additionally, Tsolaki et al. study, in 2009 (10), stated that there is no evidence to contraindicate the use of dental implants in patients with osteoporosis, but that the surgical approach should be properly adjusted and planned, and a longer healing period before loading may be taken into account to achieve appropriate osseointegration, and last but not least, Temmerman et al., in 2019 (7), deduced in his study that there is no difference in the oral implant treatment outcome between non-osteoporotic and osteoporotic patients.

Also from this study results, the recorded difference in the increase of alveolar bone density and implant stability between study and control groups was statically significant, which is in conformity with the results of other studies from the literature such as what concluded in Jing et al., study, in 2021 (36), that PEMF improved bone anabolism and titanium implants osseointegration through blatantly anabolic activities in bone defect healing, also with what proved by Cai, et al., in 2018 (37), that by fostering bone ingrowth via a canonical Wnt/-catenin signaling-associated mechanism, PEMF stimulation improved bone architecture and titanium implant osseointegration. Our fundamental understanding of skeletal susceptibility to external electromagnetic signals is enriched by this study. And also opens new therapeutic substitutes for T1DM-associated osteopenia/osteoporosis and osseous deficiencies in a stress-free, quick, and highly effective manner.

Moreover, current study recorded results were consistent with the nature of the mechanism of PEMF and its recognized therapeutic uses such as having positive outcomes for a number of bone illnesses and accelerating the healing of long bone fractures such as mandible by promoting osteogenesis through promoting mineralization, osteoblast proliferation, and osteoclast maturation, and inhibiting their activity (12-14).

This mechanism of action could be explained as physical PEMF stimulation starts the signalling cascades that efficiently stimulate angiogenesis and osteogenesis in a coordinated spatiotemporal manner, improving the bone tissue's capacity for self-repair (38).

For a deeper understanding of the PEMF action mechanism, Wang, et al., in 2018 reported that PEMFs promote osteogenic differentiation and mineralization of osteoblasts and increase bone growth and peak bone mass by stimulating soluble adenylyl cyclase (sAC), cyclic adenosine monophosphate (cAMP), protein kinase A (PKA), and cAMP response element-binding protein (CREB) signaling pathways (39).

CONCLUSIONS

Within the limitation of this study, we can conclude that the oral implant treatment is not absolutely contraindicated with osteoporotic patients, but the local alveolar bone quality, proper and well-organized surgical technique, adequate osseointegration period before loading, and patient cooperation are the main factors that directly influence the oral implant treatment success rate. Additionally, this study demonstrated the beneficial and enticing effects of PEMF on the placement of dental implants in patients with osteoporosis, suggesting that the use of PEMF after the implant surgery could be a useful procedure for the acceleration of healing, and improvement of alveolar bone density and implant clinical stability.

Thus, these results should be taken into consideration when planning and implementing immediate and early loading strategies. Additional randomized controlled trials, larger prospective cohort studies, and longer follow-up times are still required in order to draw more evidence-based conclusions.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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