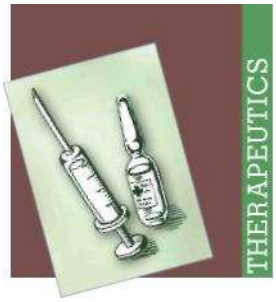


G.Posabella

PATELLO-FEMORAL CHONDROPATHY TREATED WITH MD-KNEE + ZEEL® T TRANSMITTED WITH O2 VS NIMESULIDE + CHONDROITIN SULPHATE

(TERAPIA DELLA CONDROPATIA FEMORO-ROTULEA CON MD-KNEE + ZEEL® T VEICOLATI CON PROPULSIONE DI O2 VS NIMESULIDE + CONDROITINSOLFATO)

SUMMARY

The aim of this study is to evaluate the effectiveness of the treatment with a new method, the propulsion of high pressure O_2 (2.5 atm) to transmit MD-KNEE + Zeel® T in patients with patello-femoral chondropathy *vs* controls receiving nimesulide + chondroitinsulphate.

– 40 patients (divided into 2 Groups) were administered 2 questionnaires to record the degree of disability resulting from the chondropathy; it has been adopted the WOMAC Index for the pain scale, function and stiffness of lower limbs and the Lequesne Index concerning the functional limitation. The evaluation was performed before treatment and after 1, 2, 3, 6 and 12 weeks since the first administration. The conveyance of MD-KNEE + Zeel® T was performed with the propulsion of O_2 (98%), 2.5 atm pressure, supported by a device leaned on the skin, once a week for 12 weeks *vs* a daily oral administration of nimesulide + chondroitin.

– The results were evaluated with t Student and are statistically significant at $p < 0.0001$, both with the WOMAC index of pain, stiffnes and joint function and with the scale, that assesses the Lequesne algo-functional index in patients receiving O_2 + MD-KNEE + Zeel® T. It is noteworthy the absolute lack of side effects in the Group treated with O_2 infusion + *low dose* medication + medical device in addition to the low cost of treatment if compared to that of the Group treated with oral conventional medications.

KEY WORDS:

PATELLO-FEMORAL CHONDROPATHY, MD-KNEE, ZEEL® T, NIMESULIDE, CHONDROPROTECTORS, PHYSIATRICS,ORTHOPAEDICS

INTRODUCTION

Chondropathies are generically defined as cartilage tissue stress.

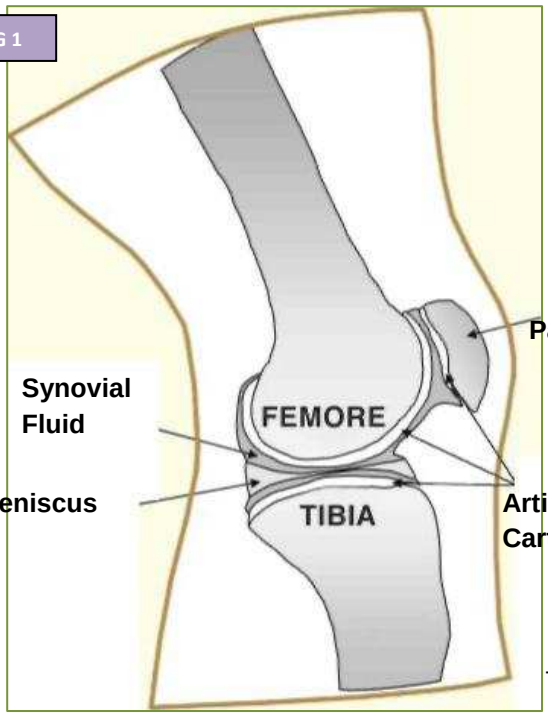
- Patellofemoral chondropathy is a pathology of the articulation with a repeated mechanical microtraumatic etiopathogeny.

(FIG. 1)

Articular cartilage is formed by an elastic connective tissue which covers the extremities of the articular heads, and is endowed with considerable resistance to pressure and traction.

- An incorrect articular biomechanic, where there is a repetition of micro-traumatic

FIG 1



Schematic Anatomy of knee, lateral standard.

-With patellar Chondromalacia the patella is damaged. Vey rarely does the cartilage reach an ulcerous state with exposure of the bone underneath.

phenomena, can generate cartilaginous stress of the femoral trochlea and the rotula.

