Effect of Intermittent Pneumatic Compression Therapy on Bone Mineral Density in Oral Contraceptive Women

Amel M. Yousef*, Sherif M. Eissa ** and Ahmed M. El-Halwagi***

* Department for Gynecology and Obstetrics, Faculty of Physical Therapy, Cairo University.
** Department of Cardiopulmonary and Geriatric, Faculty of Physical Therapy, Misr University.
*** Department for Gynecology and Obstetrics, Faculty of Medicine, Cairo University

ABSTRACT

Background: *Intermittent pneumatic compression of the lower limbs increase blood flow in the leg bones, which, in turn, may improve bone mineral density (BMD).* ***Purpose of the study:*** *this study was set out to investigate the effect of intermittent pneumatic compression on BMD in oral contraceptive (OC) women with low bone mass.* ***Study design:*** *28 multiparous OC women with BMD T score < -1 at either neck of femur and/or lumbar spine were recruited into the study from Kasr El Aini University Hospital. They were divided randomly into two equal groups in number: group (A) received intermittent pneumatic compression therapy and specific exercise training and group (B) performed the same exercise as in group (A), three times per week for 6 months. Also each woman in both groups was given daily 1000mg of calcium carbonate and 400IU cholecalciferol all through the study period. BMD at lumbar region (L_{1-5}) as well as neck of femur and markers of bone formation (Serum calcium and alkaline phosphatase) were evaluated before and after 6 months of treatment.* ***Results:*** *Data showed a significant improvement in BMD at neck of femur only in group (A) and did not show in group (B). Also, there was a non significant change in BMD at lumbar spine in both groups after 6 months of treatment. In addition, markers of bone formation did not change significantly in both groups except in group (A) which decreased significantly.* ***Conclusion:*** *Intermittent pneumatic compression has a positive effect in the prevention and treating bone loss in OC women. So, it may provide a new method for treating osteoporosis in geriatric women, but further researches are needed to find the exact effect in such cases.*

Key words: *Osteoporosis, Intermittent pneumatic compression, BMD, OC, Calcium, Vitamin D, Alkaline phosphatase.*

INTRODUCTION

The rate of hip fractures is high among OC users[9,31]. The consequences of hip fractures are dire. Between 17% to 33% of patients die within a year following the fracture while a similar proportion are so severely disabled that they never regain independence[21].

Generally, OC use is a common practice among young women which has been associated with a reduction of endogenous sex steroids that results in a marked decrease in ovarian steroidogenesis and suppresses bone remodelling[3]. So, the circulating estrogen levels are lower than levels found in the early follicular phase of normal ovulating cycles[19]. Hence, OC use can prevent the normal accretion of bone mass that would occur in young adult women[1,25].

In addition, OC use increase the concentrations of cortisol consequent to an increase in corticosteroid binding globulin[6,8] which lower bone turnover, thus the trabecular bone is more affected than cortical bone in OC users[16].

One of the effective strategies to reduce the risk for fracture is to find mechanisms to

build bone mass in younger women. Mechanical loading exerted by exercise, increase bone mass in young women[2,20]. But OC use in women between 18 and 35 years of age have a negative effect on total bone mass as well as the neck of femur when coupled with an exercise program [15] as a result of the suppression of bone turnover which noted with OC users that could reduce the osteogenic effect of an exercise program by preventing the normal increase in bone formation that would occur in response to mechanical loading of exercise[7, 33] but a positive effect was noted at the spine with exercise[20].

Calcium and vitamin D supplementation have been shown to improve bone density and reduce the risk of fracture at the spine [14], but the effects at the femoral neck are much less prominent[13,17]. Therefore, there is a need to have a new method for enhancing the effect of bone protective drugs at the femoral neck at first and secondary at the spine.

Intermittent pneumatic compression is a standard treatment for lymphoedema in upper and lower limbs[24], a prophylaxis for deep vein thrombosis[29] and is currently under investigation as a therapy for patients with lower limb arterial insufficiency[12]. The basic action of such system is to compress the blood vessels within the muscle (with a pressure generally below the normal diastolic pressure of blood), expelling venous blood or lymph proximally stimulating the action of muscle pumps. On release of the compression, the veins refill, but hyperaemia will also occur in arteries, which is the basis of its use in arterial disease. It has been proposed that general venous occlusion could affect the long bones by diverting flow through their venous sinuses, since arterial inflow to a limb during compression should not be affected, but normal outflow would be occluded[10]. A suitable intermittent pneumatic compression cycle could therefore produce intermittent increases in the blood flow through bone by 25% during the compression period[23]. Also, the direct effect of the pressure could increase capillary filtration which would enhance more cellular perfusion into bone resulting in a denser periosteal callus as found at tibial fractue[11].

