

Table 1
Analysis A: Result of the Randomised Trial

Variable	No Brace Group			Brace Group			Between Groups Difference			
	Mean difference (SD)	95% CI Lower	95% CI Upper	Mean difference (SD)	95% CI Lower	95% CI Upper	Mean difference (SE)	95% CI Lower	95% CI Upper	P
Change in Nominated Pain VAS @ 6 weeks (0–100 scale)	-1.29 (19.38)	-6.39	3.80	-18.16 (21.37)	-23.88	-12.44	16.87 (3.82)	9.30	24.43	<0.001
Change in KOOS Pain Subscale @ 6 weeks (100–0)*	2.08 (13.11)	-1.28	5.43	8.78 (16.65)	4.36	13.20	-6.70 (2.75)	-12.15	-1.25	0.02
Change in KOOS Symptom Subscale @ 6 weeks (100–0)*	-0.34 (10.60)	-3.05	2.38	7.83 (12.54)	4.51	11.16	-8.17 (2.13)	-12.39	-3.95	<0.001
Change in KOOS ADL Subscale @ 6 weeks (100–0)*	1.03 (12.14)	-2.11	4.16	6.67 (12.30)	3.32	10.03	-5.65 (2.29)	-10.19	-1.11	0.02
Change in KOOS QoL Subscale @ 6 weeks (100–0)*	1.43 (12.10)	-1.79	4.64	5.82 (14.59)	1.80	9.84	-4.39 (2.55)	-9.45	0.66	0.09

* Improvement in VAS pain is shown as a decrease, whereas improvement in KOOS scales are shown as an increase.

Table 2
Analysis B: Change After 12 Weeks of Bracing

Variable	Both Groups Pooled			
	Mean Difference (SE)	95% CI Lower	95% CI Upper	P
Change in Nominated Pain VAS @ 12 weeks (0–100 scale)	-1.55 (0.21)	-1.96	-1.13	<0.001
Change in KOOS Pain Subscale @ 12 weeks (100–0)*	7.95 (1.27)	5.46	10.45	<0.001
Change in KOOS Symptom Subscale @ 12 weeks (100–0)*	6.82 (1.19)	4.48	9.16	<0.001
Change in KOOS ADL Subscale @ 12 weeks (100–0)*	7.32 (1.12)	5.11	9.54	<0.001
Change in KOOS QoL Subscale @ 12 weeks (100–0)*	8.64 (1.33)	6.02	11.26	<0.001

* Improvement in VAS pain is shown as a decrease, whereas improvement in KOOS scales are shown as an increase.

32 COMPARING DIFFERENT PREPARATIONS AND DOSES OF ROSEHIP POWDER IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE: AN EXPLORATORY RANDOMIZED ACTIVE-CONTROLLED TRIAL

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Purpose: Alternative and complementary therapies are always of interest to patients. Some evidence from meta-analysis indicates that rosehip powder might reduce pain in patients with osteoarthritis (OA). Our aim was to examine the efficacy and safety of the original rosehip powder, and two different doses of a novel enhanced rosehip powder of selected rosehips (Rosenoids[®]) in patients with knee OA.

Methods: This was a single-center, 12 week, double-blind, randomized, active-controlled trial in 150 patients with symptomatic knee OA (Trial registration: NCT01430481). Patients were stratified by sex, and randomly assigned to receive A: 'Original rosehip powder' 4500 mg/d (6 capsules; n=49), B: 'Enhanced rosehip powder' 4500 mg/d (6 capsules; n=50), or C: 'Enhanced rosehip powder' 2250 mg/d (3 capsules; n=51). Patients were allowed to continue any non-opioid concomitant analgesic therapy; patients were not allowed to use other rosehip preparations. The primary outcome measure was the change from baseline in the KOOS-item 'Pain during walking on flat surface' graded on a 5-point Likert scale from 0 (best) to 4 (worst). Secondary outcomes included all five KOOS subscales (Function, Quality of life, Pain, Function in sport and recreation, and Symptoms). All statistical analyses were based on the Intention-to-Treat (ITT) population (N=150), replacing missing data with Last Observation Carried Forward (LOCF) imputation. Data were

modeled and analyzed using 'PROC MIXED' based on REstricted Maximum Likelihood (REML).

Results: At baseline, the average 'Pain during walking on flat surface' was 1.3 KOOS item-points. Mean age was 65 years, with average disease duration of 10 years. During the trial, the attrition rates were equal across groups (A: 8%, B: 6%, and C: 8%). The change in the primary outcome was equal across groups (P=0.95), although the interaction between time and group indicated a trend for some differences over time (Time×Group, P=0.075). The change in 'Pain during walking' assessed after 12 weeks corresponded to average improvements of A (original, 6 capsules): -0.3 (95% CI: -0.1 to -0.5; appr. 19%), B (enhanced, 6 capsules): -0.3 (-0.1 to -0.5; appr. 24%), and C (enhanced, 3 capsules): -0.4 (-0.2 to -0.6; appr. 29%). Further, improvements from baseline in one of the secondary outcomes at 12 weeks, KOOS-symptoms, supported treatment C - 3 capsules 'Enhanced rosehip powder' (8.0 [4.5 to 11.5]) compared to the 'Original rosehip powder' 6 capsules (2.1 [-1.4 to 5.6]); Mean difference: 5.97 (0.92 to 11.02) KOOS-symptoms subscale points. Limitations: Although the three different formulations could be compared and the study was masked, there was no placebo group, so actual efficacy could not be ascertained.

Conclusion: The novel 'Enhanced rosehip powder' (Rosenoids[®]), may be more potent than the other formulation (3 capsules equaled 6 capsules per day of the original formulation). This allows one to prepare appropriate dosing regimens for phase-3-like placebo-controlled trials.

33 SERUM LEVELS OF VITAMIN D AND PARATHYROID HORMONE AND PROGRESSION OF KNEE OA: THE OSTEOARTHRITIS INITIATIVE STUDY

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Purpose: Vitamin D deficiency may play a role in progression of knee osteoarthritis (OA) but the evidence remains inconsistent and warrants further characterization. Recent studies have suggested that peri-articular bone changes are integral to OA onset and progression. Vitamin D status may influence peri-articular bone, contributing to the disease incidence and/or progression. We assessed serum levels of vitamin D and parathyroid hormone (PTH) in association with progression of knee OA among 488 participants of the Osteoarthritis Initiative (OAI) Study.

Methods: Participants in the Bone Ancillary Study were recruited from the OAI progression subcohort and had at least one knee with both radiographic evidence of knee OA and pain. They underwent additional knee dual-energy x-ray absorptiometry scans and knee trabecular magnetic resonance imaging (MRI) at the 30- or 36-month (baseline) and 48-month OAI visits (follow-up). Serum 25-hydroxyvitamin D (25(OH)D) and PTH levels were measured at 30- or 36-month OAI visit.