meloxicam 15-mg tablets (2.0 vs 4.0 h, respectively). SoluMatrix meloxicam 10 mg demonstrated approximately 33% lower overall systemic exposure compared with conventional meloxicam 15-mg tablets. As described for other NSAIDs, food decreased the rate but not the overall extent of SoluMatrix meloxicam absorption (Table). Treatment-related AEs included 1 case each of mild abdominal pain and mild diarrhea in the SoluMatrix meloxicam 10 mg (fed) group and 1 report of mild somnolence in the SoluMatrix meloxicam 5 mg group. In the separate phase 3 study in patients with OA pain, 350 (86.8%) of 403 patients completed the 12-week study. SoluMatrix meloxicam 5 mg (mean [standard error] (SE) -36.5 [2.49]; P = 0.0005) and 10 mg (-34.4 [2.68]; P = 0.0059; Table) provided significantly greater pain relief as measured by the primary efficacy parameter compared with placebo (-25.68 [2.64]). Patients in the SoluMatrix meloxicam 5 mg (P = 0.0049) and 10 mg (P = 0.0012) groups reported significant differences in the distribution of responses in the patient global impression of change (from baseline) compared with placebo. Patients in the SoluMatrix meloxicam 5 mg and 10 mg groups demonstrated a numerically greater mean percentage reduction in pain (by NPRS) at 2 h (-33.44% for the 5 mg group; P = 0.0294 and -30.54% for the 10 mg group; P = 0.1357) compared with placebo (-24.32%). Low-dose SoluMatrix meloxicam 10-mg (mean ± SE: 48.4 ± 7.13 doses; P = 0.0013) and 5-mg (52.4 ± 6.61 doses; P = 0.006) treated patients required significantly fewer rescue medication doses over 12 weeks compared with placebo (73.2 ± 7.03 doses). Across SoluMatrix meloxicam groups, the most common AEs (occurring in ≥ 2% of patients) were diarrhea, headache, OA, and urinary tract infection. No deaths or serious AEs were reported.

Table. Summary of Plasma Pharmacokinetic Parameters

Parameter	SoluMatrix Meloxicam 5 mg (Fasted)	SoluMatrix Meloxicam 10 mg (Fasted)	Conventional Meloxicam Tablets 15 mg (Fasted)	SoluMatrix Meloxicam 10 mg (Fed)
T_{max} (h), median (min–max)	2.0 (0.5–4.1)	2.0 (1.0–5.0)	4.0 (2.0–8.0)	5.0 (1.5–16.0)
C_{max} (µg/mL), mean ± SD	0.64 ± 0.14	1.25 ± 0.25	1.29 ± 0.42	0.97 ± 0.17
$AUC_{0\text{-}inf}$ (µg·h/mL), mean ± SD	13.6 ± 3.3	29.2 ± 11.0	40.9 ± 11.7	27.1 ± 11.5
$t_{½}$ (h), mean ± SD	22.3 ± 10.9	22.0 ± 10.1	23.6 ± 10.0	22.3 ± 9.9
Lambda z (1/h), mean ±SD	0.036 ± 0.013	0.036 ± 0.012	0.034 ± 0.012	0.036 ± 0.013

$AUC_{0\text{-}inf}$, area under the concentration-time curve from time 0 extrapolated to infinity; C_{max}, peak plasma concentration; lambda z, terminal elimination rate constant; $t_{1/2}$, apparent terminal elimination half-life; T_{max}, time to peak plasma concentration.

Conclusions: Low-dose SoluMatrix meloxicam 5 and 10 mg, under fasted conditions, provided comparable peak plasma levels, but with an earlier time to peak plasma levels and with a 33% lower overall systemic exposure compared with conventional meloxicam 15-mg tablets. SoluMatrix meloxicam 5 and 10 mg once daily provided significantly greater relief from OA pain compared with placebo. These data suggest that low-dose SoluMatrix meloxicam is a potentially promising treatment option for adults with OA pain.

