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The effect of progressive loading protocol on bone mineral density and quality of life in osteoporotic patients: A single-blind randomized controlled trial

Saeed Mufleh Alnasser ¹, Shibili Nuhmani ¹*, Ahmed Mohamed ElSodany ², Qassim I Muaidi ¹

¹Department of Physical Therapy, College of Applied Medical Sciences, Imam Abdulrahman Bin Faisal University, Dammam, SAUDI ARABIA ²Armed Forced Hospital–Southern Region, Khamis Mushait, SAUDI ARABIA ***Corresponding Author:** snuhmani@iau.edu.sa

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ARTICLE INFO	ABSTRACT
Received: 22 Jun. 2024	The objective of this study was to investigate the impact of the progressive loading protocol (PLP) in subjects with
	osteoporosis. Ninety-two patients diagnosed with osteoporosis participated in this double-blind randomized control trial. The participants were randomly assigned into experimental and control groups. Both groups received twelve weeks of low-impact aerobics training along with a health awareness program. The experimenta group received, in addition, PLP. Bone mineral density (BMD) was measured by dual-energy X-ray absorptiometry at baseline and after 12 weeks of intervention. Quality of life (QoL), fear of fall (FOF), and risk of fall (ROF) were assessed using quality of life questionnaire of the European Foundation for Osteoporosis-41 (QUALEFFO-41), fal efficacy scale-international (FES-I), the time up and go (TUG) test, and Berg-balance scale (BBS), respectively. Self-exercise efficacy scale (SEES), and exercise benefit barrier scales (EBBS) were also measured. Participants in the experimental group revealed more improvement in BMD, QoL, FOF, and ROF post-intervention compared to the control group. Furthermore, a strong positive correlation existed between BMI, TUG, FES-I, and QUALEFFO-41 While a strong negative correlation was found between BBS, SEES, EBBS, and QUALEFFO-41.PLP offers a safe and feasible option for individuals seeking to manage the challenges of osteoporosis while improving their physical well-being.

Keywords: osteoporotic, bone mineral density, loading exercise, osteoporosis, quality of life

INTRODUCTION

Osteoporosis is a progressive systemic skeletal condition that causes bone loss and problems with the microarchitecture of bone tissue and, as a result, an increased susceptibility to fractures [1]. The growing average age of society and the tendency to an unhealthy lifestyle are increasing the severity of the issue of osteoporosis, which threatens an increasing percentage of the population. The consequence and often the first symptom leading to the detection of the disease are fractures, which require subsequent long-term hospitalization of the patient. In patients with osteoporosis, there is a pathological loss of both the inorganic and organic parts of the bone with changes in the micro-structure and function of the bone and more fracture risk. The cost of treating patients affected this way is increasingly burdening the healthcare system [2].

The incidence of osteoporosis is estimated at six to eight percent of the population worldwide [3]. Globally, osteoporosis results in over 8.9 million fractures annually, with Europe experiencing the highest prevalence of osteoporotic fractures, accounting for 34.8% [4]. About 30% of postmenopausal women in the United States and Europe suffer from osteoporosis. In the remaining years of their lives, at least 40% of these women and 15% to 30% of males will have one or more fractures [5]. According to the Saudi Arabian Ministry of Health, 28.2% and 37.8% of men and women over the age of 50 years have osteoporosis or osteopenia in Saudi Arabia [6]. A lack of vitamin D remains the primary risk factor in the country. Osteoporosis-related femoral fractures were expected to occur 7,528 times in 2015, with a direct cost of \$150.60 million [6].

The "gold standard" test for people at risk of osteoporosis is still bone mineral density (BMD). This has a rather simple explanation: in the lab, bone strength and BMD are closely correlated. What's more, BMD is still a reliable indicator of fracture risk on its own. In actuality, there is a direct correlation between older women's BMD and fracture risk. The risk of fracture increases 1.5-2.5 times for every standard deviation decrease in BMD (a one-standard deviation drop in BMD in the spine represents a loss of 10-12 percent of BMD) [7].

