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397 EFFECTS OF OSTENIL® IN DELAYING TOTAL KNEE REPLACEMENT. AN OPEN, PILOT, PHASE III STUDY

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Aim: Our aim was to determine whether one intra-articular (i.a.) injection of Ostenil® (20mg/2ml hyaluronic acid of fermentation origin) per week for 5 consecutive weeks would improve the quality of life of patients with painful advanced knee osteoarthritis (OA), delay the time to total knee replacement (TKR) and improve the viscoelastic properties of the synovial fluid (SF). Patients presenting as possible candidates for TKR within 3 months, based on Kellgren-Lawrence scale and severe clinical signs, using 1 or 2 crutches and requiring continuous NSAID treatment, were recruited after providing signed informed consent.

Prior to Ostenil® injection on Days 0, 7, 14, 21 and 28 (i.e. V1-5) efficacy parameters were assessed and SF collected (if effusion present). Patients returned on Days 56 and 84. An open visit (V8) was planned to determine the time to re-treatment or TKR (up to Month 12). NSAIDs intake was recorded.

24 patients (average age: 62.5 ± 10.6 yrs; 50% female) were included. 3 dropped out for personal reasons and 21 were evaluated. Of these, 3 underwent TKR between 4.5 - 6 months after the start of treatment. The other 19 did not require TKR up to 12 months after start of treatment (end of study).

Pain on walking 20m without support decreased from 44.0mm (V1) to 9.0mm (V5) ($p=0.0002$) and was maintained to V7. WOMAC A decreased from 7.0 (V1) to 3.0 (V7) ($p=0.002$). Joint stiffness and impairment improved significantly ($p<0.005$) from V3 to V7. At V1, 80% patients had effusion compared to 57.1% at V8. NSAID consumption did not change during the study. SF-36 improved significantly ($p=0.02$) with a 22% change in the median score. The dynamic elasticity (G') of SF increased from 43.9±8.6 mPa at V1 to 54.0±25.4 mPa at V7 while dynamic viscosity (G") increased from 112.1±81.3 mPa at V1 to 171.9±169.6 mPa at V7. Steady state viscosity (?) increased from 19.5±12.5 mPas at V1 to 28.9±27 mPas at V7.

This study showed that Ostenil® treatment delayed TKR by 4.5 – 6 months in 3 patients and up to 12 months in the other patients, significantly improving the quality of life of these patients. The relationship between the improvement in clinical signs and the change in viscoelastic properties of the SF should be further investigated in a larger study.