Prof. Dr. E. Palme, Bad Bergzabern / Germany
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First experiences with the QRS whole-body magnetic field therapy in the case of 25 discopathy patients

On the treatment of pains in the muscle and skeleton region, whole-body magnetic field therapy measures become more and more important. The good efficiency of pulsating magnetic fields for such diseases is known since the seventies where there is worked with two different field characteristics. Firstly, pulsating low-frequent magnetic fields are mainly used in the healing of bone fractures. Secondly, very weak pulsating low-frequent magnetic fields – in particular, in case of rheumatic diseases and wearing appearances – can reduce the complaints.

As ascertained through literature studies, the Quantron Resonance System can be used: for strengthening the cardiovascular system and improving the blood circulation; for improving the respiratory chain, the metabolism and the digestive system; in case of rheumatic and climacteric complaints; in case of stress, nervousness, exhaustion and sleep disturbances; for improving the regeneration ability; for reducing the pain before and after surgical operations; for preventing after bleedings and inflammations after dental extractions; for supporting the wound healing; and in case of neuralgias and depressions.

In total, there can be started from the fact that QRS applications can be useful today for the following orthopedically relevant cases:

1 Improvement of bone healing

2 Positive effect in case of osteoporosis

3 Reduction of joint pains

4 Positive influence on rheumatic diseases

5 Stabilization of backbone instabilities due to backaches

6 Favorable influence in case of Morbus Bechterew

At the Orthopedic Clinic of the Edith-Stein-Fachklinik in Bad Bergzabern, from December 4, 2000 to April 6, 2001, the QRS quantron resonance system of the Prof. Dr. Fischer AG was included into the rehabilitation treatment measures in the case of 25 discopathy patients. These patients were 19 men and 6 women in an age between 31 and 71 years. At that, patients with discopathy were chosen consciously because this clinical picture has a particular importance within the rehabilitation. For example, patients without a surgical operation in case of a prolapse of intervertebral disks as well as patients after an operation were treated. Essentially, the discopathies were in the region of the lumbar column where the segments L2, L3, L4 and L5 were affected once, the segments L3, L4, L5 and S1 twice, the segments L4/L5/L1 once, the segment L4/L5 eleven times and L5/S1 nine times. In addition, there was a prolapse at cervical spine vertebra 6 and 7.

In eight patient cases, a surgical operation had already become necessary. In three cases of them, a so-called postnucleotomy syndrome was present.

At the beginning of the QRS treatment, 16 patients took analgetic drugs (in particular, NSAR). All 25 observed and treated patients had pains in the region of the backbone that extended to a time period of two months up to 30 years.

Using the ten-value pain scale, the patients had the following complaints:

Pain scale 2 1 patient
Pain scale 4 5 patients
Pain scale 5 7 patients
Pain scale 6 5 patients
Pain scale 7 1 patient
Pain scale 8 3 patients
Pain scale 9 1 patient
Pain scale 10 2 patients

As a rule, the treatment was performed twice per day – in the morning and in the evening – with a load level between 5 and 10 in the morning and between 2 and 5 in the afternoon. Beside the mat treatment, the cushion treatment was also applied; in particular, if the complaint symptoms did not improve after a week.

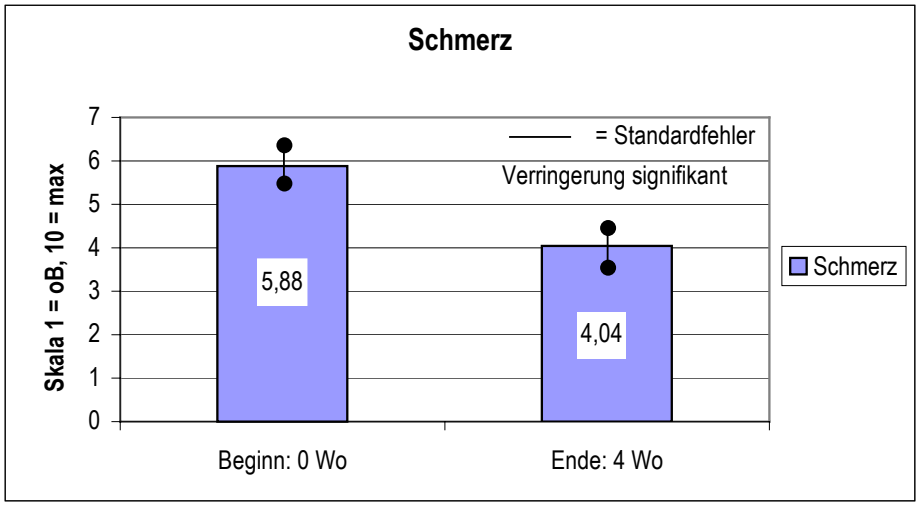
The evaluation of the results was realized using a specific record with respect to the therapy where the still existing pains, the general contentment and the still needed drugs were evaluated. Moreover, the patients could express their opinion whether they agree to be treated once again.

On the final examination, there was found out that – with only a few exceptions – the complaints had reduced clearly:

Pain scale 2 5 patients
Pain scale 3 6 patients
Pain scale 4 6 patients
Pain scale 5 5 patients
Pain scale 6 1 patients
Pain scale 8 1 patient
Pain scale 10 1 patient

In the case of one patient, there was no improvement despite mat and cushion treatment.

Figure 1 shows the summarizing comparison of the pain intensities before and after the QRS therapy in the case of these patients. Under the QRS therapy, the average values of the pain intensity decrease from 5.9 to 4.04.



1 – Pain
2 – Scale 1 = NAD, 10 = max
3 – Standard error
4 – Significant reduction
5 – 5.88
6 – 4.04
7 – Pain
8 – Start : 0 weeks
9 – End: 4 weeks

On the question regarding the contentness (scale values 1 to 10), four patients referred to 1, five patients to 2, five patients to 3, three patients to 4, three patients to 5, one patient to 7, two patients to 10, one patient had no more complaints at all and one patient was not satisfied.

The patients where also inquired whether they agree to be treated once again using the QRS method and how they assess the application and the therapy feeling. 17 patients voted with Yes, 8 patients with No.

In total, according to our first experiences, there can be started from the fact that the Quantron Resonance System is a very important mosaic piece on the therapy of chronic diseases in the muscle/skeleton region. Here, a device is available that, with respect to its handling and application, meets the requirements of an up-to-date therapy device. The application to the patient is very easy and the use guidance of the QRS control device is clear so that the patient is able to operate the device. In total, we could achieve an alleviation on a quantitatively small case material of chronic backbone patients where we consciously did this without any further electric therapy methods during the QRS treatment.

Austrian Journal for Physical Medicine and Rehabilitation, August issue 1999

"(Adjuvant) Whole Body Magnetic Field Therapy for Selected Diseases of Elderly Persons in a General Practice"

By Dr. W. Gaube, Dr. W. Kobinger, Dr. G. Fischer, Germany and Austria July 1999, Empirical report

Summary
32 patients of a general practice, predominantly with disorders of the locomotor system or other specific diseases were treated with weak pulsed magnetic fields (field strength: max. 4µT) at different time intervals and partly in conjunction with conservative therapy. Two devices were used ("QRS Salut 1" or "Bonvita") with coil-mats built into a mattress.

Upon conclusion of the magnetic field therapy we found a highly significant improvement in mobility among patients and ($p < 0.01$) a reduction in the fingertip to floor distance when bending forward. Furthermore, patients who received drug treatment needed a significantly lower dosage of drugs after completion of the magnetic field treatment.

Keywords: Magnetic field therapy, adjuvant treatment of elderly patients, reduction of drugs, improved mobility

Introduction
In this day and age, when nearly half of the population above 45 years of age is complaining of back pains and also of the peripheral joints (1) - which results in high treatment and rehabilitation costs for this segment of the population - the desire to find complementary treatment methods or alternatives to classical, mostly drug-oriented school medicine has been on the increase.

Hence, an ever growing number of consumers who are becoming more critical and in extreme cases, rejecting school medicine altogether, are gathering information in this by the mass media influenced society about fast-acting therapy methods which are "free from side-effects". This trend extends across nearly the entire broad spectrum of diseases, which a general physician sees for treatment. Since using pulsed magnetic fields in human medicine as adjuvant therapy method starting in the early 70s, treatment of diseases of the locomotor and sustentacular apparatus were of primary concern, using the following two field characteristics:

1. The classical type of magnetic field therapy was using pulsed low-frequency magnetic fields (up to approx. 1000 Hz [pulse repetition] frequency, field strengths in the milli Tesla range, mainly for the treatment of poorly healing bone fractures (7,11,16). Even the German health insurance industry recognized low-frequency magnetic fields temporarily as an "ultima ratio" therapy method (11).

2. The application of presently (still) under-appreciated very weak pulsed low-frequency magnetic fields (with field strengths not exceeding one tenths of the previously mentioned value) as an adjuvant to conventional therapy methods for diseases of the rheumatic type or for attritional symptoms of the locomotor and sustentacular apparatus (9,14), this type of treatment continuous to be subject to debate in circles of physicians who have a negative attitude towards it, despite strict supervision by physicians who are familiar with this biomedical subject matter (11,12,15). Although some critical arguments may be justified, our own research in this area, starting with the empirical report on the double blind trial, indicates that these fields with extremely low current strengths (13) induced within the tissues seem to be effective (4,5,8,10,19). This skeptical attitude, even total refusal, towards this type of therapy is directed predominantly towards diseases outside the rheumatic-degenerative range of diseases, fueled by the general lack of literature on this topic (2).

Material and Methods
The present study originates from an empirical report from a practice of general medicine in a mixed agrarian-industrial region. The population density of the commuter belt around the central town of Knittelfeld where that practice is located, or the urbanized surrounding area is approximately 50,000 inhabitants.

The treating physician who is using the magnetic field therapy has no objections towards it and has several years of experience in this field (8). The two devices used in two examination series are the "Salut I" and the "Bonvita" devices, the latter of which being structurally very similar to the first.

Both plug-in type devices with built-in timer function for a (fixed) application of 8-minute duration consist of a computer-controlled generator section, which is connected to an application mattress (1 x b approx. 180 x 80 cm) via a coaxial cable. The mattress contains 3 integrated flat coil pairs with tapered wire cross-sections, generating magnetic field strengths of varying degree in the primary target regions of shoulder, hip, and knees. For unproven reasons, based on the current state of international scientific research, the weakest applied inductive field is supposed to be near the head and the strongest field in the area of the lower extremities.

The device for which a patent has been applied generates complex, layered impulse packets with a maximum adjustable effective field strength (Level 5) of 4 µT, according to the manufacturer. The field strengths of the other adjustment levels are not documented. Both devices used in this series were so-called "Verum" devices, no comparative group was used, hence this series cannot be considered a statistically controlled study. The time period of this report ranges from January 1996 to mid-May 1997, during which the treating physician subjected certain patients to magnetic field therapy based on his many years of experience. The entire group consisted of 32 individuals (average age: 65.3 ± 10, 5a, 20 females and 12 males) with ages ranging from 38 to 84 years.

Therapy series I (see Table 1) for which the "Salut I" device was used, was conducted on a daily basis at approximately the same time every day with the patient lying down (1 hour, based on patient survey), hence no therapy-free days were noted. In series II (see Table 2) the "Bonvita" device was used for treatment at the office, which means that patients received 5 consecutive applications with a 2-day break during weekends. In this case, the treatments lasted 3 weeks, starting on Monday of the 1st week, concluded with a final examination on the Monday of the 5th week. Holidays and missed days of therapy in series II were made up at a later time.

Table 1a
Biographical Data, Diagnosis and Therapy for Series I

Pat. No.	Gender	Age	Diagnosis	Therapy	
1	F	52	Somnipathy Weak concentration Dyscardia	3 weeks, 2 x daily for 8 mins. mornings Level 3a, eves. Level 1	Soporifics Nerve tea
2	M	64			Sporifics
3	F	57			Nerve tea
4	F	38	Multilocular artralgia (shoulder, hip & knee joints) and multilocular neuralgia (BWS, LWS)	3 weeks, 2 x daily for 8 mins., Level 5, NSAR	
5	F	48			
6	F	69	Multilocular artralgia (shoulder, hip & knee joints) and multilocular neuralgia (BWS, LWS)	3 weeks, 2 x daily for 8 mins., Level 5, NSAR	
7	F	70			
8	M	65		3 weeks, 2 x daily for 8 mins., Level 4,	

9	M	82		NSAR
14	F	72	Strong stress pain after TEP Osteoporosis	3 weeks, 3 x daily for 8 mins., Level 5, NSAR
23	F	54	Lumbargia after BS-Op.; Foot Lift weakness, Osteoporosis	4 weeks, 1 x daily for 16 mins., Level 5, NSAR
29	M	63	Pronounced sensation of cold in feet and lower legs (distal); freq. nightly calf pains, morning myalgia of lower legs and starting pain in ankle joints, vascular Doppler test showed no significant min. vascularity	4 weeks, 1 x daily for 16 mins. (eves.), Level 4, no medication
30	M	68		
31	M	70		
32	M	70		

Table 1b
Therapy Success for Series I

Pat. No.	Δ FBA (cm)	Medication Reduction	Therapeutic Success	Remarks
1	N/A	yes (Soporific)	After 1 week improvement of sleep pattern, calm sleep (mostly without interruption), significant increase in daily performance, general psychogenic consolidation.	Dosage of soporifics was reduced, rarely needed (only during extreme psychic stress), continued use of nerve tea.
2				
3		0		continued use of nerve tea.
4	-6	approx. 50%	After 1-1.5 weeks significant improvement in pain levels and improved mobility of spinal column and joints. Subjective improvement in general state of health and performance during the day.	Accompanying medication therapy was reduced, improved general state of health ("feeling refreshed"). Different falling-asleep behavior when used in the evening, but always undisturbed night sleep.
5	-6	approx. 50%		
6	N/A	approx. 30%		
7	-2	approx. 30%		
8	N/A	approx. 50%		
9	N/A	approx. 75%		
14	N/A	approx. 30%	After 2 weeks significant reduction of complaints, longer walking distances.	Crutches used only infrequently. Termination of therapy due to patient relocation.
23	N/A	yes	After 2 weeks significant improvement of Lumbargia, "Foot lift weakness" remained unchanged.	NSAR only required in some cases.
29	N/A		Significant reduction of myalgia, ankle joint pains reduced in the morning, significantly improved sleep quality, cold sensation improved after approx. 3 weeks	
30	N/A			
31	N/A			
32	N/A			

Table 2a
Biographical Data, Diagnosis and Therapy for Series II

Pat. No.	Gender	Age	Diagnosis	Therapy
10	F	56	Irritated hemarthrosis after implantation of a knee endoprosthesis, severe Gonarthrosis	3 weeks, 1 x daily for 16 mins., Level 3c, NSAR
11	F	70	Diabetes mellitus, diabetic foot, diabetic Angio-, Neuro-, and Retinopathy	4 weeks, 1 x daily for 16 mins., Level 5, no medication
12	M	72	Pseudoradicular pain in the entire spinal column	3 weeks, 1 x daily for 16 mins., Level 4, NSAR
13	F	84	Polyarthritis, polyarthrosis	4 weeks, 1 x daily for 16 mins., Level 5, NSAR
15	F	67	Suspicion of loosened endoprosthesis, hip and knee joint pain	4 weeks, 1 x daily for 16 mins., Level 5, NSAR
16	M	80	Cervical Syndrome,stress-related headaches, lumbar sciaticalgia due to deg. lumbar spinal column changes	4 weeks, 1 x daily for 16 mins., Level 5, no medication
17	F	70	Chronic cervical syndrome, stress-related headaches, hip and knee joint complaints, degenerative joint changes	3 weeks, 1 x daily for 16 mins., Level 5, NSAR
18	M	62	Cervical syndrome, shoulder-arm-syndrome (both sides), acute headache relapses after SHT, Coxalgia	3 weeks, 1 x daily for 16 mins., Level 4, no medication
19	F	77	Massive, degenerative changes of cervical spinal column, radiation into the occipital region and both arms	3 weeks, 1 x daily for 16 mins., Level 5, NSAR
20	M	50	Cervical syndrome, Epicondylitis, rad. dext. lumbargia relapses	3 weeks, 1 x daily for 16 mins., Level 5, no medication
21	F	56	Pseudoradicular complaints in cervical and lumbar spinal column	3 weeks, 1 x daily for 16 mins., Level 4, no medication
22	M	55	Pseudoradicular lumbar spinal column complaints Coxalgia	3 weeks, 1 x daily for 16 mins., Level 3c, no medication
24	F	76	Pain in lumbar spinal column, pelvis-leg region (both sides) after pubic bone fracture, Osteoporosis	4 weeks, 1 x daily for 16 mins., Level 5, no medication
25	F	59	Lumbar Syndrome Relapse	3 weeks, 1 x daily for 16 mins., Level 5, no medication
26	F	73	Lumbar Syndrome Relapse	3 weeks, 1 x daily for 16 mins., Level 3c, no medication
27	F	66	Lumbar Syndrome Relapse	3 weeks, 1 x daily for 16 mins., Level 3c, no medication
28	F	73	Selected diffuse sceletal complaints, include diffus metastasizing N. Coli	4 weeks, 1 x daily for 16 mins., Level 5, analgesics

Table 2b
Therapy Success for Series II

Pat. No.	∆ FBA (cm)	Medication Reduction	Therapeutic Success	Remarks
10	N/A	yes	Significant pain reduction, decreasing hemarthrosis, improved mobility	Initial NSAR, was reduced to occasional intake after great stress
11	N/A		Pain reduction (feet), reduced secretion from plantar fistulas, partial healing of small plantar ulcers	
12	-8	40-60%	Significant pain reduction after only 1 week	
13	N/A	40-60%	Improved mobility and reduced pain in most joints during night sleep	
15	N/A	40-60%	Rapid improvement of subjective complaints, mobility remained unchanged	
16	-7		Improved mobility	
17	N/A	yes	Improved mobility in cervical spinal column, infrequent headaches, knee and hip joints more mobile	
18	N/A		Rapid reduction of arm and hip joint pain, headache relief	Reduction of NSAR from daily intake to 1-2 x per week after greater stress
19	N/A	40-60%	Satisfactory improvement of arm joint complaints, headache relief	
20	N/A		Satisfactory improvement of complaints, primarily of cervical spinal column, later also in elbow region	
21	N/A		Improvement primarily in lumbar spinal column, later also in cervical spinal column	
22	-5		Good improvement in spinal column symptoms, improved general state of health	
24	N/A		Good reduction in pain, significant improvement of general state of health	Improved night sleep already after 1st week of therapy
25	-7		Good improvement in mobility and pain reduction	
26	-4		Satisfactory improvement in mobility, significant pain reduction	
27	-7		Improved mobility	
28	N/A	0	Satisfactory pain reduction, improved mobility using the same analgesic dosage	Improved night sleep, significant improvement in general state of health

During the treatment period, control examinations were conducted in order to adjust individual therapy measures, if necessary. Collectively, there were 18 patients receiving medication (antirheumatics, soporifics, analgesics) based on their complaints. A possible reduction in medication during the treatment period or after the magnetic field treatment was also taken into consideration. Patients who were released "without medication" received no medication for the listed diagnosis. The measure of mobility improvement among patients who suffered from mobility-limiting diseases of the spine was the fingertip-floor distance in cm when bending forward, determined before and after the therapy series (D FBA, Table 1a + 2a).

In evaluating the success of the therapy among the patients, a comparison was made between the intake of medication and the change of fingertip - floor distance before and after the magnetic field therapy, assuming an equal distribution (50% / 50%) of the values in the Chi2 Test.

Results

With respect to a reduction in medication, a significant success was achieved in reducing the dosage among 16 cases in comparison to 2 cases who maintained their dosages ($Chi2 = 10.89$, $df = 1$, $p < 0.001$). All 9 patients who were tested for mobility after the therapy, showing a significant improvement in reducing the fingertip-floor distance ($Chi2 = 0.9$, $df = 1$, $p < 0.01$), indicating an improvement in their mobility. When considering those patients whose successful therapy can only be evaluated qualitatively based on their verbal response, one can deduce a collectively positive effect as a result of the magnetic field therapy. No failures were noted, patients reacted differently, but during the course of treatment, an improvement of varying degree was noted in every case.

Discussion

In a comparison with partially positive results of magnetic field therapy using relatively strong fields (3,6,17,18,20) for diseases of the locomotor and sustentacular system (2), it may be more interesting for scientific, practice-relevant considerations to continue and extend future systematic research efforts on the effects of very weak, magnetically fluctuating impulse fields on other kinds of diseases. This effort should be conducted without the objections stemming from certain interest groups in school medicine in order to avoid a suppression of positive results released to the general public. On the other hand, in order to avoid the promotion of diverse magnetic field therapy devices for the purpose of self-healing among patients gravitating in that direction, emphasis should be placed on the use of these devices adjuvantly by physicians familiar with these devices. Manufacturers often recommend in their brochures and advertisements certain treatment methods by suggesting parameter adjustments (diagrams, field strengths, frequencies, application intervals, field sources) which may not be substantiated by research. Many of these claimed successes which are sometimes based on just one patient, are justifiably criticized by knowledgeable specialists.

