0EUR MED PHYS 2004;40(Supp. 1 to No. 3):594-8

Gonarthrosis: Treatment with Horizontal® Therapy Electrotherapy. Multicenter Study

R. SAGGINI[1], R. CARNIEL[2], V. COCO[3], F. CANCELLI[2], M. IANIERI[2], D. MACCANTI[1]

[1] Chair of Physical and Rehabilitative Medicine,
University "G. D'Annunzio", Chieti;
[2] C.U.M.S. University "G. D'Annunzio", Chieti;
[3] School of Specialization in Physical and Rehabilitative Medicine,
University of Catania

Introduction

Osteoarthritis is a degenerative joint pathology characterized by the progressive destruction of joint cartilage, bone sclerosis and particular osteochondral proliferation, which is clinically manifested by pain exacerbated by movement (initially localized to one or few joints) and progressive functional impotence.

Symptomatology onset, often limited to just one joint, is insidious and undermined by subjective symptoms: pain is initially exacerbated by movement of the joint, especially after a period of immobility, typically on waking in the morning. In a successive phase the pain also appears after prolonged use of the joint, especially in the evening, and goes away on resting. In severely affected joints the pain may reappear even during nightly rest. Intensification in pain may occur on the appearance of a more important inflammation, independently of joint use. There is also a muscular contribution to the onset of pain, as there is often an accompanying antalgic contraction. Pain is often intensified by changes in the weather. Morning stiffness lasting just a few minutes is common, such duration being considerably less than that seen with inflammatory joint diseases. The stiffness recedes with gradual mobilization of the joint which progressively "warms up" and regains functionality.

Objectively, the joint may present hard swellings due to osteophytic proliferation and capsule thickening. Palpation may highlight localized pain. The skin above may be hot, but is not usually reddened, unless inflammation is increased in which case fluid build-up may also be noted. On passive mobilization there may be joint crepitation, demonstrating the loss of kneecap congruity (Figs. 1 and 2).

In addition, there will also be some limitation in joint function, at first limited to a few of the possible movements, initially due to antalgic muscular contraction and subsequently to altered knee cap morphology (Figs. 1 and 2).
Osteoarthritis therapy is multi-disciplinary.

When the affected joint is not too painful, gradual exercise is useful in maintaining mobility.
Especially painful attacks may benefit from the assumption of various drugs, such as salicylates (acetylsalicylic acid) or other non-steroidal anti-inflammatories (NSAIDS) such as naproxen, ibuprofen, ketoprofen, diclofenac, and nimesulide,

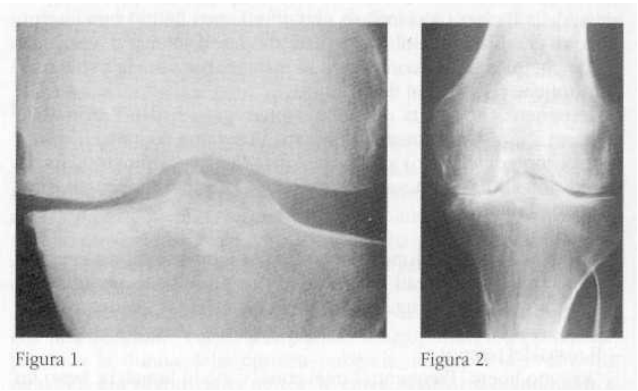

Figura 1. Figura 2.

Figures 1-2 – Radiography demonstrating the reduction in articular rim of the knee joint. In figure 1 (initial stage), the reduction is not uniform, while in figure 2 (advanced stage) it seems much more uniform.

which act as excellent pain symptom reducers. Pharmacological therapy can also make use of chondroprotecting drugs which offer excellent basic support.

Rehabilitation objectives are regaining of function, possibility of recovering new, more developed motor behavior and the adaptability of a skeletal region to more motor tasks. It is often the case that even for the most common motor actions the patient is constrained to use altered movements, in which compensation is sometimes excessive in comparison with that actually needed: the rehabilitative intervention will act exactly at this level.

