were used to assess which parameters (age, sex, BMI >30, prescription of opioids or physical therapy, WOMAC, whether the OA was mainly treated by an orthopaedist) were associated with having discussed a TJR.

Results: Of 2352 persons with knee or hip OA, 932 had symptomatic OA of the knee, 478 of the hip, 94 of both, and 848 did not report pain in the relevant joint(s). Mean age was 64 to 67 years, 63% to 68% were female and mean BMI was high, especially in patients with knee OA (29 kg/m²). 54%–74% had considerable impairment (WOMAC>39). 72%–83% had any pain medication, 12%–25% opioids and 33%–46% physical therapy. 63%–72% were treated by orthopaedists and 45%–50% had discussed TJR. In knee as well as hip and knee OA male sex and an orthopaedist as main treating physician was associated with having discussed a TJR (table 1). Age, WOMAC and opioid prescription was only associated with a higher OR of discussing a TJR in knee OA.

Abstract FRI0526 – Table 1. Results from multivariable logistic regression models showing parameters associated with having discussed TJR.

	OR for knee and hip OA (n=94), 95% CI	OR for hip OA (n=478), 95% CI	OR for knee OA (n=932), 95% CI
Orthopaedist is treating	7.2 (1.9,26.8)	1.6 (0.9,2.8)	1.7 (1.1,2.6)
Age, per 10 years	1.0 (0.56,1.8)	1.0 (0.8,1.3)	1.2 (1.1,1.5)
BMI≤30 vs>30	0.9 (0.2,3.6)	1.0 (0.6,1.8)	1.3 (0.9,2.0)
Male vs female	5.3 (1.3,21.8)	1.1 (0.6,1.8)	1.5 (1.1,2.2)
WOMAC, per 10%	1.3 (0.8,1.9)	1.1 (0.9,1.3)	1.3 (1.2,1.5)
Opioids	0.8 (0.1,6.1)	0.5 (0.2,1.2)	1.9 (1.0,3.3)
Physical therapy	1.1 (0.3,3.3)	1.1 (0.6,2.0)	1.2 (0.8,1.7)

Conclusions: Disease burden is highest in persons with concomitant knee and hip OA. Men are more likely to discuss TJR with their physician, but not in hip OA. Disease burden and treatment recommendations were only weakly associated. Therefore, other factors may be more important when considering surgery in knee and hip OA.

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FRI0527

EFFICACY OF BIO-OPTIMISED CURCUMA EXTRACT (FLEXOFYTOL®) FOR PAINFUL KNEE OSTEOARTHRITIS: DATA FROM COPRA, A MULTICENTER RANDOMISED CONTROLLED STUDY

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Background: Flexofytol is a Curcuma Longa extract with an increased bioavailability (bio-optimised) by mixing curcuma extract with polysorbate.

Objectives: To demonstrate the effects of Flexofytol on OA symptoms and soluble biomarkers.

Methods: 141 patients with symptomatic knee OA (mean age 61.8 years [min.45-max.86]; 80.1% female; mean K and L grade of the knee 2.4; mean BMI 29.7 kg/m²) were randomised in a prospective double blinded, 3 parallel groups, comparative and multicenter, study (NCT02909621). At inclusion, all patients took pain killers or anti-inflammatory drugs which were authorised during the study. Patients received 6 months continuous treatment with either high dose Flexofytol (n=49, 140.01 mg Curcuma longa L. extract/treatment), low dose Flexofytol (n=47, 93.34 mg Curcuma longa L. extract/treatment) or placebo (n=45, Sunflower seed oil fill ingredient). Each treatment corresponded to 3 oral capsules two

times a day to respect the blinding. All patients had clinical assessment (knee pain, knee function and patient global assessment of disease activity [PGADA]) and blood sampling for biomarkers measurements (usCRP and sColl2-1) at baseline (T0), 1 month (T1), 3 months (T3) and 6 months (T6). Additionally, patient compliance, satisfaction and tolerance were assessed at each timepoint following baseline. Primary outcome was the change at 3 months versus baseline in type II collagen degradation-specific biomarker sColl2-1 and VAS PGADA.

