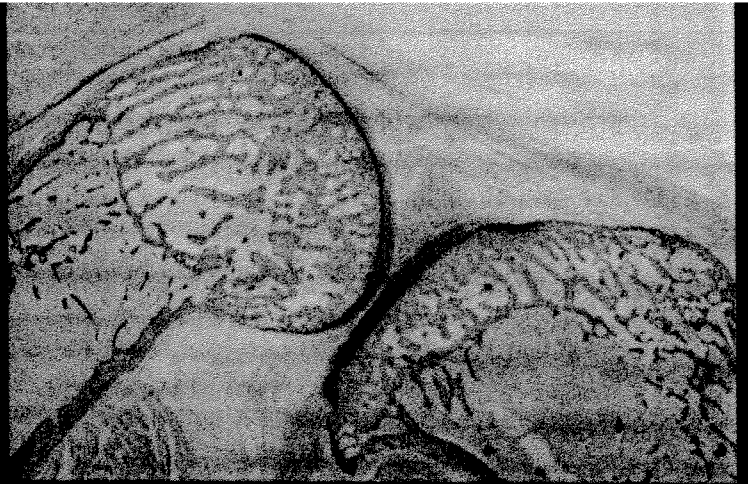


9<sup>th</sup> World Congress of the  
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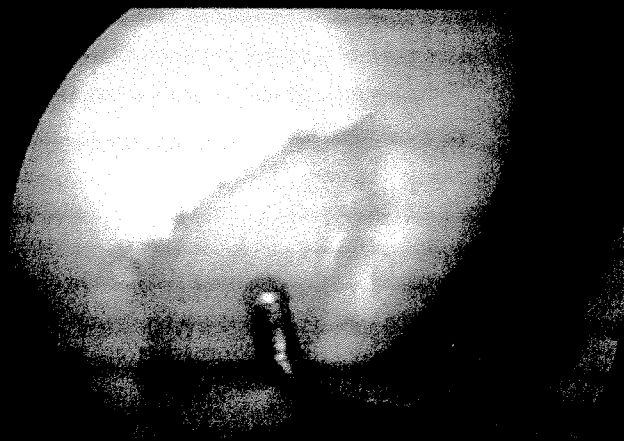
2-5 December 2004  
Chicago, IL, USA



# Osteoarthritis and Cartilage



International  
Cartilage Repair  
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ISSN 1063-4584

between group I and II, but it was observed that group II showed at 6 months a higher pain relief than group I (-108.6 vs -55.8). Change in WOMAC articular mobility subscale at 6 months when compared to baseline score was -4.3 in Group I and -44.8 in Group II ( $P = 0.081$ ). Both change in WOMAC functional capacity subscale (Group I = -74.9 vs Group II = -420.1) and change in total WOMAC index score (Group I = -134.9 vs Group II = -573.5) at 6 months when compared to baseline score were statistical significant. From all patients of Group I and II, three and nine patients did not receive KRS, respectively. The determination of the NNT was 5. Total cost of all the patients included in the Group I, II and III after 6 months to start the study was 132,969.20€, 106,375.36€ and 239,951.12€, respectively.

**Conclusion:** Patients treat with intra-articular HA seems to show a better efficacy profile than those from placebo. Intra-articular HA could delay the moment of KRS. In patients waiting by KRS, the treatment of knee OA with HA reduces the cost.

This clinical trail was supported by TEDEC-MEIJl Farma-SPAIN.

### P346

#### BOTULINIC TOXIN FOR THE REHABILITATION OF OSTEOARTHRITIS FIXED-FLEXION KNEE DEFORMITY

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**Introduction:** Patients with knee osteoarthritis eventually develop flexion attitude of the knee that can progress to fixed-flexion deformity. Fixed-flexion deformity impairs walking and can contribute to cartilage degradation. Fixed-flexion deformity is caused, at least partially, by hamstring muscles contracture, which is usually difficult to revert with physiotherapy.

**Aim:** In this preliminary study we evaluate the effectiveness of botulinic toxin injections to improve fixed-flexion deformity in patients with knee osteoarthritis.

**Patients and methods:** Six patients with knee osteoarthritis and fixed-flexion deformity were included in this study. All patients answered Lequesne functional questionnaire and had range of motion measured by goniometry before and 4 weeks after treatment. Four patients had Kellgren/Lawrence (KL) scale grade III for knee osteoarthritis and the other 2 had grade IV. Botulinic toxin in a single dose of 300 IU was injected in the hamstring muscles guided by electro stimulation. Patients were asked to perform stretching exercises at home.

