PST Osteo®
Pulsed Signal Therapy
Technology

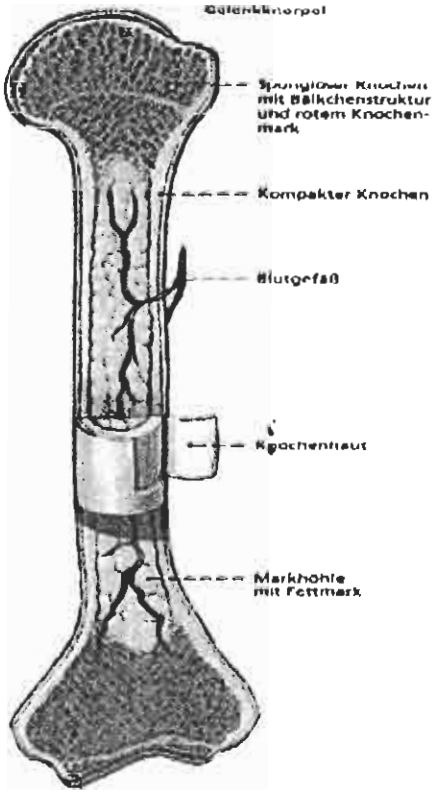
Studie zum Nachweis

Preliminary data from our previous Osteoporosis Clinical Study

Studie zum Nachweis der Wirksamkeit der PST bei Patienten mit gesicherter Osteoporose

Aim:

To investigate the effects of Pulsed Signal Therapy on both Trabecular and Cortical Bone Density.



Study Design (Methodology):

For this Pilot Study, post-menopausal women[1], below the age of 75, with established Osteopenia, or onset of Osteoporosis (no fractures), were selected. With the exception of calcium (1000mg/day) and Vitamin D_3 (800-1000 units/day), these women were not prescribed any new osteoporotic medication. They were, however, able to continue with their medication, provided they had been on it for at least a year, or more. In this way, any positive effect observed in bone density measurements, would not be attributable to the medication, but rather either to PST® alone, or to a synergistic, positive effect. Patients with a history of previous fractures, those with other serious underlying illnesses, including Diabetes, Morbus Crohn, Colitis ulcerosa, Hyperthyroidism, as well as those taking oral corticosteroids in the last six months, were not included in the study (for brevity, other exclusion criteria have not been listed here). Patients befitting the selection criteria had to have a trabecular bone mineral density below 180mg/cm^3, that is, a T-score of –1,5 SD (moderate Osteopenia). Those with a trabecular bone mineral density below 110mg/cm^3, that is, with a T-score of –2,8 SD (definite osteoporosis), were excluded.

The volumetric bone mineral density (vBMD) of both trabecular and cortical[2] bone was measured at the ultradistal radius (wrist). Each patient served as his/her own control - that is, one wrist was subjected to PST® treatment and the other not (the control). All measurements were conducted on both wrists.

Treatment was conducted for one-hour daily, over 12 days, with follow-ups at 3-months, 6-months and 12-months, thereafter. Any patients experiencing a mineral loss at 3-, or 6-months, or at any point during the study, were immediately withdrawn and treated appropriately. No such cases, however, were reported.

As mentioned above, the volumetric bone mineral density (vBMD) of both trabecular and cortical bone, of the treated and control wrist, was measured. These measurements were conducted using pQCT (Peripheral Quantitiative Computer Tomography) - specific for

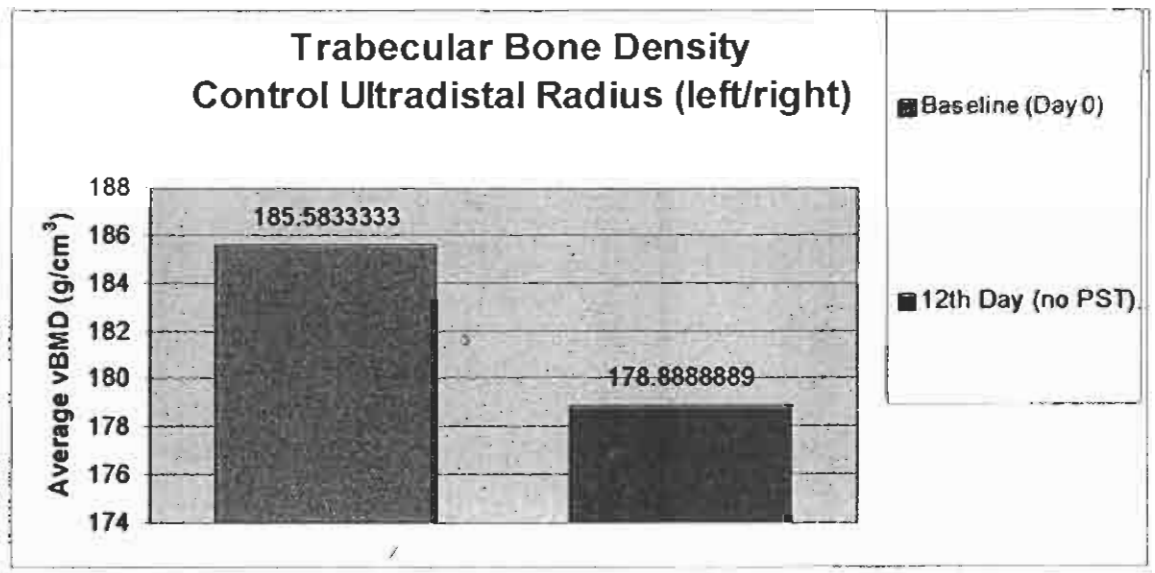
[1] Women had to be at least 3 years post-menopausal.
[2] Trabecular Bone = Spongiöser Knochen; Cortical Bone = Kompakter Knochen

