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Clinical Data

Efficacy in joint pain relief and quality of life

1 Objective

To study the efficacy of Mobilee® on pain relief and quality of life in subjects with osteoarthritis of the knee.

2 Methods

Twenty subjects aged ≥40 years with knee osteoarthritis (pain for at least 15 days in the previous month, symptoms present for ≥6 months, Kellgren/Lawrence score ≥2) participated in a randomized double-blind controlled trial. Ten subjects received Mobilee® (80 mg/day) and ten received placebo for 8 weeks. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and quality of life by the Short Form-36 (SF-36v2) were assessed at baseline and after 4 and 8 weeks of treatment.

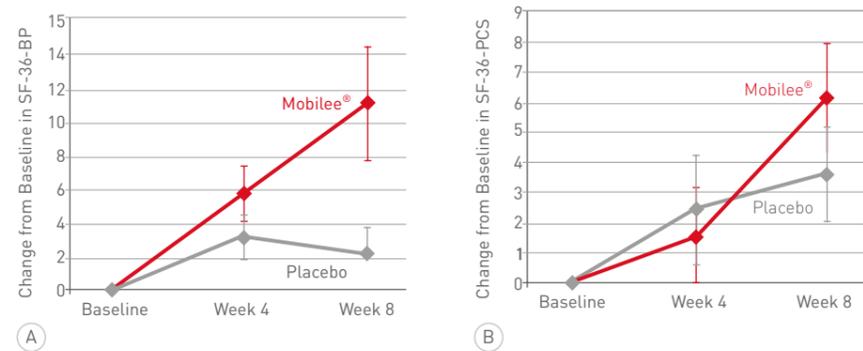
3 Results

As compared with baseline, both groups showed significant improvements in WOMAC scales, but the magnitude of changes was higher in the Mobilee® group for WOMAC physical function and total symptoms. Patients receiving Mobilee® also scored higher than those given placebo in the SF-36 scales, reaching significant improvements from baseline to week 8 for Bodily Pain Subscale and Physical Component Summary.

The mean number of capsules of acetaminophen used per week was higher among subjects assigned to placebo than among those using the active supplement, and more subjects in the supplemented group compared with placebo answered affirmatively to perceived improvement in joint pain (75% vs 50%) and muscle aches (75% vs 38%).

4 Conclusions

Results of this pilot clinical trial suggest that daily supplementation with Mobilee® at a dose of 80mg/day during 8 weeks may decrease pain, improve physical function and enhance several aspects of quality of life in subjects with knee osteoarthritis.



Efficacy in joint pain relief and Synovial effusion

1 Objective

To obtain preliminary information about the effectiveness of oral administration of Mobilee® to patients with moderate to severe osteoarthritis of the knee presenting with persistent knee pain and synovial effusion.

2 Methods

This is an observational, retrospective cohort study involving 70 consecutive outpatients with knee OA and synovitis who took the selected treatments during a period of at least 6 months. Studied treatments were Mobilee® (MBL) (80mg/d) and paracetamol (PCT) (500mg/d). The evolution of the synovial effusion was assessed with ultrasonography, and the evolution of joint pain was assessed with the VAS Huskisson's scale.

3 Results

At baseline the absolute number of patients with synovial effusion (≥4mm) was not different between groups (33 vs. 36 patients for MBL and PCT respectively; P=0.245). The supplementation with Mobilee® resulted in a significant decrease on the number of patients with synovial effusion from the first month of treatment (5 vs. 29 patients for MBL and PCT respectively; P=0.001) until 6 months follow-up (0 vs. 14 patients for MBL and PCT respectively; P=0.001).

Pre-treatment number of patients with severe synovial effusion (>6mm) was not different between groups (16 vs. 15 for MBL and PCT respectively). On the MBL group no cases of severe synovial effusion were detected from 1 until 6 months follow-up, while on the control group a number of severe cases remained at 1 month (14 patients) and 3 months (6 patients), resulting in differences between treatments at both time points.

Joint pain was reduced (P<0.05) along the 6 months studied in both groups, but it was reduced faster in the MBL group and reached a lower value after 6 months of treatment (P<0.001).

4 Conclusions

The results of the present study suggest that Mobilee® intake strongly inhibits synovial effusion and reduces knee pain. It has been demonstrated that synovial effusion is an independent risk factor for OA, and it correlates with faster cartilage degradation. Therefore, the reduction of synovial effusion demonstrated as a result of Mobilee® treatment may delay OA progression.

