Enhancement Of Fracture Healing And Rehabilitation In Diaphyseal Long Bone Fracture Of The Lower Limbs By Low-Magnitude High-Frequency Vibration - A Prospective Randomized Controlled Clinical Trial

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Disclosures:

Introduction: Diaphyseal long bone fracture is a common injury in high-energy trauma among young people. It usually takes at least 4-6 months to heal and the functional recovery takes even longer time. Mechanical stimulation plays a critical role in fracture healing. We have investigated the effect of Low-magnitude high-frequency vibration (LMHFV) on fracture healing in rat model previously. [1] It was confirmed that LMHFV accelerates femoral shaft fracture healing by 30% on average in terms of time to radiologic healing. Callus maturation and mineralization are all enhanced. Since LMHFV can provide mechanical stimulation non-invasively, it is of high potential to be applied in routine clinical management in diaphyseal long bone fracture once the positive effects are confirmed. Therefore, a randomized controlled clinical trial is conducted in order to investigate the multiple effects of LMHFV treatment on long bone fracture healing in terms of radiographic healing, mobility and other functional outcomes. We hypothesize that LMHFV can enhance long bone fracture healing by enhancing callus formation and maturation, bone mineral density and muscle functions.

Methods: This is a three-year study in which patients recruited from four acute hospitals in Hong Kong. Inclusion criteria include males or non-pregnant females aged 20-40 years old with reamed intramedullary nail fixation done on the unilateral diaphyseal long bone closed fractures. They will be randomized into either vibration or control group. Patients in vibration group were treated with LMHFV (35Hz, 0.3g) for 20mins/day, 5 days/week from the 5th day to 26th week post-operatively while control group received conventional post-operative management. Radiographic callus width was assessed throughout post-operative 2nd week to 52nd week. Functional outcomes including muscle strength, balancing ability in terms of limit of stability, physical mobility in terms of lower extremity functional scale (LEFS) and Harris Hip Score (HHS), chair-rising test (CRT), bone mineral density (BMD) and quality of life (QOL) by SF36 questionnaires were assessed throughout post-operative 8th week to 52th week. Plasma bone-specific alkaline phosphatase (ALP) activity and osteocalcin were analyzed throughout the study as well. All these parameters were compared between groups in order to evaluate the effects of LMHFV on functional outcomes by repeated measures ANOVA. Human experiments approvals were obtained from all three Cluster Clinical Research Ethics Committees (Ref. CRE-2008.530; KC/KE-11-0030; NTWC/CREC/1005/11) and this study was registered with the ClinicalTrials.gov (Ref. NCT01386749). Written consents were obtained from all patients.

Results: To date, 18 patients were recruited in vibration group while 9 patients in control group. The mean ages in vibration and control groups were 38.5 ± 14.24 and 47.3 ± 17.51 respectively with no significant difference. 15 patients in vibration group and 5 patients in control group had completed the 26th week clinical follow-up. The average callus width in vibration and control groups at 8th week were 16.52±2.27 mm and 12.43±2.38 mm respectively. Vibration group showed an increasing trend while control group maintained a plateau trend. There was significant difference between 2 groups in terms of pattern of change of callus width over time. (Fig.1) For the functional outcomes, patients in vibration group performed significantly better than control group in terms of average rise time in CRT (p = 0.016), quadriceps muscle strength (p = 0.036) and QOL (p = 0.018) at their 8th week follow-up. Greater lower limb muscle power was noted during the CRT in vibration group than in control group with marginal significance at their 8th week follow-up (p=0.067). No significant differences were found in BMD, biochemical markers in terms of ALP and osteocalcin and balancing ability between two groups at their 8th week follow-up. Vibration group showed significant improvement in balancing ability in terms of movement velocity (+25.9%, p=0.038), maximum point excursion (+6.82%, p=0.004) and directional control (+4.69%, p=0.023) from 8th week to 26th week post-operatively. Also, vibration group improved significantly when compared with control group in terms of pattern of change of quadriceps and hamstrings muscle strength on fracture side and physical mobility (LEFS and HHS) over time (all p<0.001).
Discussion: In this study, the patients receiving LMHFV treatment have significant increasing trend of callus width at early stage. This finding supported by our previous study that LMHFV enhanced early phase of fracture healing through enhanced callus formation and faster mineralization. [2] In addition, there were significant improvements in quadriceps muscle strength, balancing ability and physical mobility at 8th week post-operation in vibration group than control group. This indicated patients receiving LMHFV treatment have significant improvement of the lower limb muscle performance and balancing ability. These findings echo with the results in our previous study of whole body vibration on elderly women. [3] However, there was no significant difference for BMD measurement in both groups. This may imply that muscle is a metabolically active tissue that may react to mechanical stimulation faster, while bone may take a longer time to respond. But due to the limited size of population, interim analysis does not have sufficient power to draw a solid conclusion and the results of on-going study may help to depict. In conclusion, the interim results of this study confirm the beneficial effects LMHFV treatment in enhancing callus formation, improving muscle strength as well as muscle power performance. No serious adverse event was reported from the vibration group. LMHFV can be applied early as postoperative management after diaphyseal fracture of long bone in the lower limb to enhance fracture healing and functional recovery. It needs further data to confirm its efficacy.

Significance: Low-magnitude, high-frequency vibration is effective in enhancing callus formation, improving muscle strength and balancing ability in the patients with diaphyseal long bone fracture in the lower limbs.

Acknowledgments: General Research Fund (Ref.: 470410) Research Grant Council, Hong Kong
