Efficacy and Safety of a Distraction-Rotation Knee Brace (ODRA) in Medial Knee Osteoarthritis - a Phase III Randomised Controlled Trial (Ergonomie Study)

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Background: According to EULAR and OARSI guidelines, evidence is inconclusive for the symptomatic benefits of an unloader knee brace in medial knee osteoarthritis (OA).

Objectives: The objective of this multicentre randomised controlled trial (RCT) (ClinicalTrials Id. NCT02765685) was to compare the efficacy and safety of the ODRA brace, a distraction-rotation custom-made knee brace versus usual care over one year in medial knee OA.

Methods: Patients with symptomatic medial knee OA (VAS pain scores at rest >40/100 for the medial compartment) and Kellgren-Lawrence (KL) grade II-IV were randomised in two groups: brace group (ODRA 'usual care') vs usual care alone (UCA). Patients were followed up every two months for one year. Usual care consisted of all the pharmacological and non-pharmacological treatments used for the management of knee OA. The primary end-point was the difference of VAS-pain between M0 and M12. Secondary end-points included patient global assessment of disease severity (PGA) on VAS, % of patients reaching the PASS (VAS-pain <30/100) and MCI (delta VAS-pain >20/100) thresholds at M12, KOOS scores, OA-specific quality of life questionnaire (OAKHQOL), as well as drug intake. Safety and compliance were evaluated by recording side effects and average knee brace duration of wear, respectively.

Results: Overall 120 patients (57% women) from 7 centres were included. Their characteristics were the following: mean age 63.6±11.4 years; BMI 29.6±5.5 kg/m²; OA duration 5.6±5.6 years; 52% KL III; 21% KL IV. The VAS pain decrease was statistically higher in the ODRA group (from 61.9±17.4 (M0) to 38.6±25.3 (M12)) than in the UCA group (54.9±18.2 to 45.5±23.8) in the intent to treat bivariate and multivariate analyses (delta VAS-pain: 13.1±4.9, p<0.01). At M12, ODRA patients experienced a significant higher improvement than the UCA patients for PGA, all KOOS domains and for 3 of 5 domains of OAKHQOL (PGA, Pain, Physical activities, Mental health). Patients reaching PASS threshold at M12 were 42% in ODRA group vs 27% in UCA group (OR=3.04; 95% CI: 1.11 to 8.30; p<0.05) and were 46% vs 28% for MCI respectively (OR=2.65, 95% CI: 1.01 to 6.96; p<0.05). The overall analgesic use decreased more frequently in the ODRA group at M12 than in the UCA group (32.7% vs 15.4%, p<0.05) except for NSAIDs, HA or steroid injections. The compliance was good: the brace was worn for a median [IQR] duration of 5.7 [4.0–7.0] hours a day between M0 and M6 and 5.3 [3.7–6.3] hours a day between M6 and M12. Non-serious side effects were more common in the ODRA patients (p=0.05) which justified the definitive withdrawal of the brace in 8 ODRA patients (8%, mainly for cutaneous side effects).

Conclusions: In this RCT, the use of the ODRA brace in addition to usual care was shown to be superior to usual care alone in reducing symptoms and improving quality of life of patients suffering from medial knee OA, with good compliance.

Disclose of Interest: None declared

Low-Dose Radiation Therapy as Treatment for Hand and Knee Osteoarthritis: Two Double-Blinded RCTs

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Background: Synovial inflammation plays an important role in osteoarthritis (OA) pathophysiology. In some countries, low-dose radiation therapy (LD-RT) is widely used as treatment for OA, while relatively unknown in others. Studies in vitro and in OA animal models have shown anti-inflammatory effects of LD-RT. However, systematic literature review has shown that high-level evidence for beneficial effects in clinical practice is lacking.

Objectives: To assess the effect of LD-RT on clinical outcomes and inflammation in patients with hand or knee OA, using two parallel prospective RCTs.

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Table 1: Discriminatory accuracy of imaging and serum/synovial fluid biomarkers at 2 years with respect to knee osteoarthritis (OA) development at 5 year according to 4 definitions using logistic regression model maximising area under receiver operating characteristic curve (AUC).

<table>
<thead>
<tr>
<th>Outcome at 2 years</th>
<th>MRI features only (M1)</th>
<th>Serum biomarkers only (M2a)</th>
<th>MRI and serum biomarkers (M2b)</th>
<th>MRI and synovial fluid biomarkers (M3a)</th>
<th>MRI and synovial fluid biomarkers (M3b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>0.70 (0.60–0.78)</td>
<td>0.49 (0.42–0.56)</td>
<td>0.44 (0.42–0.47)</td>
<td>0.70 (0.58–0.78)</td>
<td>0.70 (0.58–0.78)</td>
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<tr>
<td>TF OA</td>
<td>0.80 (0.73–0.86)</td>
<td>0.75 (0.68–0.82)</td>
<td>0.69 (0.62–0.76)</td>
<td>0.80 (0.73–0.86)</td>
<td>0.80 (0.73–0.86)</td>
</tr>
<tr>
<td>PF OA</td>
<td>0.69 (0.56–0.83)</td>
<td>0.65 (0.52–0.79)</td>
<td>0.61 (0.49–0.75)</td>
<td>0.69 (0.56–0.83)</td>
<td>0.69 (0.56–0.83)</td>
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Abstract OP0056: The concordance between MRI and synovial inflammatory biomarkers was weak. The associations between MRI and synovial biomarkers at 2 years as analysed here predicted ROA or MROA at 5 years.

Conclusions: Neither MRI-defined inflammation, nor synovial/serum inflammation biomarkers at 2 years as analysed here predicted ROA or MROA at 5 years.

REFERENCE:
[1] Struglics, A. et al. Changes in cytokines and aggrecan ARGS neoepitope in synovial fluid and serum and in synovial fluid. The concordance between MRI and synovial biomarkers was weak and not statistically significant, apart from effusion–synovitis and IL-8 (log 10 IL-8 levels were 0.23 and 0.43 higher in persons with grade 1 or 2/3, respectively).