In contrast to these claims, this empirical report shall serve as an orientation (no blind trials, no control groups, no rigid marginal conditions of an exact clinical study), which can be repeated by other researchers interested in this method or for further development.

With the exception of individual cases, other groups of diseases besides the diseases of the locomotor and sustentacular system are being treated successfully and the documented therapeutic treatments are repeatable.

Another reason why some researchers exhibit reservations regarding the use of weak magnetic fluctuating fields in human medicine is justifiably based on the uncertainty which of the well-researched or theoretical interactive mechanisms are actually responsible for the observed effects.

No specific receptors are known which operate solely on a physical basis of magnetic field effects, while they have been shown, even structurally, to react with pharmacological agents. Many drug-induced physical-chemical reactions are far from being fully understood with respect to their action and their action can often only be described in a round-about way to specific organic structures or defined control circuits.

Low-frequency, fluctuating magnetic fields, even those with field strengths of nearly 1 Tesla, tend to penetrate the body unhindered, showing no adverse thermal effects. Exceptions are metallic implants which heat up as a result of being irradiated by these fields.

Nevertheless, we have observed on numerous occasions positive effects (4,5,8,10,19), and given the fact that these magnetic fields do not seem to cause any side-effects, based on the present state of science, they do tend to aid in medicated treatment therapies to some degree and, in this sense, should be desirable within a broader treatment spectrum for suffering patients.

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Nuβloch, 13.11.99

PROOF OF ION TRANSPORT DUE TO APPLICATION OF QRS SYSTEM SALUT-II

1. At the Medical University in Szeged, at the Institute of analytical pharmacy, tests were carried out from 30.5.99 until 27.10.99.
   There it was shown that in the blood of Turkeys, which is more or less like human blood, by using Salut-II as a full body application for two weeks for 2-hours per day (exactly as in therapy), the following changes occurred in the body's dominating free moving ion concentration:

	Na+ (mg/l)	K+ (mg/l)	Ca++(mg/l)
Treated (P)	3815	126	123
Control (K)	3593	157	111
Difference (Δ)	+222	-31	+12
Difference in (%)	+5.8	-24.6	+9.8

(Measured with an atomic absorption-measuring instrument: Perkin-Elmer AAS4100)

For movement of ions a force of

$$F_e = Q - E = Q(E + v\text{-}B)$$

Q = Electric Charge……..As
E = Electric Field Strength…...V/m
v = Velocity (Speed of ions)…m/s

is necessary.

In the bodies of treated people the mean value of parameters produced by Salut-II were calculated as follows:

$E \approx 2 \times 10^{-2}$ V/m (at $E_K \approx 10^5$ and $E_L = 2000$ V/m) as well as

$B \approx 3 \times 10^{-5}$T = 30 uT (peak measured with Radian f. BMM3).

The order of magnitude of the electromagnetic fields produced by Salut-II and the electric charge in the body cannot be disturbed by the Brownian (thermal) molecular movement.

Proof:

- Handbook of Biological Effects of Electromagnetic Field, CRC Press, Inc. Boca Raton, Florida (Editor Ch. Polk and E. Postow)
- Radiation, Waves, Fields Cause and Effects on the Environment and Health (Georg Thierne Publishing House, Stuttgart, New York, N. Leitgeb).

2. ELECTROPHORETICAL MOBILITY OF IONS

   Electrically charged particles (cells, ions) in an electric field will move according to polarity.
   The above ions, as well as erythrocytes have shown the following electrophoretical movement:

	Erythrocytes	Na+	Ca++	K+
Mobility B	1.27	5.2	6.2	7.6

(Measured with cytopherometer by Dr. Derlat at the Max-Planck-Institute)

It can be seen that the mobility of charged particles in the electric field is proportional to the electric charge and inversely proportional to the size of the particle.

The calculation follows the principal that the electric force (F_e) has to be greater than the restraining frictional force (Stokes).

$$F_e = Q - E \geq 6\pi\eta rv$$

where:

η = Viscosity of the environment
r = Radius of the particles
v = Velocity

Therefore the mobility is $B = \frac{v}{E}\left\{\frac{10^{-8}m^2}{v_s}\right\}$

The order of magnitude of the electromagnetic fields produced by Salut-II and the electric charge in the buffer cannot be disturbed by the Brownian (thermal) molecular movement.

Proof:

- Cell Electrophoresis a symposium convened by the British Biophysical Society (E.J. Ambrose in J.u.A. Churchill Ltd., London)
- Scientific Charts Geigy, Physical Chemistry, Blood, Human Genetics. (Publisher: Ciba-Geigy AG, Basel).

3. ASSESSMENT:
   1. Both the above measuring results in VIVO(1) as well as in VITRO(2) prove that the generation of ion transport through electromagnetic forces in the range of Salut-II, as in the treatment of experimenters, is possible, regardless of the Brownian molecular movement.

   2. Obviously the temperature of the free moving ions in the human body is always higher than total zero (-273°K) and will inevitably be accompanied by thermal movement.

3. But the dispersed thermal movement of ions is changed into a guided movement by means of electromagnetic forces (from Salut-II). By the way the Brownian thermal movement has no binding force and therefore no influence on ion transport.

4. The statement by Dr. V. Warnke, that only “energies” above 6.46THz (=$6.46 \bullet 10^{12}$Hz) have a biological effect, is in terms of frequencies nonsense. As it is well known that low frequencies with an appropriate amplitude are also biologically effective.

Proof:

- Theoretical Biochemistry Physical-Chemical Foundation of Life’s Processes (N.Nether, Springer Publishing House, Berlin, Göttingen, Heidelberg.
- Extremely Low Frequency Electromagnetic Fields (B. Wilson et al., Battelle Press, Columbus, Ohio).

QRS â -Osteo-Study 2001

Randomized Double Blind Study with the **QRS â Magnetic Field Therapy (Model: Salut 1)** with **71 Osteoarthritis Patients** from 02.11.2000 – 25.01.2001 at the General Hospital Maribor/Slovenia

Study conducted by: Lecturer Dr. Z. Turk (Maribor), Prof. Dr. G. Fischer (University Graz); Statistics: W. Kobinger (Graz)

Report on the Biometrics (re) Analysis
On the basis of patient data and short reports by G. Fischer and W. Kobinger

Rainer B. Pelka[1]

Munich, 16th June 2001

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QRS â -Osteo-Study 2001

Randomized double blind study with **QRS â magnetic field therapy (appliance: Salut 1)** with **71 osteoarthritis patients** from 02.11.00 until 25.01.01 in Maribor/Slovenia

- **Keywords**
  Therapy with pulsed low frequency magnetic fields (System QRS® – Salut 1) ♦ pain reduction and improvement of function in cases of osteoarthritis ♦ randomized double blind study with 71 osteoarthritis patients ♦

QRS â -OSTEO-Study 2001

Biometrics Analysis of a Randomized Double Blind Study in Cases of Osteoarthritis

(Rainer B. Pelka)

Keywords: Therapy with pulsed, low frequency magnetic fields (System: QRS® – Salut 1) ♦ pain reduction and improvement of function in cases of osteoarthritis ♦ randomized double blind study with 71 osteoarthritis patients ♦

0 Summary

Formulation of Problems: Osteoarthritis of the knee joint is a disseminated degenerative disease, especially in adults, which mostly develops due to an imbalance of use and constitutional capacity of the joint tissues. Clinical symptoms are stiffness and pain, and in long term cases also knee joint instability. The standard therapy up to now is rather symptomatic than causal, mostly physical therapy and analgesic medicines.

Objective: This controlled study examines three important theories:

1. QRS® reduces pain in cases of osteoarthritis and the ability to function is improved.
2. The advantage of QRS® therapy decreases in the follow-up of non-QRS therapy, but not to the initial position.
3. The laboratory parameters accompanying the inflammation process are improved where necessary towards the norm with QRS®.

Design: Testing Equipment and Dosage: Testing equipment was a QRS® Salut 1 device with a patented function, which activates the metabolism, especially of the cells, through the so-called ion transport.

Study Model and Extent of Random Survey: There was a control (placebo) group of 36 and an active group with 35 participants in this randomized double blind study. The check duration was a daily application of 16 minutes for 6 weeks, then a follow-up of 4 weeks. Check times after commencement were 0,4,6,10 weeks.

Criteria: The effectiveness of QRS therapy was judged by several, classical criteria, amongst those being knee joint rating with the KSS (knee society score) and pain with several indicators (theory 1 and 2). The CRP, the P-fibrinogen and the BSG recorded the inflammation parameter (theory 3).

Trial Participants: Of the **71 patients** (all from the Maribor General Hospital), **28%** were **male**, the **average age** was 60 +/- 10 years. With a Broca of >1.2, about 35% of patients were clearly overweight. In 83% of the collective, both knees were affected, in a further 14% only the right knee and in 3% only the left knee was affected. Over 70% had one or more diagnoses, often also in the spinal/joint area. Over 50% had been suffering from the disease for more than 5 years. The general condition (GC) of the patients was mostly satisfactory, only in 25% was it (very) bad.

Effectiveness: The **KSS: Knee evaluation (Zwisu)** improved significantly only in cases of the active group ($P<0.01$) compared to the placebo group ($P<0.05$). The same applies to KSS - knee pain. Also the knee function ($P<0.01$) and the walking ability ($P<0.05$) improved significantly, with a short “dip” after 6 weeks.

Pain and Sensitivity: The sensitivity to pain was reduced in both groups, but significantly more so in the active group ($P<0.01$). Similarly this applies to GC and the subjective sense of well being. The initial (not significantly) higher dose of medicine in the active group finally falls even under the dose of the placebo group in the follow-up (effect has to be checked with a longer trial).

Laboratory Parameter: After 6 weeks P-fibrinogen is reduced highly significantly in the active group compared to the placebo group. Following this trend it also applies to C-reactive protein and for

sedimentation of blood (BSG). The systolic blood pressure also improved significantly after 6 weeks and remained (compared to placebo) stable for a further 4 weeks without therapy.

Side Effects: The analysis of the numerous study results supports the assumption that there are no unpleasant side effects with QRS®.

Discussion: This study clearly supports the 3 theories. It shows that QRS can be used effectively if "osteoarthritis" is diagnosed. The effects exceed the common, rather symptomatic therapy by far. The relatively good values in the follow-up point to a stabilized improvement. However the optimum is surely not achieved with a 6-week therapy. Therefore the study should be repeated with a longer duration (therapy 3 months, follow-up 3 months) and be completed with health economic parameters.

1 Formulation of Problems and Objective

1.1 Formulation of Problems

Osteoarthritis of the knee joint is a disseminated degenerative disease, especially in adults. It mostly develops due to an imbalance of use and constitutional capacity of the joint tissues. The soundness of the joint capsule is significant. Typical causes especially in cases of knee osteoarthritis (gonarthritis) are joint dysplasia (malformations) and dysostosis (= bone growth disorders), but also damage due to trauma or inflammation. Lifestyle, as in all diseases caused by today's lifestyle is very important, especially in regard to nutrition and exercise (Pschyrembel 1996, Roche Medicine 1995).

In the beginning a feeling of tension and stiffness in the knee joint and later initial pain, load pain and finally continuous pain are considered the most important clinical symptoms. In long lasting diseases an instability of the joint develops in the form of contractures, rarer are malpositions or muscular atrophies.

The standard therapy up to now is rather symptomatic than causal. Main treatments are physical therapy as well as suitable medicines especially against pain.

Health Economic Importance: Analgesics, the most common therapy also in cases of the above-mentioned diagnosis, belong to the most bought and overall most expensive medicines in Central Europe. Steroids often have undesired side effects and especially the so-called antirheumatics are not only expensive, but because of their sometimes severe side effects are very problematic. Within the frame of a future study many directly and indirectly occurring costs/savings per patient should be registered as well, in order to be able to conduct an efficiency calculation (benefits minus costs).

By now numerous results in literature show that the therapeutic and also the preventative effect of QRS® – independently of the special diagnosis – is primarily in its long term application[2]. This can also be seen in a customer field study on the therapeutic effects of QRS® when applied for an average of 12 months (s. Pelka 2000).

1.2 Objective of Study

About the Therapy: This study had the purpose to prove the advantage of QRS® as an adjuvant therapy in a shorter time frame. This had already been assumed due to theoretical considerations, experimental results and repeated experiences in individual cases. It was planned to use QRS® as an

[2] Regarding experimental and clinical results of QRS® see: Bassett 1989; Becker 1999; Bondemark 1994; GE Fischer 1996;, G. Fischer 2001; Gaube 1999; Pelka 2000; regarding fundamental works on the effectiveness of magnetic fields and especially QRS® see: GE Fischer 1996; G Fischer 1994, 1996; Grohmann 1996a, 1996b, 1999b, 2001; Jacobsen 1995; Konig 1986; Kokoschinegg 1996; Krauss 1997, 2001; Kyriakoulis 1997; Marino 1997; Schauff 1993; Turk 1992; Wagner 1995.

adjuvant therapy therefore we tried to keep the primary therapy (see analgesics) standardized and to define it in advance. Due to the pilot character of the study well-standardized therapy concepts were used for the active and the control group. A therapy duration of 2 months is recommended due to the latest findings (Krauss 1999). The control duration should be 3 months. The control phase should include a preliminary phase as well as a follow-up of 14 days.

The examination of the therapeutic effect of QRS® refers to parameters, which are relevant in the context of the symptoms of osteoarthritis. The following claims formed the core theory.

Theory 1:

- The use of QRS® in cases of osteoarthritis reduces pain and is followed by improved ability to function.

Theory 2:

- The advantage of QRS® therapy is slightly reduced in the follow-up (no QRS therapy), but not as far as the initial situation.

Theory 3:

- The use of QRS® results in a partial improvement of the typical (deviating from the norm) laboratory parameters[3] for this disease.

Theoretically these theories, see also Theory 1, are substantiated by the effects of QRS® on the improved exchange of ions, which was proven in experiments (see e.g. Fischer G.E., 1996). Empirical results of the positive effects of magnetic fields, especially QRS®, in cases of the examined disease are also available.

- In the late '80s Turk propagated the adjuvant treatment of diseases of the locomotive system because of positive clinical results (Turk *et al*, 1990).
- P. Kokoschinegg (Salzburg) and G. Fischer (Graz) reported in 1991-1992 (report Kokoschinegg 1996) about a randomized study with 15 Hz-Elf-waves in connection with conventional treatment methods in cases of rheumatic diseases. Amongst the analyzed 78 patients (39 placebo, 39 active) were cases of myalgia, cervical syndrome, sponylogenous neuralgia and even a few cases of coxarthrosis (degenerative hip joint disease) and osteoarthritis (degenerative knee joint disease). The results (slightly significant, P<0,1) showed the therapeutic advantage of magnetic field therapy.
- In a positive report of experiences of 16 patients with diseases of the locomotive system (frequency individual 2-24Hz, field strength 2.52-8.82 µT) there were two cases of osteoarthritis, which were positively treated (only magnetic field therapy, no analgesics; pain reduction on the dole scale by 9 or 8 points {=good therapy success, =improved}; see Wagner *et al*, 1995).

All this, together with the related empirical findings and theoretical models and in combination with the latest experimental results, can be enlisted to present the above-mentioned theories that are well founded.

2 Trial Planning and Trial Participants

2.1 Trial Planning

Testing Equipment and Dosage: The testing equipment was a QRS® *Salut 1* device with a patented function, which activates the metabolism, especially of the cells, with the so-called ion transport. In regard to details refer to literature (e.g. Fischer GE 1996).

[3] According to Turk *et al* (2001) this relates mainly to: **C-reactive protein** (very selective inflammation parameter for joint pain and rheumatism) and **BSG and P-fibronigen** (slightly less specific inflammation parameter).

According to the manufacturer an application of therapy applied once or twice daily for a duration of 8 minutes each time is sufficient to attain the desired positive therapeutic effect. Generally therapy duration of at least 4 weeks is expected in order to attain statistically secured effects in the important parameters of the physiological capabilities.

This study was about the assumed effects after 4 and after 6 weeks of treatment duration, as well as about their decrease after a break (follow-up) of a further 4 weeks in the important parameters of the development of the disease, as they are expected according to the available findings and the theory.

Inclusion/exclusion Criteria: Only osteoarthritis patients were included. They could however have other diagnoses as well. Possible exclusion criteriaare not known, however obviously only patients were accepted where no complications due to other reasons were expected during therapy.

2.1.1 Design of the Study

Study Type and Extent of Sample Survey: The trial is a *prospective, randomized double blind study.* The assignment to the active or placebo group[4] should be coincidental. Every patient participating in the trial should and has in the main received the planned treatment and met the stated requirements of the trial plan.

The intention was to have a gross participation of 72 trial participants, 36 each for placebo and active. Actually 71 patients with the diagnosis "osteoarthritis of the knee" were included in the study (36 placebo, 35 active).

Course of Study: Before the therapy phase a washout phase of about 2 weeks, then a therapy phase of about 8 weeks and a follow-up phase of a further 2 weeks should take place, all in all a control phase of 3 months per patient. A registration of the criteria should take place at recruitment into the study (–2 weeks), at commencement of therapy, 4 weeks after commencement of therapy, at the end of therapy after 8 weeks and at the end of the follow-up phase after 10 weeks.

The washout phase was in fact almost in all cases much decreased; therefore an assessment of the course of study from 0 to 1 is not possible. Treatment duration – due to organizational reasons – was only 6 weeks (16 minutes per session, Mondays to Fridays, always approximately at the same time).

The selected level of the QRS therapy device was continually increased during the first 4 weeks and was kept constant for the following 2 weeks.The follow-up was 4 weeks, so a control of the course of the study for an overall duration of 10 weeks per patient was possible and especially a possible fading effect after discontinuation of QRS® therapy could be examined (course of study see Illustration 1).

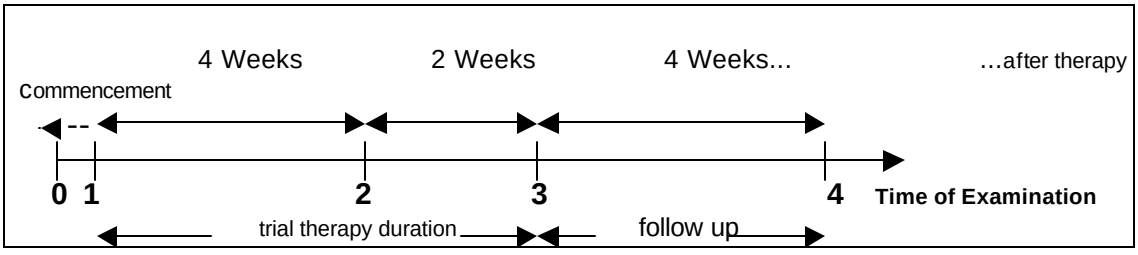


Illustration 01: Plan for the course of study. During the follow-up phase only the conventional standard therapy was applied.

[4] **Active:** A fully functional device; **placebo:** device that was fully functional, but did not produce QRS® magnetic fields (done by the manufacturer).

2.2 Criteria and Predictors

Primary Target Parameters

Pain: The numerical analog scale (NAS) in connection with the verbal rating scale was used for assessment. In addition the affective rating scale was used.

Knee joint rating: The standardized KSS (Knee Society Score) was used, which carries out (separately for each knee) a knee assessment (pain, mobility, stability, deficits [see sample test sheet, appendix]: values 0 = worst case, 100 = no complaints), as well as an evaluation of function (walking ability, climbing stairs, walking support: values 0 = worst case, 100 = no complaints).

Secondary Target Parameters

Laboratory (blood) parameters: CRP (C-reactive protein) is considered a specific and BSG (blood decrease) and P-fibrinogen as a slightly less specific inflammation parameter for joint pain and rheumatism. In addition important parameters of the differential haemogram were recorded: leucocytes, erythrocytes, neutrophil granulocytes, staff cell leucocytes, segmented leucocytes and especially lymphocytes, monocytes, eosinophiles and basophiles.

Blood pressure as a circulation parameter: Fischer (Graz) suggested oxygen partial pressure assessment by means of joint puncture as an objective measure for the subjective pain parameter. Unfortunately it could not be used.

Medicines: A useful semi objective parameter is the taking of medicines i.e. medicines taken.

- Type ([0: none, 1: analgesics, 2: steroids, 3: not clear, 4: antirheumatics, 5: combination, 9: no details])[5],
- Extent (=frequency [0: never, 1: rarely, 2: 1x per week, 3: 2-3 x per week, 4: every day]),
- Dosage (0: not at all, 1: low [1 tablet], 2: medium [2 tablets], 3: high [3 tablets], 4: very high [>3 tablets per day]).

Contrary to the initial planning, this information was not recorded by the patients but only by the doctor for the previous period of 4 (or 2) weeks.

Tertiary Target Parameters

In coordination with medicine, characteristics like the recording (as possible) of *radiological findings (interarticular space control),* as well as general findings like *height, weight, blood pressure, breathing, general condition, general state of health* and references to other *degenerative joint findings* are included.