However, there are no published studies on the effect of intermittent pneumatic compression therapy on bone mineral density. Therefore, the purpose of this study was set out to investigate the effect of intermittent pneumatic compression therapy on bone mineral density in OC women with low bone mass.

SUBJECTS, MATERIALS AND METHODS

Subjects

From large sample only 28 multiparous (1-3 times), OC women with a bone mineral density (BMD) at their femoral neck and/or lumbar spine (L_{1-5}) T score <-1, their body mass index (BMI) <30Kg/m^2 (29.78±1.46Kg/m^2) and their age ranged from 32 to 40 years old (38.37±1.98years) were recruited in this study from the Outpatient Clinic of Family Planning at Kaser El Aini University Hospital.

All women were taking OC pills of low doses estrogen compounds (50 mg ethinyl estradiol) as well as they did not participate at any exercise training program for at least two years before starting this study.

Exclusion criteria included: medication or bone, kidney or hormonal disorders that might affect calcium metabolism, any secondary causes of osteoporosis, less than nine menstrual cycles in the year before the study, deep vein thrombosis as well as varicose veins, fracture of the femur, tibia and

fibula, leg wounds and pregnancy or lactation for the prior 6 months of starting the study.

Women were assigned randomly into two equal groups in numbers: Group (A) received intermittent pneumatic compression therapy at both lower limbs and participated in specific exercise training program and Group (B) participated in the same specific exercise training program as in group (A). All women in both groups (A and B) received 1000mg calcium carbonate and 400IU cholecaciferol daily [13,14,17] and the same program of exercise training all through the study period (6 months). An informed consent was signed by the participated women before the study.

Instruments

1- Evaluative instruments

A- Weight and height scale was used to measure the weight and height of each woman in both groups (A and B).

B- Dual X-ray absorptiometry (DXA) was used to measure BMD at the neck of femur and lumbar spine (L_{1-5}) for both groups (A and B).

C- RA- 50 chemistry system was used to estimate serum calcium and alkaline phosphatase in both groups (A and B).

2- Treatment instruments

A- C85 Auto pulse compression machine used for the application of intermittent pneumatic compression therapy for group (A).

B- Wall bars and mats were used to perform specific exercise training in both groups (A and B).

C- Stop watch was used to estimate the time of sustained muscle contraction and relaxation of specific exercise training for each woman of both groups (A and B).

PROCEDURES

1- Evaluative procedures

All the following evaluations were done for each woman in both groups (A and B)

* Initially each woman was subjected to a careful history taking including personal and medical history. Then, weight and height were measured to calculate BMI by dividing weight (Kg)/ height^2 (m^2).
* Dual X-ray absorptiometry (DXA) was done to measure the BMD at the neck of femur and lumbar spine (L_{1-5}) before starting the study to confirm that all women in both groups (A and B) their BMD at the two sites of assessment was below normal score of the same age population i.e. T score <-1 and repeated again after 6 months of treatment.
* Chemical markers for bone formation (serum calcium and alkaline phosphatase) were assessed before and after 6 months of treatment. Blood samples were collected during early follicular phase of the menstrual cycle (days 2-5) to control this potential confounding variable in both groups (A and B).

2- Treatment procedures

Before starting the treatment procedures, each woman in both groups (A and B) was informed to follow the same regimen of calcium (1000mg calcium carbonate) and vitamin D (400 IU cholecalciferol) supplementation daily all through the study (6 months)

*** Intermittent pneumatic compression treatment**

Each woman in group (A) received intermittent pneumatic compression three times / week for 6 months. Each woman was instructed to lie in a relaxed comfortable

supine lying position with the head of the bed raised 15°. The pressure sleeve was fitted to the right lower limb from just above the toes to a level above the knee joint (mid thigh), while all knobs of the auto pulse compression machine were in zero position. The machine was applied compression on for 1minute at an inflation pressure of 60mmHg followed by 1minute of rapid deflation at pressure of 20mmHg by a programmable automatic pump for 1hour[23]. The left lower limb was received the same as right lower limb.