The function of the cartilage is similar to that of *shock-absorbing ball-bearings*, safeguarding normal articular relations and permitting movement(FIG.2).

- To further facilitate a friction-free movement, the articulation produces synovial fluid, a viscous liquid which acts mainly as a lubricant.

Healthy cartilage allows a reciprocal smooth movement between the articular surfaces and acts as a shock –absorber during movement.

Chonromalacia patellae presents with an anatomical pathology of damage to the cartilage of the rotula and the femoral trochlea, which faces thepatella. The lateral compartment is that most frequently affected.

The lesions can be of greater or lesser degrees of gravity, depending on the seriousness of the damage to the cartilage. (FIG.3)

- Often, patients affects from this pathology show some incorrect bio-mechanical peculiarity: the **Q angle** of the knee (the angle between the femur and the tibia)

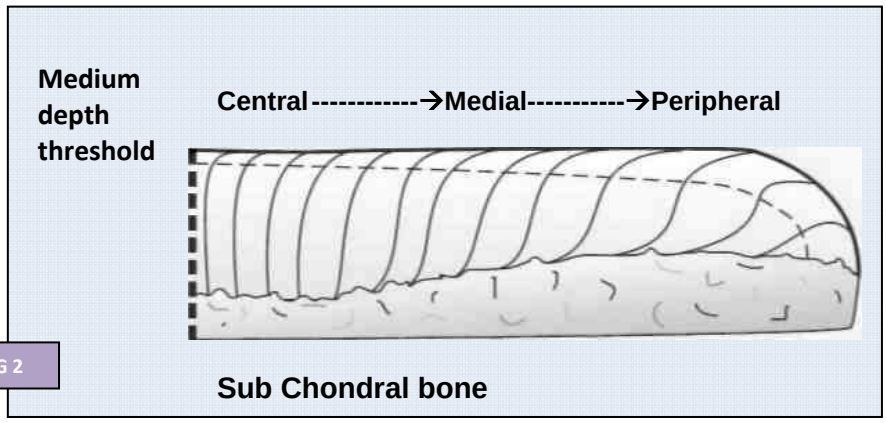


FIG 2

Schematic representation of nornale collagen fibers.
–The laminae are indicated according to the position of the articulation.

is more open in the middle, with a tendency to bow-leggedness /valgus condition; the tibia is in an extra-rotatorial position; there can present an excessive tension of the mm. Crural ischium, which creates a greater force of impact between the trochlea and the patella; anatomically, the latter can be high (*retracted quadricipital tendon*), or low (*retracted rotular tendon*).

A frequent area of intrinsic poor alignment is the direction of the *patellar ligament* in reference to the mechanism of the extensor muscles, defined as Q angle. (FIG 4).

This angle expresses the relation between the ant. tibial tuberosity and the ant. sup. iliac spine; it is determined -in the distal direction- by the intersection of a segment traced from the ant. sup. iliac spine to the center of the rotula with a segment that joins the ant. tibial tuberosity to the center of the rotula.

- The Q angle is normally inferior to 10° in the male and to 15° in the female. The upper limit of a standard Q angle is between 13° and 15°.

A Q angle > 15° can depend on a femoral ante-version increase , on an external tibial torsion and on a lateralization of an ant. tibial tuberosity, which can determine an increase in the forces which lateralize the patella during muscle contraction, according to " the valgus' law".

- It is necessary to mention the concept of the "static" Q angle and the "dynamic" Q angle. In this case a hypotonic VMO (an oblique part of a medial muscle) can transform a static Q angle, of standard measurements, into a dynamic Q angle predisposed for patello-femoral pathology.

The decrease in size of the Q angle does not cause a possible medial dislocation of the rotula, but, by increasing the varum