There are several health advantages to regular physical activity; however, not all forms of ex-ercise are bonepromoting in the same way. Despite the widespread belief that long-term aerobic exercise like swimming, cycling, and walking benefits everybody, there is inconsistent evidence that these activities stimulate bone growth [8]. Cohort studies showing that greater levels of self-reported physical activity are linked

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to increased bone density are commonly misinterpreted as proof that any activity would enhance bone mass. A metaanalysis of intervention trials shows that frequent walking and other low-intensity exercises had little or no impact on postmenopausal women's bone mass [9]. While walking can improve aerobic fitness, adiposity, and other cardi-ometabolic parameters, prescribing it alone is insufficient to enhance bone health and has a negli-gible effect on other fall and fracture risk variables in postmenopausal women, such as muscle mass, strength, and balance [10].

On the other hand, different kinds of activity can potentially increase bone density. It is sug-gested that dynamic loading must replace static loading to cause relatively large bone stresses and be administered quickly [11]. If appropriate load intensity is obtained, just a few repetitions of loading are necessary to induce a responsive bone adaptation. Because bone cells become desensitized to repeated loading, short bursts of loading followed by rest intervals are more effective than per-forming the same number of loads in a single session. [12].

Osteoporosis related issues can have a detrimental influence on one's quality of life (QoL), making it an important public health issue. Injuries to the spine, hips, or wrists are causing physical, emotional, and psychological difficulties for men and women with osteoporosis [8]. QoL should be comprehensively investigated before a fracture occurs to take remedial action [13]. Osteoporotic individuals without fractures are also reported to have low QoL scores [14]. In addition, health re-search and clinical studies on osteoporosis are evaluated for their impact on QoL. As a result of the enormous financial and human toll that osteoporotic fractures exact, it has been suggested that ef-forts to find new treatments and methods should be bolstered by a focus on patient well-being and QoL [15]. Therefore, the current study aimed to examine the impact of the progressive loading protocol (PLP) in subjects with osteoporosis.

MATERIALS AND METHODS

Study Design

A double-blind randomized control trial was conducted to investigate the efficacy of PLP in osteoporosis. This study was approved by the Institutional Review Board at Imam Abdulrahman Bin Faisal University (IRB-PGS-2022-03-329) and the Research Ethics Committee at Armed Forced Hospital– Southern Region (AFHSRMREC/2022/Rehabilitation Health Services/648) on 6 November 2022. The study was registered in ClinicalTrials.gov with the registration number NCT05889104 and conducted in accordance with the consolidated standards of reporting trials checklist.

Sample Size

Considering the prior research [16] and an alpha level of 0.05 with 0.8 power and an effect size of 0.57, to decide even low variances between the study groups, a power analysis was carried out to estimate the proper sample size using G-power software for windows and it was estimated to be 80. To account for dropouts during the course of the study, the sample size was expanded by 15%, re-sulting in a final enrollment of 92 participants.

Participants

Participants diagnosed with osteoporosis were assessed and referred by independent physicians from Armed Forced Hospital–Southern Region, Saudi Arabia, confirmed by dualenergy X-ray absorp-tiometry (lumbar spine [L2-4], T-score of less than -2.5) and more than 40 years of age were included in this RCT. Subject with a history of kidney diseases, cardiopulmonary diseases, throm-bosis, hyperprolactinemia, spondylolisthesis, back/leg deformities or surgeries, osteoarthritis, pacemakers, implants of the lower extremity and spine, tumors, migraines, or have any other dis-eases that affect bone metabolism, or neuromuscular performance were excluded.

After screening for inclusion and exclusion criteria, 92 patients were randomly allocated into two groups (experimental and control groups) using online GraphPad and generating a random number for each participant, with 46 patients in each group. The experimental group received low-impact aerobics training along with a health awareness program in addition to the PLP. The control group underwent twelve weeks of low-impact aerobics training along with a health awareness program. All participants signed a consent form before the beginning of the study.

Outcome Measurements

Osteoporosis assessment

BMD was assessed using dual-energy X-ray absorptiometry at both the lumbar spine (L2-4) and the head of the femur (Tscore of less than -2.5). A substantial scanning arm covered the body during the scan in order to gauge bone density. The lumbar and femoral head were exposed to a narrow beam of low-dose X-rays as the scanning arm gently moved across the subject's torso.

Health-related quality of life assessment

Quality of life questionnaire of the European Foundation for Osteoporosis-41 (QUALEFFO-41) was used to assess healthrelated QoL of the participants. It is a disease-specific questionnaire that was developed to assess people with osteoporosis and vertebral fractures. QUALEFFO-41 contains seven domains of life: pain, daily living tasks, household chores, mobility, recreational and social en-gagement, overall wellness perception, and mental functioning. The total QUALEFFO-41 score is determined by adding together all responses to the items. Lower scores reveal the best QoL [17].