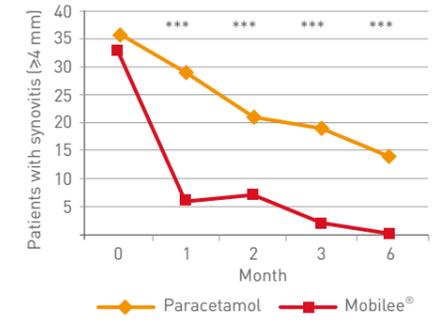


Fig 1. Evolution of the number of patients with synovial effusion during 6 months of treatment

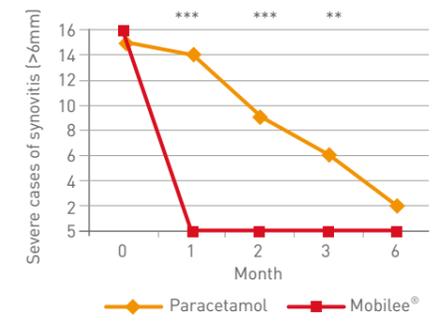


Fig 2. Evolution of the severe cases of synovial effusion during 6 months of treatment

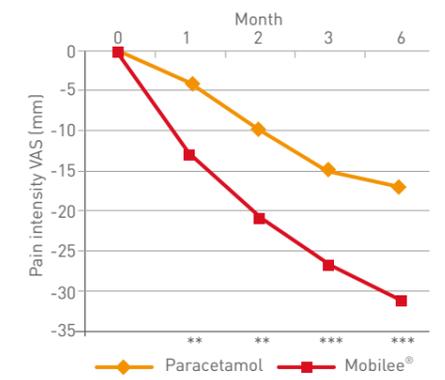


Fig 3. Evolution of joint pain according to VAS (mm) during 6 months of treatment. Values within a month with a star differ between groups * (P < 0.05); ** (P < 0.01); *** (P < 0.001)

Centre where the study was performed: Department of Nutrition and Clinical Endocrinology and Department of Rheumatology, Miami Research Associates, Miami, Florida (USA)

Bibliography: Douglas S Kalman, Maria Heimer, Anita Valdeon, Howard Schwartz and Eric Sheldon. Effect of a natural extract of chicken combs with a high content of hyaluronic acid on pain relief and quality of life in subjects with knee osteoarthritis: a pilot randomized double-blind placebo-controlled trial. Nutrition Journal 2008;7(3):1-9

Centre where the study was performed: Instituto POAL de Reumatología, Barcelona (Spain)

Bibliography: Möller I, Martínez-Puig D, Chetrit C. Oral administration of a natural extract rich in hyaluronic acid for the treatment of knee OA with synovitis: a retrospective cohort study. Clinical Nutrition Supplements 2009;4(2):171-172

Efficacy in muscle strength and quality of life

1 Objective

To determine the efficacy of the oral administration of yoghurt supplemented with Mibilee® in healthy individuals with mild joint discomfort.

2 Methods

A prospective, randomized, double-blind, placebo-controlled study was designed including 40 healthy individuals with mild joint discomfort (VAS <4). They were divided into two groups (n=20) and ate yoghurt either supplemented or not with Mibilee®, daily for a period of 90 days. Efficacy was evaluated in terms of functional and quality-of-life parameters. An Isokinetic dynamometer was used to measure maximum muscle strength, total work and mean power of knee flexors and extensors at two different angular velocities.

3 Results

The increase in the maximum muscle strength of the knee extensors compared to baseline values was 7.6 ± 7.6 Nm for the supplemented group and 2.5 ± 4.7 Nm for the control group at $180^\circ/s$ ($P = 0.0582$), and 6.5 ± 5.8 Nm for the supplemented group and -1.0 ± 7.1 Nm for the control group at $240^\circ/s$. The same pattern of response was observed in total work and in mean power. Differences were less pronounced in the knee flexors. A significant difference in favor of the supplemented group was detected in the quality-of-life social functioning subscale at 1 month follow-up.

4 Conclusions

Taken together, these results show that oral supplementation with Mibilee® improves joint mechanics and muscle function as determined through isokinetic testing, thus attenuating risk factors of OA.

