R. Funk[1]
R. B. Pelka[2]

Osteoporosis treatment under QRS: Results of a double blind study at the Universitätsklinik Frankfurt

Introduction and objective

Since the sixties, there are emphatic hints that pulsating magnetic fields (PMFs) could also have a favorable effect in case of osteoporosis (Bassett et al. 1989; Dalas et al. 1989, Greene 1966, Kolodit 1993, Watson 1979). This means: Through a regular use of PEMFs, the bone mineral reduction that inevitably appears with increasing age cannot be stopped continuously, but could be reduced substantially. Disregarding theoretical considerations, this is also naturally suggested by the fact that, in case of bone fractures, a faster and better healing process is achieved through PEMFs (Weil 1988). With the increasing average age of the population, we also have to accept an increasing share of people with osteoporosis, compared with therapeutic assistances so far relatively small (Kanis 1991). Therefore, in the following, there shall be reported about a very interesting pilot study where highly interesting results were achieved. At that, the hypothesis had to be tested that PMFs slow down or even partly stop the development of the osteoporosis.

Methods and case material

Measuring methods: (1) Measurement of bone density: The most important criterion was the objective measurement of the bone density for what the 1st to 4th vertebral bodies of the lumbar column are particularly suitable [physiologically and statistically known as high-risk region for osteoporosis, Cooper et al.1991, Ross et al. 1991]: **WK-BMD** (German abbreviation for vertebral-body bone mineral density). Another bone-density-evident area is at the femoral neck, at the **trochanter** (bone projection to which important ligaments and muscles are attached). This area in connection with a **femur total measurement** allow a more global assessment (Melton et al. 1991, Suman et al. 1993).

(2) In addition to that, first of all indicators of the bone destruction rate (= **Cross Laps** = C-Terminal Telopeptid = relevant indicator enzyme to bone destruction rate) and, possibly, of the bone formation rate again (**bAP** = bone-specific Alcalic Phosphatase = relevant indicator enzyme to bone formation rate (Okta et al. 1992, Kanis 1991) were of interest.

Devices: For the treatment, a QRS mat system or a placebo device that not noticeably differed from the verum device for the physician and for the patient were used. The magnetic field in case of the verum device provided a spectrum of frequencies between 0.1 and 1000 Hz with focal points at 3.23 and 200 Hz as well as a [mean] field strength of 2 µTesla (stage 1) to 20 µTesla (stage 10).

1) - Funk (Frankfurt, Germany): Doctoral thesis at the University of Frankfurt
2) - Pelka (Munich, Germany): Statistical analysis and editing for the conference proceedings]

Design: 20 female osteoporosis patients were randomly subdivided into two groups (treatment vs. placebo). The therapy with **PMFs** (pulsating magnetic fields) was applied for a period of 18 months. The bone density measurements were made in intervals of 6 months (in total, four times) whereas the Cross Laps and bAP measurements were made 7 times in intervals of 3 months. In addition to that, some further objective and subjective parameters were acquired. In this time, both the physician and the patient recorded all the special features (symptoms, special treatments, etc.) regarding the disease development. Neither the examining physician nor the patient knew whether the devices were verum or placebo devices (double blind).

Patient collective: The 20 female osteoporosis patients (5 placebo cases, 15 verum cases) finally included in the study were in an age between 58 and 73 years (mean age of 65 years). The most patients were overweight (BMI mean = 26.06; after Funk, values < 20 were included with a higher fracture risk). In both features, the differences between verum and placebo were not significant.

Results

Compliance and complications: The main problems first of all were in the compliance of the patients. Of the 20 study patients, 3 patients abandoned their participation so early that they could not be included into the assessment. There was no difference between placebo and verum. Of the remaining patients, three patients left the study after about 1 year, a further one after nearly 18 months short time before the end of the study (again, little study-relevant or not study-relevant at all). All patients who abandoned were in the verum group. The other patients remained in the study. Nevertheless, 12 verum patients and 5 placebo patients were available for the statistical comparison. The reasons for the abandoning first of all were of psychological nature (Funk). The patients did not sufficiently believe in the success to be willing to bear the long-lasting procedure. Apart from one case, complications have not become known. This female patient complained of pains that had not been present before. After Funk, a connection with the therapy could not be detected, but could not be excluded.

Therapy results: (1) The bone density measurements resulted in findings that are in favor to the verum therapy. Despite the small and asymmetric group sizes, they are partly even significant or at least slightly significant.

(a) **BMD (bone density):** Despite clear advantages for verum, the initial values are not significantly different. After 12 months, an advantage in favor of verum (P = 0.04, **Figure 1**) turns out. Its deterioration after 18 months is insecure due to a partial data loss.
(b) **Minimal BMD**: Similar findings occur in case of the minimal BMD. However, the difference in favor of verum after 12 months is not significant (P = 0.14, no figure).
(c) **Femur (total):** Due to significant differences already at the beginning (P < 0.1), a significance test for the course is not indicated, but advantage tendencies in case of verum turn out (see **Figure 2**).
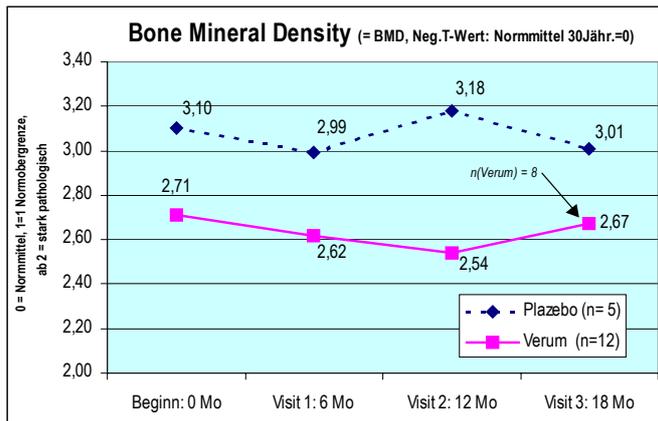
Figure 1: After an initially parallel development, the advantage of verum vs. placebo turns out after a therapy of 12 months ($P < 0.05$).