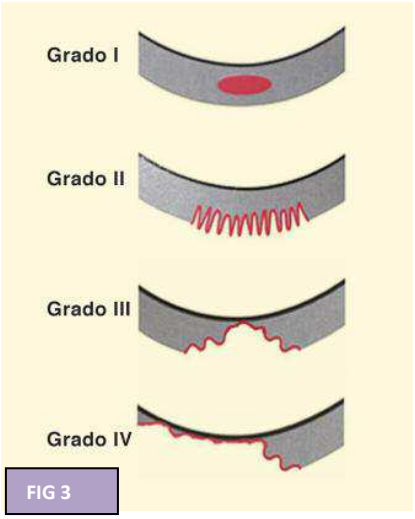


FIG 3

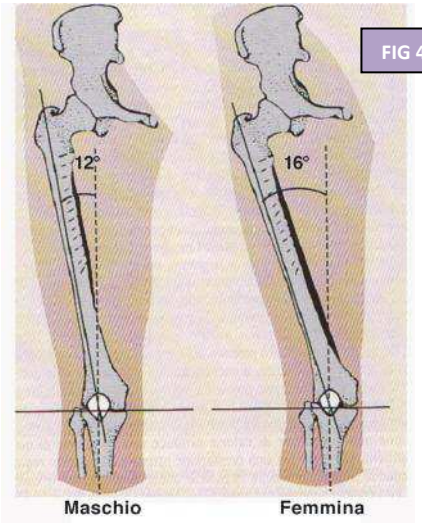


FIG 4

Measuring the Q angle allows us to evaluate the alignment of the extensor system of the lower limb.

– In a poor aligned knee, its' value increases or diminishes with respect to normal values, which differ slightly according to sex.
An increased valgus condition means an increase in the Q angle

.

orientation of the knee's articulation, it is responsible for an increase in the compression of the medial tibiofemoral compartment and for a consequent progressive damage of the medial articular compartment.
One must keep in mind that the articular cartilage, generally speaking, finds its original shape after intense, but limited in time, strain.

On the contrary, after lesser intense, but longer lasting strain (endurance or great endurance sports), the cartilage shows a marked mechanical damage

Clinical femoral anteversion is a clinical sign which appears when the internal rotation of the femoral diaphysis brings the medial femoral groove with respect to the ant. tibial tiberosity and the *patellar ligament* to a more lateral position respect to the rotula, increasing –thus- the lateral vectorial pressure which acts on it during the contraction of the quadriceps muscle.

Another intrinsic factor is represented by the laxity of the anteromedial quadrant of the rotula (both static and dynamic).
Static patella stability is guaranteed by the patello-femoral ligaments which surround the capsular tissue.
Diminished medial static stability, together with an excessive tension of the lateral compartment (retinaculum, aponeurotic ileotibial band) can cause an excessive tension in the structures.
- This poor alignment is defined as " lateral hyperpressure syndrome" and can be highlighted radiologically when the knee is bent at a **30°** angle.

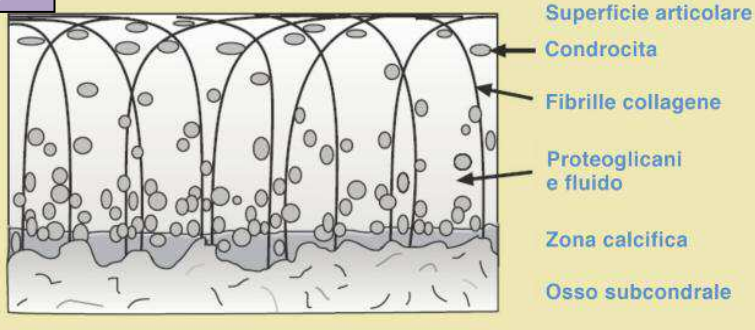
Regarding the dynamic part, patellar poor alignment can be the result of pathological mechanics of the VMO (hypo-development, dysplasic affectations, post lesion atrophy).
The VMO, infact, guarantees the dynamic stability of the patello-femoral articulation (it is the only medial dynamic stabilizer).
- Its insertion is at the III proximal of the rotula with an 55° angle with respect to its' vertical axis.

► Its particular action is to counterbalance the lateral vastus muscle (VL) during the contraction and to provide ligament tensioning.

In pathological conditions the VMO does not reach the upper III or the middle of the rotula, and its' action line is more vertical and –consequently- less effective.
The combination of these anomalies compromises the medial stabilizing function of the VMO.
EMG tests on healthy knee muscles have shown that the ratio between the activities of the VMO and of the VL is of **1:1** and that the VMO's is more tonic.

Tests performed on knees presenting the patella-femoral syndrome show a ratio VMO/VL < 1:1 and that the VMO's activity is phasic. This could be the result of a loss of asymmetry of the quadriceps muscle (an accumulation of 20-30 ml of liquid can inhibit the VMO, whilst an accumulation of 50-60 ml is needed to inhibit the VL's activity) and consequent lateral shift of the rotula.