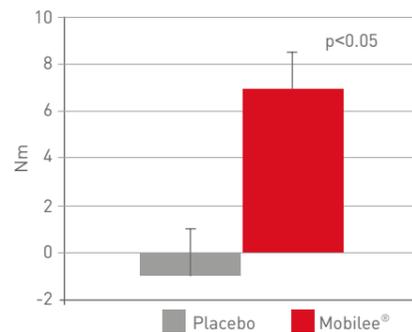


Fig 1. Increase in maximum peak torque compared to baseline values (Nm) for knee extension at $240^\circ/s$

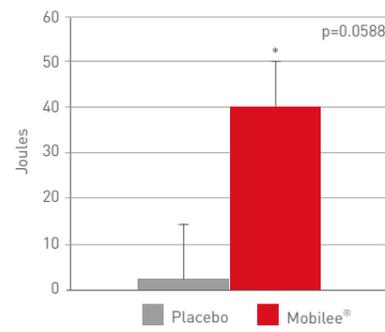


Fig 2. Increase in total work compared to baseline values (J) for knee extension at $240^\circ/s$

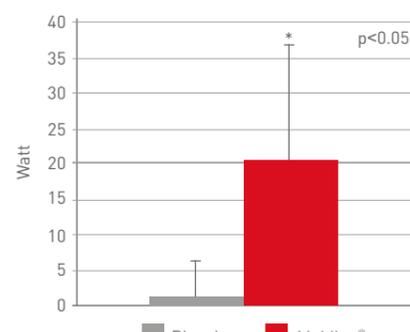


Fig 3. Increase in mean power compared to baseline values (W) for knee extension at $240^\circ/s$

Efficacy in joint pain relief, muscle strength, effusion and gene expression

1 Objective

To determine the efficacy of the oral administration of yoghurt supplemented with Mibilee® in healthy individuals with mild joint discomfort.

2 Methods

This is a randomized, double-blind, placebo-controlled nutritional intervention trial in which 77 participants with mild knee pain (VAS between 30 and 50 mm) were randomized into two groups. The study group ate one yoghurt per day supplemented with 80 mg of Mibilee® for a period of 90 days. The control group ate the same yoghurt without any supplement. Clinical assessment included isokinetic test of thigh muscles, ultrasonographic evaluation of the knee, and pain assessed using the VAS scale. Whole-genome microarray analysis of blood samples from a subset of 20 subjects collected pre and post intervention was assessed to explore the feasibility of using total human blood RNA as a source of biomarkers of articular health improvement.

3 Results

The daily eating of yoghurt supplemented with Mibilee® reduced pain intensity, reaching significantly lower values compared to placebo from the second month of treatment (32.5 ± 4.96 vs. 34.0 ± 3.85 mm respectively; $P=0.005$), and specially at the third month (21.1 ± 12.36 vs. 31.9 ± 15.81 mm; $P=0.0005$).

The ultrasonographic assessment revealed a significant reduction on the degree of synovial effusion associated with the eating of yoghurts supplemented with Mibilee® as compared to placebo (44% vs. 22% respectively; $P<0.05$).

The subanalysis of the muscular strength evolution excluding those participants with a pathologic degree of synovial fluid at baseline, showed a reduction in muscular strength on the placebo group after 3 months of study (-2.3 ± 2.71 Nm), while in Mibilee® group it was significantly increased ($+2.9 \pm 1.67$ Nm; $P<0.05$).

Transcriptomic analysis revealed that 165 known genes were differentially expressed in blood cells between Mibilee® and placebo groups post-intervention, but not pre-intervention ($P<0.05$; fold-change ≥ 1.2). Some of them are related to GAG metabolism and extracellular matrix dynamics. In particular, lower expression of cartilage degrading enzymes as glucuronidase-beta and matrix metalloproteinase 23B were found in the Mibilee® group.

4 Conclusions

This prospective placebo-controlled nutritional study confirmed that 3 months of intake of a natural product containing Mibilee® in healthy individuals with knee discomfort reduces pain and joint effusion, and provides improvements in muscle strength in those patients without joint effusion. Genes related to GAG metabolism and extracellular matrix dynamics are differentially expressed in blood cells between the supplement and placebo groups post-intervention, and the expression of some of these genes correlates with indicators of articular pain and muscular strength.

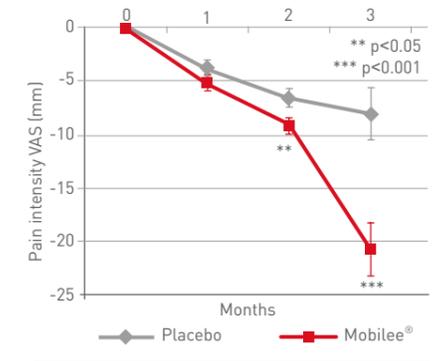


Fig 1. Time evolution of pain intensity according to VAS (mm)