Results: Comparison of time evolution curves showed that sColl2-1 levels were lower in the treated groups but differences were not significant. The decrease in PGADA overtime was significantly more important in low dose group than in placebo group only at the 1 month evaluation timepoint (low dose Δ T1-T0, -12.5 mm vs placebo Δ T1-T0, -2 mm, p=0.035). Further, the knee pain relief was significantly higher in low dose group at T1 and T3 than in placebo (low dose Δ T1-T0, -16.5 mm vs placebo Δ T1-T0, -4 mm p=0.046; low dose Δ T3-T0, -36.5 mm vs placebo Δ T3-T0, -8 mm p=0.043). No difference was observed at T6. No differences were seen for any parameter when the high dose group was compared with the placebo group at any time point. The global KOOS score and its subscales significantly decreased overtime but changes were comparable in each group. Additionally, patient compliance was good and patient satisfaction remained stable overtime in each group. The ratio of patients with adverse events (AE) related to the product were similar in placebo and treated groups but the number of AE linked to the product was higher in the high dose group than in placebo (p=0.012).

Conclusions: Flexofytol, at a low dose, induced a rapid symptomatic relief on knee pain and a beneficial effect on the patient assessment of disease. This study also provides information on the dose to use and the design of a larger phase III clinical trial.

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FRI0528

LONG-TERM EFFECTS OF VITAMIN D SUPPLEMENTATION AND MAINTAINING VITAMIN D SUFFICIENCY ON KNEE OSTEOARTHRITIS OVER 5 YEARS

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Background: Epidemiological studies suggest that vitamin D deficiency is associated with knee symptoms and structural progression of knee osteoarthritis (OA). However, randomised controlled trials (RCTs) failed to demonstrate a significant effect of vitamin D supplementation on OA, probably due to selecting OA participants with and without vitamin D deficiency, short duration of follow-up and a large proportion of participants in the placebo group reaching vitamin D sufficiency (61.3% of patients in the placebo group achieved a serum 25(OH)D level of >60 nmol/L at 3 months of a clinical trial).

Objectives: To examine whether those maintaining sufficient serum vitamin D levels over 5 years had reduced knee symptoms compared with those who did not maintain adequate vitamin D levels in patients with knee OA. We also explored the effect of 2 year vitamin D supplementation on knee symptoms compared to placebo after 3 years of cessation of treatment.

Methods: Participants with symptomatic knee OA and low 25-hydroxyvitamin D [25(OH)D] (12.5–60 nmol/L) were randomly assigned to receive monthly treatment with oral vitamin D3 (50 000 IU; n=209) or an identical placebo (n=204) for 2 years. 172 participants who enrolled in the study from Hobart were followed up after 3 years (5 years from baseline) of the cessation of the treatment to assess knee symptoms and vitamin D levels. Participants were classified as maintaining sufficient vitamin D group if they maintained serum 25(OH)D>50 nmol/L at month 3, 24 and 60 (n=79), and not maintaining sufficient vitamin D group (25(OH)D≤50 nmol/L at month 3, 26 and 60, n=62) groups. Knee symptoms were assessed at baseline, 3, 6, 12, 24 and 60 month using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Results: The level of 25(OH)D dropped in the vitamin D group (87.0 nmol/L to 53.3 nmol/L) and slightly increased (53.3 nmol/L to 61.7 nmol/L) in the placebo group 3 years after the cessation of the treatment. Knee pain increased from the end of the study to 5 years of follow-up in the treatment (81.8 to 91.7) and placebo (75.8 to 101.1) groups. 16.7% of the participants in vitamin D and 18.5% of the participants in placebo group underwent total knee replacement (TKR) surgery. There were no significant differences in WOMAC symptoms, TKR rates or change in symptoms between Vitamin D and placebo groups after 3 years of cessation of the supplementation.