Risk of fall assessment

Time up and go test: The time up and go (TUG) test is a simple screening test that is a sensitive and particular measure to assess fall risk and determine the advancement of balance, sitting to stand, and walking. An older adult who com-pletes TUG test in 12 seconds or more is at high risk of falling. The test has excellent reliability and validity in the elderly population [18]. TUG test was conducted with the patient sitting on an armrest chair, wearing his regular shoes and using his walking aid if needed. Upon the therapist's command, the patient stood up, walked for 3 meters, turned around, returned to the chair, and sat down. The time started with the therapist's command and ended when the patient sat back on the chair.

Berg-balance scale: Berg-balance scale (BBS) is a widespread, therapist-recorded scale used to objectively assess sitting and standing, static and dynamic balance. It

Tab	ole 1	. Com	parison	of the	base	line d	ata	bet	tween	the	treat	tmen	t groups
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	Control group (mean ± standard deviation)	Experimental group (mean ± standard deviation)	p-value
Age (year)	58.98 ± 5.38	58.48 ± 5.62	0.660
Weight (kg)	76.59 ± 10.54	78.89 ± 10.37	0.290
Height (cm)	166.22 ± 8.57	165.57 ± 8.72	0.720
Body mass index (kg/m ²)	27.97 ± 4.93	28.95 ± 4.42	0.320
T-score of the femur	-3.41 ± 0.24	-3.36 ± 0.24	0.270
T-score of the lumbar spine	-3.39 ± 0.23	-3.37 ± 0.20	0.707
QUALEFFO-41	48.74 ± 2.02	48.97 ± 2.35	0.507
FES-I	30.28 ± 4.38	31.15 ± 2.85	0.331
TUG	8.39 ± 0.95	8.17 ± 1.16	0.329
BBS	51.13 ± 2.12	50.93 ± 1.94	0.673

contains 14 purposeful balance items that are targeted to find the elderly capability to sustain a position and achieve postural modifications to finish functional tasks. Previous studies showed high intra- and inter-rater reliability [19] with moderate to high validity [20]. A score from 41-56 indicates low fall risk and a score from 0-20 indicates high fall risk.

Fear of fall assessment: Fall efficacy scale-international (FES-I) was used to assess FOF. FES-I was established as part of the prevention of falls network Europe project from 2003 to 2006 [21]. It is a 16-item questionnaire, with a rating score that varies from 16 (least worry about falling) to 64 (utmost worry about falling). On a 4-point Likert scale, 1 representing not at all concerned and 4 representing ex-tremely concerned, participants were prompted to indicate how concerned they were about falling during an activity. The item scores are added up to attain the overall score. The scale demonstrated high validity and test-retest reliability in community-dwelling and geriatric nursing home-dwelling individuals [22].

Self-exercise efficacy sclae assessment: The efficacy of self-exercise was evaluated using Self-exercise efficacy scale (SEES). SEES is an 8-item self-scale on an 11-point measure ranging from 0 (no confidence) to 10 (highly confident) designed to evaluate the patient's beliefs in his ability to maintain moderate-intensity exercise thrice weekly for more than 40 minutes per session. SEES proved high internal reliability consistency and scale integrity with face and construct validity are reasonable [23]. High scores indicate increased confidence in self-exercise.

Exercise benefit barrier scales assessment: Exerciserelated benefits and barriers were evaluated using exercise benefit barrier scales (EBBS). The instrument was composed of 43 items with a four-answer, mandatory choice responses from 1 (strongly disagree) to 4 (strongly agree) in a Likert-style manner. The benefit element included 29 benefit questions, while the barrier element of the scale consisted of 14 barrier questions. The scale showed high test-retest reliability and internal consistency [24]. The better the score, the more favorably the person views exercise.