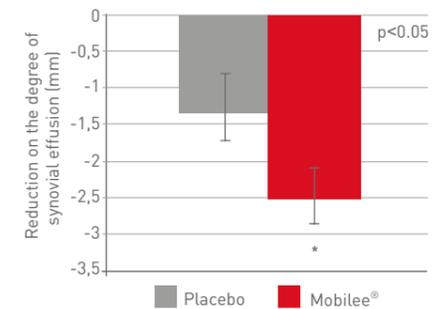


Fig 2. Degree of synovial effusion after 3 months compared to basal values

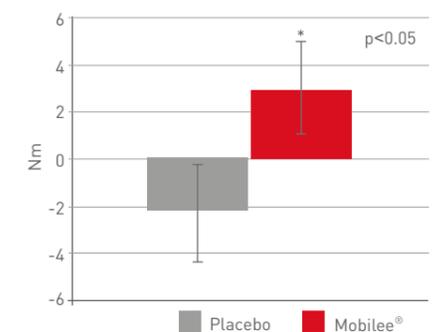


Fig 3. Change in muscular strength (peak torque) in extension at $240^\circ/s$ within participants without synovial effusion at baseline

Efficacy in joint pain relief and muscle strength

1 Objective

To determine the efficacy of the oral administration of yoghurt supplemented with Mobilee® in healthy individuals with mild joint discomfort.

2 Methods

84 participants with mild knee pain (VAS between 30 and 50 mm), were included in a randomized, placebo-controlled, double-blind, parallel intervention trial. 40 participants received daily a low-fat dairy product with 80 mg of Mobilee® and 40 participants consumed the same low-fat dairy product without supplement during 3 months. The knee muscle function was determined by peak torque, total work, and mean power in flexion and extension at angular velocities of 180°/s and 240°/s using an isokinetic dynamometer Biodex System 4. Synovial liquid volume was measured by an echography and pain evolution was assessed by VAS.

3 Results

80 subjects (30 men and 50 women; mean age 42.52±13.16 years) were analyzed by Intention-To-Treat. Results show a general tendency to greater improvement for participants supplemented with Mobilee®. In additional exploratory sub-analysis, people over 50 taking the supplemented yoghurt showed a significant increase in peak torque measured in flexion at 180°/s compared to placebo (P=0.032). When dividing the sample according to gender, men supplemented with Mobilee®, independently of age, significantly improved all isokinetic parameters studied as compared to placebo (P<0.05), except maximum peak torque at 240°/s.

At 3 months, synovial effusion was reduced in the supplemented group whereas it increased in the placebo group.

4 Conclusions

Long-term consumption of a low-fat dairy product supplemented with Mobilee® improves muscle function suggesting lower pain and a better performance of the flexor and extensor muscles of the affected knee, thus providing new dietary therapeutic perspectives.

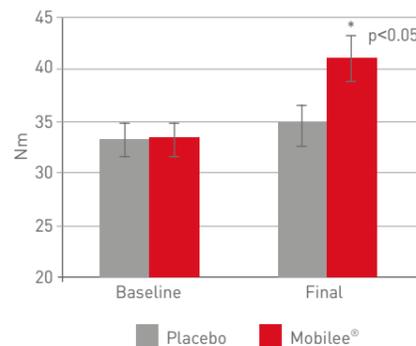


Fig 1. Change in muscular strength (peak torque) in subjects older than 50, in flexion at 180°/s

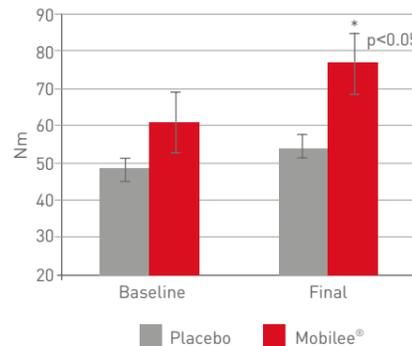


Fig 2. Change in muscular strength (peak torque) in men, in flexion at 180°/s.

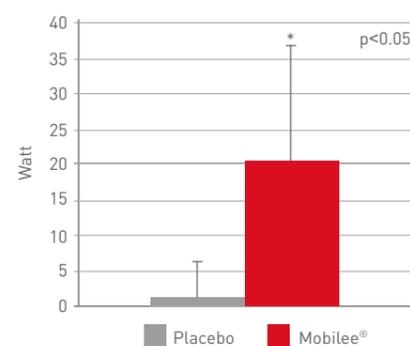


Fig 3. Increase in mean power compared to baseline values (W) for knee extension at 240°/s

Meta-analysis of clinical trials

1 Objective

To determine the efficacy of daily consumption of a low-fat dairy product supplemented with Mobilee® (80 mg/day) compared with a non-supplemented low-fat dairy product consumed during 3 months on healthy volunteers with knee discomfort.