*** Specific exercise training program**

Each woman in both groups (A and B) was performed specific exercise training program for the muscles around hip joints of both lower limbs and spine, three times per week for 6 months. Exercise performed from prone as well as standing position in which the woman was instructed to hyper extend her hip joint to train the gluteus maximums muscles, followed by exercise to train the gluteus medius muscles by abducting hip joints from side lying as well as standing position. Another group of exercise was performed to train the erector spinae muscles which performed from prone lying as well as crock lying position in which the woman was instructed to hyper extend her back followed by an exercise to decrease lumbar lordosis (posterior pelvic tilt) from crock lying position.

Sustained muscle contraction of each specific exercise was maintained for 5 seconds followed by 10 seconds of relaxation. Each exercise was repeated 10 times, therefore, the exercise session consisted of 110 repetitions.

3- Data analysis

Data collected and statistically analyzed to determine changes in variables over the course of the 6 months of treatment by paired and unpaired T test at a level of significance $P<0.05$.

RESULTS

The physical characteristics as age, height, weight, BMI, parity and the period of OC usage were found to be statistically non significant differences ($P>0.05$) between both groups (A and B) before starting the study as summarized in table (1).

Table (1): Statistical summary of the physical characteristics of both groups (A and B).

Variables	Mean±S.D.		Level of significance
	Group (A)	Group (B)	
Age (years)	38.81±1.78	37.92±2.39	P<0.14
Height (cm)	161.89±1.76	162.19±1.62	P<0.21
Weight (Kg)	76.95±2.86	77.04±1.88	P<0.34
BMI (Kg/m_2)	29.69±0.95	29.87±1.04	P<0.16
Parity (Times)	1.84±0.78	1.76±0.70	P<0.37
OC usage period (Years)	2.79±1.31	2.88±1.45	P<0.22

In the present study, the response of BMD to intermittent pneumatic compression was investigated. The data collected from both groups (A and B) after 6 months of treatment were compared with the pre treatment values. As revealed in table (2) and figure (1), the baseline row data of all women showed a statistically non significant differences between both groups (A and B) ($P>0.05$), therefore confirming that baseline values of

the BMD at right as well as left neck of femur and lumbar spine (L_{1-5}) were comparable. Results showed a marked increase in group (A) at right as well as left neck of femur and a minimal increase in group (B) which was significantly increased in group (A) only and showed a statistically non significant at lumbar region (L_{1-5}) in both groups (A and B) after 6 months of treatment. Also, comparison between both groups (A and B) after 6 months of treatment showed a statistically significant increase in group (A) at neck of femur compared to group (B) and did not any significant difference at lumbar spine between both groups (A and B).

Table (2): BMD at femoral neck and Lumbar spine (L_{1-5}) before and after 6 months of treatment.

BMD	Group (A)				Group (B)			
	Before ttt	After ttt	% of change	Pvalue	Before ttt	After ttt	% of change	Pvalue
Spine (mg/cm^2)	1.040±0.22	1.060±0.34	↑1.92	0.09	0.979±0.65	1.001±0.59	↑2.247	0.08
Spine T score	-1.32±0.84	-1.22±0.76	↑7.59	0.08	-1.41±0.69	-1.28±0.49	↑9.219	0.07
Rt. Femoral neck (mg/cm^2)	0.751±0.08	0.792±0.09	↑5.45	0.05	0.749±0.08	0.756±0.07	↑0.934	0.12
Rt. femoral neck T score	-1.68±0.65	-1.41±0.69	↑16.07	0.05	-1.71±0.59	-1.63±0.39	↑4.678	0.64
Lt. Femoral neck (mg/cm^2)	0.758±0.061	0.790±0.07	↑4.91	0.05	0.747±0.10	0.754±0.08	↑0.937	0.33
Lt. femoral neck T score	-1.62±0.72	-1.40±0.65	↑13.58	0.05	-1.64±0.62	-1.56±0.51	↑4.878	0.74