Intervention

Progressive loading protocol

Subjects in the experimental group performed four days of moderate to high-impact loading exer-cises per week for 12 weeks. PLP is adapted and modified based on exercise and sports science Australia's position statement on exercise prescription for the prevention and management of osteoporosis [5, 25]. PLP included bounding, hopping, skipping rope, drop jumps, bench stepping, and jumping in many directions vertically. The weight-bearing intensity progressed by changing orientations, adding weighted vests, and raising the height at which certain maneuvers, like bounding and drop leaping, were performed. To prevent the risk of injury, the participants were instructed to avoid the flexion or twisting of the spine while loaded. Frail individuals were watched after and exercised close to a railing or other sturdy support. Within the pain threshold, the intensity ranged from mild to high weightbearing impact loads (> 2 times body weight) that were progressive, novel, and multidirectional, rising as tolerated aiming to gradually increase the repeti-tions up to 50 (5 sets of 10 repetitions with 1-2 minutes between sets).

Aerobics training

Participants in both groups received low-impact aerobics training. The training included stair climbing, cycling, and walking on a treadmill for 20 minutes with 10 minutes of warming up and cooling down and 10 minutes of a relative speed adjusted according to patient tolerance and intensity of 40% to 60% of the maximal heart rate.

Health awareness program

Participants in both groups received a health awareness program. The program consisted of an awareness visual program that focuses on a set of awareness instructions with a view to improving health knowledge, promoting behavioral attitudes, and explaining the risk of slips & falls in the osteoporosis patient's community)

Statistical Analysis

IBM SPSS statistics version 25 was used to analyze all the data collected for this study. The paired t-test was used to compare the baseline measures of BMD and TUG with the post-treatment within-group measures, while Wilcoxon signed-ranked test was used to compare the QUALEFFO-41, FES, and BBS. To compare both groups' mean values, the unpaired t-test was used to reveal the difference between BMD and TUG, while Mann-Whitney test was used to compare QUALEFFO-41 score, FES, and BBS scores pre- and post-treatment. In addition, Cohen's d was used for effect size estimation. Spearman's correlation was used to demonstrate the correlation between QUALEFFO-41 scores, ESES, EBBS, TUG, FES, and BBS. The significance difference was set to $p \le 0.05$.

RESULTS

A total number of 92 patients (42 men and 50 women) with a mean age of 58.73 ± 5.48 years, weight 77.74 ± 10.46 kg, height 165.89 ± 8.60 cm, and BMI 28.45 ± 4.68 kg/m² participated in this study. There were no dropouts. The results revealed no significant differences in the mean age, weight, height, or BMI among treatment groups, as illustrated in **Table 1**.

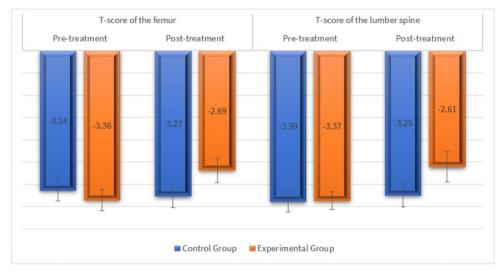


Figure 1. Graphical presentation of T-score offemure and lumber spine pre- and post-treatment (Source: Authors' own elaboration)

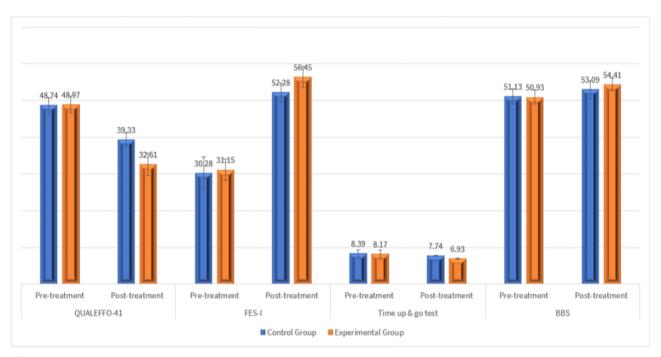


Figure 2. Graphical presentation of QUALEFFO-41, FES-1, TUG test, and BBS pre- and post-treatment (Source: Authors' own elaboration)