2 Methods

Pooled analysis of the individualized results from 148 volunteers included in two randomized, controlled, double-blind, parallel trials performed on healthy patients with mild knee pain (VAS between 30 and 50 mm) developed in medical centers of Barcelona and Reus (Spain) by implementing the same protocol.

The primary outcome was the muscle function determined by peak torque, total work, and mean power using an isokinetic dynamometer Biodex 4. Secondary parameters were the ultrasonographic evolution of the affected joint using an osteoarthritis risk parameter scale and the level of joint discomfort using VAS scale.

3 Results

Subjects taking the yoghurt supplemented with Mobilee® showed greater improvements in the majority of the isokinetic parameters, with the difference between groups being statistically significant for the total work of the affected joint measured in flexion at 180°/s (p=0.0391).

The ultrasonographic evaluation showed a significantly greater reduction in the synovial fluid in the volunteers supplemented with Mobilee® in comparison to the non-supplemented group (p=0.0293).

The pain perceived by the volunteers that consumed the supplemented yoghurt decreased throughout the trial, reaching significantly lower values compared to the control group at the end of the study (p=0.0036).

4 Conclusions

Long-term consumption of low-fat dairy products supplemented with Mobilee® improves muscle function, synovial effusion and reduces pain, providing clinical benefit for healthy people with mild knee pain. These results support the use of Mobilee® to reduce the risk and progression of osteoarthritis.

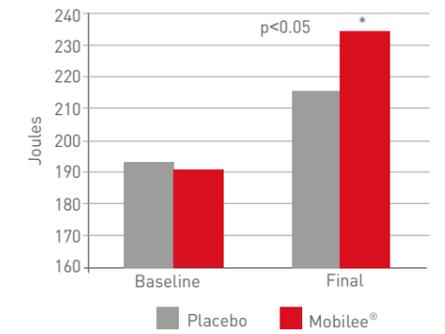


Fig 1. Changes in total work of the affected knee in flexion at 180°/s

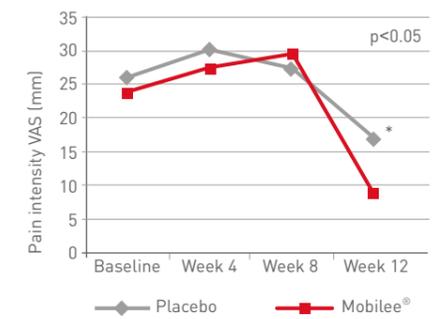


Fig 2. Time evolution of pain intensity according to VAS (mm)

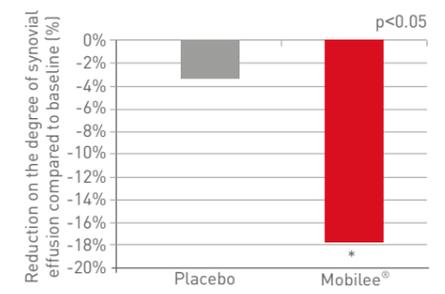


Fig 3. Relative change in synovial effusion after 3 months compared to baseline values.

Centre where the study was performed: Hospital Universitari Sant Joan, Reus (Spain). Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Reus (Spain). CTNS-TECNIO-Technological Center of Nutrition and Health, Reus (Spain).

Bibliography: Solà R, Valls RM, Martorell I, Giralte M, Pedret A, Taltavull N, Romeu M, Rodríguez À, Moriña D, Lopez de Frutos V, Montero M, Casajuana MC, Pérez L, Faba J, Bernal G, Astilleros A, González R, Puiggrós F, Arola L, Chetrit C, Martínez-Puig D. A low-fat yoghurt supplemented with a rooster comb extract on muscle joint function in adults with mild knee pain: a randomized, double blind, parallel, placebo-controlled, clinical trial of efficacy. Food Funct. 2015 Nov;6(11):3531-9.

Centre where the study was performed: Instituto POAL de Reumatología, Barcelona (Spain). Hospital Universitari Sant Joan, Reus (Spain). Facultat de Medicina i Ciències de la Salut, Universitat Rovira i Virgili, Reus (Spain). CTNS-TECNIO-Technological Center of Nutrition and Health, Reus (Spain).

Bibliography: Moriña D, Solà R, Valls RM, López de Frutos V, Montero M, Giralte M, Papell I, Bernal G, Faba J, Casajuana C, Rodríguez A, Chetrit C, Martínez-Puig, D. Efficacy of a Low-fat Yogurt Supplemented with a Rooster Comb Extract on Joint Function in Mild Knee Pain Patients: A Subject-level Meta-analysis. Annals of Nutrition and Metabolism 2013;63(S1):1386

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