Occurrence of Undesired Events (UEs) (as a reference to possible problems while using QRS®). This should be recorded with great care, as it is useful for the checking of possible, even though not expected , side effects of QRS® therapy. Overall, however, one can assume that judging by available findings, no strong side effects were expected. The ones responsible for the study against initial plans – drew up no separate sample test sheet.

2.3 Patient Selection and Conduct of Study

Patient Selection (actual extent of sample survey): The actual sample survey consisted of 71 trial participants (36 placebo, 35 active), all of whom had osteoarthritis and often at least one more diagnosis. The method of selection is not known. It can however be assumed that it is a typical collective for the General Hospital Maribor.

Conduct of Study: For reasons unknown, during the conduct of the study the following difficulties arose: in all 4 trial participants were so-called latecomers (placebo and active). From the study

[5] This variable was recorded alpha numerically; therefore corresponding recoding had to be made.

documents the extent of the delay is not discernible, as only in the case of one patient the initial data is missing.

There were dropouts in all 6 of the trial participants. From the data protocol this affected the measurements 2 and 3 only in 2 cases (1 placebo, 1 active), the other 4 cases (3 placebo, 1 active) were only affected in the follow-up, so after 10 weeks there were still the measurements of 64 patients (30 placebo, 34 active) available. However at the end of therapy after 6 weeks there were still 69 patients (34 placebo, 35 active). The reasons of the study dropouts are not known.

Study Duration: The study was conducted relatively fast over 14 weeks (according to plan) and was finalized on 25 January, 2001. The admission of the 71 patients took place over a period of less than 4 weeks. This was only possible, as a large number of osteoarthritis patients were available almost simultaneously.

2.4 Biometrics Evaluation

Data Evaluation: Prof. Fischer and Mr. Kobinger (Graz) initially took responsibility for data management and statistical analysis. Mr. Turk took medical responsibility and Mr. Barovic took responsibility for the actual therapy, examination control and data recording[6].

Only the second more extensive data analysis (on the basis of available patient data and two short reports) and the drawing up of the report on hand was conducted by the Bureau for New Technologies **(BNT)** under the scientific consultation of Prof. Dr. R.B. Pelka, Armed Forces University Munich. The hardware used was a PC with sufficient capacity (Pentium PC), for software SPSS (Windows Version 10) was used.

Data Coding and Control

The basis for data coding in cases of undesired events is WHO adverse reaction dictionary. Data is entered by means of independent entry repetition. Entries are checked in advance for logical consistency and plausibility. For later auditing suitable data listings were drawn up.

I do not know which procedure was used to guarantee that consistent and reliable data was available for the following statistical analysis.

Analysis Population: One differentiates between two analysis populations:

Intent-to-treat: (ITT analysis): This population includes all patients, who were allocated to one of the two treatment (age) groups and who had at least one measurement taken (n=71: 36 placebo, 35 active).

Per-protocol: (PPT analysis): This population includes all above mentioned patients except those where one or more of the following criteria exist:

- patient breaches inclusion or exclusion criteria, - deviates from protocol/guidelines during study, - drops out of the study prematurely (as the follow-up question is only discussed descriptively, the dropouts during this phase could remain in the PPT analysis (n=63: 34 placebo, 30 active).

Analysis based on the intent-to-treat population would utilize the LOCF procedure (LOCF= last observation carried forward) for estimation of missing data. This however does not apply for analysis based on per-protocol population, which was the basis for this course of analysis.

Baseline Comparison: Group specific statistics serve the purpose to show up possible existing imbalances between the comparative groups, while global statistics serve the purpose to characterize the reference population – also in respect to demographic characteristics. A significance test to examine

[6] This is my present level of knowledge derived from the documents and informal information. The results of this analysis, which are known to me are a 3 page document on hand about the most important significancies and a 1 page document about the most important laboratory changes from a sample survey.

the baseline equivalence was not generally conducted, but simply in individual cases. There were however no significant differences between placebo and active in regard to important parameters.

Data Analysis: The important ascertained primary parameters according to the examination design were illustrated for their frequency distribution in tabular form and/or graphically. The secondary and tertiary target parameters were calculated according to the examination design as well, and illustrated in tabular form or graphically. Furthermore the suitable statistical tests were utilized for examination of theories.

Data Quality: About the quality of the data I cannot say anything, but due to my own plausibility contro, I can assume that the data is at least acceptable, but is most probably of good quality, therefore the so derived statements can be considered reliable.

2.5 Statistical Analysis Procedure

As a statistical analysis procedure especially the t-test for independent sample surveys, as well as variance and trend analysis was used, besides the explained illustration (Chow 1998, Fischer 1993, Rao 1991).

Where useful or indicated by the measuring theoretical preconditioning, the non-parametric procedures like the *chi-quadrate-test*, the *U-test* of Mann-Whittney or the *Wilcoxon-test* (Bortz 1990, Fischer 1993) and methods for handling missing data were used (Schafer 1997).

2.6 Patient Collective

The details in this section relate to the ITT analysis and refer to the total collective of 71 patients.

Sex: In the overall sample survey out of **71 participants: 28%** were **male** and **72%** were **female (**no missing values). Obviously it is a typical female ailment. This becomes even clearer if the Broca index or the BMI are enlisted.

With a Broca of > 1.2 about 35% of the patients were clearly overweight (mean value = 1.23; statistical deviation = 0.22)[7]. In reference to females only this was 33 (=65%). There was no significant difference between active and placebo in regard to sex or Broca index or BMI (body mass index).

Age Group: The mean value was 60 +/-10 years (+/- standard deviation). The youngest patient was 36, the oldest 80 years old. Placebo (mean value 62 +/-9 years) and active (mean value 58 +/- 11 years) were significantly different ($P<0.05$)[8]. About one third of the collective was 65 years old or older.

Diagnoses: In 83% of the collective both knees were affected, in 14% only the right knee and in merely 3% (=2 patients) only the left knee. For this reason it made sense to select, at therapy commencement, the "worst" affected knee from the available findings right or left and to compare it's status during the course[9].

Further Diagnoses: Only 20 (=28% of the total collective, 31% of the active group) had no further diagnoses. Of the others 33 (=47%) suffered from one more, 12 (=17%) two more and 6 (=8%) three or more chronic diseases. Specifically 67% of all patients had further diseases of the joints or bones.

[7]Broca = weight/(height – 100). A Broca of 0.9 (0.85 for women) is ideal, of 1 is normal weight. A Broca above 1.2 is considered overweight (risk factor). The calculation for the BMI (=body mass index) is: $BMI=weight/(height/100)^2$.

[8]This corresponds to partly different initial values in both examination groups. In my estimation this however does not at any point lead to a qualification of the found, statistically guaranteed statements.

[9]Here I deviated from the procedure of the study group in Graz, who in their separate analysis of both knees (without reaching fundamentally different results), could only enlist 86% or 97% of the collective and were also forced to use a less clear illustration.

X-ray Findings: The X-ray findings showed an interarticular space of less than 3mm in 4 (=6%; difference between placebo and active was not significant) cases on only one knee joint and in a further 9 (=13%) cases even on both knees.

Duration of Suffering: In only 33 (47%) patients the osteoarthritis problem (painful) existed for less than 5 years. 25 (36%) already suffered between 5-10 years and 12 (17%) for over 10 years (24% active, 11% placebo). Nevertheless there is no significant difference towards the active group ($P<0.1$). This shows the patient collective as "difficult" clients, who could with conventional means, despite long or continuous therapy, not really be helped in terms of a status improvement.

Intensity of Physical Day to Day Strain: The frequency of 36% of the patients with below average physical strain and only 10% with above average strain shows, together with the frequent overweight that the genesis of the disease is mostly due to lifestyle (overeating, lack of exercise).

Findings (general condition, subjective general state of health): Only 10% felt well (none very good) and 65% satisfactory, 22% felt bad and 2 patients (=3%) even very bad.

Table 01: General Condition (GC)

Class	Quarter	Absolute frequency	Frequency in %	
			With MV	without MV
1	Very good	0	0	0
2	good	7	10	10
3	satisfactory	46	65	65
4	bad	16	22	22
5	Very bad	2	3	3
-	*Missing values* (=**MV**)	-	0	-
	Sum	76	100	100
Min./Max.	2/5	Mean value/median	3.18/3	

Table 01: General Condition (GC) in 5 classes 1 = very good , 5 = very bad.
The median is 3,2 between satisfactory and bad.

There were no significant differences between the examination and the control group in these as well as in the other variables relevant to the theories.

3 Results of the Biometrics Analysis

3.1 Compliance and Tolerance

Compliance and Therapy Termination: 6 patients dropped out of therapy (4 active, 2 placebo). Nonetheless the compliance of the participants can be regarded as good, because:

- only two participants (Nr. 35 of active group, Nr. 70 of the placebo group) dropped out after the first measurement. A connection with the therapy effect is unlikely and also was not reported,
- four further dropouts (3 from the active group Nr. 32, Nr. 33 and Nr. 34; one from the placebo group Nr. 71) only terminated during the follow-up, so only the check measurements were not taken.

All in all 4 patients (1 active, 3 placebo) are classified as latecomers. From the available material it is not discernible for what period of time the therapy phase was shortened for those patients, as all measurements Nr. 0 and 1 to 4 were taken. Because it only concerns one patient of the active group and therapy started in any case before the second measurement the patients concerned can without large error be treated as if they had been present from the beginning.

Evaluation of Undesired Events (UE)

Phase 1: 0 – 4 weeks: In the first 4 weeks all in all UEs (unexpected events) occurred in 23 patients, 8 active and 15 placebo.

Table 02a: Time and Type of Undesired Events:

Type of complication	**Phase 1** (0-4 weeks)		**Phase 2** (4-6 weeks)		**Phase 3** (6-10 weeks)	
	Placebo	Active	Placebo	Active	Placebo	Active
Spinal / joint pain	10	4	3	2	3	2
Cardiovascular			3		1	
General pain	1		1			
Gynecological problems		3				
Dizziness	2		1	1		
Tiredness		1	2	1		
Cold / flu	1		1	1	1	
Other	1					
K.A.			1	1	1	
Missing values						
Sum	15	8	12	6	6	6
Sum total	23		18		8	

Table 02a: Type of Undesired Events and Steps Taken by the Doctor: In most cases nothing had to be done. In the cases of spinal / joint pains about 20% were given medicines, more frequently in the placebo than in the active group; in the cardiovascular cases (only placebo) 2 were treated appropriately, this applied also to the 3 gynaecological problem cases. In the cold / flu cases 2 were given antibiotics, in one case the dizziness was treated with medicine; otherwise nothing was done; towards the end of therapy one placebo patient wished to be treated conventionally again.

Table 02b: Types of undesired events (in phase 3):

Type of complication	Total collective		Absolute frequency		Frequency in % (no MV)	
	Absolute	in % (no MV)	Placebo	Active	Placebo	Active
0 = none	61	88	29	32	82	94
Hip pain	1	1.5	0	1	0	3
Spinal pain	3	4.5	2	1	6	3
Knee pain	2	3	2	0	6	0
Raised RR (blood pressure)	1	1.5	1	0	3	0
cardiomyopathy	1	1.5	1	0	3	0
Missing values	2	-	1	1	-	-
Sum	71	100	36	35	100	100

Table 02 b: Types of Undesired Events in Phase 3 and Steps Taken by Doctor: The **2 active cases** (hip pain + spinal pain) were treated with medicine; the **6 placebo cases** were treated variously: one spinal pain patient was treated with medicine, a second patient nothing was done; also one patient with knee pain nothing was done, while a second patient demanded standard therapy; nothing was done in the case of the raised RR and in the case of cardiomyopathy the appropriate medical procedure was put in place. No patients with complications dropped out of the study. In 88% of all cases (and even 94% of the active group) there were no complications.

Nothing can be said about the UE's intensity as this was not documented, but due to the medical steps that followed it can be assumed that the intensity in all cases, especially in the cases of the active group

was not severe. The decrease of cases during the course of therapy points towards habituation problems with the special situation.

The fact that there were more placebo complications than active group complications leads to the assumption that first and foremost these are complications, which arose from the patients' multimorbidity. The analysis of patients with complications also showed a higher quota of side findings, a higher rate of being overweight (50% above 1.2 Broca) and a higher age (75% older than 55 years).

3.2 Effectiveness

The testing of the effectiveness takes place in three areas, firstly the effect on "knee assessment" and "walking ability" (see theory 1), secondly the development of general pain and finally also the important blood parameters (theory 3). Furthermore the changes are examined in the follow-up (see theory 2).

3.2.1 Effect on Knee Assessment (KSS) – Theory 1 and 2

The scale for knee assessment from the KSS (knee society score, see appendix sample sheet) is made up of several sub scales (knee pain, mobility, stability), deductions due to structural defects (flexion contracture, stretch deficit, tibiofemoral angle) and can have a value between 0 (extremely bad assessment) and 100 (no complaints) (**see Table 3a** and **Illustration 2a**).

Table 03a: Evaluation Knee Assessment (KSS, max. = 100 = no complaints)

Time	Situation	Placebo Standard Error	Placebo mean	Active mean	Active Standard Error
1	At commencement of therapy	2.4	76.0	78.4	3.3
2	During therapy After 4 weeks	2.4	79.1	83.5	2.6
3	End of therapy After 6 weeks	2.4	78.5	84.1	3.1
4	After follow-up	2.5	78.0	80.9	3.6
	valid		35	32	
	missing		1	3	
	Total		36	35	
1	Difference beginning		not	significant	
1 versus 3	Course: active		significant	(P<0.02)	
1 versus 3	Course: placebo		not	significant	
3	Difference end		Trend in favour	of active (P<0.15)	

Table 03a: Course for Evaluation Knee Assessment Placebo Compared to Active: Table and accompanying Illustration 02a show a significant improvement for the active group (P<0.05) after QRS® in comparison to the placebo group, where the improvement was not significant (see Illustration 0.2a).

Table 03b: Interim Evaluation Knee Assessment (KSS, max. = 100 = no complaints)

Time	Situation	Placebo Standard Error	Placebo mean	Active mean	Active Standard Error
1	At therapy commencement	2.2	77.6	80.6	2.6
2	During therapy After 4 weeks	2.3	80.2	85.5	2.2
3	End of therapy After 6 weeks	2.4	79.8	86.9	2.4
4	After follow-up After 10 weeks	2.4	79.5	83.4	2.7
	valid		35	32	
	missing		1	3	
	total		36	35	
1	Difference beginning		not	significant	
1 versus 3	Course: active		significant	(P<0.01)	
1 versus 3	Course: placebo		not	significant	
3	Difference end		Sig. towards	Active (P<0.05)	

Table 03b: Interim evaluation of knee assessment placebo compared to active (no deductions): Table and illustration 03b show a very significant improvement (P<0.01) after QRS® for the active group in comparison to the placebo group, which improved only insignificantly; also the difference between the groups is significantly in favour of the active group.

Table 03c: Knee Pain (KSS, max. = 50 = without complaints)

Time	Situation	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	2.3	31.3	32.9	2.4
2	During therapy After 4 weeks	2.3	32.6	37.7	2.0
3	End of therapy After 6 weeks	2.4	32.6	37.7	2.0
4	After follow-up After 10 weeks	2.3	31.8	35.7	2.5
	valid		35	32	
	missing		1	3	
	total		36	35	
1	Difference beginning		not	significant	
1 versus 3	Course: active		significant	(P<0.01)	
1 versus 3	Course: placebo		not	significant	
3	Difference end		Sig. towards	Active (P<0.05)	

Table 03c: Course Knee Pain Placebo Compared to Active: Table and accompanying illustration 02c show a significant improvement (P<0.01) for the active group after QRS® in comparison to placebo, which improved only insignificantly. Also the difference between the groups is significantly in favour of active (P<0.05).

Table 03d: Valuation Knee Function (KSS, max. = 100 = without complaints)

Time	Situation	Placebo Standard	Placebo mean	Active mean	Active standard

		error			error
1	At commencement of therapy	2.2	66.9	73.4	2.5
2	During therapy After 4 weeks	2.9	66.5	76.3	2.8
3	End of therapy After 6 weeks	2.5	69.4	74.7	2.7
4	After follow-up After 10 weeks	2.8	66.8	75.7	3.0
	valid		33	34	
	missing		3	1	
	total		36	35	
1	Difference beginning		Slightly significant	(P<0.1)	
1 versus 3	Course: active		not	significant	
1 versus 3	Course: placebo		not	significant	
3	Difference end		not	significant	

Table 03d: Course of Evaluation of Knee Function Placebo Compared to Active: Table and accompanying Illustration 02d show no significant improvement after QRS® for the active group, but neither for placebo, which improved in the short term. Only after 10 weeks is the difference significant towards the active group.

Table 03e: Interim Evaluation Knee Function (KSS, max. = 100 = no complaints)

Time	Situation	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	2.2	66.9	73.4	2.5
2	During therapy After 4 weeks	2.9	66.7	76.3	2.8
3	End of therapy After 6 weeks	2.5	69.4	74.7	2.7
4	After follow-up After 10 weeks	2.8	66.8	75.7	3.0
	valid		33	34	
	missing		3	1	
	total		36	35	
1	Difference beginning		Trend towards	Active (P<0.1)	
1 versus 3	Course: active		not	significant	
1 versus 3	Course: placebo		significant	(P<0.05)	
3	Difference end		not	significant	

Table 03e: Course of Evaluation of Knee Assessment Placebo Compared to Active: Table and Illustration 02e show no significant improvement after QRS® for the active group in comparison to the placebo group, which only improved significantly; also the difference between the groups is not significant towards active at the end of therapy.

Table 03f: Walking Ability (KSS, max. = 50 = no complaints)

time	situation	Placebo standard error	**Placebo** mean	**Active** mean	Active standard error
1	At commencement of therapy	1.7	33.1	35.7	1.5
2	During therapy	1.7	31.7	37.1	1.7

	After 4 weeks				
3	End of therapy After 6 weeks	2.5	32.1	36.8	1.6
4	After follow-up After 10 weeks	1.8	32.6	37.1	1.6
	valid		33	34	
	missing		3	1	
	total		36	35	
1	Difference beginning		not	significant	
1 versus 3	Course: active		not	significant	
1 versus 3	Course: placebo		declined		
3	Difference end		Sig. towards	Active (P<0.05)	

Table 03f: Course of Knee Pain Placebo Compared to Active: Table and accompanying Illustration 02f show only a slight improvement after QRS® for the active group, but for placebo even a decline. The difference between the groups is significantly towards the active group at the end of therapy (P<0.05).

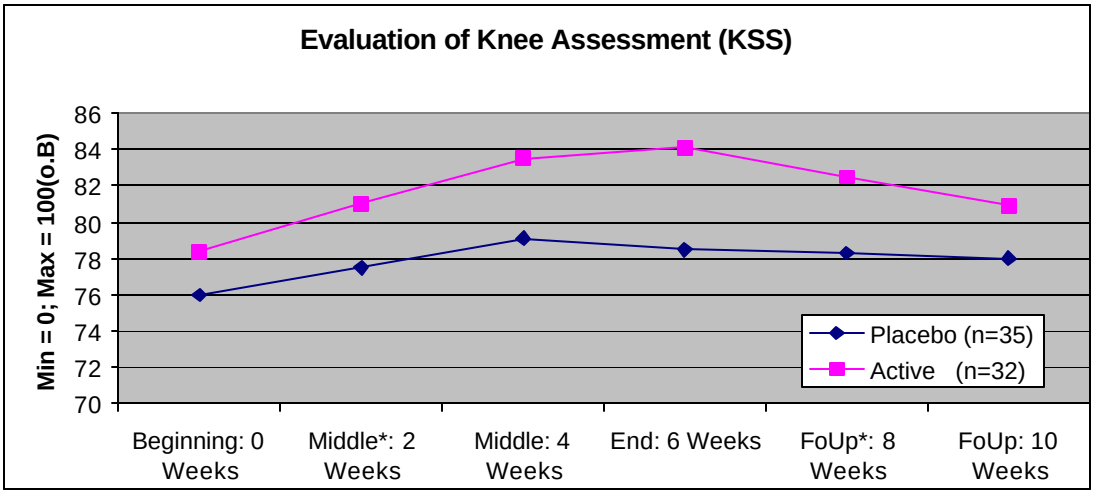


Illustration 02 a: Development of Evaluation of Knee Assessment (KSS - mean value comparison): The initial conditions are, despite slightly better values in the case of the active group not significantly different. The improvement during the course of therapy (0 to 6 weeks) is only significant in the active group (P<0.02). Also the results after QRS® tend to be in favour of the active group (P<0.15). In the follow-up the values deteriorate towards the initial values.