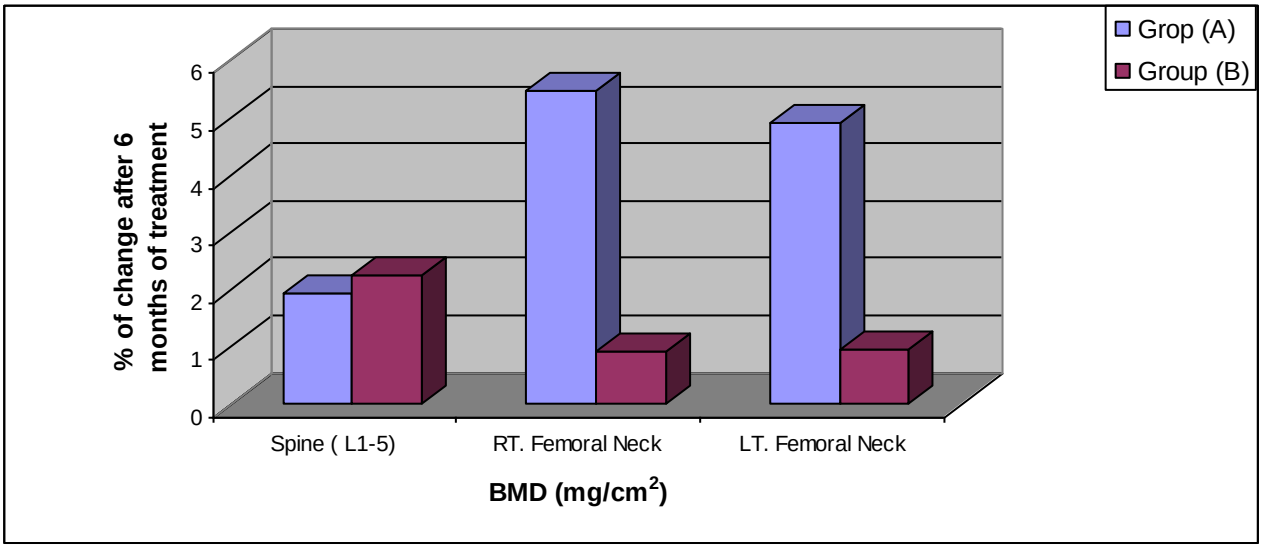

Fig. (1): Percentage of change in BMD (mg/cm^2) in both groups (A and B).

The serum calcium and alkaline phosphatase reported in this study were considered as measures markers of bone formation as indicated in table (3) and figure (2), women in both groups (A and B) showed a statistically non significant difference (P>0.05) at baseline values, while after 6 months of treatment, there was a minimal changes in both

groups that showed a statistically non significant changes (P>0.05) except serum alkaline phosphatase which decreased significantly (P<0.05) in group (A) only.

Table (3): Serum calcium and alkaline phosphatase before and after 6 months of treatment

Variables	Group (A)				Group (B)			
	Before ttt	After ttt	%of change	Pvalue	Before ttt	After ttt	%of change	Pvalue
Calcium (mg/ml)	8.80±0.38	9.11±0.37	↑3.52	0.07	8.82±0.35	8.97±0.34	↑1.70	0.66
Alkaline phosphatase (IU/liter)	157.11±36.23	150.60±35.966	↓4.07	0.05	154.48±36.44	150.96±35.92	↓2.27	0.75

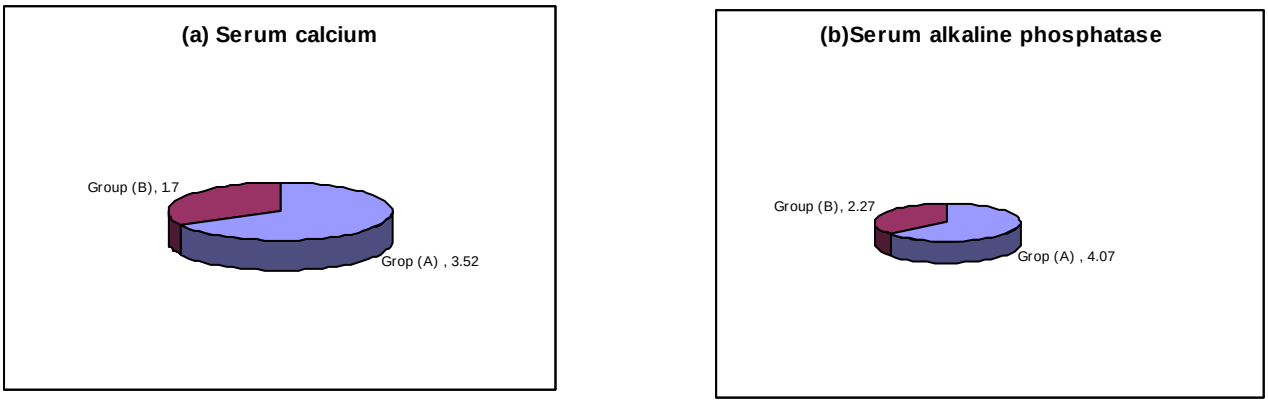

Fig. (2): Percentage of change in markers of bone formation after 6 months of treatment.