However, while the problem of joint limitation and reduced muscle recruitment can be confronted with appropriate use of therapeutic exercise in its various applicative possibilities, the approach to pain is more complex, above all in relation to the multitude of possible originating structures and causes. This characterizes the therapeutic choice after careful and exhaustive evaluation.

As already noted, pharmacological treatment of painful symptomatology in these cases is obviated through opportune assumption of pain relievers. However, pharmacological therapy can also be flanked or even

substituted in some case by the use of specific electric currents with an analgesic action. Numerous studies have demonstrated the efficacy and usefulness of electric therapies in the treatment of the pain characteristic of degenerative pathologies, while in international literature there have even been papers illustrating the action of new electrotherapy forms in a biological context.
Electrotherapy is considered as a branch of physical therapy which uses electrical current for therapeutic purposes.

All live tissue cells use both electricity and chemistry in every process: for example, electrical processes are used in metabolism, in trans-membrane mechanisms in transmission of pain signals, in inflammatory processes, in muscular contractions and for transmission of nerve signals.

All these processes are always accompanied by biochemical processes, and vice versa, i.e. chemical processes are always simultaneously accompanied by electrical processes.

The use of electricity in the form of electrical currents thus has the aim, within the therapeutic objectives, of influencing the electrical processes in cells.

Horizontal® Therapy is a generation of electrotherapy used in the treatment of osteoarthritis due to its ability to stimulate both deep-down and surface joint tissues, simultaneously obtaining both bioelectrical effects (deriving from low frequency, variable intensity stimulatory therapies) and biochemical effects (deriving from non-stimulatory, medium frequency alternating current therapies).

Interferential therapy

This form of therapy was developed by combining the action mechanisms discovered in both classes to produce greater inter-cell communication (function imitation principle).

Interferential therapy requires the application of 4 electrodes: crossing two medium frequency circuits (e.g. 4000 and 4010 Hz) where in the centre, the meeting point of the two circuits, the frequencies neutralize each other, producing low frequency i.e. bioelectric effects (4010-4000 = 10 Hz).

Interferential therapy is characterized by the different effects obtained in diverse treatment zones: live tissue in the centre of the treatment area is deeply bioelectrically stimulated. In areas beyond the meeting point (near the electrodes) surface biochemical effects are obtained.

In contrast with the various forms of traditional electrotherapy, Horizontal® Therapy is able to simultaneously combine all action mechanisms, horizontally exceeding the stimulation threshold and utilizing a constant electrical intensity setting, with biochemical-type frequencies (over 1000 Hertz). According to Wyss, an increase in frequency leads to an equal increase in intensity, achieving a physiological effect. Horizontal® Therapy exploits this concept, keeping electrical intensity constant and modifying only the frequency.

In effect, we are “horizontally” crossing the stimulation threshold in the low frequency rhythms to create an action potential, and simultaneously keeping the intensity constant, for biochemical effects. Bioelectrical effects are thus produced by creating the action potentials. Biochemical effects are achieved by keeping the intensity constant. It is clearly noted that Horizontal® Therapy is able to achieve both effects simultaneously in the same treatment area. By varying the frequency, i.e. how many times a second the stimulation threshold is crossed, various bioelectric effects can be obtained. With regard to intercellular effects, chondrocyte energy production occurs primarily through glycolysis, i.e. anaerobically. Glycolysis begins with the phosphorylation of glucose through the enzyme hexochinase. The necessary phosphate is derived from adenosine-triphosphate (ATP), creating adenosine diphosphate (ADP). Magnesium is necessary to activate hexochinase. In all glycolysis stages the substrates contain one or two phosphoric acid residues. All substrates in intermediate products, apart from the sugars glucose, fructose and glycerine, are organic acids. This means that all substrates are in the form of ions and thus directly exposed to the Horizontal® Therapy electric field forces. The enzymes, the foundation of the various glycolysis reaction phases, are also electrically charged. Furthermore, the enzymes and substrate molecules react with one another in well defined positions, through opposite electrical charges. In this way Horizontal® Therapy has an effect which facilitates metabolism. Through its alternating electric field, with a frequency of many thousands of oscillations per second, the probability of an encounter between substrate and enzyme is increased. The probability of an encounter between a substrate molecule and an enzyme molecule in their specific reaction position is improved. These effects prevalently occur in the cells, favoring metabolism. Chondrocytes and cells, involved in the inflammatory process, thus perform a repair function.