Table 2. Comparison of post-treatment data between the treatment groups

	Control group		Experimer	ntal group	- Cohen's d	Confidence
	(M ± SD)	p-value	(M ± SD)	p-value	- Conen's d	interval
T-score of the femur	-3.27 ± 0.26	< 0.001*	-2.69 ± 0.27	< 0.0001	2.180	-0.693 to -0.471
T-score of the lumbar spine	-3.25 ± 0.26	< 0.001*	-2.61 ± 0.34	< 0.0001	2.120	-0.761 to -0.505
QUALEFFO-41	39.33 ± 1.83	< 0.001*	32.61 ± 3.06	< 0.0001	2.665	-1.143 to 6.474
FES	52.28 ± 2.51	< 0.001*	56.45 ± 2.90	< 0.0001	1.538	-4.693 to 1.617
TUG	7.74 ± 0.17	< 0.001*	6.93 ± 0.13	< 0.0001	5.353	-0.580 to 11.286
BBS	53.09 ± 2.42	< 0.001*	54.41 ± 1.69	< 0.0001	0.632	-3.473 to 2.208

Note. M: Mean & SD: Standard deviation

Neither groups had significant differences in pre-treatment mean BMD values, QUALEFFO-41score, TUG test scores, and BBS as demonstrated in **Table 1**, **Figure 1**, and **Figure 2**.

Post-treatment analysis using unpaired t-test compared with baseline mean values in both groups showed a significant decrease in BMD and TUG scores with a more significant effect on the experimental group than the control group. Wilcoxon signed ranks test exhibited significant differences in the QUALEFFO-41, FES, and BBS scores post-treatment compared with pre-treatment for both groups.

The Mann-Whitney test, which was used to compare QUALEFFO-41 score, FES-I, and BBS scores post-treatment, revealed a more significant effect on the experimental group than the control group (**Table 2**, **Figure 1**, and **Figure 2**).

Table 3. Spearman's correlation between QUALEFFO-41, SEES,EBBS, TUG test score, FES-I, and BBS

Characteristics		QUALEFFO-41	Type of correlation			
TUG test score	r	0.827	Strong positivo			
TUG lest score	р	0.00010	 Strong positive 			
FES-I	r	0.888	- Strong positivo			
FES-I	р	<0.00010	 Strong positive 			
BBS score	r	-0.811	- Strong positivo			
DDS SCORE	р	<0.00011	 Strong positive 			
Body mass index	r	0.817	Strong positivo			
bouy mass muex	р	0.00010	 Strong positive 			
SEES	r	832	- Strong positivo			
3223	р	< 0.00010	 Strong positive 			
EBBS	r	-0.712	Strong positivo			
EDDS	р	< 0.00010	 Strong positive 			

As shown in **Table 3**, there was a strong positive correlation between QoL as measured by QUALEFFO-41, TUG score, FES-I, and BMI while a strong negative correlation existed between ESES, EBBS, BBS, and QUALEFFO-41.

DISCUSSION

This study aimed to investigate the impact of PLP in subjects with osteoporosis. Our results demonstrated a statistically significant increase in BMD in the experimental group that received PLP post-treatment compared to the control group although the BMD remained under normal values. These outcomes are in line with earlier research, which showed that premenopausal women who performed short, high-impact jumping exercises for 5 to 6 months experienced equivalent increases in BMD [26, 27]. Even though premenopausal women may only see moderate increases in BMD from high-impact exercise, studies on brief, convenient high-impact, unilateral exercise interventions may improve BMD but prefer to be conducted daily for optimal response [27].

BMD begins to decline after reaching its peak around the age of 30. Consequently, the current BMD serves as the primary determinant of BMD in older in-dividuals [18]. Age, gender, and other genetic and environmental factors have an impact on bone loss from peak to present [28]. A woman's genetic predisposition accounts for 50-80% of the maximal bone mass. Calcium and vitamin D intake, exercise level, body weight, diseases, and postponed puberty are other factors that affect peak bone mass [29]. Women's maximal bone mass is 10-30% lower than that of men, as has already been established [30].

In terms of bone adaptation, the intensity of the load appears to be significantly more crucial than the number of repetitions [31]. Athletes whose sports involve lifting large objects have higher bone density levels than other athletes [32]. The rate of strain also affects the intensity of loading in addition to the load magnitude, which affects how much bone is affected by physical activity [33]. Thus, exercises including hopping or jumping while standing on both legs, may help avoid OP. Given that a higher percentage of daily exercisers withdrew from the intervention early on due to discomfort during exercise, it may be advisable to begin the intervention more gradually. Additionally, the intervention's high-impact nature may require some adjustments for frail, elderly people with a higher risk of injury.