(* The values after 2 weeks and after 8 weeks are linearly interpolated)

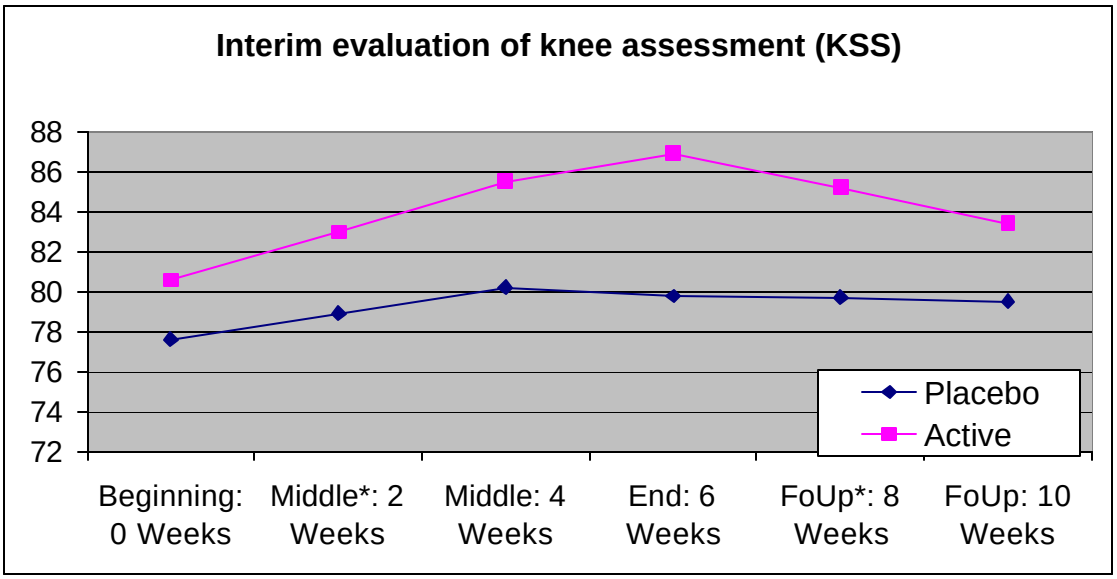


Illustration 02 b: Development of Interim Evaluation of Knee Assessment (KSS): The initial conditions are, despite slightly better values in the case of the active group not significantly different. The improvement during the course of therapy (0 to 6 weeks) is only significant in the active group ($P < 0.01$). Also the results after QRS® tend to be significantly in favour of the active group ($P < 0.05$). In the follow-up the values deteriorated again towards the initial values.

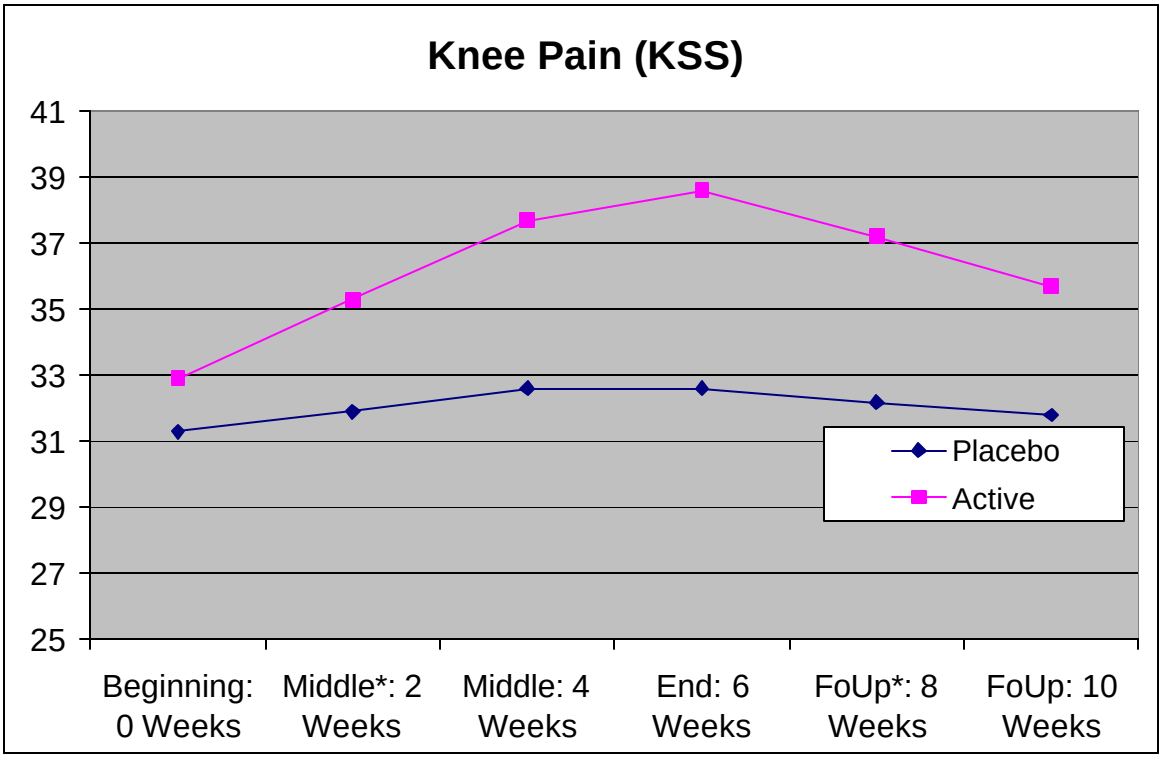


Illustration 02 c: Development of Knee Pain (KSS): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is only significant in the active group ($P < 0.01$). Also the result after QRS® is significantly in favour of the active group ($P < 0.05$). In the follow-up the values deteriorate again towards the initial values.

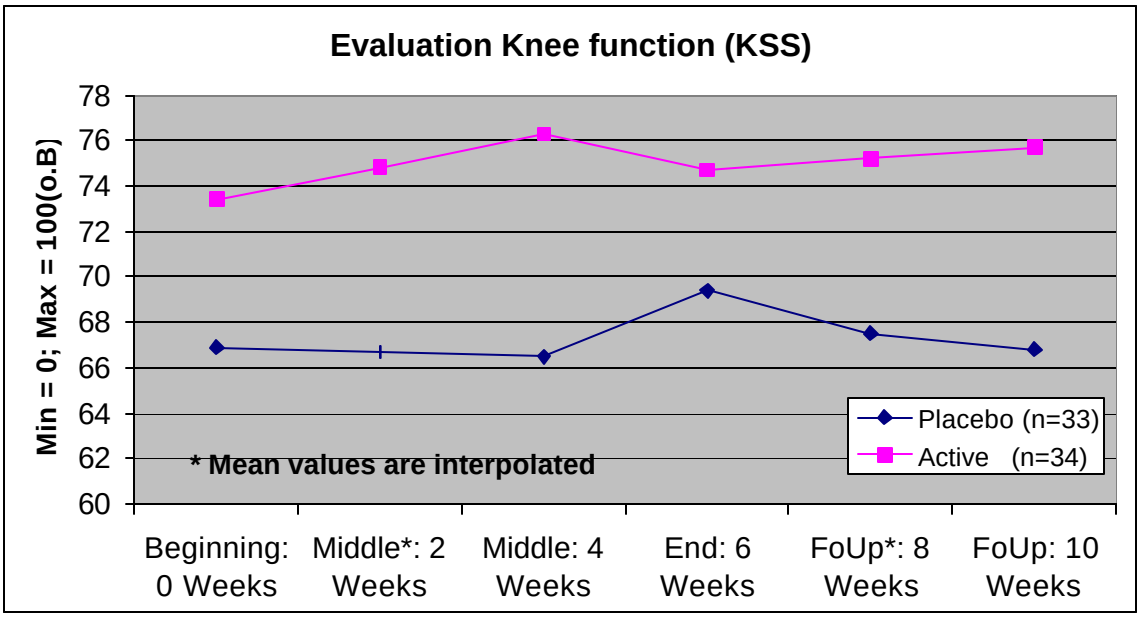


Illustration 02 d: Development of Evaluation of Knee Function (KSS- mean value comparison): The initial conditions are slightly significantly better in the active group. The improvement during the course of therapy (0 to 6 weeks) is only significant in the active group ($P < 0.01$). Also the results after 4 weeks QRS® is significantly in favour of the active group ($P < 0.05$). In the follow-up the values of the active group improve towards the 4 weeks value.

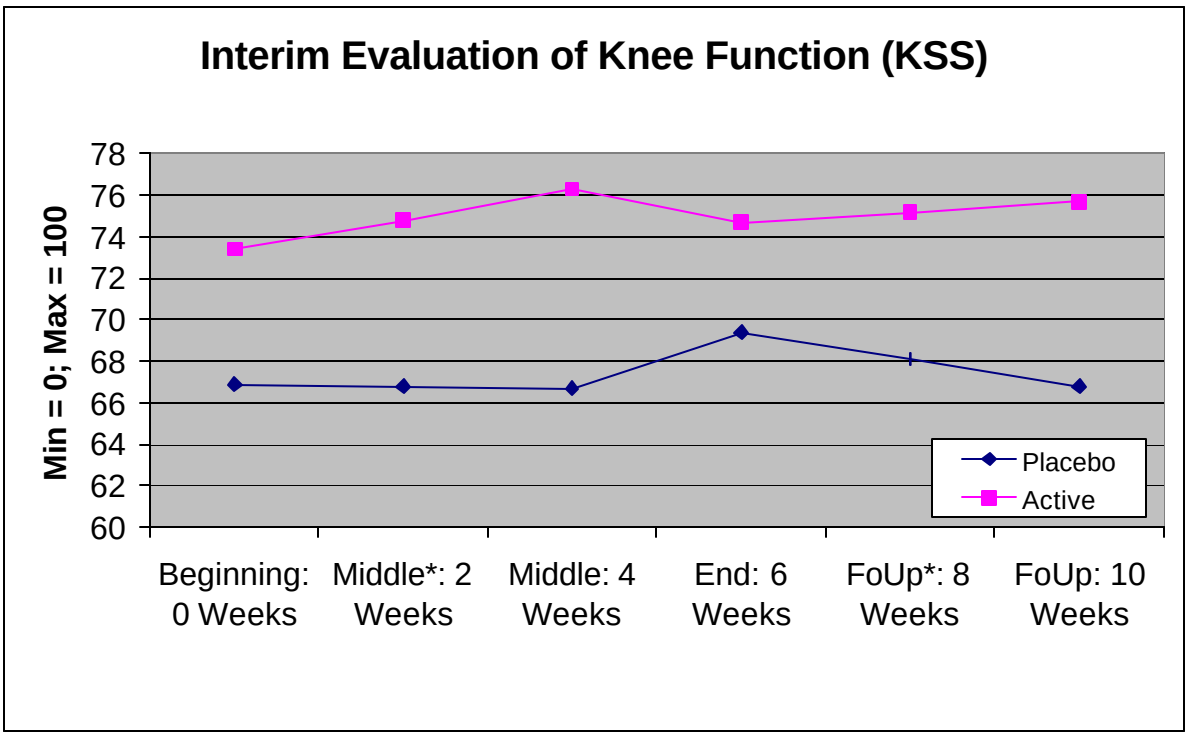


Illustration 02 e: Development of Interim Evaluation of Knee Function (KSS): The initial conditions tend to be better in the active group ($P<0.1$). The improvement during the course of therapy (0 to 4 weeks and 8) is only significant in the active group ($P < 0.05$). Also the results after QRS® is significantly in favour of the active group ($P < 0.05$). In the follow-up the values of the active group improved again towards the 4 weeks value.

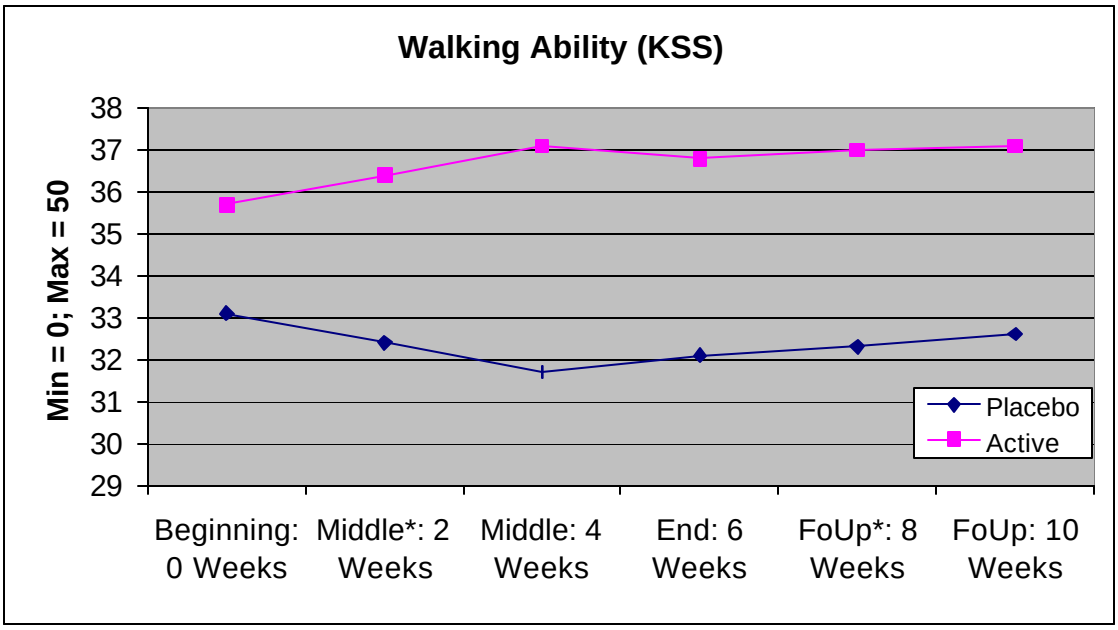


Illustration 02 f: Walking Ability (KSS) (mean value comparison: placebo =35 Pbn, active = 32 Pbn): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 4 and 8 weeks) is significant for the active group ($P<0.05$). Also the finding after QRS® is significantly in favour of the active group ($P<0.05$). in the follow-up the values for the active group improve again towards the 4- week value.

Interpretation of the Findings Knee Assessment and Knee Function: The development of the active group regarding knee assessment was in all three variables clearly superior to the placebo situation. Due to the insignificance of the initial difference it should not matter that the initial values in the active group were basically better than in the placebo group. The slow decrease in the follow-up phase should be noted. This signals the necessity of at least longer therapy duration.

The examinations on function show their maxima at 4 weeks of therapy but at first decrease, then recover during the follow-up. Regardless of the fact that these findings should be checked in a further study, it indicates that after initial success there is in certain indications a remission, which only later can be compensated for (and with longer therapy maybe even overcompensated).

3.2.2 Effect on the General Pain and State of Health Situation (Theory 1 and 2)

This sub-theory was also possible to be checked with several parameters, which were practicable and available. As direct pain parameters these were:

- *pain severity (5 scale); pain severity (11 scale); pain severity (100 scale); pain sensitivity (5 scale) (see tables 4),*
  and as indicators for the general state of health:
- *general condition GC (5 scale, subjective general state of health (5 scale) (see tables 5),*
  and as indicators for limitations due to pain and functional limitations or/and the hope for an additive effect of QRS® and conventional therapy:
- *frequency of medicines (prescribed medicines), dosage of medication, frequency of doctors' consultations (see tables 6)*

Table 04a: Pain Severity (5 scale 0=none, 4=extreme)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.09	2.28	2.15	.10

2	During therapy, after 4 weeks	.12	1.89	1.63	.11
3	End of therapy, after 6 weeks	.10	1.91	1.32	.13
4	After follow-up, after 10 weeks	.12	1.91	1.55	.16
	valid		35	33	
	missing		1	2	
	total		36	35	
1 versus 3	Course: placebo or active	very	Significant (P<.01)	highly	Significant (P<.001)
1	Difference beginning: P versus a		not	significant	
3	Difference end: p versus a		Highly significant	In favour of Active (P<.001)	

Table 04a: Course of Pain Severity (=Actual Pain Conception) Placebo Versus Active: Table and accompanying Illustration 03a show a parallel improvement for active and placebo, but a stronger improvement for active (P<0.001).

Table 04b: Pain Severity (11 scale 0=none, 10=extreme)

Time	Time of examination	Placebo standard error	Placebo mean	Active Mean	Active standard error
1	At commencement of therapy	.2	5.75	5.35	.2
2	During therapy, after 4 weeks	.3	4.72	4.23	.3
3	End of therapy, after 6 weeks	.3	.54	3.71	.3
4	After follow-up, after 10 weeks	.3	5.00	4.43	.4
	valid		35	33	
	missing		1	2	
	total		36	35	
1 versus 3	Course: placebo or active	very	Significant (P<.01)	very	Significant (P<.01)
1	Difference beginning: P versus a		not	significant	
3	Difference end: p versus a		Trend in favour of	Active (P<0.1)	

Table 04b: Course of Pain Severity Placebo Versus Active: Table shows a parallel improvement for active and placebo (P<0.02). The advantage for the active group is not as obvious as in table 04a.

Table 04c: Pain Severity (NAS=100scale: 0=none, 100=extreme)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At therapy commencement	2.2	58.1	54.6	2.3
2	During therapy, after 4 weeks	3.0	47.9	42.3	2.6

3	End of therapy, after 6 weeks	3.1	45.2	36.8	3.4
4	After follow-up, after 10 weeks	2.9	51.3	44.5	3.8
	valid		34	34	
	missing		2	1	
	total		36	35	
1 versus 3	Course: placebo or active	very	Significant (P<.01)	highly	Significant (P<.001)
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		Significantly in favour of	Active (P<.05)	

Table 04c: Course of Pain Severity Placebo Versus Active: Table shows a parallel improvement for active and placebo, but more obvious for the active group (P<0.05).

Table 04d: Pain Sensitivity (5 scale: 0=neutral, 4=unbearable)

Time	Time of examination	Placebo standard error	Placebo Mean	Active mean	Active standard error
1	At commencement of therapy	.07	2.19	2.09	.10
2	During therapy, after 4 weeks	.11	1.79	1.56	.12
3	End of therapy, after 6 weeks	.12	1.79	1.28	.13
4	After follow-up, after 10 weeks	.10	2.08	1.54	.15
	valid		33	30	
	missing		3	5	
	total		36	35	
1 versus 3	Course: placebo or active	significant	(P<.05)	Highly significant	(P<.001)
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		Very significant in	Favour of active (P<.1)	

Table 04d: Course of (Actual) Pain Sensitivity Placebo Versus Active: Table and accompanying Illustration 03b show an improvement for both active and placebo, but more obvious for the active group (P<0.01)

All indicators verify equally the effectiveness for active clearly stronger than for placebo, even if this is not equally well discernible in all scales. Probably the judges are overtaxed by the supposed higher accuracy, as has been known from other studies.

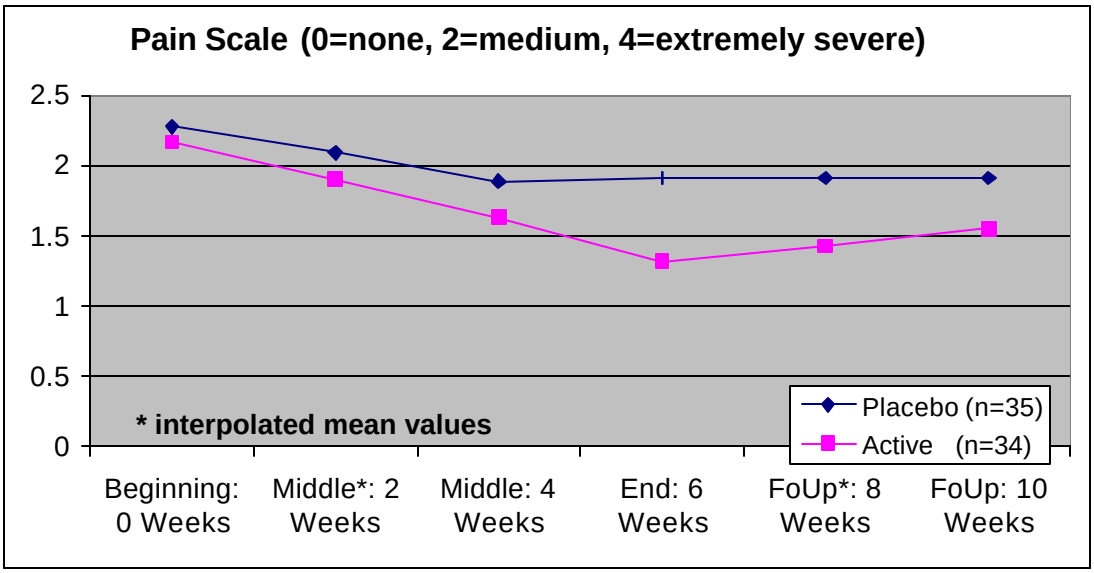


Illustration 03a: Pain Severity (mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is highly significant for the active group (P<0.001). Also the findings after QRS® is significantly in favour of the active group (P<0.001). In the follow-up the values for the active group worsened towards the 4-week value.