In synovial liquid and the cartilage tissue matrix, rich in water, an alternating electric field induces the effect of equilibrating concentrations. Only inorganic and organic ions are directly exposed to the electrical force of the alternating field and they move in oscillation. This Horizontal® Therapy effect favors diffusion and thus distribution of pain mediators and is particularly important for patients with osteoarthritis, who due to pain are forced to control and reduce their joint movement. Through higher intensities, well tolerated by the joints, a further effect is added which blocks the fibers transmitting pain.

The aim of this multimember study, effected in 5 Italian centers and coordinated by the Chair of Physical and Rehabilitative Medicine of the University G. D’Annunzio, was to verify the usability and efficacy of Horizontal Therapy in a functional re-education program in a sample of subjects with moderate osteoarthritis of the knee.

Materials and Methods

After abundant analysis of the tool's physical characteristics and the cellular modifications it induces, 200 subjects, 100 male and 100 female, mean age 62 (56-74) were enrolled in this study in the period December 02 to April 03. They were studied for 12 months and were selected on the following basis:

- patients who were diagnosed with a moderate osteoarthritic process in the knee joint according to the Kellgren-Lawrence classification, enrolling subjects presenting knee flexing of not more than 100°.

The application method with respect to frequency and electrode position was chosen from those suggested in the international instruction manual tables.

The 200 cases were followed meticulously, with particular attention to pain, swelling and joint movement limitation, as the most frequently encountered elements. Their modification was evaluated vertically for the 200 subjects (that is, at the end of treatment and 1, 3, 6 and 12 months after its end), studying VAS progress.

With respect to management aspects, HT requires a longer treatment time than traditional electrotherapies, with c. 30 mins therapy plus 5 mins for electrode positioning.
The 200 patients analyzed in our study had a mean age of 62 (max. 74, min. 56) (Tabs. I and II)

Table I – Patient age

Age	Number	%
0-20	-	-
21-40	-	-
41-60	30	15
61-80	170	85
> 81		

Table II – Patient sex prevalence

Sex	Number	%
Males	100	50
Females	100	50

In the cases analyzed the use of Horizontal Therapy was proposed through cycles of 10 sessions.

18 men and 12 women left the study and follow up and were excluded from statistical analysis, as they had undergone physical treatments of various types, all from the end of the third month of treatment.

The VAS values before treatment (baseline), at the end of treatment and at 6 and 12 month follow-ups were processed for arithmetical means and standard deviations. Anova for repeated measurements enabled evaluation of statistical significance among VAS variations during the follow-up (within STEP factor).

The Wilcoxon test was applied to evaluate the statistical significance of VAS modifications at diverse control STEPS of the experimental group.
The different VAS results at every STEP were verified with the Mann-Whitney test, whose results are reported in the figure.

Data were recorded and statistically analyzed with the SPSS program 7.5 for Windows 95 (Tab. III).

Table III - Most common symptoms in analyzed patients

Symptoms	Ratio	% of presence
Pain	200/200	100
Stiffness	200/200	100
Contraction	90/200	45
Hypertrophy of muscles around joint	180/200	90
Fluid build-up in joint	65/200	32.5
Presence of fluid build-up	30/200	15
Joint crepitation on movement	60/200	30

Some patients presented one or more of these symptoms on observation.

The frequencies used in our osteoarthritis-specific treatment are those given in the programs already memorized in the Hako-Med PRO ElecDT® 2000 apparatus in the "osteoarthritis" file.