wrist measurements. Measurements were recorded pre-PST® treatment, in order to restablish the baseline reading, for later comparison with measurements recorded after the 12-day treatment course, as well as, at 3-, 6-, and 12-months thereafter. Since some individuals are fast-losers (high bone turnover rate) while others are slow-losers, measurements recorded, and compared, at such long intervals, would enable more statistically significant data to be obtained and assessed.

Results:

Since trabecular bone turnover rate is greater than cortical bone turnover rate, it was expected that the greatest change in vBMD measurements, would be observed when assessing trabecular bone. As early as 12 days post PST®-treatment, an increase in trabecular vBMD (volumetric bone mineral density) was already observed, compared to controls, where there was an overall decrease.

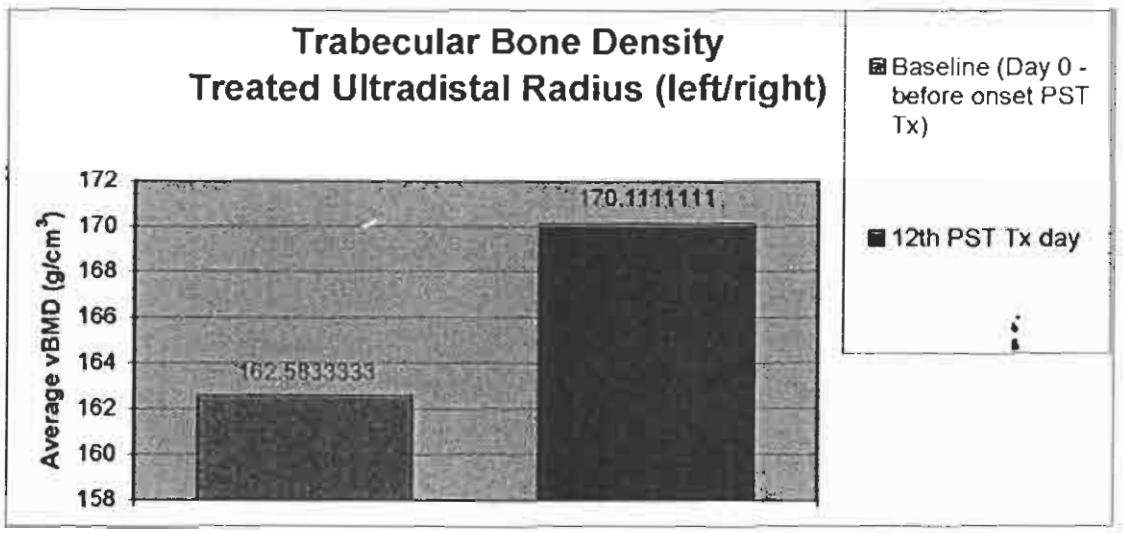
Graph 1: Progression of Patients NOT treated with PST®



Graph 1 depicts the results of the control group (that is, the wrist was NOT subjected to PST® treatment).

If Day 1 is that point in time at PST® was administered to the wrist undergoing treatment, it is clear that at the 12-Day mark, there was a definite and understandable decrease in trabecular vBMD, in the control group, based on the progression of the underlying condition.

Graph 2: Results of Patients Treated with PST®



Graph 2 depicts the results of the group subjected to PST® treatment for 1-hour daily, over 12 days.
After the 12th Day treatment, there was a significant increase in trabecular BMD following PST® treatment.

Conclusions:

The definite and statistically significant increase in trabecular vBMD observed, after the 12-day PST® treatment period, clearly demonstrates PST® positive effects on bone formation. This observed positive effect of PST® on cortical bone will undoubtedly also be observed at a later period, due to its innate slower overall turnover rate. In the long-term, it is postulated that PST® will continue to stimulate bone formation, and retard bone resorption, in order to restore the innate balance existing between bone formation and bone resorption.