**Results:** Botulinic toxin was beneficial for most patients, increasing range of motion and decreasing Lequesne scores. Before treatment average flexion deformity angle and Lequesne score were 11.3° and 10.5, respectively. After treatment these parameters were 8.6° and 8.5, respectively. Separate analysis showed that patients with KL grade IV had no benefits from the injections, while KL grade III patients had accentuated reduction in Lequesne scores in spite of small increase in range of motion.

**Conclusion:** Further prospective controlled studies will be needed to evaluate whether hamstring blockage with botulinic toxin has therapeutic potential in the management of knee osteoarthritis with fixed-flexion deformity.

### P347

#### OSTENIL® MINI IN THE TREATMENT OF HALLUX LIMITUS. A SINGLE BLIND, RANDOMISED STUDY

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**Aim:** To assess the efficacy and safety of Ostenil® mini (TRB CHEMEDICA AG, Germany), a synovial fluid substitute containing

1.0% hyaluronan, in the treatment of osteoarthritis (OA) of the first metatarsophalangeal (FMTP) joint, compared to standard steroid injection.

**Methods:** Patients (40–80 years old) with painful OA of the FMTP joint were recruited after giving written informed consent and randomised after confirmation of inclusion/exclusion criteria. Those in the Ostenil® group (OG) received one intraarticular (i.a.) injection of Ostenil® mini (1.0 ml), while the steroid group (SG) received one i.a. injection of 1 ml of 1% triamcinolone acetonide. Only paracetamol 500 mg tablets were allowed as escape medication. Patients were assessed on days 0, 14, 28, 56 and 84 (end of study). Efficacy was evaluated with the following parameters: pain at the MTP joint (VAS) on palpation, on passive motion and on walking 20 m with standard shoes; the Hallux Metatarsophalangeal-Interphalangeal Scale of the American Orthopaedic Foot and Ankle Society (AOFAS); general evaluation of treatment by patients and physician (5 level scale); and the use of analgesics. Tolerability to treatment was assessed by patients and physician (5 level scale) and all adverse events were recorded. Variables were analysed using the Chi-square test, non-parametric Mann-Whitney *U* test, Wilcoxon test and Friedman test.

**Results:** Thirty-seven patients (mean age: 62.0 years; females: 85%) (40 joints) were recruited and completed the study (OG:  $n = 20$  joints; SG:  $n = 20$  joints). Pain on palpation and on passive motion decreased significantly ( $P < 0.01$ ) in both groups throughout the study compared to baseline, but there were no differences between groups ( $P > 0.05$ ). Pain on walking 20 m decreased more in the OG being significant ( $P < 0.05$ ) at Days 28 and 56. AOFAS scale evaluation showed no differences in function and alignment, but a significant reduction ( $P < 0.05$ ) in pain and total score was observed for OG at all visits. General evaluation of treatment by the patient showed increased patient satisfaction in both groups, but it was significant ( $P < 0.05$ ) only in OG. Adverse events appeared in two joints in OG and in one in SG ( $P > 0.01$ ) and consisted of pain and/or swelling at the injection site.

**Conclusion:** Ostenil® mini is effective and safe in decreasing pain due to OA of the FMTP joint. Pain and AOFAS total score showed significant improvement with Ostenil® mini compared to a steroid injection. No severe adverse reactions were observed.

### P348

#### PRELIMINARY STUDY TO EVALUATE THE EFFICACY AND TOLERANCE OF JOINT LAVAGE IN SHOULDER PAIN VS INTRA-ARTICULAR INJECTION OF HYALURONIC ACID

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**Objectives:** To evaluate the efficacy and tolerance of joint lavage in shoulder pain vs intra-articular injections of hyaluronic acid.

**Methods:** In this prospective comparative and randomized study, were treated 30 patients (24 females), 15 in each group. Both groups were evaluated at baseline, 1 week, 1 month and at 3 and 6 months after the treatment procedure.

The main inclusion criterion was a minimum pain score of 50 mm on a visual analogue scale (VAS) from 0 to 100 mm.

The primary endpoints were the efficacy on the pain level; mobility (active and passive) and patient's and physician's opinion and ability (LDA). The secondary endpoint was the treatment tolerance.

A comparison response rates between two groups were made for ANCOVA model: one variant analysis of two factors: time factor (two levels, before and after) of repeated measurements and group factor (two levels, hyaluronic acid and joint lavage) the independent measures, evaluating both factors and interactions between them. The significant level was 0.05.

**Results:** Both treatment groups were comparable at baseline. There was a significant improvement in the VAS score, mobility and patient's and physician's opinion and ability at 1 week, 1 month, and 3 and 6 months ( $P < 0.0001$ ) compared at baseline. Tolerance results showed no adverse events in either group. No patient dropped-out.