From the three sub-files present the two used during our study were: Osteoarthritis with strong pain, in 125 cases, and Osteoarthritis with strong swelling, in 65 cases where there was fluid build-up (Tab. IV).

Table IV – Reference protocols

Program	Number	%
Osteoarthritis with strong pain	125	67.5
Osteoarthritis with strong swelling	65	32.5

Table V – Sittings effected

Number of therapies	Number	%
0-2	-	-
3-5	-	-
6-8	-	-
8	-	-
10	200	100

Analysis of results

Our main objective in this study was to evaluate the efficacy of Horizontal Therapy in articular pathology such as osteoarthritis, both immediately after the end of the cycle effected in patients and in the short term of one month after the end of treatment, medium term of 6 months and long term of 12 months. Parameters considered for evaluation were the variation in assumption of pain relievers (Tab. VI), the subjective pain index through VAS scale, following therapy Tabs. VII, VIII and IX) and improvement in joint range (Figure 3).

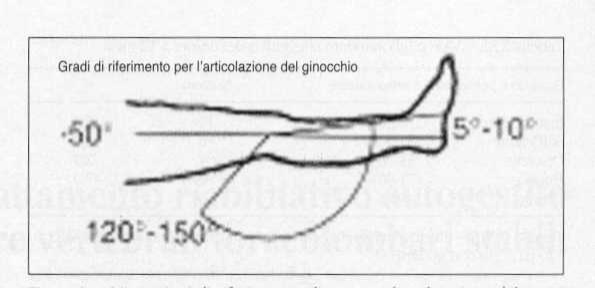

Figure 3 - Reference measurements used in evaluation of joint range; Reference angle for knee movement

Table VI – Use of drugs before an after Horizontal® Therapy (HT)

				Follow-up		
Drugs		Number of patients				
	Dosis/day	Drugs used before HT	Drugs used after HT	No Drugs after 3 months	No Drugs after 6 months	No Drugs after 12 months
Nimesulide	2	64	0	20	34	46
Piroxicam	2	52	0	26	18	33
Ketoprofen	1	30	0	21	29	26
Diclofenac	1	40	0	18	27	34
Salicylates	1	14	0	2	6	12
Total		200	0	87	114	151

As can be seen from the table VI, in the short term following Horizontal® Therapy assumption of non-steroidal anti-inflammatories and pain relievers completely stopped and this data remained significant ($p \leq 0.001$) at 3 months and also at 6 months ($p \leq 0.05$).

In the vast majority of cases, 58 out of 65, the values of the considered parameters improved with a visible reduction of swelling in those subjects where it was present (although this was not demonstrable through objective measurement).

Table VII – VAS initial, at the end of HT treatment, and 1 to 12 months after HT treatment

	Number of patients (%)											
			Follow-up									
VAS	Initial		End of treatment		1 month		3 months		6 months		12 months	
0 – 2	0		108	(54)	108		68	(40)	34	(20)	8	(5)
3 – 5	20	(10)	92	(46)	64		102	(60)	52	(31)	130	(76)
6 – 8	142	(71)	0		28		0		80	(47)	22	(13)
>8	38	(19)	0		0		0		4	(2)	10	(6)
10	0		0		0		0		0		0	
Total	200		200		170		170		170		170	

Table VIII – VAS subjective improvement in pain at end of HT treatment, and 1 to 12 months after HT treatment

		Number of patients (%)									
		Follow-up									
		End of treatment		1 month		3 months		6 months		12 months	
Insufficient	0-30%	0		0		0		10	(6)	10	(6)
Sufficient	31-50%	0		0		32	(16)	52	(30,5)	76	(45)
Fair	51-70%	24	(12)	48	(24)	30	(15)	108	(63,5)	4	(2)
Good	71-90%	100	(50)	120	(60)	126	(63)	0		80	(47)
Excellent	>90%	76	(48)	32	(16)	12	(6)	0		0	
	Total	200		200		200		170		170	

Table IX – Results of follow-up after treatment with HAKO in 170 patients with gonarthrosis

	VAS (mean ± SD)			
		Follow-up		
	Baseline values	End of treatment	6 months	
Gonarthrosis (n=170)	7.43±1.64	3.88±1.71*	3.9±1.38**	5.80±1.34***

*p<0.01 Wilcoxon test: end treatment vs. baseline values
**p<0.05 Wilcoxon test
**p<0.01 Wilcoxon test: 6 months vs. end treatment
*** p<0.01 Wilcoxon test: 12 months vs. 6 months
† p<0.01 Wilcoxon test: 12 months follow-up vs. end treatment.