FIG 5



TAB. 1

WOMAC Lower limb – PAIN
How much pain do you feel when:
• Walking?
• Going up or coming down stairs?
• At night, in bed?
• Getting up from, or lowering yourself onto a chair?
• Standing?

TAB. 2

WOMAC Lower limb – STIFFNESS
How stiff are your joints:
• When you get up in the morning?
• When you move after having been seated, or in bed,or after resting, during the day?

Even retraction or permanent hypertonia of the rectus femoris muscle can cause a patellar hypertension starting from 30°bend, determining also anterior pelvic tilt. In this case the ischio-crural muscles elongate, decreasing the vertical femoro-tibial brake favoring –thus- the anterior translation of the tibia and aggravating patellar overload.

- An important retraction of the ischio-crural muscle can determine a bent knee with rotatory disharmony.

►It is thus obvious how most of the patellar syndromes are the consequence of a **dysfunction of the extensor system** and, more in general, of the skeletal- muscle structures ,which have to be corrected with rehabilitation treatments or surgery.

The rotula, during the stretching and bending movements of the knee, runs along the femoral trochlea (patellar tracking): when stretching it runs upwards, when bending it runs downwards.

One must remember that cartilage is made of a liquid part (which allows for trauma absorption) and a solid part (which increases its resistance).

- Cartilage tissues are connective and their extracellular matrix (ECM) is noticeably dense, compact and solid. So solid in fact that it is able to imprison chondrocytes within. (FIG 5)

These, from inside the niches that host them, can go through 1 or 2 mitosis maximum, so -often- small groups (isogen groups) of 2, 3, or 4 chondrocytes can be seen.

- The most representative component of cartilage is chondroitin sulphate; its molecules are firmly tied to many sulphur bonds.

- Cartilage **is not vascularized**, this means that the cells can perform metabolic exchanges only by means of diffusion through the ECM.

CONSUMED KNEE CARTILAGE

The clinical expression of osteoarthritis has a varied symptomatology; its evolution is slow and not easily predictable. The clinical symptoms of osteoarthritis are: osteoarticular pain, articular rigidity, cracking, articular deformation, functional limitations.

Painful states

- They present themselves during deambulation, going up or coming down stairs;
- They increase under strain , together with short term morning rigidity.

Inflammatory states

- at times intense, can flare up at night time;
- presence of articular inflammatory liquid, often abundant.

TAB. 3

WOMAC Lower limb – FUNCTIONALITY
How much difficulty do you have:
• Coming down the stairs?
• Climbing the stairs?
• Getting up from a chair?
• Standing?
• Bending forwards?
• Walking on a flat surface?
• Getting in and out of cars?
• Carrying out your usual activities?
• Putting on your socks?
• Lying on bed?
• Getting in and out of the bath?
• Doing the daily cleaning?

In the more modern understanding, osteoarthritis is distinguished from the physiological ageing of cartilage and is defined as a proper sickness caused primarily by a metabolic alteration of the chondrocyte.

Patello-femoral chondropathy consists of a series of morphofunctional alterations which determine the insurgence of an anterior knee pain.
- From an etiopathogenetical point of view the basic alterations of this pathology are essentially ascribable to bad alignment, or to a dysplasia of the rotula and /or of the femoral trochlea.

In addition to the anatomic and biomechanics factors, there are a series of functional factors that, if occurring in the "predisposed" individual, can cause the insurgence or worsening of the symptomatology (age, weight, profession, practiced sports, etc.).

Lesion and pain in the knee structures are very common in the population because the rotula is interjected between the extensor system and subjected to great stress during sports practiced.
- The structures that can be associated with pain and patella-femoral instability include:

1. muscles
2. patellar tendon
3. the rotula (and its connections to the femoral groove)
4. patella-femoral and meniscus femoral ligaments
5. adipose pads (infrapatellar and suprapatellar regions)
6. bursae in the suprapatellar and parapatellar regions
7. the synovial membrane and the capsule in the anteromedial and anterolateral portion of the articulation

The pain localized in the patella-femoral articulation is frequently encountered clinically and requires various elements to be examined: anatomical alignment; static and dynamic stabilization system; level of activity to determine the mechanical articular stress.