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DIFFERENCE IN BODY COMPOSITION BETWEEN PATIENTS WITH EARLY KNEE OSTEOARTRHRITIS COMPARED WITH LATE KNEE OA IN A MEXICAN POPULATION

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Purpose: Introduction. Osteoarthritis (OA) is a chronic and degenerative condition. It affects not only cartilage but also bone, synovial and periarticular soft tissue. Obesity is a recognized risk factor for knee OA and weight loss reduces the risk of OA progression. Some studies have examined the relationship between other components of body composition (BC), such as muscle mass and the risk of OA. Although several studies have failed to determine a significant relationship between fat distribution and the risk of knee OA. We did not found studies that it examined differences in body composition between early and late OA. If there are difference, it could be part of the preoperative treatment before undergo to total knee arthroplasty.

Objective: To describe difference in BC between patients with early and late knee OA in a Mexican population.
Methods: Patients and methods. The study was performed in a tertiary hospital care. The patients in the early OA (EOA) had the following inclusion criteria: patients with knee OA criteria according to American College of Rheumatology, younger than 55 years old, a Kellgren-Lawrence score less than or equal to 2 on the knee X-ray and without previous surgery in the studied knee; Patients with late OA (LOA) group had the following inclusion criteria: evaluation in the outpatients clinic of joint surgery department, with a proposal of a primary joint replacement surgery due to pain and/or disability due to knee OA, Kellgren-Lawrence III or IV score on knee X-ray. Exclusion criteria in EOA and LOA: patients with autoimmune inflammatory joint disease, traumatic or congenital lesions. Clinimetric evaluation. All patients had an interview to collect epidemiological data, joint function with WOMAC knee index; All patients were evaluated using bioelectrical impedance analysis in order to collect BC with multifrequency bioimpedance (InBody 720®). Analysis. We used a descriptive and bivariate analysis using appropriate to compare median between EOA vs. LOA.
Results: Results. 110 patients were evaluated, 56 with EOA and 54 LOA. The EAO group were younger than LOA patients: median 48.5 vs. 65.5 years old (p =0.001). The women proportion was superior in both groups: 71.8 women vs. 28.2 men. The EOA had a median of 11 education years vs. 7 in LOA (p= 0.03). The OA evolution was 20.3 months in EOA vs. 60 months in LOA (p=0.001).
In table 1 we describe the BC in EOA vs. LOA The differences that we found were only in female gender. In LOA group women had less total lean mass, lean mass index and fatter mass index than EOA group. We also found that women in LOA had less lean mass in the extremity affected by OA compared to EOA group. We did not find differences between men gender groups. (Table 2).
Conclusions: Conclusions. The female patients with LOA in the knee had more problems with the body compositions compared with the female with EOA. The men groups (EOA vs. LOA) did not have differences. The lean mass is lower en female patient with LOA compared with EAO. Probably It is one of the first study that evaluate leg affected composition between EOA vs. LOA; it finding could have preoperative treatment implications.

Table 1- Body composition between Early OA (EOA) vs. Late OA (LOA)

Variable		EAO n= 56	LOA n=54	p value
Body mass index (kg/m2)*				
	Women	29.8 (22.2-45.6)	30.4 (20.2-42.9)	0.43
	Men	28.3 (24.3-40.1)	29.3 (23.1-38)	0.58
Total lean mass (kg)*				
	Women	25 (18-36)	20.8 (13.4-26.6)	0.001
	Men	27.6 (19-38.5)	27.9 (21.5-41.3)	0.71
Lean mass Index (kg/m2)*				
	Women	9.9 (8.1-12.8)	8.8 (7.1-10.8)	0.001
	Men	10.2 (8.4-13.3)	10.1 (8.5-12.6)	0.71
Fat mass (kg)*				
	Women	28.4 (14-60)	32.5 (14.4-52.2)	0.14
	Men	26 (13-48)	27.1 (13.8-45.3)	0.71
Fatter mass index (Kg/m2)*				
	Women	11.2 (4.7-24.3)	14.2 (6.2-23.4)	0.005
	Men	10.2 (5-17.8)	10.2 (5.7-16.8)	0.71

*median (range)

Table 2. Affected leg composition and EOA vs. LOA

Variable		EOA	LOA	p value
Total lean mass in affected right leg (kg)				
	Women	6.57 (4.84-9.81)	5.1 (2.44-7.63)	0.009
	Men	7.28 (5.31-8.64)	7.65 (6.08-10.76)	0.508
Total lean mass in affected left leg (kg)				
	Women	6.44 (4.59-8.75)	5.12 (4.07-7.12)	0.008
	Men	7.39 (6.95-10.41)	7.45 (5.77-8.33)	0.819