1 – Bone Mineral Density (= BMD, neg. T value: standard mean / 30 years old patient = 0)
2 – Dezimalkommas → Punkte
3 – From 2 = Strongly pathological
4 – 0 = Standard mean, 1 = 1 standard upper limit
5 – $n_{Verum} = 8$
6 – Placebo (n = 5)
Verum (n = 12)
7 – Beginning: 0 months
8 – Visit 1: 6 months
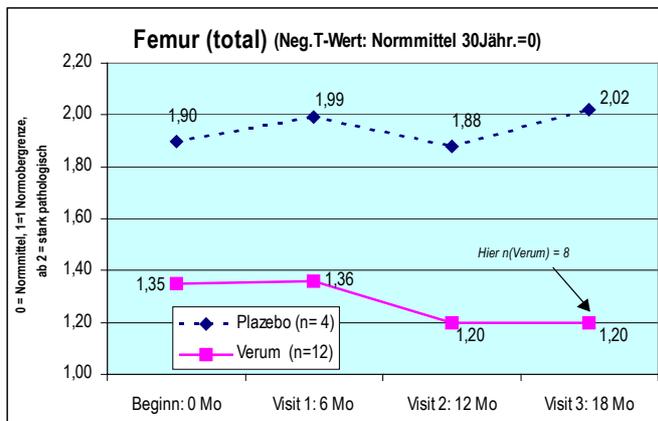9 – Visit 2: 12 months
10 – Visit 3: 18 months

Figure 2: After an initially similar course, verum has advantageous development tendencies compared with placebo.

1 – Femur (total) (neg. T value: standard mean / 30 years old patient = 0)
2 – Dezimalkommas → Punkte
3 – From 2 = Strongly pathological
4 – 0 = Standard mean, 1 = 1 standard upper limit
5 – Here, $n_{Verum} = 8$
6 – Placebo (n = 4)
Verum (n =12)
7 – Beginning: 0 months
8 – Visit 1: 6 months
9 – Visit 2: 12 months
10 – Visit 3: 18 months

(d) **Cross Laps bone destruction rate**: Here, there are significant effects in favor of verum (P < 0.05, see **Figure 3**). Moreover, the starting conditions for verum and placebo are nearly identical. The advantage in case of the bone formation rate is less clear (**bAP**, effect is not significant there).
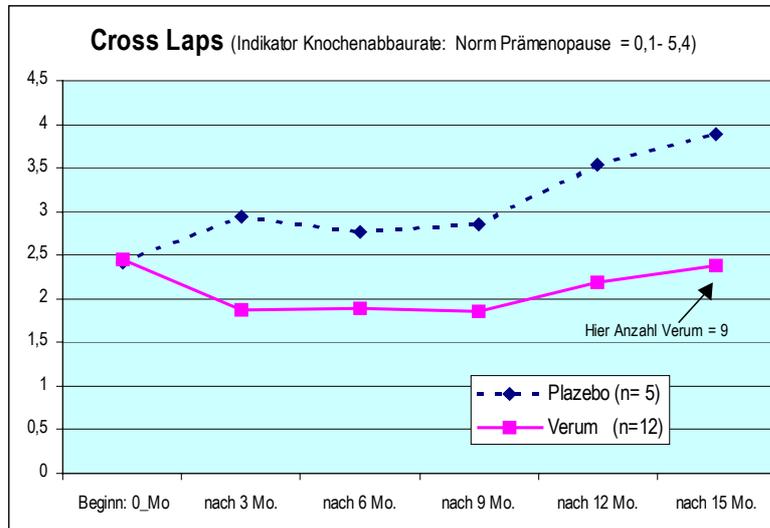

Figure 3: With identical initial values, only in case of verum, the rate at first develops even in favorable direction and then stays constant or nearly constant for a long time (P < 0.05).

1 – Cross Laps (indicator of bone destruction rate: standard of premenopause = 0.1 – 5.4)
2 – Dezimalkommas → Punkte
3 – Here, n_{Verum} = 9
4 – Placebo (n = 5)
Verum ((n = 12)
5 – Beginning: 0 months
6 – After 3 months
7 – After 6 months
8 – After 9 months
9 – After 12 months
10 – After 15 months

Discussion

In view of the small sample numbers, the asymmetric groups and the different starting situation, the results are to be understood as first effectiveness hints only. However, regardless of this, they are to be viewed as substantial due to the durability of the effects in case of this clinical picture (Hansen 91). It is interesting that not only the objective density measurements prove advantages, but – with Cross Laps – an important indicator of the bone destruction rate speaks for the therapy. In each case, these results justify further systematic studies with QRS.

For example, further details on the nature and duration of the effect of the QRS fields specifically on the osteoporosis can be found out or proved. In view of the absence of undesirable effects and in front of the background of the presently small therapeutic possibilities, this therapy is quite accepted already in this stage of findings, at least under controlled conditions (Hansen 1991).

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