THE LEQUESNE FUNCTIONAL INDEX

►Knee pain
A) Nocturnal
None/ Depending on movements/ Even when not moving.
B) Morning blockage
<1 min. / 1 – 15 min. / >15 min.
C) Standing still or walking downhill for half-an hour
No / Yes.
D) Walking
No/ After a certain distance /Immediately and progressively.
E) Getting up from a chair without using your arms to help you.
No / Yes/ > 15 min.

►Maximum length of a walk:
No limit / Limited, < 1 km / About 1 km (about 15 min.) / 500 – 900 mt (8 – 15 min.) / 300 – 500 mt / 100 -300 mt / <100 mt / With a stick or a crutch / With two sticks or crutches.

►Difficulties in daily life:
Going up one flight of stairs / Coming down one flight of stairs / Crouching / Walking on an uneven surface

TAB. 3

Patello-femoral articulation bad alignment can hesitate in a lateral patellar shift, associated to subluxation, dislocation or both.

Patellar instability can be classified in three different degrees:

I degree: patellar lateralization

The increase of the Q angle, during the extensor muscle contraction, causes a small contact area between the patellar and the trochlear articular surface.
- The consequence of this situation causes a lateral hyperpressure syndrome.

II degree: accentuated patellar inclination or patellar subluxation.
When there is an excessive patellar inclination a thickening and retraction of the lateral retinaculum associated with a capsular thickening occurs.
-This situation determines, during the bending of the knee, a patellar inclination which hesitates in a lateral hyperpressure. In the more serious cases an actual lateral patellar subluxation occurs, generally caused by a sudden contraction of the quadriceps muscle when the knee is extended.
- Recurring subluxations cause, in the long run, serious suffering of the patellar and trochlear cartilage.

III degree: patellar dislocation:
Condition causing a serious and progressive damage of the articular cartilage.

AIM OF THE STUDY

-Aim of this controlled randomized clinical study, is the evaluation of the clinical response of two homogeneous groups of patients affected by patella-femoral chondropathy to the administration of FANS + a protector of the cartilage vs MD (Medical Device – KNEE + Zeel T vehiculated by Oxygen Infusion.

MATERIALS AND METHODS

Different published clinical studies on hyperbaric O2 have demonstrated the benefits of this treatment in a variety of pathologies of the ECM.

Hyperbaric O2 therapy is used for support and for an anti-inflammatory action in osteomyelitis, wounds and necrotic sores, necrotic fasciitis, gangrene, pyodermitis, skin sores,

diabetic foot, psoriasis and purulent acne(1).
The effect of topic hyperbaric O2 therapy is due to the stimulation of chemo tactic action , of phagocytosis, of fibroblast proliferation and of collagen neo synthesis (mostly of type I and III), of epithelial proliferation and waterfall process final remodeling (2).
O2 present in the atmosphere penetrates the superficial strata of the skin up to a maximum depth of 0.25 – 0.40 mm, whilst O2 carried by the emetic flow has less impact on the superficial strata (3,4).
- An in vivo study [animal model(adult swine)] of Atrux-Tallau et Al. (5) has emphasized how O2 reaches the derma by:

1) **penetration** (capture)
2) **permeation**

Hyperbaric O2 therapy does not reduce the neutrophils vitality and functions such as degranulation and phagocytosis; oxidative lysis in response to the chemo-attractors is unaltered (6).

►**20 randomized patients** (Group A: 15 M, 5 F) were administered a weekly dose of **Nimesulide + Chondroitin sulphate;**

►**20 randomized patients** (Group B: 15 M, 5 F)were administered weekly doses of **MD-KNEE** (Guna Laboratories, Milano) + **Zeel T** (-Heel, Baden Baden-D), vehiculated by O2 Infusion.

All patients were informed of the aim and modality of the studies and written informed consent was required.

-When they were included, all patients were given 2 questionnaires to try and define the degree of incapacity induced by the Chondropathy.

The indexes used were: **WOMAC** (*Western Ontario and Mc Master Universities Osteoarthritis Index)* for pain, rigidity and functionality of the lower limbs (TABB 1,2,3) and Lequesne for functional limitation (TAB 4).

-The WOMAC is the main reference test for the measurement of the results deriving from the treatment of knee pathologies.
Each WOMAC *item* lists 5 possible answers (from “none” to “very strong”).

The Lequesne Index instead assigns a score to each answer up to a total which is registered and that represents the reference number for the subsequent measurements.