DISCUSSION

Women with significantly more bone "in the bank" at menopause will take longer time to reach the fracture threshold. So, the purpose of this study was set out to investigate the effect of intermittent pneumatic compression therapy on bone mineral density in OC women with low bone mass.

In the present study, BMD at lumbar spine increased by 7.59% and 9.21% respectively in group (A and B) while at neck of femur in group (A) it increased significantly and did not in group (B).

The different responses of both groups (A and B) after 6 months of treatment appear to be a good evidence that intermittent pneumatic compression of the lower limb increase BMD at neck of femur in group (A) only. So, it is difficult to attribute such increase to the calcium and vitamin D supplementation as the literature suggests that the effect on BMD if occurs it predominantly at the spine [14], while the effect at femoral neck is negligiable[13,17].

However, a trend toward increased gain in bone mineral density which noted at the femoral neck in group (A), indicating a possible localized effect of intermittent pneumatic compression.

The most possible explanation for the results in group (A) is that compression increased blood flow through the bone[23].

Hence, the effects of intermittent pneumatic compression on blood flow are well known, so, 1 minute of compression is sufficient time for the veins under the cuff to begin to re-open; however, if the deep venous

flow under the cuff is insufficient to account for the overall outflow, another mechanism must be sought. It has been suggested that under those conditions blood could be diverted through the central venous sinuses of the long bones[5, 10]. The route through the thigh of the popliteal vein→ femoral inferior metaphyseal veins→ central venous sinus of femur → superior metaphyseal veins→ medial and lateral circumflex femoral → gluteal veins→ internal iliac →inferior vena cava depends on the fact that the venous sinuses of bone have no valves and that the normal flow direction could be reversed in the inferior metaphyseal veins[5]. This hypothesis could be confirmed by experiments in cats after femoral vein ligation or external venous compression, when metaphyseal flow increased, as measured by heat loss from a heated thermocouple[22].

Also, long term increases in epiphyseal flow in rats have been observed after vein ligation[26], which have increases the intermedullary venous pressure[34].

Also, it was proved that direct mechanical stimulation increase the trabecular bone density and bone volume[5]. However, it has been argued that shear stress of fluid flow, rather than mechanical strain, might liberate nitric oxide and prostaglandin E_2 in osteoblasts and promote bone growth[28], this theory is in agreement with the results of experiments with hind limb suspended rats[4]. Therefore, intermittent pneumatic compression may influence bone density irrespective of whether it is flow or the bone itself that is affected. Also, it has been shown in animals' experiments that venous occlusion or ligation can increase the mass and length of bone[5,26] as well as venous compression with a tourniquet also appears to promote fracture healing[11]. Since, it is known that the blood flow through bone will increase due to compression, it has been proposed that the reason increased flow can affect the growth via the higher concentration of Co_2 in the venous blood shunted through the bone might provide the ideal environment for osteogenesis[5]. However, while the potential for affecting bone growth is still speculation, if intermittent pneumatic compression enhances the blood flow through bone, so substances (calcium and vitamin D supplementation) introduced into the circulatory system could be encouraged to reach bone more rapidly. Also, following leg compression, fat mass was reduced and muscle mass increase stimulating, in essence, physical stimuli. These are known to obtain both an endogenous anabolic stimulus to bone tissue and an antiresorptive factor that can actively inhibit osteoclastogenesis[27].

As revealed in the present study, exercise alone in OC women did not significantly increase their BMD at lumbar spine and neck of femur which are consistent with several earlier reports that failed to detect a significant increase in femoral neck BMD in OC young women following an exercise program[7, 33]. Similarly, young adult female macaques on OC, who would presumably be active, had less bone accretion and lower serum calcium levels than the non use group[25]. A recent cross-sectional study of 20 to 35 years old women also suggested a negative impact on bone with a combination of long term OC use and exercise history[15].