Considerations and conclusions

1. From examination of the results obtained in this study, it can be seen that treatment with Horizontal Therapy is effective in a statistically significant way in the short and medium term.

2. After treatment (VAS2 vs. VAS1) a significant reduction of pain (Tab. IX); the stabilization expressed by objective and subjective VAS and the reduction in anti-inflammatory drug assumption is statistically significant for up to three months to
three months for the sample of 200 subjects and then in a population sample reduced by 15% at 6 months. In the 12 month checks maintenance of an appreciable result is highlighted subjectively in 40% and objectively in 15% of the population studied.

3. Use of this form of physical energy is thus important in the size of therapeutic impact that the physiatrist must plan in formulating the rehabilitative treatment of subject with osteoarthritis, in particular in the knee.

Bibliography

1. Cisari C, Severini G. Fisioterapia clinica pratica: Laserterapia- Ultrasuonoterapia-Elettroterapia.
2. Geddes, IA, Baker, IE, Moore AG, Couiter, TW. Hayards in the Use of Low Frequencies for the Measurement of Physiological Events by Impedance. Med. & Bio. Eng. 1969;7:289-96.
3. Hansjürgen A, Mayer-Waarden K. Feldverteilung ausgewählter Parameter interferierender mittelfrequenter Ströme in inhomogenen biologischen Medien. Biomed. Technik Ergänzuingsband. 1980;25:298-300.
4. Hodgin AL, Horowicz P.: Potassium contractures in single muscle fibres. Journal of Physiology. 1960; 153:386-403.
5. Kottle - Stillwell – Lehmann: Trattato di terapia fisica e riabilitazione.
6. Kumazawa T. Excitation of muscle fibre membrane by means of transversely applied middle-frequency current pulses. Helv. Physiol. Acta 1968/69;26:257-69.
7. Lehninger, A.L.- Biochemie (2, Auflage). Weinheim, New York. Verlag Chemie, 1979.
8. mcGraw – Hill: Malattie reumatiche
9. Meyer-Waarden K. Hansjürgen s, A, Friedmann B. Darstellung elektrischer Felder in inhomogenen biologischen Medien. Biomed. Technik 25, Ergänzungsband , 1980; 295-97.
10. Nernst W. Zur Theorie des elektrischen Reizes. Pflügers. Arch. 1908;122, 275-314.
11. Netter F: Atlante di anatomia, fisiopatologia e clinica. Volume 8. Apparato muscolo-scheletrico parte II
12. Nikolova L. Balchev: Röntegenologischer Verlauf der Sudeck- 0steoporosis nach Interferenzstrombehandlung. Med. Klinik 1977;72:751-3-
13. Nikolova, L.: Lecenije s interferenten tok (trattamento con corrente Interferenziale). Sofia: Medicina I Fiskultura, 1971.
14. Nikolova L.: Physiotherapeutische Rehabilitation bei Knochenbruchkomplikationen. Munich. Med. Wschr. 1969;111:592-9,
15. Nikolova L. Treaunent with Interferential Current. Edinburgh, London, Melbourne, New York. Churchhill Livingstone, 1987.
16. Nikoloya-Troeva L. Physiotherapie der chirurgischen Erkrankungen, München, Berlin, Wien: Urban & Schwarzenberg, 1970.
17. Perfetti *et al*. Riabilitazione ed apprendimento 1994;3/4
18. Pfluger E. Untersuchungen über die Physiologie des Electrotonus. Berlin: August Hirschwald, 1859.
19. Pizzetti Caruso. La cartella per la pianificazione del trattamento rabilititativo.
20. Prentice WE: Tecniche di Riabilitazione in medicina dello sport.
21. Senn E. Reactive depoloralization of muscle fibre membrane with slowly increasing middle frequency current flow. Exper. 1969;25:948-9.