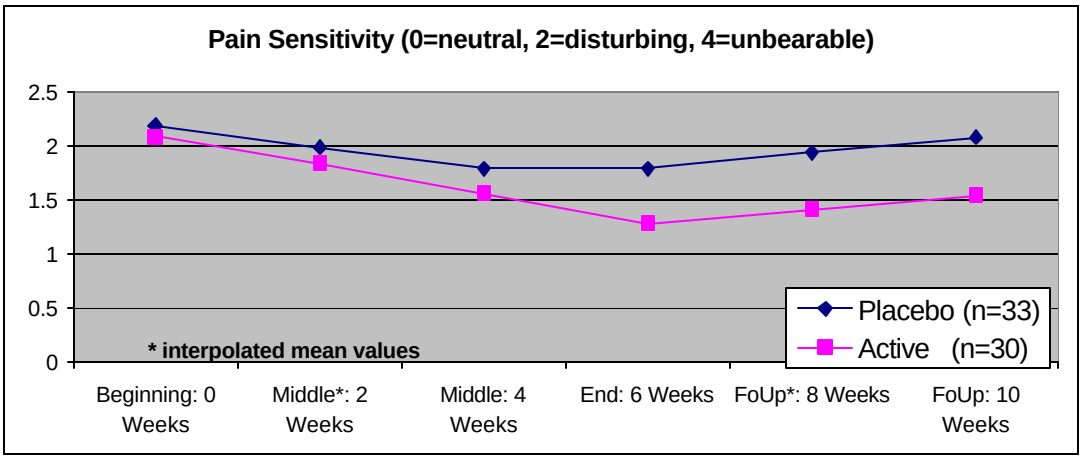


Illustration 03b: Pain Sensitivity (mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is highly significant for the active group (P<0.001). Also the findings after QRS® are significantly in favour of the active group (P<0.01). In the follow-up the active group worsened towards the 4 week value, while the placebo group almost worsened towards the initial value.

For graphic visualization for **Illustration 4a** in terms of pain severity Table 4a (5 scale) was used and for **Illustration 4b** the pain sensitivity (5 scale). Here it is interesting that the differences are more obvious in the sensitivity than in the supposedly (or real) more objective "pain assessment".

Basically similar correlation can be found for all indicators of the general state of health, here the doctor's opinion (GC) and the patient's opinion (subjective general state of health) do not vary much (see tables 5a and 5b).

Table 05a: General Condition GC (5 scale: 1=very good, 5=very bad)

Time	Time of examination	Placebo	Placebo	Active	Active

		standard error	mean	mean	standard error
1	At therapy commencement	.10	3.11	3.23	.11
2	During therapy, after 4 weeks	.13	2.74	2.91	.11
3	End of therapy, after 6 weeks	.13	2.91	2.64	.13
4	After follow-up, after 10 weeks	.15	3.09	3.03	.14
	valid		35	33	
	missing		1	2	
	total		36	35	
1 versus 3	Course: placebo versus active	not	Significant	highly	Significant (P<.001)
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		Significantly in favour of	Active (P<.05)	

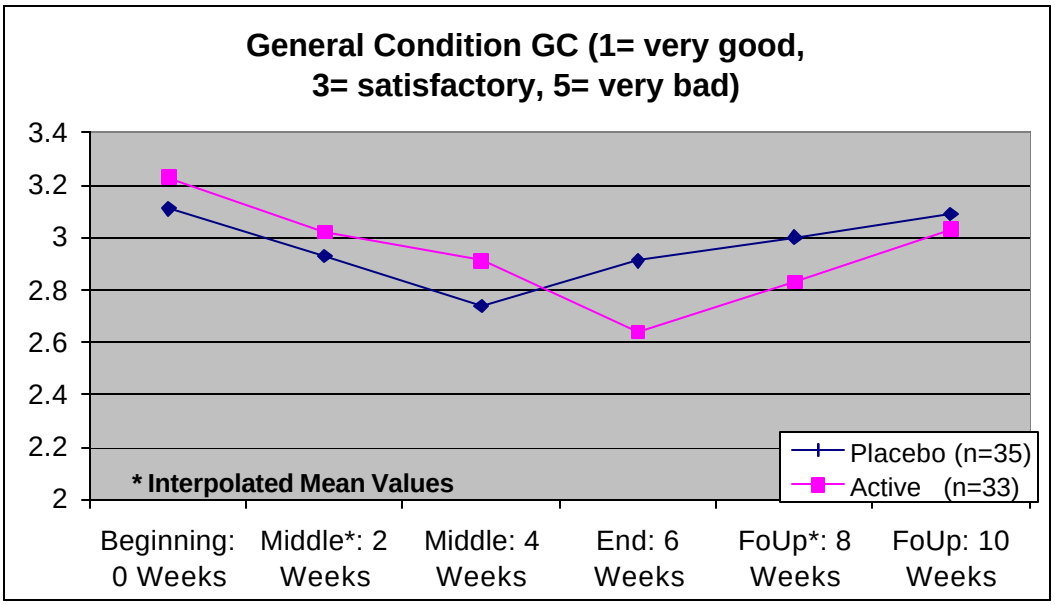
Table 05a: General Condition GC (scales, mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to6 weeks) is only in the active group highly significant and the result at the end of therapy, even with worse initial values, is significantly better (P<0.05, t-test single sided).

Table 05b: Subjective General State of Health (5 scale: 1=very good, 5= very bad)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.10	3.11	3.23	.11
2	During therapy, after 4 weeks	.13	2.83	2.97	.11
3	End of therapy, after 6 weeks	.13	2.97	2.61	.13
4	After follow-up, after 10 weeks	.15	3.06	2.97	.14
	valid		35	33	
	missing		1	2	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	highly	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		Significantly in favour of	Active (P<.05)	

Table 05b: Subjective General State of Health (scale, mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is only in the active group highly significant, and the result at the end of therapy, even with worse initial values is significantly better (P<0.005).

For graphic visualization for **Illustration 4a** in terms of GC table 4a (5 scale) and for **Illustration 4b** the state of health (5 scale) was used. Here it is interesting that the difference in patient sensitivity were also here more obvious than in the supposedly (or real) more objective “assessment” of GC by the examining doctor.



Ilustration 04a: General Condition (mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is highly significant in the active group (P<0.001). Also the findings after QRS are significantly in favour of active (P<0.01). In the follow-up the active group worsened towards the 4 week value, the placebo group worsened almost towards the initial values.

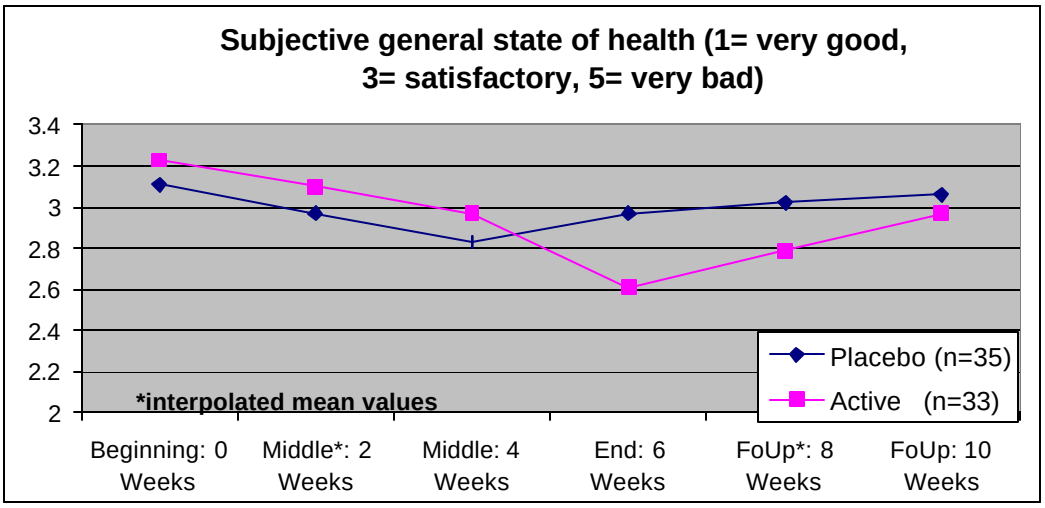


Illustration 04b: Subjective General State of Health (mean value comparison): The initial conditions are not significantly different. The improvement during the course of therapy (0 to 6 weeks) is highly significant in the active group (P<0.001). Also the findings after QRS® are significantly in favour of the active (P<0.01). In the follow-up the active group worsened towards the 4 week value, the placebo group worsened towards the initial values.

Table 6a: GON Frequency of Medication (5 scale: 0=never, 2=1per week, 4= daily)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy.	.18	.47	.86	.23
2	During therapy, after 4 weeks	.15	.31	.66	.21

3	End of therapy, after 6 weeks	.20	.53	.67	.20
4	After follow-up, after 10 weeks	.27	.88	.86	.25
	valid		34	33	
	missing		2	2	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		not	significant	

Table 06a: Course of GON Frequency of Medication Placebo Versus Active: Table shows at times a slight but not significant improvement and also no significant difference for active and placebo.

Table 06b: Dosage GON Medication (5 scale: 0=0,2=2, 4=>3 tablets per day)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.09	.25	.34	.09
2	During therapy, after 4 weeks	.07	.17	.31	.10
3	End of therapy, after 6 weeks	.10	.24	.27	.09
4	After follow-up, after 10 weeks	.10	.30	.24	.14
	valid		34	33	
	missing		2	2	
	total		36	35	
1 versus 3	Course: placebo or active	not	significant	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		not	significant	

Table 06b: Course of Tablet Dosage in Placebo Versus Active: Table and accompanying Illustration 05a show a slight but not significant improvement for active and placebo. But there is a better trend in the active group, which could be sustained with longer duration of therapy.

Table 06c: Doctors consultation due to GON (p.a. min.=0, max.=24)

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	1.02	6.08	5.12	1.35
2	During therapy, after 4 weeks	1.29	5.88	4.90	1.14

3	End of therapy, after 6 weeks	1.92	6.00	3.40	1.48
4	After follow-up, after 10 weeks	1.29	5.39	4.38	1.09
	valid		17	21	
	missing		19	14	
	total		36	35	
1 versus 3	Course: placebo versus active	not	determined	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		not	significant	

Table 06c: Doctors Consultation Due to GON: Table shows – despite a positive trend for active – no reliable improvement for neither active nor placebo (missing number to large and individual estimates not clear enough, due to a too long period of time for reference.

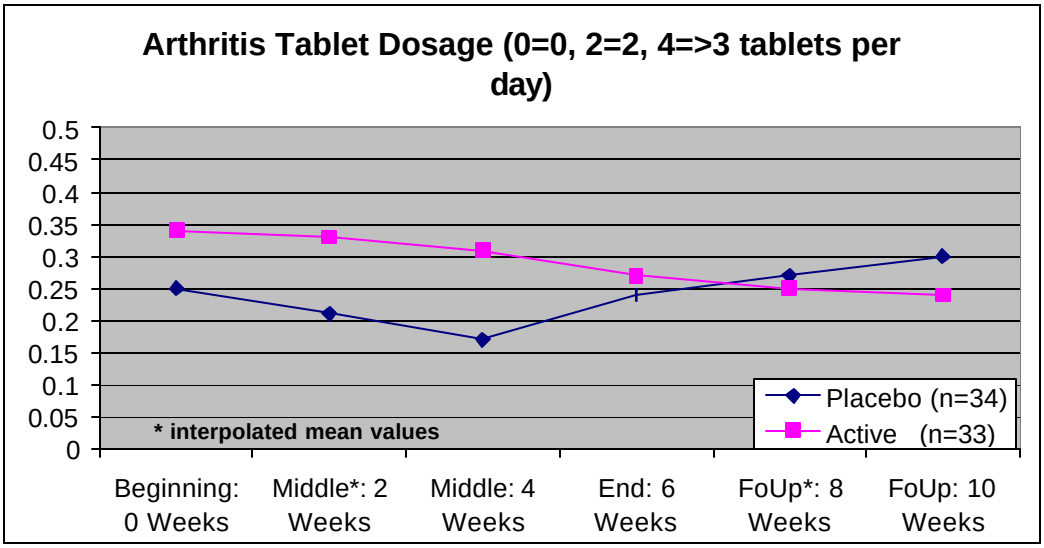


Illustration 05a: Arthritis Tablet Dosage (mean value comparison): The initial conditions are (due to high variation) not significantly different, but the active group had worse starting conditions. The improvement during the course of therapy (0 to 6 weeks) is as insignificant as the group difference, but the trend is more favourable for the active group - even still lasting in the follow-up.

Almost all indicators for the pain and state of health situation refer to a significant or even very significant effect of the QRS® therapy. But it is seen in the follow-up that this improvement is not necessarily stable after 6 weeks of therapy. A longer duration of therapy seems useful and there is no reason, in regard to possible side effects, not to do so.

Also in regard to costs a longer therapy is no problem, provided that the patient owns a treatment mat. An “accounting therapy” can here not be checked for its efficiency, as the necessary health economical data is not available. This is left to a later study.

3.2.3. Effects on Laboratory- and Vital Parameters (Theory 3)

Amongst the laboratory parameters especially those are of interest, which give an indication on the course of chronic inflammation, according to G. Fischer *et al*. The C-reactive protein (specific for articular rheumatism) as well as ESR values and the P-fibrinogen (less specific).

Table 07a: Blood sedimentation (ESR, 1 hour?)
Norm: sex-specific, less specific inflammation parameter

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	1.5	13.1	12.8	1.5
2	During therapy, after 4 weeks	1.2	11.9	11.3	1.5
3	End of therapy, after 6 weeks	1.2	12.2	10.4	1.5
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	significant	(P~.05)
1	Difference beginning: p versus a		not	significant	

Table 07a: Blood Sedimentation Placebo Versus Active: Table shows only for active a (almost) significant improvement, but not for placebo during the course of therapy **(see Illustration 06a).**

Table 07b: C-Reactive Protein (selective inflammation parameter)
Norm:

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.39	2.05	2.94	.77
2	During therapy, after 4 weeks	.85	2.11	2.34	.90
3	End of therapy, after 6 weeks	.79	2.46	1.91	.53
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	not	significant
1	Difference beginning:		not	significant	

	p versus a				
3	Difference end: p versus a		not	significant	

Table 07b: C-Reactive Protein Placebo Versus Active: Table shows only for active a tendency towards, but not significant improvement during the course of therapy, but not for placebo **(see Illustration 06b).**

Table 07c: P-fibrinogen (less specific inflammation parameter)
Norm:

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.11	3.41	3.64	.12
2	During therapy, after 4 weeks	.11	3.52	.56	.14
3	End of therapy, after 6 weeks	.12	3.48	3.12	.16
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	highly	Significant (P<.001)
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		slightly	Significant (P<.1)	

Table 07c: P-Fibrinogen Placebo Versus Active: Table shows only for active a highly significant improvement during the course of therapy, placebo values actually worsened. Group difference is slightly significant **(see Illustration 06c).**

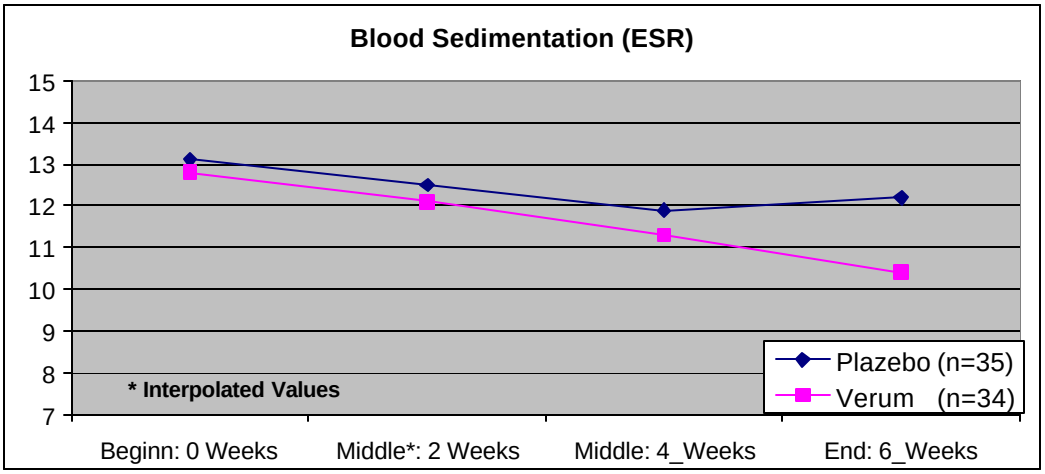


Illustration 06a: Blood Sedimentation ESR mean value comparison: The initial conditions are (due to high variation) not significantly different. The advantage of active compared to placebo only becomes clear after 6 weeks of therapy (P<0.05)

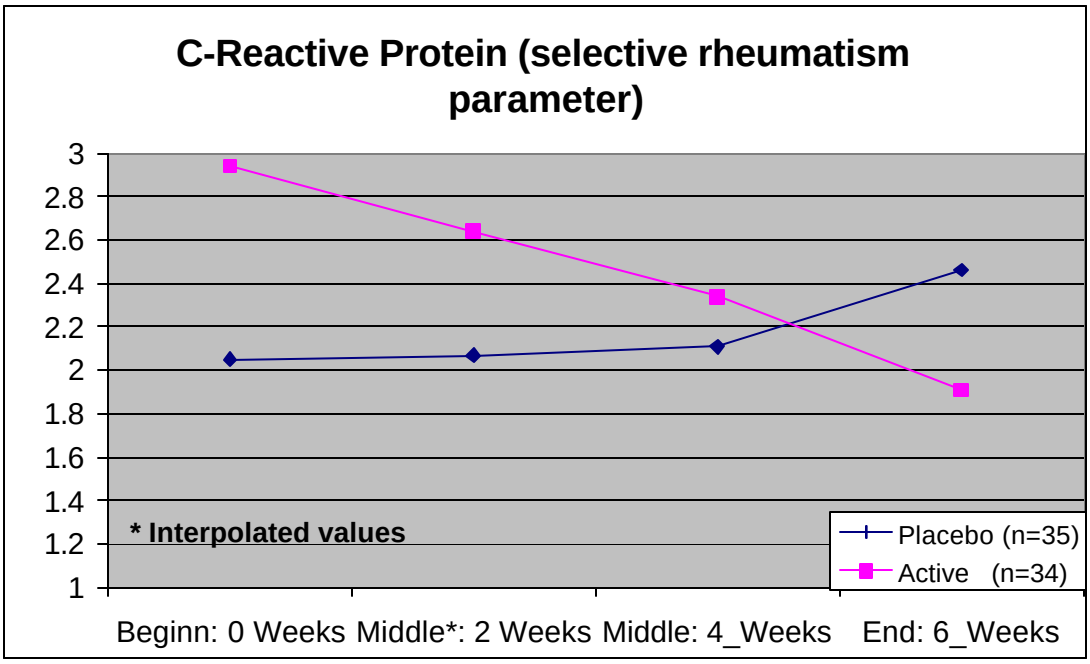


Illustration 06b: C-reactive protein (mean value comparison): Due to a high mean variation there are no significant differences, the trend however is clearly favourable towards active.

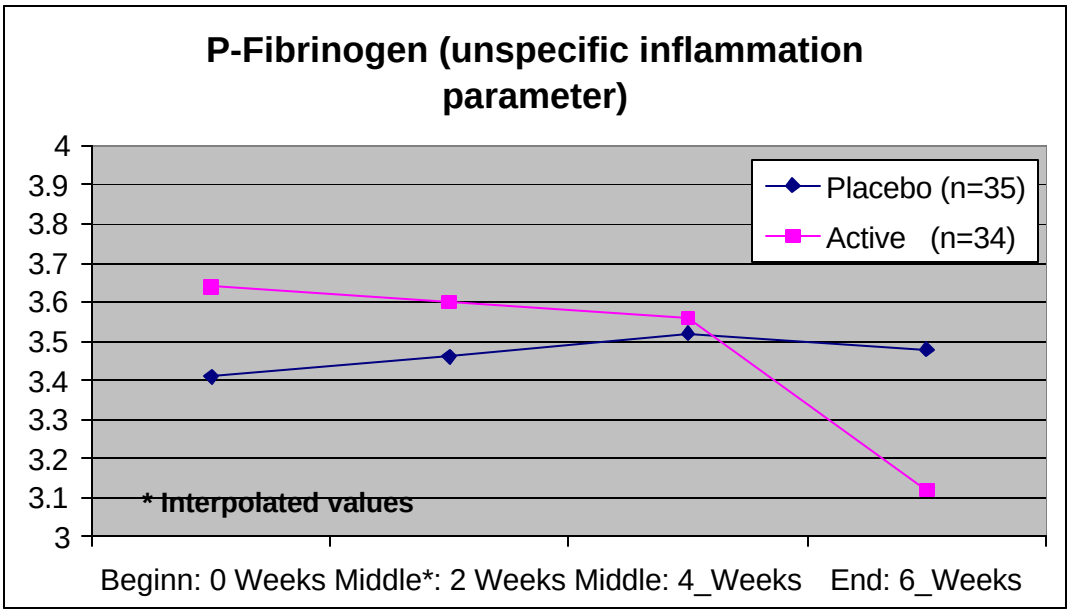


Illustration 06c: P-fibrinogen (mean value comparison): Due to high mean variation and unfavourable initial values there is only a slightly significant difference in favour of active ($P<0.1$); however the course shows a highly significant improvement only for active ($P<0.001$).

All important clinical inflammation parameters show effects in the direction “hoped for”. In the case of the leucocytes (see Table 07d) there is no effect determinable, but was also not expected as these are already well within the norm.