These measurement s are performed **before** the beginning of the treatment and after **1, 2, 3, 6, 12** weeks. The statistical analysis was performed using the t of Student.

-Each patient underwent a clinical test to measure his /her compliance to **patello-femoral Chondropathy** criteria.

Each patient, when he was included, showed recent Rx of the articulations.
-These were classified according to the Kellgren-Lawrence Scale.

The scale describes 4 phases of arthritis:

Phase I: initial not clearly determinable reduction of the articular space with possible presence of osteophytes; Phase II: osteophytes and possible reduction of articular space; Phase III: moderate osteophytosis , clearly defined reduction of articular space, subchondral sclerosis and possible deformation of the subchondral bone; Phase 4: severe arthritis.

- The study includes patients suffering from patello femoral chondropathy clinically and radiographically documented in phases I, II or III according to the Kellgren-Lawrence Scale.

The patients included in the study did not mention having had surgical procedures performed on the knee, nor rheumatic nor auto immune pathologies in the past or the present.

-The 20 patients of **Group A** received nimesulide sachets 100 mg + galactosaminglucuronoglican sulphate sodium salt 400mg (Condral) once a week per os.

-The 20 patients of **Group B** were administered 1 vial **Zeel T** + 1 vial **MD-KNEE** applied on the skin of the knee through Oxygen Infusion.

The patients were treated once a week after careful skin disinfection(alcohol or iodine based antiseptic solution).

The infusion of pure Oxygen (98%) technique was performed with a device which takes O2 from the surrounding air, concentrating it (Zeolite filters) and which –by means of a compressor- administers O2 at a pressure of 2.5 atm by means of a handpiece placed on the skin (Maya Beauty Engineering, Medical Oxyendodermia).
- The patient was placed in supine position with the knee slightly bent thanks to a popliteal cushion; Zeel T + MD-KNEE were mixed with a neutral serum solution and applied on the treated area.

-Immediately after this O2 at 2.5 atm was administered on the area for 20 minutes.

• In **Group A** (nimesulide + chondroitin sulphate) there were 15 M and 5 F, average age 46.9 (min 28, max 65), with Standard deviation (SD) 11.8; average BMI of 25.4 with a SD of 2.45. The average body fat percentage was also calculated (20.32 % with a SD of 7.04) taking into consideration neck, abdomen and, in females, also hip circumference.

- The average WOMAC score pre-treatment was of **59 points** (min 34, max 80), on a scale of 0 to096.
- The algo-dysfunctional average of the Lequesne Index was 1**8 points** (min 12, max 22) on a scale of 0 to 24. The treated knee was the right one in 15 cases and in 5 cases the left.

• In **Group B** (Zeel T + MD-KNEE +Oxygen infusion) there were also 15 M and 5 F, average age 49.4 (min 31 and max 66) with SD of 9.1; average BMI of 24.4 with SD of 2.4. the average body fat percentage was also calculated (26.11% with SD 17.8) taking into consideration neck, abdomen and, in females, also hip circumference.

- The average WOMAC score pre-treatment was of **58 points** (min 42, max 89)
- The algo-dysfunctional average of the Lequesne Index was **18 points** (min 12, max 22). The treated knee was the right one in 10 cases and in 10 cases the left.

RESULTS

All patients concluded the prefixed treatment period.
The results are presented according the group they belong to (A; B) and according to the 5 ***follow-up*** treatments which took place 1, 2, 3, 6, **12 weeks** after the first administration.

• After the **first week:** the patients of both Groups present a not statistically relevant decrease in the WOMAC total score, respect to the "base" score.
- The average score of Group A patients was of **54 points** WOMAC (min 30, max 78), p<0.374.
- The average score of Group B patients was of **50 points** WOMAC (min 34, max 74), p< 0.087.

• **Second week**: patients of both Groups present a decrease of the total WOMAC score compared to the previous sc ore.
- The average score of Group A patients was of **53 points** WOMAC (min 30, max 78), p<0.217.

- The average score of Group B patients was of **47 points** WOMAC (min 30, max 68), p< 0.0047.

• **Third week**: patients of both Groups present a decrease of the total WOMAC score compared to the previous sc ore.
-The average score of Group A patients was of **51 points** WOMAC (min 30, max 74), p<0.0109.
-The average score of Group B patients was of **47 points** WOMAC (min 30, max 66), p< 0.0031.