The present study revealed a decrease in QUALEFFO-41 scores that indicated improvement in QoL post-treatment in

the experimental group compared to the control group. Osteoporosis can adversely impact QoL, thus impeding and hampering routine daily activities [34]. It is strongly believed that performing exercises has become essential to developing self-confidence in the elderly in performing their activities and tasks [35]. In addition, steady exercise practice has a favorable influence on overall health, social inclusion, self-esteem, mood, and awareness for better body shape, and diminished depression, anxiety, and FOFs [36]. This study agrees with previous studies that found improvement in all domains of QUALEFFO-41either using exercises alone [37], in combination with other modalities [13], with short [38] or long follow-up periods [13].

The current study yielded a significant difference in FOF post-treatment in the exper-imental group compared to the control group. Agreeing with preceding studies, people with osteoporosis have a greater tendency to fall due to their old age, reduced balance, and de-creased strength [39, 40]. Furthermore, due to FOF, older people are less likely to participate in exercises or other types of physical activity [41]. This results in an increased loss of independence beyond what is required to avoid physical injury from falls or normal ageing. These results are supported by other studies that found a strong positive correlation between osteoporosis and FOF [42, 43].

Consistent with the literature, the current study showed a significant increase in TUG and BBS scores after PLP intervention compared to the control group. Age-related declines in mobility, balance, and TUG test results have been demonstrated in prior studies [44]. Addi-tionally, functional tests are impacted by the rising incidence of ailments and illnesses linked to aging [45] and the TUG test has the capacity to depict the load of multimorbidity across many body systems involved in balance, movement, and coordination [46]. The key reason for the association between aging and increased risk of mortality is the emergence of several comorbidities that result in deficient physical function [47]. The TUG test is advised as a regular fall screening exam, and its value in predicting poor physical performance and neg-ative outcomes has been reported [48]. According to some research, failure to perform well on the TUG test has been linked to a higher mortality risk, as it indicates underlying malaise, sarcopenia, and chronic disease, all of which impact mobility, balance, strength, and gait [46].

In the current study, the functional balance was improved, as revealed by an increase in the BBS score in the posttreatment results, with a more significant difference observed in the experimental group than in the control group. BBS showed high diagnostic accuracy, as a gold standard, with the recommended cut-off points [49, 50]. The most frequent type of os-teoporotic fracture, vertebral fracture, is associated with decreased physical activity, height loss, kyphosis, back pain, balance, and mobility issues. Being physically healthy can help older adults maintain their functional independence [35]. Physical fitness is the ability to carry out daily activities safely and independently without feeling worn out. The idea is multifac-eted and involves body composition, dynamic balance, flexibility, muscular strength, aerobic endurance, and agility/mobility [35]. According to recent recommendations, elderly people with osteoporosis or osteoporotic vertebral fractures should follow a multi-component ex-ercise regimen that incorporates balance and resistance training [51]. People with osteopo-rosis may have a decreased ability to maintain

balance compared with normal subjects, which increases their chance of falling. This could be due to a decline in cognitive processes such as memory affection, decreased concentration, and attention [36], in addition, subjects with osteoporosis appear to use a hip strategy despite the ankle strategy used by normal subjects to keep their balance, which may lead to instability [52].

Not all the risk factors for falls can be influenced by exercise (e.g., history of falls, visual changes, age). Some risk factors can be improved by exercise, comprising muscle weakness [53]; gait deviations [54]; reduced activities of daily living [35], and depression [36]. A person's ability to use the ankle method to stop falling is limited by weak muscles in the muscles surrounding the ankle joint and limits the capacity to employ a hip technique to maintain balance and can impact lateral stability when present in the hip region. The lateral stability needed for walking is primarily controlled by the adductor and abductor muscle groups [38]. People who frequently fall have weaker ankle dorsiflexion and guadriceps muscles than people who rarely fall [55]. Decreased gait speed results from shorter strides, which also result in shorter arm swings, less hips, knee, and ankle rotation, and longer stance phase times [56]. According to [57], the cause of the reduced gait speed and step length during the penultimate stage of the stance phase is a decrease in ankle power output, which also appears to have an impact on the frequency of falls.