Table 07d: Leucocytes (less specific inflammation parameter)
Norm: 4.5 – 9.0

Time	Time of examination	Placebo standard error	Placebo mean	Active Mean	Active standard error
1	At commencement of therapy	.3	7.2	6.7	.3
2	During therapy, after 4 weeks	.2	6.8	6.6	.3
3	End of therapy, after 6 weeks	.2	7.1	6.9	.2
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		not	significant	

Table 07d: Leucocyctes Placebo Versus Active: Mean values are within the norm.

Table 07e: Erythrocytes
Norm: sex-specific

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.06	4.32	4.43	.06
2	During therapy, after 4 weeks	.06	4.31	4.43	.06
3	End of therapy, after 6 weeks	.05	4.23	4.41	.05
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	significant	(P~.05)
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		significant	(P<.05)	

Table 07e: Erythrocytes Placebo Versus Active: Values within the norm.

Table07f: Eosinophil

Norm: sex-specific

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	.28	2.09	2.37	.32
2	During therapy, after 4 weeks	.26	2.05	2.74	.35
3	End of therapy, after 6 weeks	.40	2.37	2.73	.32
	valid		35	34	
	missing		1	1	
	total		36	35	
1 versus 3	Course: placebo versus active	not	significant	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		not	significant	

Table 07f: Eosinophil Placebo Versus Active: Table shows no significant change. The not known tendency for increase in the active group after 4 weeks (would be unfavourably interpreted, if there was significance) cannot be interpreted by doctors (note Kobinger).
However the changes in the blood pressure can be assessed as a favourable therapy effect:

Table 07g: Systolic Blood Pressure (RR sys)

Norm: 100 – 135

Time	Time of examination	Placebo standard error	Placebo mean	Active mean	Active standard error
1	At commencement of therapy	2.9	136	136	2.3
2	During therapy, after 4 weeks	4.1	144	135	2.1
3	End of therapy, after 6 weeks	2.9	139	131	2.8
4	After follow-up, after 10 weeks	2.6	144	131	2.7
	Valid		35	34	
	Missing		1	1	
	Total		36	35	
1versus 3	Course: placebo versus active	not	significant	not	significant
1	Difference beginning: p versus a		not	significant	
3	Difference end: p versus a		almost	Significant (P~.05)	
4	Difference 10 weeks: p versus a		highly	Significant (P<0.001)	

Table 07g: Systolic Blood Pressure Placebo Versus Active: Blood pressure improved only for active group significantly. As the values for placebo even worsened, the difference especially after the follow-up in favour of active is highly significant (P<0.001). There are no significant changes in the diastolic blood pressure (are favourable; development trend is more favourable in active than in placebo-group.

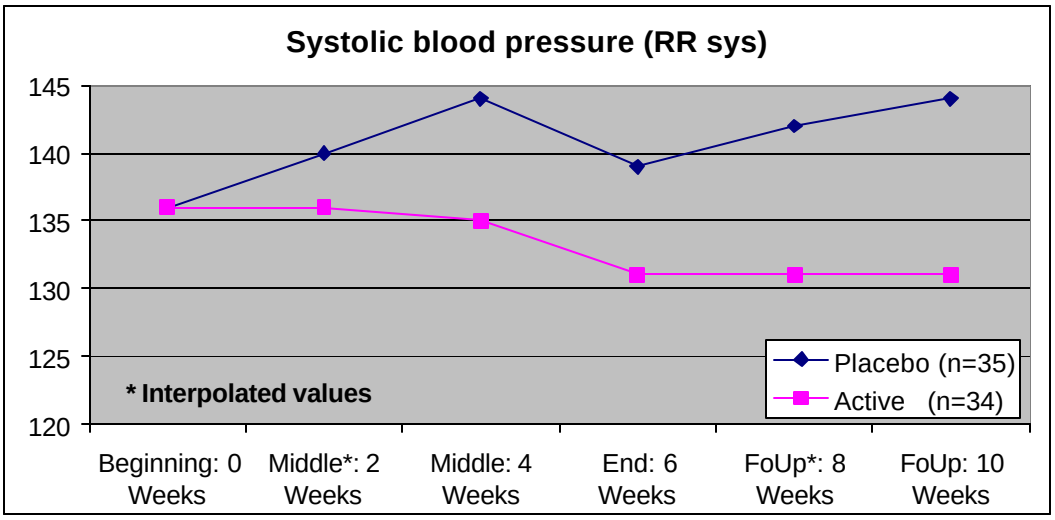


Illustration 06d: Systolic Blood Pressure (RR sys) (mean value comparison): As not only active improves highly significantly and with a stable follow-up (P<0.001), placebo at the same time worsens significantly (P<0.05), the group difference is especially in the follow-up highly significant in favour of active (P<0.001).

4 Discussion

The results are astounding for the medical profession, who know the discussion about QRS® therapy or generally about magnetic field therapy primarily from the mass media, but are not so familiar with the specialist scientific discussion.
For the user and the QRS® specialist, it is not quite so astounding that this (unspecified) therapy delivers such clear results in a narrowly defined diagnosis. This makes QRS® a real alternative in therapy applications, which up to now has hardly been considered causally treatable, if general recommendations for a better lifestyle (appropriate exercise and diet) are disregarded.

Many of the examined indicators refer to the fact that the optimum attainable is not fully reached after 6 weeks. It further shows that, for most, the therapy should not be terminated too soon, if one does not want to risk a quick re-worsening of the findings. There are no definite references in regard to necessary / useful duration of therapy as yet, but the retrospective analysis of one-year-users (see Pelka 2000 and Haas 2001) suggests that a therapy duration of at least 3 months and even for a year should be useful.

The 3 theories put forward in the beginning were verified by all data. Only in the case of assessment of knee function (KSS) the advantage was only seen in the follow-up, not quite during therapy. In agreement with the observations by Haas (2001) and the results of the DSSV study (Pelka 2001), this is acceptable for the theory and other clinical findings.

The integrative concept of this approach to therapy is characteristic and recognizable e.g. in the improvement of the systolic blood pressure **(see Illustration 6d)**. That is the therapy seems to be especially useful for certain diagnoses e.g. gonarthosis, but the effects usually go clearly beyond narrowly defined areas of diagnosis.

Discussion about Selected Individual Findings

KSS: The knee society score (KSS) serves specifically for the mentioned diagnosis as an appropriate standardized measuring instrument, where the interim evaluation is a knee assessment without deductions and the evaluation is a knee assessment with deductions (flexion contracture, stretch deficit and tibiafemoral angle). The latter cannot easily in such a short time be improved. It is no surprise that the active advantage here and for the net function is not so obvious. Even with slightly better initial values the development for the active group is convincingly positive in regard to the initial situation compared to the placebo group. The relatively quick decline in the follow-up indicates the necessity for

longer therapy. This does not contradict the seemingly contrary finding in case of the knee function and the stable findings in the case of walking ability. Obviously these functional results are only reached with a time delay, dependent or at least corresponding to the assessment 2 weeks earlier. Especially the KSS results and the later pain values suggest a longer to long duration of therapy.

General Pain Assessment: All indicators show similar results. The more the subjective sensitivity of patients is taken into account, the more clearly advantageous QRS® therapy is (see pain sensitivity versus pain scale, page 22 or subjective general state of health versus general condition, page 24). All developments have in common, that the advantage of active is lost relatively soon. After 4 weeks only 20 to 80% of the attained differences to placebo remain. This indicates a systematic examination about the correlation of therapy duration and the following stability of findings.

Use of Medication / Doctors' Consultations: To assess these results (not bad for QRS®) one has to note that several effects play a role, which possibly cover up the advantage of active. On one hand there is a high correlation between use of medication (frequency, dosage) and doctors' consultations, which signals a certain behaviour pattern that is not really dependent on the actual state of health status. On the other hand the findings are not very accurate, because e.g. the doctors' consultations refer to an interval longer than the one judged here. In particular the Illustration: Dosage GON Medication indicates that the willingness to reduce the dosage has not reached its maximum after 6 weeks of therapy. This is also indicated in the retrospect analysis of the 1-year-user study (see Pelka 2000).

Laboratory (Inflammation) Parameters: Here the trends are so much better than the statistically significant verified differences in favour of active, which are just over or under the significance level. It is important is to realize that QRS® has a favourable effect on the blood parameters as it reduced the inflammatory processes in the knee and (probably) beyond in the whole organism. These findings (see Illustration 06a to c, pages 28-29) also indicate the necessity for a further study with longer duration of therapy.

The systolic blood pressure reacts relatively quickly in a convincingly favourable way (see Illustration 6d, page 31). The result should be checked in further studies.

Resume: Finally it can be determined that despite not yet optimal therapy duration the study indicates strongly that QRS® in the case of diagnosis "gonarthrosis" is one of the most attractive therapies at present.

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Presented at the 26th Conference of the Austrian Society for Internal Medicine.

"Using Magnetic Fields to Increase Flexibility and Reduce Pain with Respect to Ailments of the Ambulatory Apparatus."

By Dr. W. Kobinger, Dr. G. Fischer, Dr. T. Barovic, Dr. Z. Turk, Dr. N. Skat, Dr. D. Zivac., Slovakia and Austria, July 1995
Study conducted at Marburg Teaching Hospital, Drau (Slovakia) and the Institute of Hygiene, Graz University (Austria)

Between 01/02/95 and l2/05/95, 14 male and 14 female patients with ambulatory and sustenticular apparatus ailments, were treated solely using a magnetic field treatment device (QRS) . The patients had no prior surgical treatment related to their ailments. The QRS was previously unavailable on the Austrian market.

The patients (Ave. age 46.1 + 10.8 a) were suffering from intervertebral disc prolapse (diagnosed via myclography), spinal stenosis (on basis of CT), and osteoporosis (densiometry). They were treated in 20 sessions (8 minutes, twice daily - once in the morning and once in the afternoon) over a two-week period (Mon-Fri) on a mattress-like application mat using the maximum field-level setting on the QRS device (Bmax = 4 mt).

Success of the therapy was evaluated using a 10-point Dole scale, comparing a measured distance between the fingertips and the floor while the patients were bending forward both prior to, and following, treatment. Evaluation of tile subjective pain experienced by the subjects was carried out using non-parametric maximum, sequential-range, and semi-qualitative Chi2 tests. Flexibility was evaluated using the two-tailed t-Test for unequal variances (parametric test).

Using the sequential-range and maximum tests (111.2), there was a significant reduction in pain ($p<0.05$). Further level of significance could not be determined in either case due to methodological reasons.

Proceeding on the null hypothesis of an equal distribution for the categories, "improved" and "worsened", the results of the Chi2 test ($p<0.001$) were highly significant in favor of the effect of the magnetic field treatment. Increased flexibility in bending was also highly significant ($p<0.001$) (see 111.2).

The results presented in both categories reflect those indicated in international literature. Further cases are currently being studied.

1. Evaluation of "Pain Reduction"

a. Sequential Range Test. The limits for significance (p0.05) were far exceeded which indicates that improvement was achieved on this level.
b. Maximum Test. The negative (and positive) differences in the Dole scale values were compared (end of therapy minus beginning of therapy). This resulted in highly significant differences ($p<0.001$) indicating a reduction in pain through magnetic field application.
c. One-dimensional Chi2 test with one degree of freedom (including correction of continuity): There were 28 improvements and 0 deteriorations. Assuming equal distribution (equal amount of improvements and deteriorations), the result was as follows:
   Chi2 -26.04 (N=28).
   This indicates a highly significant decrease in pain ($p<0.001$).

2. Evaluation of "Mobility"

The t-test (two-tailed, unequal variances), on the average distance from the floor when bending forward, before and after the MFT series, had the following result:
(Temp = 3.56; FG = 51.07).
This indicates a highly significant increase in mobility ($p<0.001$)

Presented at the Annual Conference of the Austrian Society for Physical Medicine and Rehabilitation

"Using Magnetic Fields to Increase Flexibility and Reduce Pain with Respect to Ailments of the Ambulatory Apparatus."

Author: Dr. Joze Barovic
Co-Authors: Dr. G. Fischer, Dr. Z. Turk, Dr. W. Kobinger
Study conducted at Marburg Teaching Hospital, Drau (Slovakia) and the Institute of Hygiene, Graz University (Austria), 1995

Between 01/02/95 and 01/09/95, 23 female and 23 male patients suffering from ailments of their ambulatory and sustentacular apparatus, were treated with a new magnetic field device, QRS, in two research phases. The patients had not been surgically treated for their ailments.

The patients (Ave age: 51.0 +/- 1 15.la) were suffering from intervertebral disc prolapse (n=25, diagnosed via myclography), spinal stenosis (n=18, diagnosed on basis of CT), and osteoporosis (n=-2, diagnosis using densiometry). There was also one patient with spinal stenosis and osteoporosis (See 3. Paragraph 1).

The subjects were treated in 20 sessions (8 minutes twice daily - once in the morning and once in the afternoon) over a two-week period (Mon-Fri) on a mattress-like application mat (3 pairs of reels for neck, trunk and legs) using the maximum field-level setting on the device (Bmax = 4 mt).

Success of the therapy was evaluated using a 10-point Dole scale and (only in the first phase of the experimental tests n = 28) comparing a measurement of the distance between the finger tips and the floor while the patients were bending forward - both prior to, and following, treatment. Evaluation of the subjective pain experienced by the subjects was carried out using the preliminary non-parametric maximum, sequential range, and semi-qualitative Chi2 tests. Due to organizational reasons, flexibility was only measured in the first experimental phase and was evaluated by using the two-tailed V-Test for unequal variances (parametric test).

The results of the individual pain assessments accrued, using the 3 (non) parametric tests, showed the following results with respect to the overall group (3 paragraph 2):

Using the sequential range test there was already a significant result after 8 of the 46 Improvements ($p<0.05$). The exact level of error could not be determined due to methodological reasons. The maximum test showed a highly significant reduction in pain ($p<0.00l$) after computing only the 11 largest Dole scale differences.

As before, it was not possible to determine the exact probability of error. Proceeding on the null hypothesis of an equal distribution of improvement / worsening of the perception of pain following.

The application of the magnetic field treatment the results of the Chi2 test ($p<0.001$) were highly significant in favor of the positive effect of the magnetic field treatment.

Although only measured in 28 patients, due to organizational reasons, the increased flexibility in bending forward was also highly significant ($p<0.0001$) (see 3 paragraph 2).

The results presented in both categories reflect those indicated in international literature.

Further cases are currently being statistically substantiated.

Publication Article

Medizinisch-Orthopadische Technik (Medical- Orthopedic Techniques)
"Conservative Treatment of 240 Patients with Magnetic Field Therapy"

March/April 1976, Issue 2, page 78
By M. Schroter

Summary:

Magnetic field therapy (MFT) is a clear therapeutic gain in conservatively oriented therapeutics. By no means does it constitute an alternative solution to other forms of therapy, but it has become an established component in the entire treatment spectrum of orthopedics. The indications and results are presented briefly.

The following data relate to a group of 240 patients treated with magnetic field therapy in a conservative orthopedic practice. Any secondary treatment by medication was dropped in 90% of the cases treated with MFT in order not to obscure the therapeutic success, if any. However, in two of Morbus Bechterew's cases, aged 24 and 27, Indometacin was applied. After about 50 sessions of MFT, we discontinued the medication, following gradual reduction, over time, of the daily dose.

Prof. Dr.-Ing.habil. M. Krauß, Prof. Dr. Fischer AG Chemnitz
Dr. med. G. Grohmann, Klinik Bergfried Saalfeld
Dr. med. V. Rasch, Augenklinik Potsdam
Prof. Dr.-Ing.habil. mult. J. Waldmann, MIRA GmbH Chemnitz

Blood flow changes in the retina in the case of normal probands under the QRS therapy as well as before and after sublingual administration of 0,4 mg trinitroglycerin– results of a preliminary study

1 Introduction

Important works on the use of the magnetic field therapy on the **ophthalmology** were mainly published in the former Soviet Union (up to 1980, already 50 dissertations; abstracts of essential works are contained in the literature overview "The effect of pulsating magnetic fields in the ELF range applied to the animal and to the human being" that was provided to the authors by the Magnovit International AG Eschen /Liechtenstein). Independently of the form of the magnetic field, there is stated as a summary /8/ (taken from the literature overview mentioned above):

- There is a positive effect on the epithelization of the cornea. The blood vessels in the retina are dilated. In the magnetic field, a lower intraocular pressure is created. In part, in case of therapy resistance, the field can activate the blocked blood feed to the retina.
- The magnetic field has a pain-reducing effect.
- Haematomas disappear faster.
- In 50 % of the cases, the glaucoma treatment is positive even if the drug treatment is not successful.
- Neither in the eye nor in the brain tissue, negative side effects have occurred.

Within a preliminary study, there shall be examined whether blood vessels in the retina dilate analogously to the cardiovascular system /7, 14/ in the case of normal probands when a magnetic field therapy using the Salut 1 QRS® Quantron Resonance System device is applied. Furthermore, comparative measurements before and after a sublingual administration of 0.4 mg trinitroglycerin shall be performed.

2 Examination persons and methods

Examination persons: Four voluntary, clinically healthy persons (1 woman, 3 men) having an average age of 58.3 ± 1.8 years were treated. The state of the eyes was according to the age. All four persons had reading glasses of medium strength prescribed by the physician. The measurements were carried out in a quiet room in the morning between 8:00 a.m. and 11:00 a.m..

QRS magnetic field therapy: To the backside – head-neck-shoulder region – of the sitting test persons, a small QRS therapy mat ("coil cushion") was attached. These test persons were treated using the QRS® Quantron Resonance System device for 8 minutes.

To compare occurring changes on a QRS therapy, 0.4 mg **trinitroglycerin** were sublingually administered to one test person. As known, a nitrate fed in this way – as the endogenously nitrate does – dilates the vessels. Thus, nitroglycerin is a stimulus by means of which the vasodilation can be stimulated in an endothelium-independent manner. In the cardiovascular system, this effect can be acquired non-invasively by means of high-resolution ultrasound duplex equipment, the laser Doppler flowmetry, the NIRP method /7/ and the vein occlusion plethysmography.

The examinations of the ocular fundus during the influence of the QRS magnetic field as well as under trinitroglycerin were performed using the Heidelberg Retina Flowmeter produced by HEIDELBERG ENGINEERING /5/. The Heidelberg Retina Flowmeter combines two specific measuring techniques – the confocal laser scanning technique and the laser Doppler flowmetry – to form a novel device for the non-invasive and two-dimensional mapping of the retinal microcirculation /5/.

On an examination using the *Heidelberg Retina Flowmeter*, the retina or the pupil is two-dimensionally scanned with an infrared laser beam. Due to the optical Doppler effect, light that is reflected or scattered from moved red blood cells is subject to a frequency change. It interferes with light that is reflected at non-moved structures in the surrounding tissue and retains its original frequency. This interference causes a characteristic variation of the detectable intensity of the light that is reflected at a certain place. By means of the Heidelberg Retina Flowmeter, these intensity variations are measured at each point of a two-dimensional scanning field and are used to determine the local Doppler frequency change and, thus, to quantify the local blood flow. This leads to a two-dimensional representation of the retinal blood flow with a spatial resolution at capillary level. The size of the measuring field on the retina amounts to 10° * 2.5° to 20° * 5°. Inside this field, in total, 256 * 64 (16,384) independent laser Doppler measurements are performed. The total data taking time amounts to 2 seconds. For data taking, a pupil dilation is not required. The data are evaluated in less than one minute. At that, two-dimensional blood flow maps are created that allow a visualization of the network of active capillaries and vessels. Moreover, in a certain sense, local blood flow parameters such as speed, flow and volume can also be determined quantitatively. The operating software of the device is running on a personal computer under DOS or Windows 95. It comprises database functions, image pick-up, image processing, contrast amplification, creation and printing of examination reports as well as image archivation /5/.

3 Results

Figure 1 shows a retina section with small arteries acquired with the Heidelberg Retina Flowmeter, as well as an analyzed window from which the corresponding blood flow volume is derived. In the case of the corresponding test person, such a window was kept (nearly) constant before and during the QRS therapy; otherwise, the measuring point was varied. In the case of each test person, the arithmetic mean value for the chosen measuring point was calculated from the measuring values before the therapy. All succeeding measuring values, i.e. those under the therapy, were divided by this mean value. With that, the **relative** changes both under the QRS therapy and under trinitroglycerin can be determined, related to the mean blood flow volume before the therapy in the window used as basis (normalized mean value = 1 in the case of each test person).

