Treatment of Postmenopausal Osteoporosis with Pulsed Signal Therapy PST®
Primary Data of an Open-label Trial

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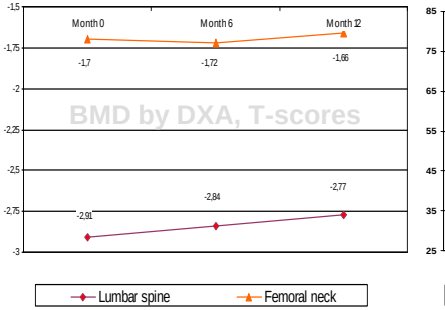
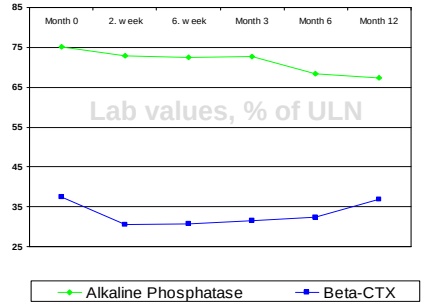
BACKGROUND:
Pulsed Signal Therapy® (PST) uses a specific configuration of pulsating electromagnetic fields. Over the past 10 years PST has consistently demonstrated clinical benefit in patients treated for osteoarthritis and other musculoskeletal disorders. Some patients treated with this technique reported improvement of osteoporotic pain and/or bone density. PST had been shown to improve bone density (by pQCT) at the treated compared to the contralateral forearm of the same person in a small trial. Primary data of a prospective open-label study to measure the effect of PST Osteo® in postmenopausal osteoporosis patients (PMO) are reported.

The device „PST Osteo®"

PATIENTS AND METHODS:
Up to March 2006, 58 PMO patients were included in this study after having given their informed consent. They were treated for 1 hour with the whole body PST device on 12 consecutive days (without weekends), a device that covers thoracic and lumbar spine, pelvis, femora, humeri and forearms. Bone densitometries were performed with DXA LUNAR at lumbar spine (LS) and total hip (TH) prior to PST (=M0), after 6 and 12 months. Lab values, especially markers of bone turnover (beta CTX and alkaline phosphatase AP), were collected at M0, at end of PST (week 2), week 6, month 3, 6 and 12.

RESULTS:
Of the 58 patients included, to date 27 passed the 6th month and 12 passed the 12th month follow up visits for BMD measurements. BMD at M0 was T-score -2.81 at LS (= 0.750 mg/cm²) and -1.70 at TH (= 0.773 g/cm²). A slight increase in BMD at LS (T + 0.14/ BMD + 0.018 g/cm² at M12) and at TH (T + 0.05/BMD + 0.004 g/cm²) was found, but these changes were not significant.
AP values are at the moment available for 45 patients at start of study, but CTX only for 22. The AP showed a slow decline reaching -10 % at M12 (significant at week 6 and month 6), while the bone degradation marker beta CTX showed a fast drop of -18 % already at end of PST treatment, which persisted until M6 and showed a rebound at M12 (changes were not significant due to small numbers, p=0.07 at M3 vs. M0). No treatment related side effects were reported. One pelvis fracture occurred after a fall.





DISCUSSION:
- Treatment with 12 hours of PST stabilized BMD in this small study population of PMO patients without side effects.
- While alkaline phosphatase showed a slow decline over 1 year, beta CTX decreased over a period of 2 weeks - these trends are not statistically significant due to the low number of samples available at the moment. PST seems to inhibit osteoclast activity.
- More data will be reported as all recruited patients reached at least M6.
- Additional studies with larger patient groups, randomization and placebo treatment should be performed in the future.

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