Effect of 12 months treatment with chondroitin sulfate on cartilage volume in knee osteoarthritis patients: a randomized, double-blind, placebo-controlled pilot study using MRI.

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Abstract
This pilot study aimed to evaluate the correlation between clinical symptoms and cartilage volume through MRI in patients with knee osteoarthritis after 48 weeks of treatment with Structum®. Multicenter, double-blind, placebo-controlled, parallel-group study. Symptomatic knee osteoarthritis patients aged 50-75 years received either Structum® (500 mg twice daily; N = 22) or placebo (N = 21) during 48 weeks. Inclusion criteria were global pain in the target knee ≥30 mm (VAS 0-100) and radiological Kellgren-Lawrence grade 2 or 3. Clinical assessments included Lequesne index and VAS for pain on motion, at baseline, 24 and 48 weeks, and MRI at baseline and at 24 and 48 weeks. Global and compartments cartilage volume, joint cartilage abnormalities, meniscal lesions, ligaments abnormalities, synovitis, synovial effusion, osteophytes, subchondral cysts, popliteal cysts and subchondral oedema were quantified. The quantitative and qualitative reproducibility of MRI was tested by the Spearman correlation coefficient and kappa coefficients, respectively. Treatments were compared by an analysis of covariance with baseline value as covariate. Groups were comparable at baseline for demographics, disease characteristics, and cartilage volumes. A significant inter-readers correlation was seen for the assessment of cartilage volumes, number of cysts, and osteophytes (correlation coefficients from 0.951 to 0.980 within investigator and from 0.714 to 0.957). After 48 weeks, symptoms improved in both groups. The total cartilage volume increased in the Structum® group (+180 mm(3) + SD) which opposed to a loss in the placebo (-46 mm(3) + SD; NS). No statistically significant differences between groups were observed for the other MRI parameters. No correlations were evidenced between key MRI parameters changes and symptoms. The difference in the evolution of cartilage volume between the two groups could reflect a structure modifying effect of Structum®. This pilot study confirms the usefulness of quantitative and qualitative MRI as a sensitive tool to assess a structure modifying drugs in knee osteoarthritis.