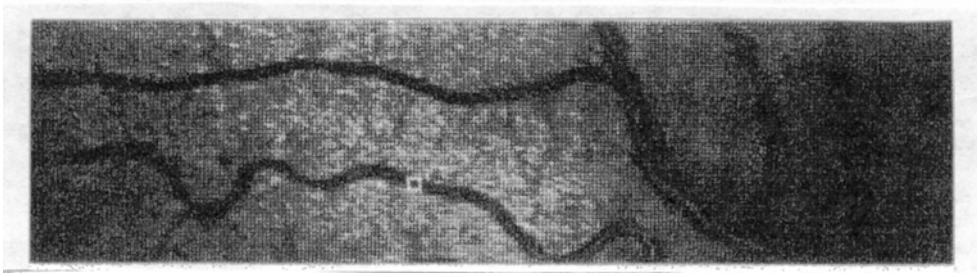
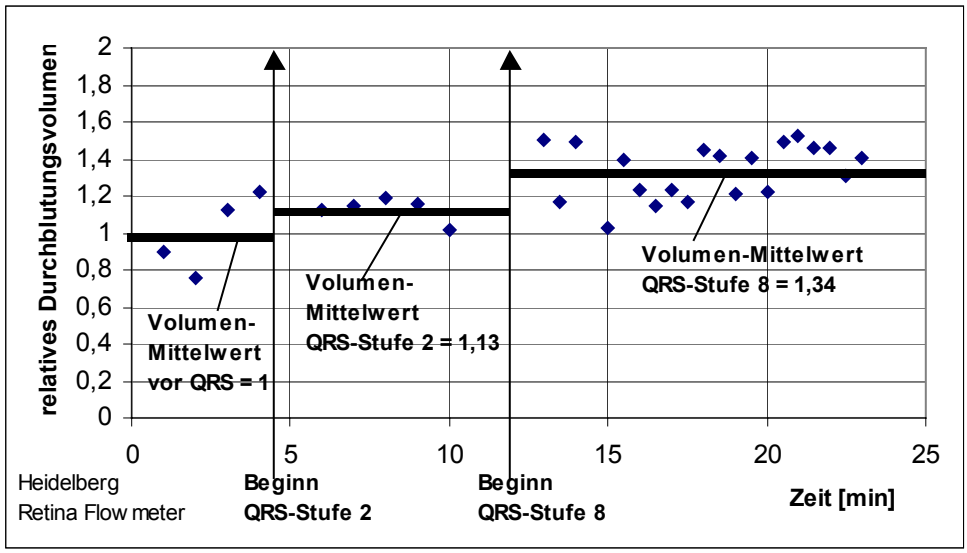


Figure 1: Retina section A with small arteries acquired with the Heidelberg Retina Flowmeter, as well as an analyzed window

Figure 2: Blood flow changes in a small eye artery of the retina under QRS therapy (before QRS, QRS levels 2 and 8) in the case of a 60 years old female proband



1 – Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Volume mean value before QRS = 1
3 – Volume mean value under QRS level 2 = 1.13
4 – Volume mean value under QRS level 8 = 1.34
5 – Heidelberg Retina Flowmeter
6 – Beginning of QRS level 2
7 – Beginning of QRS level 8
8 – Time [min]

After the shown algorithm, the following measuring values were obtained in the case of the test persons under the corresponding magnetic field intensities. **Figure 2** shows the mean values before QRS as well as under the levels 2 and 8 in the case of a 60 years old female proband. Analogously, **Figure 3** shows the mean values in the case of a 58 years old male patient (Figure 3a: under QRS level 2, Figure 3b: under QRS level 8), **Figure 4** shows the mean values in the case of a 60 years old male patient (Figure 4a: under QRS level 2, Figure 4b: under QRS level 8), and **Figure 5** shows the mean values in the case of a 55 years old male proband under level 8 only. In **Figure 6**, for the male proband of Figure 4, the changes after a sublingual administration of 0.4 mg trinitroglycerin are shown as comparative representation.

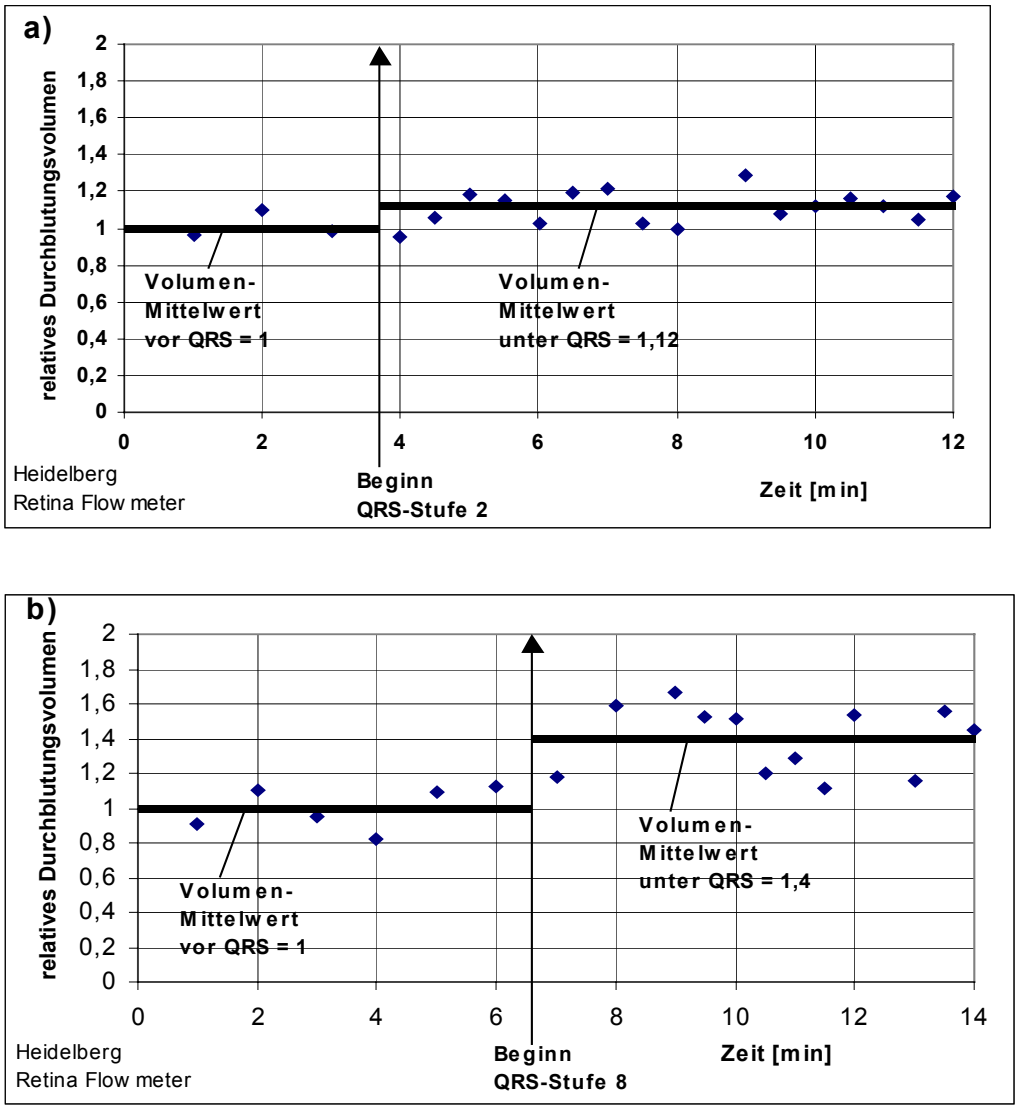


Figure 3: Blood flow changes in a small eye artery of the retina under QRS therapy [a) level 2, b) level 8] in the case of a 58 years old male proband

1 – Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Volume mean value before QRS = 1
3 – Volume mean value under QRS = 1.12
4 – Heidelberg Retina Flowmeter
5 – Beginning of QRS level 2
6 – Time [min]
7 – Volume mean value under QRS = 1.4

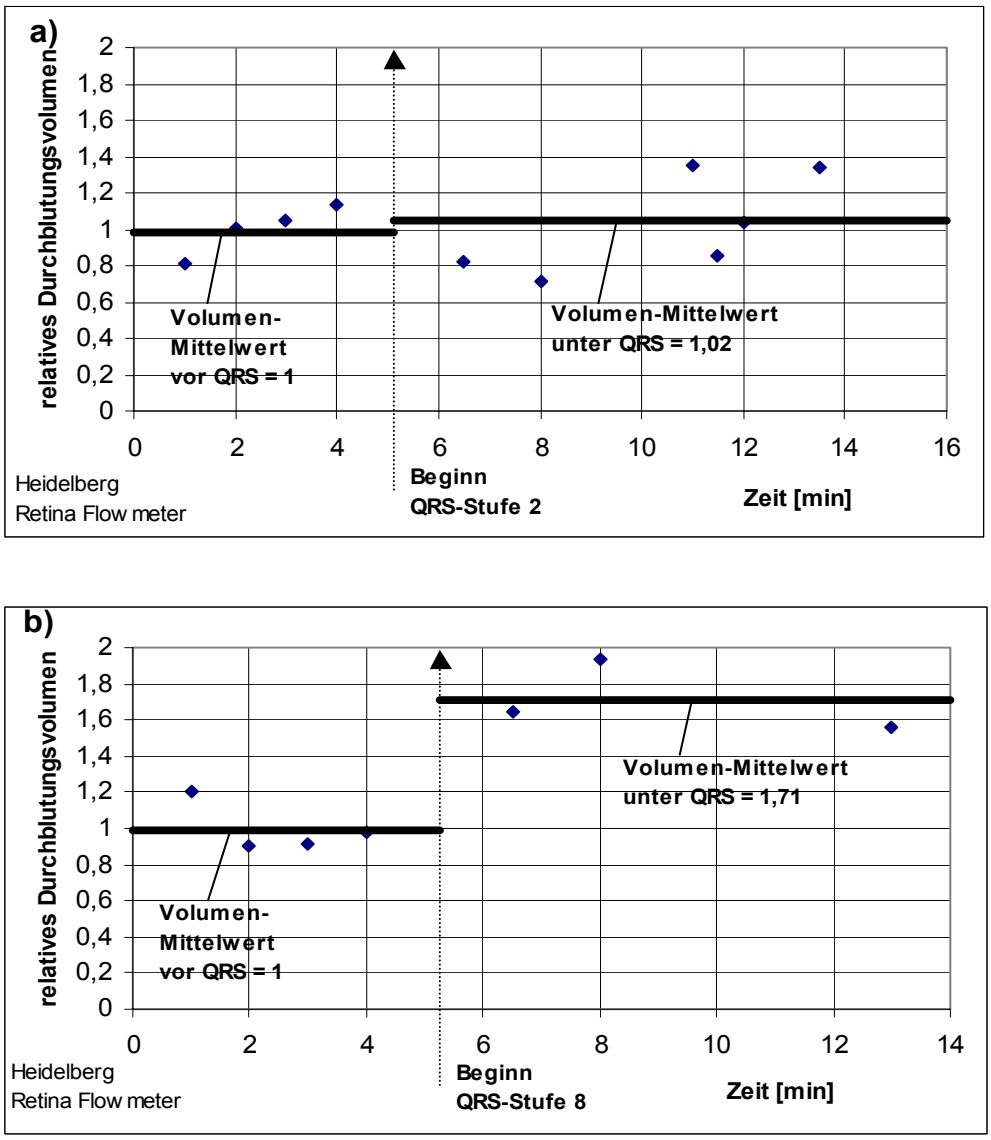


Figure 4: Blood flow changes in a small eye artery of the retina under QRS therapy [a) level 2, b) level 8] in the case of a 60 years old male proband

1 – Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Volume mean value before QRS = 1
3 – Volume mean value under QRS = 1.02
4 – Heidelberg Retina Flowmeter
5 – Beginning of QRS level 2
6 – Time [min]
7 – Volume mean value under QRS = 1.71

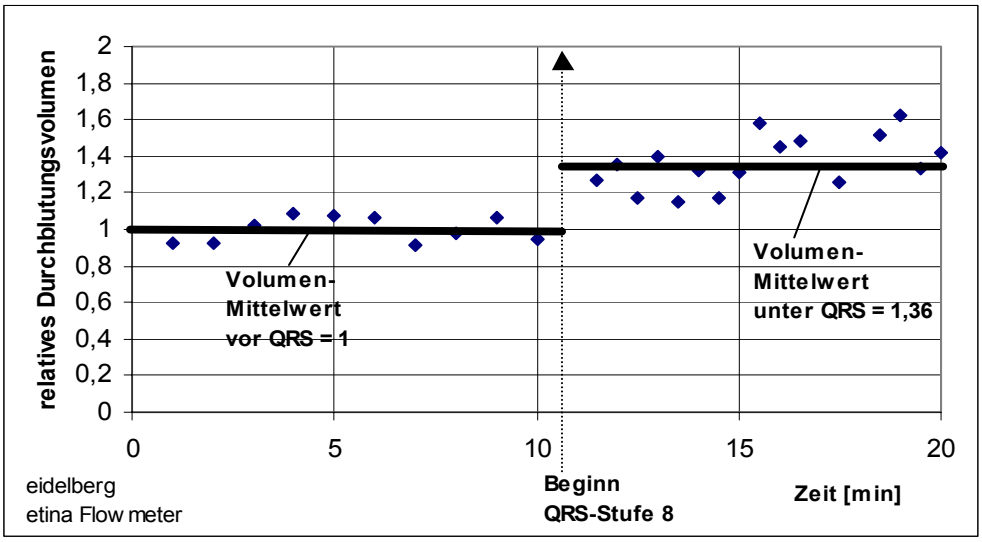


Figure 5: Blood flow changes in a small eye artery of the retina under QRS therapy [level 8] in the case of a 55 years old male proband

1- Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Volume mean value before QRS = 1
3 – Volume mean value under QRS = 1.36
4 – Heidelberg Retina Flowmeter
5 – Beginning of QRS level 8
6 – Time [min]

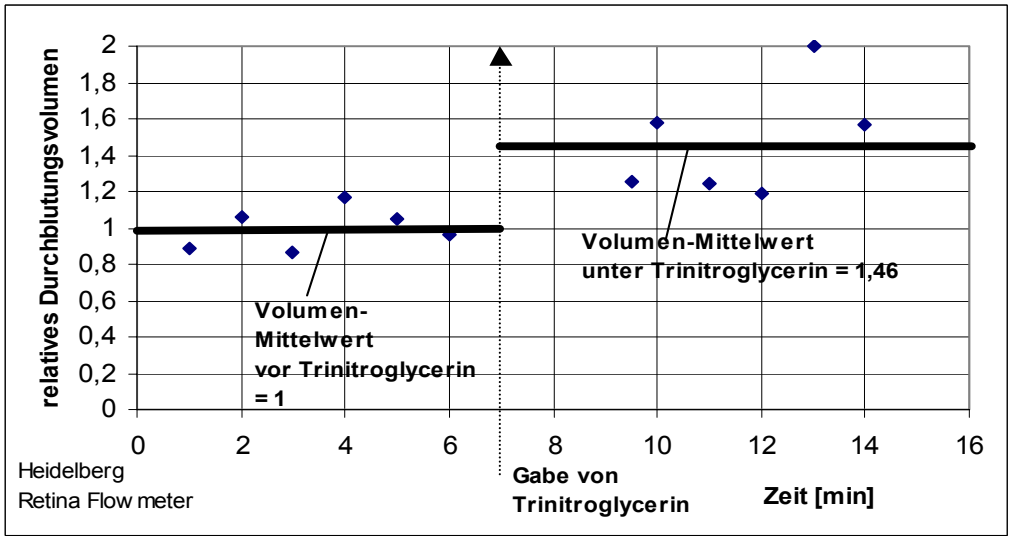


Figure 6: Blood flow volumes in a small eye artery before and after the sublingual administration of 0.4 mg trinitroglycerin in the case of a 60 years old male proband

1 – Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Volume mean value before trinitroglycerin = 1
3 – Volume mean value under trinitroglycerin = 1.46
4 – Heidelberg Retina Flowmeter
5 – Administration of trinitroglycerin
6 – Time [min]

To determine the dependence of the appearing relative blood flow changes in the case of the 4 test persons independently of the measuring point, all measuring values before the therapy as well as under the corresponding QRS magnetic field levels (intensities) 2 and 8 were summarized in a diagram as shown in **Figure 7**. The obtained arithmetic mean values and the standard deviations are shown in **Table 1**.

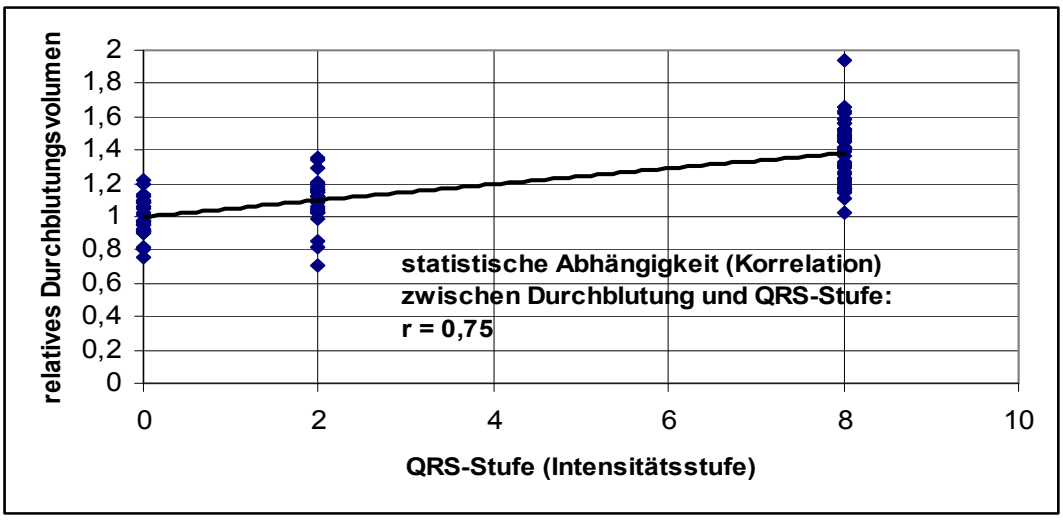


Figure 7: Dependence between the relative blood flow volumes and the QRS magnetic field levels 2 and 8 in the case of the 4 test persons, independently of the measuring point

1 – Relative blood flow volume
1.a – Dezimalkommas → Punkte
2 – Statistical dependence (correlation) between blood flow and QRS level: r = 0.75
3 – QRS level (intensity level)

QRS- level	**Arithmetic mean values of the relative blood flow volumes**	**Standard deviation**
– Before therapy	1	0,09
2	1,1	0,11
8	1,39	0,15

Table 1: Arithmetic mean values including standard deviations of the relative blood flow changes of the 4 test persons in case of the QRS magnetic field levels, derived from Figure 7

4 Discussion

The represented results show for the 4 test persons under QRS therapy: With an increase of the intensity of the QRS magnetic field, the blood flow volumes in the windows used as basis – i.e. independently of the measuring point – will increase too. Thus, a vasodilation occurs that can be different and possibly depends on the vessel state. That the process does not have a linear course, this is shown by the scatters of the measuring values around the respective mean values. However, a reason for the scatters could also consist in the measuring accuracy of the Retina Flowmeter.

Obviously, the occurrence of a vasodilation in case of an increase of the magnetic field intensity (Figures 2 to 5) also shows that the vessels of the retina – in contrast to the vessel periphery – are not innervated by the sympathicus. In a work of the authors not published up to now, there is shown: With an increase of the QRS magnetic field intensity, the peripheral sympathicotonus is increased and, thus, a peripheral narrowing occurs. At the same time, there is pointed to the fact that this causes a reduction of the NO production. Inversely, a low QRS level causes a reduction of the peripheral sympathicotonus and, thus, a vessel extension. Obviously, this does not occur in the retina.

The effect of exogenously fed trinitroglycerin is shown in Figure 6. The results are comparable with those under magnetic field therapy: The sublingually fed nitrate has a vessel-dilating effect as the endogenously created nitrate does. Thus, nitroglycerin is a stimulus by means of which the vasodilation can be stimulated in an endothelium-dependent manner.

Between the QRS level and the appearing magnetic field intensity, there is a completely linear relation: minimally selectable field strength of 2 µT at the level 1, field strength of 20 µT at highest level 10. Figure 7 shows that the approximate assumption of a linear correlation between the relative blood flow volumes and the magnetic field intensities seems to be justified because a relatively high correlation factor of $r = 0.75$ resulted in the case of these 4 test persons. Whether such a dependence in the case of normal probands appears generally, this has to be ascertained in further examinations. If endothelium affections (for example, in the case of diabetics), such a correlation occur scarcely as it was analyzed in studies.

Whether the changes listed in Table 1 will prove to be normal ranges, this has to be determined in the case of a greater number of test persons.