According to the results of this study, there was a strong positive correlation between QoL as measured by QUALEFFO-41, TUG score, FES-I, and BMI. Studies in the literature demonstrated that osteoporosis patients' QoL has declined compared to healthy controls, whether or not they have fractures [58]. In a study evaluating the QoL of women with post-menopausal osteoporosis without fractures, it was discovered that old age, an elevated BMI, an inadequate level of education, early menopause, and low BMD values were harmful to QoL [34]. In addition, it has been revealed that increased kinesophobia is strongly correlated with lower QoL in osteoporosis and osteopenia. It has been noted that osteoporosis patients have a higher prevalence of psychological issues than the general population, such as anxiety and depression [36].

Importantly, longer FOF duration was linked to a higher risk of functional decline, and its effect was much stronger than other risk variables' mediation influence, supporting the notion that FOF is probably a causal role in impaired physical function in older adults. Be-cause FOF causes activity avoidance and physical deconditioning, it has been recognized as a risk factor [43].

The current study showed a strong negative correlation between ESES, EBBS, BBS and QUALEFFO-41. As high scores of ESES indicate higher confidence in self-exercise, EBBS's high score means more positively the individual perceives exercise more, and BBS high score reveals a low ROFs. While the lower the QUALEFFO-41 scores the better the QoL. So, a negative correlation means increased QoL is associated with high ESES, EBBS, and BBS scores. The literature presents numerous hypotheses that elucidate the impact of QoL on func-tional performance. In addition, A remarkable convergence of biological processes, encom-passing genetic, ambient, acute, and adoptive neurobiological processes, likely underpins the mechanism. Consequently, a synergistic collaboration of researchers and theorists from the domains of exercise science, cognitive science, and neurobiology will yield definitive solutions [59, 60]. Conversely, a pivotal component of bone architecture is mechanical loading [61]. Numerous animal experimental studies have demonstrated that loading rate and frequency are significant factors influencing how an animal responds to mechanical loading [62]. Re-sults from "high strain" loading studies on individual limbs appear to contradict "low strain" vibration study results regarding the effect of loading frequency. Studies on "high strain" individual limb loading indicate a point at which loading loses its osteogenic properties. Studies on "low strain" vibration have shown an osteogenic effect. These studies are mostly considered a single frequency [63].

The current study did not include follow-up which is considered as limitation of the study in addition to the relatively small sample size, thus more studies may be conducted with a larger sample size. In addition, the average age of the participants was 58, and more than 50 percentage of the participants were females. Women at this age generally undergo meno-pause, which may profoundly affect bone density. However, due to the small sample size, a gender base comparison of the participants was not conducted in this study. Our findings may have implications for the PLP to help individuals with osteoporosis improve their physical activity level, minimizing their FOF and thus optimizing their QoL. It may also be incorpo-rated into routine care to prevent agerelated functional deterioration over the long term. Further investigations, including long-term studies and larger cohorts, are encouraged to confirm and expand upon these promising findings. Ultimately, the integration of PLP into osteoporosis management plans has the potential to improve the lives of those affected by this condition significantly.

While the precise mechanisms underlying the observed outcomes in our study warrant further investigation, it is plausible that the PLP may have stimu-lated bone remodeling processes, contributed to increased BMD, and poten-tially facilitated enhancements in the overall QoL for the osteoporotic patients. It is conceivable that the mechanical stimuli introduced through the progressive loading regimen might have elicited adaptive responses at the cellular and tissue levels, thereby influencing bone health and functional well-being in this cohort.

CONCLUSIONS

Our research underscores the potential of PLP as a valuable adjunctive therapy for individuals with osteoporosis. It not only promotes increased bone density and strength but also enhances overall QoL. As a non-pharmacological intervention, it offers a safe and feasible option for individuals seeking to manage the challenges of osteoporosis while improving their physical well-being.

Author contributions: SMA, SN & QM: conceptualization, methodology; SMA & AME: data collection, data curation; SMA & SN: writing - original draft, writing – review & editing; AME & QM: data analysis, interpretation; SN & QM: supervision, writing – review & editing. All authors have sufficiently contributed to the study and agreed with the results and conclusions.

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Ethical statement: The authors stated that the study was approved by the Institutional Review Board at Imam Abdulrahman Bin Faisal University (IRB-PGS-2022-03-329) and the Research Ethics Committee at Armed Forced Hospital–Southern Region on 6 November 2022 (AFHSRMREC/2022/Rehabilitation Health Services/648).

Declaration of interest: No conflict of interest is declared by the authors.

Data sharing statement: Data supporting the findings and conclusions are available upon request from the corresponding author.

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