• **Sixth week**: between the 3rd and the 6th week from the 1st treatment in Group A, no variation has taken place in the average WOMAC score, whilst the average WOMAC score of the patients of Group B was statistically significant for the decrease in pain, rigidity and functionality.

- The average score of Group A patients was of **50 points** WOMAC (min 32, max 72), p<0.097.
- The average score of Group B patients was of **41 points** WOMAC (min 30, max 68), p< 0.0004.
The difference is statistically relevant (p<0.001)

• **Twelfth week:** the last follow-up performed showed that the average WOMAC score of the patients from Group A was of **47 points** (min 32, max 70), p<0.014.
- The average WOMAC score of the patients of Group B decreased even more reaching **39 points** (min 24, max 60), p<0.0001.
The difference between the 2 experimental Groups is statistically significative (p<0.001)
(TABB. 5,6,7).

Regarding the algo-dysfunctional Lequesne Index patients of Group A went from **18 to 15 points**, patients from Group B went from **17 to 10 points** (TABB.8,9).

	WOMAC BASALE	WOMAC 1ª settimana	WOMAC 2ª settimana	WOMAC 3ª settimana	WOMAC 6ª settimana	WOMAC 12ª settimana
M	36	30	30	30	34	34
	34	30	30	30	32	34
	66	54	54	50	52	48
	34	30	30	32	34	34
	72	68	64	64	66	55
	68	62	62	58	60	54
	68	62	64	62	60	56
	68	62	60	60	60	50
	70	68	60	58	52	48
	68	60	58	50	50	46
	68	60	58	54	50	46
	70	68	60	54	54	46
	66	60	60	58	60	48
	39	34	34	34	32	32
	70	70	68	66	66	64
F	80	78	76	74	72	70
	36	34	34	34	30	32
	34	30	34	34	34	32
	48	44	40	40	42	42
	78	74	70	70	68	66
	58,65	**53,9**	**52,3**	**50,6**	**50,4**	**46,85**
	16,68	**16,74**	**15,29**	**14,29**	**13,80**	**11,69**
	p	0,374401	0,217196	0,109516	0,096581	0,013509

TAB 5 :
group A

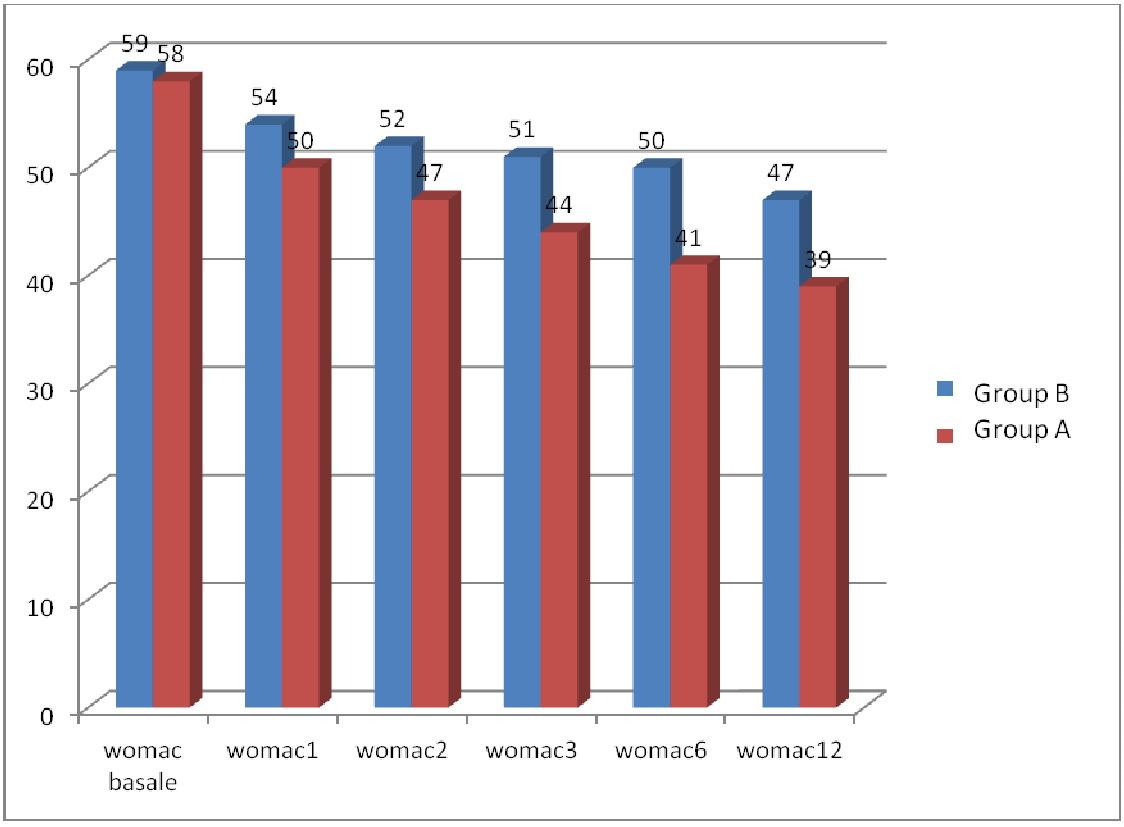
-analitic WOMAC (basale measurements and taken on week 1, 2, 3, 6 &12 ftom the beginning of the therapy)