Hence, there are several possible reasons for the failure to observe a significant positive effect of exercise on the femoral neck in younger women as the normal gain in bone mass at the femoral neck in adolescent women begins to decline by age14 – 17 years old and/ or 2 years post menarche in which there is no further gain in bone mass at this site[30]. This may suggest that exercise programs instituted in third decade of life will not produce significant benefit to the strength of the

femoral neck. Also, in this age these women are highly active so, they were already adapted to high mechanical load thus adding exercise in that period may have not any additional effect on bone. Moreover, the effect of exercise on bone tend to be site specific[18] and exercise programs instituted even during youth may not have a significant beneficial effect on the femoral neck even though they produce positive effects in the spine[32].

In the present study, the significant decrease in alkaline phosphatase in group (A) and the non significant change in group (B) after 6 months of treatment could explain the positive results gained in group (A) who received intermittent pneumatic compression therapy. So, the minute increase in BMD in group (B) could be attributed to the interaction between exercise and calcium supplementation gave to those women which protect their bones from the negative interaction of OC use and exercise as mentioned in the study of Weaver et al., 2000[33].

Conclusion

As a conclusion intermittent pneumatic compression is an effective method for treating bone loss in OC women. Thus, these findings however are promising and encourage the performance of a larger trial with intermittent pneumatic compression of the leg in women who are immobile and exercise is not an option. This technique may also provide a means of enhancing the effect of pharmacological compounds at the femoral neck. But, the results of this study support the need for further larger trial, particularly focused on osteoporotic women with restricted activity.

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الملخص العربى

تأثير العلاج بالضغط الهوائى المتقطع على كثافة العظم عند سيدات يتعاطين حبوب منع الحمل

يزيد الضغط الهوائى المتقطع على الأرجل من سرعة سريان الدم فى عظام الأرجل و هو ما يمكن أن يترتب عليه تحسن كثافة العظم . **هدف الدراسة :** وتهدف هذه الدراسة الى معرفة تأثير العلاج بالضغط الهوائى المتقطع على كثافة العظم عند سيدات لديهن نقص فى كتلة العظم ويتعاطين حبوب منع الحمل . **خطوات الدراسة :** اشتركت فى هذه الدراسة 28 سيدة متكررة الحمل يتعاطين حبوب منع الحمل و كثافة عظامهن اقل من -1 فى منطقة عنق الفخذ و المنطقة القطنية من مستشفى القصر العينى. و تم تقسيمهن الى مجموعتين متساويتين: مجموعة (ا) شاركن فى برنامج العلاج بالضغط الهوائى المتقطع لمدة ساعة (كان الضغط على الرجل لمدة 60 ثانية بواقع 60 ض.ج. يعقبة استرخاء لمدة 60 ثانية بواقع 20ض.ج. و يكرر حتى انتهاء زمن العلاج) يعقبة برنامج للتمرينات للعضلات حول الفخذ و كذلك العضلات حول العمود الفقرى و مجموعة (ب) شاركن فقط فى برنامج التمرينات. برنامج العلاج كان لمدة 6 أشهر بواقع 3 مرات أسبوعيا متلازم مع اعطائهن 1000مجم كربونات الكالسيوم و 400 وحدة فيتامين (د) يوميا. وتم تقييم المجموعتين قبل وبعد الانتهاء من برنامج العلاج (6 اشهر). **النتائج:** و قد أظهرت النتائج زيادة فعالة فقط فى كثافة عظم عنق الفخذ فى المجموعة (ا) عنه فى المجموعة (ب) اما كثافة العظم فى المنطقة القطنية و كمية الكالسيوم و الفوسفات القلوية فى الدم فلم تظهر اى نتائج ايجابية فى المجموعتين(ا) و(ب) ما عدا المجموعة (ا) فقد أظهرت نقص فعال فى الفوسفات القلوية. المقارنة بين المجموعتين بعد 6 اشهر من العلاج اظهرت فرق ايجابي فى كثافة عظم الفخذ. **الخلاصة :** مما سبق نستنتج ان العلاج بالضغط الهوائى المتقطع يمكن أن يكون له دور فى علاج نقص كثافة العظم لدى السيدات اللاتى يتعاطين حبوب منع الحمل. و بالتبعية فان هذه النتائج توجد بصورة ايجابية وسيلة جديدة لعلاج هشاشة العظام وبخاصة لدى السيدات المسنات و لكن لابد من اجراء دراسات اخرى لمعرفة كيفية تاثير هذا العلاج فى مثل هذه الحلات.

الكلمات الدالة: هشاشة العظام-والضغط الهوائى المتقطع ، كثافة العظام – حبوب منع الحمل – الكالسيوم – فيتامين د – الفوسفات القلوية.