5 Outlook

In the plenary lecture "QRS magnetic field therapy – presence and future", there was shown: At the vessel endothelium, in the most general sense, the control of the synthesis of **nitrogen monoxide** (NO) /3, 4, 6, 7, 9, 10, 11/ and **prostacyclines** as vasodilators takes place, also activated by the specifically formed QRS magnetic field /1, 2, 12, 13/. As Kelm /6/ states, nitrogen monoxide is created by the endothelium cells already in the resting state and essentially contributes to the regulation of the vessel tonus, i.e. of the blood flow and pressure. On the other hand,

in case of various diseases of the cardiovascular system in the early stage, the vessel endothelium is affected and the protective effect of NO as vasodilator and thrombocyte inhibitor is not present (occurrence of endothelium dysfunctions) as stated in /6, 9, 10/. Furthermore, it is known that NO set free from endothelium cells into the blood is first oxidized in the plasma to nitrite that is converted to nitrate very quickly that is eliminated in the urine /6/. The oxidation is also referred to as a "deactivation mechanism for NO". It is very likely that this mechanism is the reason for the fact that the production and the drain of the ocular humor hold the balance and a constant intraocular pressure results. If the NO production is reduced in case of a endothelium dysfunction, the intraocular pressure can rise pathologically, the optic nerve can be affected and a glaucoma can occur. If a strong endothelium dysfunction is present, after /9/, an increased NO catabolism is released by an activation of the renin-angiotensin system (RAS).
If there is stated in /8/ that a glaucoma treatment using a magnetic field could be assessed as positive in 50 % of the cases, then the mentioned NO deactivation mechanism should be the reason for that.
The possible applications of the QRS magnetic field therapy in the entire ophtalmology stated as an outlook have to be examined in future works.

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Geriatrische
GESUNDHEITSZENTREN

Stadt GRAZ

Report on the application of full body magnetic field therapy with the Quantron Resonance system (QRS) Salut 1 at the Geriatric Hospital in Graz, Graz, Albert Schweizerg. 36

Medical Director: Dr Eric Stoiser
Practising Doctor: Dr Petra Wagner

Duration: April until September 2000
Equipment: 3 units QRS – Salut 1, Nr.: SI-1 – M300160, 162, 167

Summary:

In all the following cases the patient's condition can be described as clearly diminished. Previous therapies did not show significant improvement.

The therapies were conducted with pulsating magnetic fields of extremely low field strengths (Level 3) and have led to very positive results in all cases.

In principle the results confirmed the statements of the existing scientific studies and application reports.

It can therefore be summarised that not only the patient's condition concerning quality of life has improved, but also that the level of care needed can be reduced due to the overall improvement of the patient's wellbeing. Furthermore the therapy using these magnetic fields does not cause any known side effects.

Medical director

Practising doctor

Graz, Oktober 2000.

Case 1

72 year old female patient

Diagnosis on admission: - **Extensive sacral decubitus ulcer**
- **Alzheimer's**
- **Erysipelas on right lower thigh**
- **PEG tube due to massive dysphagia**
- **Total immobility**
- **Global aphasia**

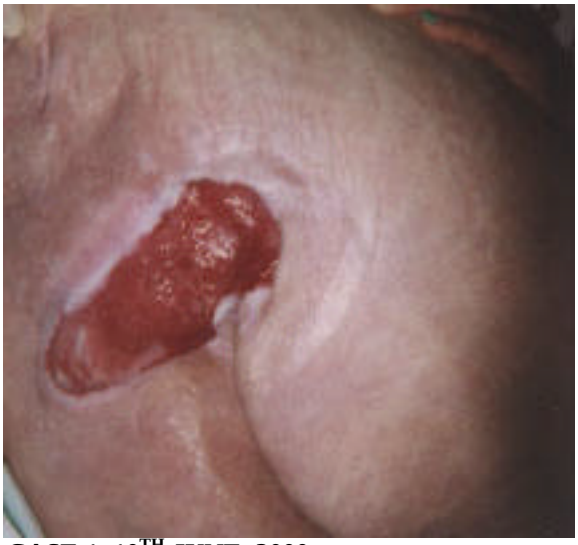
Main problem: **massive sacral decubitus ulcer 18x10x2cm with a wound pocket to the right side 6-8cm**
The decubitus ulcer had already been treated with the **Vacc-system** with no considerable results.

Despite various highly proven wound management systems in our hospital relapsing infections of the decubitus ulcer and fevers occurred, the ulcer remained with a very unpleasant smell and is highly coated.

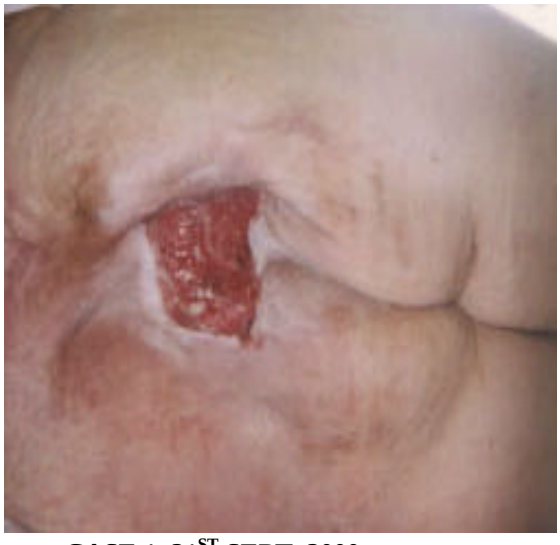
6th April, 2000:
Start of magnetic field therapy; level 3, 2x8 minutes daily

After six weeks the patient starts to take nutrition orally and to formulate words.
The decubitus ulcer becomes visibly cleaner at the base of the wound.

21st September, 2000:
Today the decubitus ulcer is 13,5x6,5cm in size, flat and well circulated at the base. A good healing tendency can be observed from the sides of the wound. Ephitelial bridges are forming towards the centre of the wound.



CASE 1 10TH JUNE, 2000



CASE 1 21ST SEPT. 2000

The patient is gaining wheelchair mobility.
The PEG tube is currently not being used. Verbal communication, using a few words is possible.

Case 2

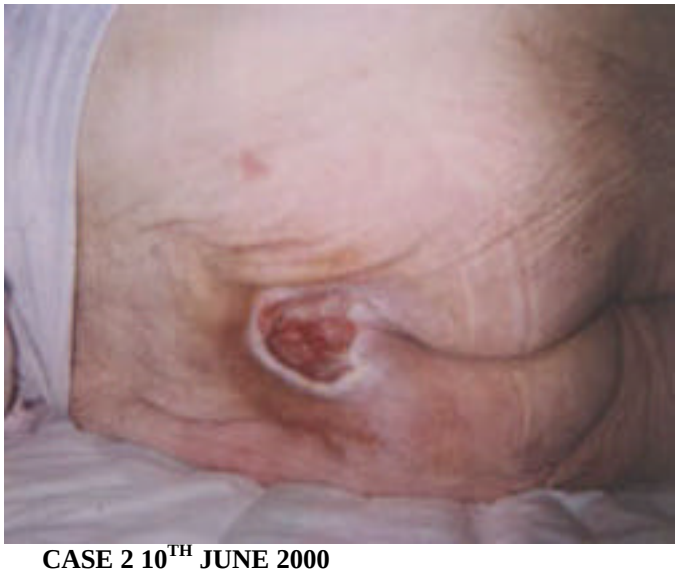
79 year old female patient

Diagnosis on admission: - **Sacral decubitus ulcer**
- **Senile dementia of the Alzheimer type**
- **Depression**
- **Parkinson syndrome**
- **Relapsing urinal tract infections**
- **PEG tube with dysphagia**

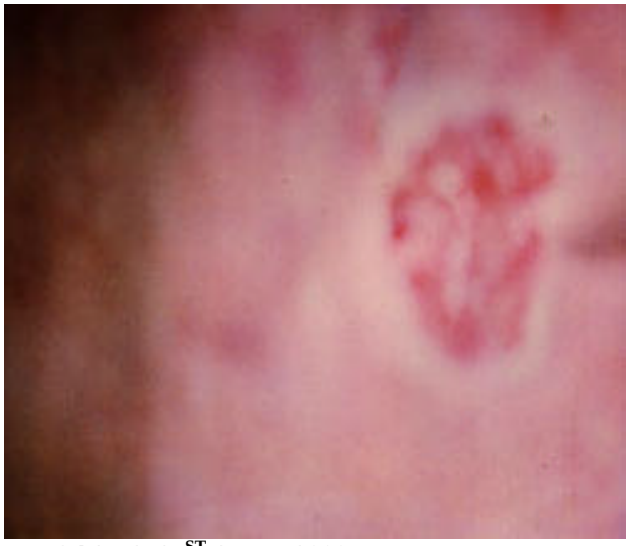
On admission the general condition of the patient is visibly diminished. Verbal communication is very poor. No mobility at all.
Main problem: sacral decubitus ulcer 6x4cm, very coated

5th May, 2000
Start with magnetic field therapy, level 3, twice daily for 8 minutes.

21st September, 2000
The PEG tube does not need to be used at present. The patient uses her own hands to eat independently at times, is wheelchair mobile and verbal communication is possible. (small talk)
The ulcer has hardly changed in size, but is very well circulated and shows a tendency to form ephitelial bridges.



CASE 2 10TH JUNE 2000



CASE 2 21ST SEPT. 2000

Case 3

80 year old female patient

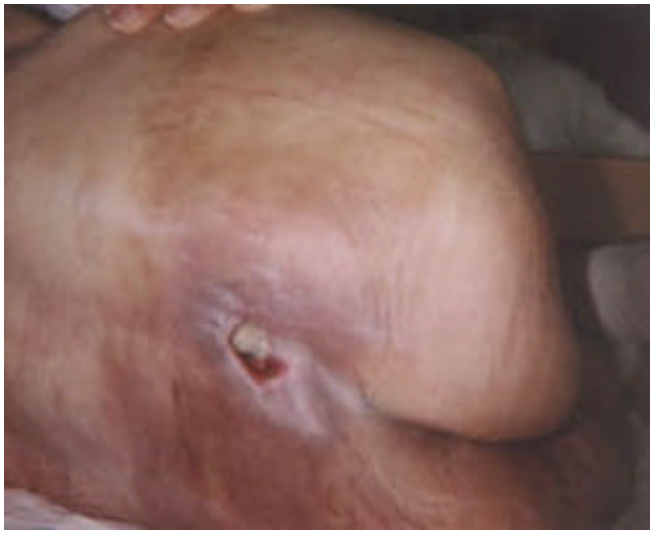
Diagnosis on admission: - **CVI with severe confusion**
- **Relapsing urinal tract infections**
- **Relapsing fever**
- **Decubitus sacralis I**

At the beginning of June 2000 the sacral decubitus ulcer shows deep pockets, a strong coating at the base of the wound, accompanied by a foul smell.
The patient suffers from relapsing fevers, no improvement is achieved using proven wound-managing systems, and antibiotics do not reduce the infection.

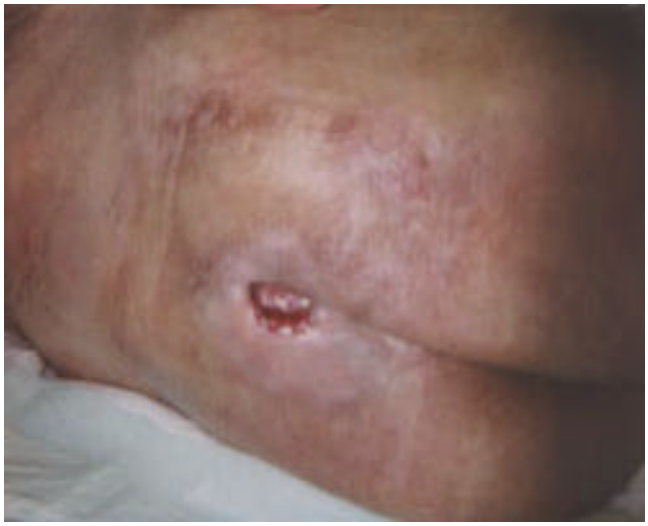
7th June, 2000
Start of magnetic field therapy, level 3, twice daily for 8 minutes.

6th July, 2000
The ulcer has visibly improved and is very well circulated.
Since the start of magnetic field therapy there has been no more fevers and no further infections of the decubitus ulcer.

21st September, 2000
The ulcer is without coating. The wound pocket is clearly smaller and the left side of the wound does not show any tendency for pocket building. Granulation tissue is growing from the side of the wound towards the centre. The general condition of the patient remains diminished, but stable.



CASE 3 10TH JUNE 2000



CASE 3 21ST SEPT. 2000

Case 4

38 year old female patient

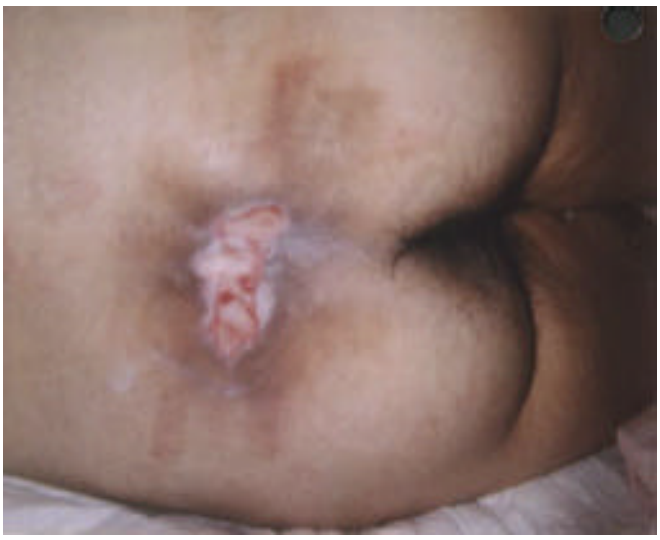
Diagnosis on admission: - St.p. strangulation
- apallic syndrome
- symptomatic epilepsy

Due to the relapsing respiratory infections caused by the patient's primary illness (total immobility) and the resulting bad blood circulation, the patient develops a sacral decubitus ulcer on the 10th May, 2000. Despite various therapy approaches there is no sign of improvement. Under consideration of the symptomatic epilepsy and the related relative contra indication of the magnetic field, the therapy was started with specific attention to the possible occurrence of epileptic fits.

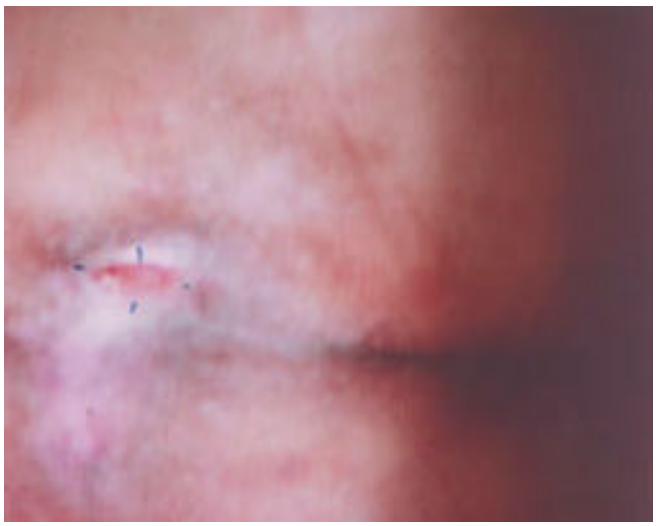
30th May, 2000
Start with magnetic field therapy, level 3, twice daily, 8 minutes

The infections become rarer and the decubitus ulcer is looking much better.

22nd September, 2000
The sacral decubitus ulcer is nearly healed (minor surface defect)



CASE 4 10TH JUNE 2000



CASE 4 22ND SEPT. 2000

Case 5

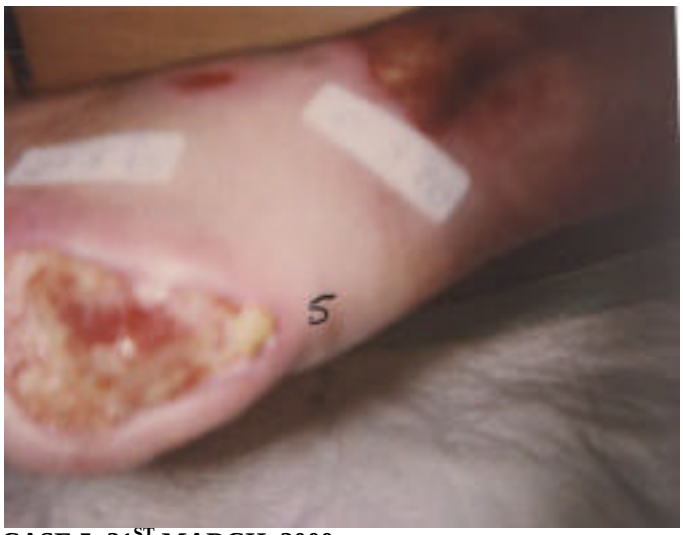
76 year old female patient

Diagnosis on admission: - **Ulcera cruris (multiple ambilateral)**
- **Parkinson syndrome (++)**
- **Multiple infarcts**
- **Diabetes mellitus**
- **Art. Hypertonus**

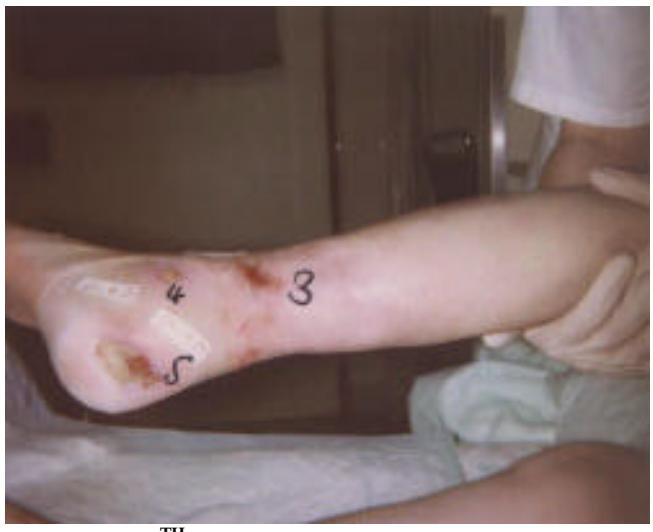
There is a stagnating healing tendency of the ulcera cruris
Increasing pain requires stronger pain treatment.

27th June, 2000
Start with magnetic field therapy, level 3 for one week, then level 4, twice daily for 8 minutes

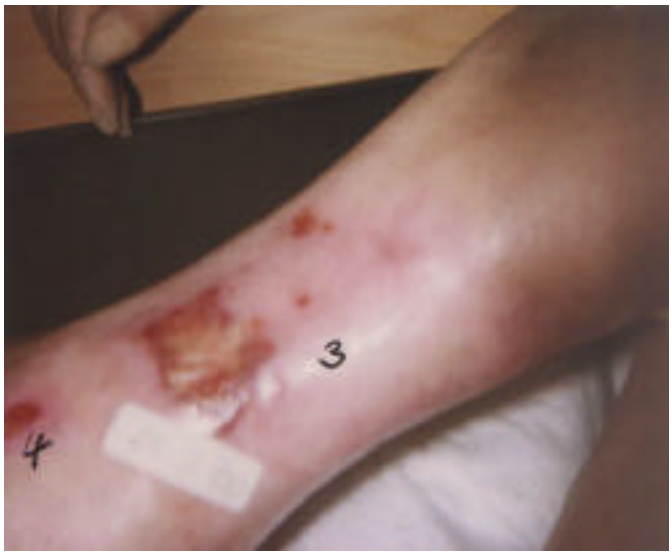
21st September, 2000
At present a very good healing tendency can be observed. The pain treatment could be stopped altogether.



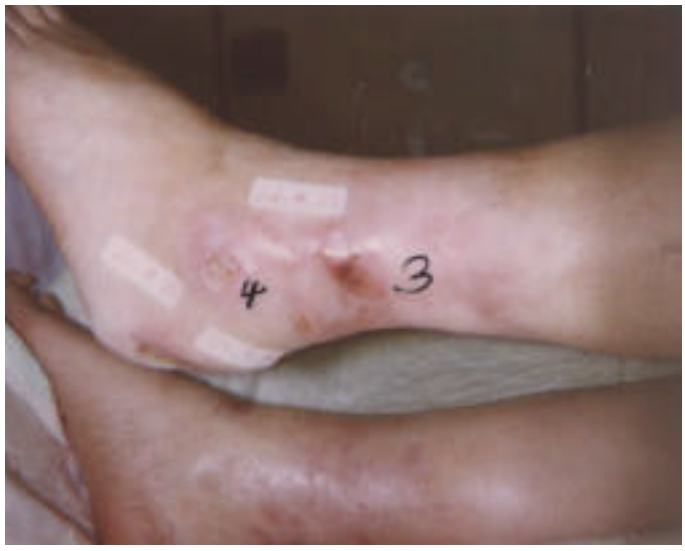
CASE 5 21ST MARCH, 2000



CASE 5 24TH SEPT. 2000



CASE 5 21ST MARCH 2000



CASE 5 24TH SEPT. 2000

Case 6

82 year old female patient

Diagnosis on admission:
- **IDDM**
- **Relapsing infections**
- **PNP**
- **Parkinson syndrome**

The patient has been an in-patient in GKH (geriatric hospital) since 7th October, 1999. During the entire time she continues to relapse due to her diabetic metabolism.
On 10th September 2000 a decubitus ulcer develops on her back, due to bad blood circulation the ulcer is spreading fast. It has a very unpleasant smell and is coated.

10th September, 2000
Start with magnetic field therapy, level 3, twice daily, 8 minutes

21st September, 2000
The ulcer is clearly defined, shows diminished signs of infection and the smell has disappeared.