	WOMAC BASALE	WOMAC 1ª settimana	WOMAC 2ª settimana	WOMAC 3ª settimana	WOMAC 6ª settimana	WOMAC 12ª settimana
M	42	38	38	36	34	28
	46	38	34	30	36	32
	64	60	48	48	52	44
	44	38	38	36	34	36
	89	74	68	66	68	60
	60	60	56	50	44	46
	46	44	44	42	40	40
	42	40	34	34	30	28
	86	72	68	66	64	60
	46	36	30	30	28	24
	46	38	40	42	38	34
	80	74	68	60	54	50
	77	70	60	52	45	38
	76	60	60	58	54	50
	64	49	45	40	34	34
F	49	38	34	30	24	24
	42	34	34	34	30	32
	50	42	42	40	34	34
	68	60	60	58	50	52
	52	34	34	36	34	32
	58	**49,95**	**46,75**	**44,4**	**41,35**	**38,9**
	15,91	**14,63**	**13,17**	**12,03**	**12,14**	**10,98**
	p	**0,086603**	**0,01551837**	**0,00317**	**0,0004773**	**0,00005**

TAB :6

group B

- analitic WOMAC (basale measurements and taken on week 1, 2, 3, 6 &12 from the beginning of the therapy)



14	12	20	15	22	16	18	16	18	20	18	20	20	14	20	22	14	19	18	22	Media 17,9	DS 2,99
10	10	15	14	15	11	14	15	18	18	18	15	14	11	18	18	14	18	18	22	Media 15,3	DS 3,21

TAB: 8

Group A – Lequesne score before and after 12 weeks or treatment

12	15	19	14	20	18	16	15	20	16	16	20	22	19	18	22	18	14	15	12	Media 17,05	DS 3,00
9	8	12	10	12	12	11	10	10	11	11	10	12	12	10	12	10	8	8	10	Media 10.4	DS 1,39

TAB: 9

Group A – Lequesne score before and after 12 weeks or treatment

CONCLUSIONS

Conservative treatment of patello femoral Chondropathy has a well documented back ground in medical literature over the last 50 years. The use of FANS, of cortisone and chondro protectors is common in conventional medicine.

The action of corticosteroids is very clear: inhibition of the prostaglandin synthesis, collagenosis decrease and decrease in the production of IL-1, TNFα and various proteases which attack the cartilage.

- The FANS and the cortisones act only on the painful symptomatology.The use of chondro protectors should be aimed at restoring the natural rheological and metabolic homeostasis of the articulation affected by the arthrosic process, improving the protective, lubricant and "*shock-absorbing*" effect of the synovial liquid.
- Both Groups (A; B) presented a considerable improvement of the pain aspect and of the functional limitation tied to knee arthritis during the 12 weeks examined.

-The data show that the improvement of the clinical-functional picture is **more immediate** in those patients treated with 98% pure O2, vehiculated at 2.5 atm + MD_KNEE * ZEEL T: as a matter of fact patients from Group B registered a **more relevant decrease of the average WOMAC** score from the statistical point of view regarding parameters such as joint pain, rigidity and functionality if compared to patients from Group A treated with nimesulide + chondro protector.

- The total absence of collateral effect registered in patients of Group B and the use of a non invasive, not painful and very simple therapy (one treatment a week) has guaranteed better acceptance and a definitely more advantageous cost. ■