22. Senn E. Wirkungsweise der Niederfrequenzetherapie. Z. f. Unfallmedizin und Berufskrankheiten 1978;1:21-41.
23. Wyss OAM. Nouveau princip de stimulation électrique: L'Excitation ambipolaire par courant alternatif, sinusoidal pur, de fréquence moyenne. Expet 1962a;18:341-2.
24. Wys OAM. Nervenreizung mit Mittelfrequenz-Stromstößen. Helv. Physiol. Acta 1976;25,85-102.
25. Wyss OAM. Principe "apolaritarie" de la stimulation électrique per courant alternatif de fréquence moyenne. Ran. Internaz. Elettr. Nucl. IX Congr. Internaz. Elettronica, Roma, 1962d;1-14.
26. Wyss OAM. Principi della stimolazione elettrica, 1976.
27. WM OAM. Elektrische Reizung nach neuem Prinzip. Experimentelle Grundlagen und praktische Erfolgsaussichten der Mittelfrequenzreizung. Schweiz. Med. Wschr. 1962c;92:1531-7.
28. Wyss O.AM. Die Reizwirkung mittelfrequenter Wechselströme. Helv. Physiol. Acta 196321:173-88.
29. Wyss OAM. Querreizung des Nerven mit mittelfrequentem Wechselstrom. Helv. Physiol. Acta. 1962b;20:C10-C11..
30. Dowdy PA, Cole BJ, Harner CD. Knee Arthritis in Active Individuals: Matching Treatment to the Diagnosis. The Physician and SportsMed. 98; 26:6.
31. Sun Y, Sturmer T, Gunther KP, Brenner H. Incidence and prevalence of cox-and gonarthrosis in the general population. Z Orthop Ihre Grenzgeb. 1997;135:184-92.
32. Røgind H, Bibow-Nielsen B, Jensen B, *et al.* The Effects of a Physical Training Program on Patients With Osteoarthritis of The Knees. Arch Phys Med Rehabil. 1998,79.
33. Fransen M, Crosbie J, Edmonds J. Physical theraphy is effective for patients with ostearthritis of the knee: a randomized controlled clinical trial. J Rheumatol. 2001;28:156-64.
34. Vangness CT, Ghaderi B. A literature review of lasers and articular cartilage. Orthopedics. 1993;16:593-8.
35. Trock D, Bollet A, Markoll R. The effects of pulsed electromagnetic field in the treatment of ostearthritis of the knee and cervical spine. Report of randomised, double blind, placebo controlled trials. J Rheumatol. 1994t;21:1903-11.
36 Welch V, Brousseau L, Peterson J, *et al.* Therapeutic ultrasound for osteo-arthritis of the knee (cochrane Review). Cochrane Database Syst Rev. 2001;3:CD003132.
37 Gigante G, Severini G. Tempia fisica strumentale. Milano, Italy: Edi-Ermes; 1997.
38. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Ann. Rheum. Dis. 1957;16:494.501.
39. Scott - Huskisson EC. Graphic representation of pain. 1976;2:175.
40. Fisher NM, Pendergast DR, Gresham GE, Calkins E. Muscle rehabilitation: Its effect on muscular and functional performance of patients with knee osteoarthritis. Arch Phys Med Reabil. 1991;72:367-74.
41. Fisher NM, Gresham GE, Abrams M, *et al.* Quantitative eftcts of physical theraphy on muscular and functional performame in subjects with osteoarthritis of the knee. Arc Phys Med Rehabil. 1993;74.840-51.
42. Berger RG. Nonsteroidal anti-infiammatory drugs: making the right choises., J Am Acad Orthop Surg. 1994;2:255-60