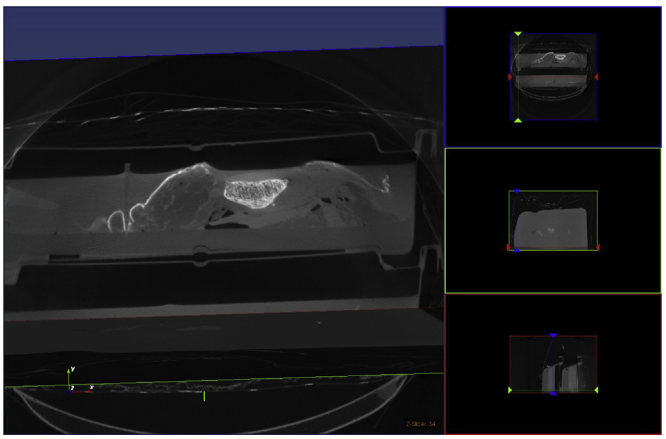

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EVALUATING THE EFFICACY OF AN EXTENDED INJECTIONS REGIMEN OF ANTI-OX-VS VISCOSUPPLEMENT (HYALURONIC ACID + SORBITOL) IN PATIENTS WITH HIGH GRADES KNEE OSTEOARTHRITIS & CONTRAINDICATED CORTICOTHERAPY

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Purpose: To investigate the efficacy of a regular and intensive injections regimen of Synolis V-A on patients with high Kellgren–Lawrence (K–L) grades who are contra-indicated for corticotherapy and for knee replacement.
Methods: Prospective, open-label 52 weeks study including 15 patients diagnosed with knee OA.
Inclusion criteria: Symptomatic patients with K–L grades III and IV and considered as requiring viscosupplementation. High surgical risk with cardiovascular disease and/or severe venous insufficiency and/or insulin-dependent diabetes, contra-indicated to corticotherapy.
Treatment procedure: The 1st treatment period is composed of 3 consecutive injections of 2ml, one week apart (at D0, D7 & D14). The 2nd treatment period is composed of a monthly single injection of Synolis V-A for a period of 4 months starting at the second month after treatment initiation (W9–W22). At D182, this treatment cycle is repeated, starting with 3 injections one week apart (D182, D189 & D196) followed by the 2nd "single injections" period (W35–W52).
Study criteria: Primary end points: variation of the mean perceived pain and stiffness vs. baseline (using a 4 points Likert scale and WOMAC questionnaire), secondary end point: percentage of responders and of patients needing oral pain killers.
Results: Mean WOMAC A (Pain) score evolved from 13.60 at baseline to 9.20 at D182, to 7.67 (−43.6%) at W52. Response rate (defined as a score decrease $\geq$ 4) ended up at 100% at W52.
Mean WOMAC C (Stiffness) score evolved from 6.33 at baseline to 3.80 at D182, to 3.20 (−49.4%) at W52. Response rate (defined as a score decrease $\geq$ 2) also ended up at 100% at W52.
Percentage of patients having pain-killers intake was of 40% at baseline, down to 13.3% at D182, reaching 6.7% at W52.
Conclusions: This exploratory study on patients for whom corticotherapy or knee replacement is not an option demonstrates the feasibility and the sustained efficacy of a regular and intense injections regimen of Synolis V-A over one year: Cycles of a "loading" period of 3 weekly injections every 6 months, alternating with single monthly injections. At the end of the 1st cycle, a slight efficacy slowdown could be observed, but the second cycle further improved clinical results and decreased the need for pain-killers intake. Sustained pain and stiffness improvement is expected to improve patients' quality of life, while decrease of pain-killers intake is expected to generate less associated side effects.
During this one year period, patients received a total of 14 injections of SynolisV-A (2 ml) with no side effect reported.

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EFFICACY OF VISCOSUPPLEMENTATION WITH HYALURONIC ACID + SORBITOL IN PATIENTS WITH AND WITHOUT PATELLO-FEMORAL PAIN

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Purpose: Viscosupplementation is a therapeutic modality widely used in the management of knee osteoarthritis (OA). The knee joint is constituted of three different joints, medial tibiofemoral, lateral tibiofemoral and patellofemoral. Tibiofemoral involvement is the main inclusion criteria of most of the controlled trials aimed to assess efficacy of viscosupplementation in patients with knee OA. However very few study have focused on patients suffering from patellofemoral OA, isolated or associated with tibio-femoral OA.Those which did, suggested a lower rate of response in case of patello-femoral involvement.
The aim of the study was to compare the magnitude of the response to intra-articular injections of a combination high molecular weight 2% HA+ sorbitol in patients suffering from knee OA with and without patellofemoral symptoms.
Methods: Two subgroups of patients were obtained from 1147 OA patients included in an observational clinical trial and treated IA injections of HA + sorbitol for symptomatic knee OA: The first group (PF) was made of patients experiencing patello-femoral symptoms such as Zohlen sign and retropatellar pain at examination. The second one (NoPF) was constituted of those without any sign of patellofemoral pain.
Pain score (5-point Likert scale) was obtained at baseline, and then at weeks (W)1, 2, 3, 12 and 26.
For the quantitative variable pain in scoring points, means and standard deviations were calculated as well as the absolute and relative mean changes from post-baseline visit (W1, W 3, W3, W12, W26) to baseline visit. The assessment of significant differences in the different subgroups was performed by using the two-sample *t*-test.
Results: PF and NoPF subgroups included 680 and 467 patients respectively. Most of the patients in both subgroups showed severe or very severe pain at baseline. At Visit 6 approximately one fifth of the patients were free of pain in both subgroups. Moreover, the proportion of patients with severe or very severe pain decreased markedly, without between-group difference.
At each assessment point there was no significant difference for both absolute and relative changes in pain ratings, between subjects with and without patello-femoral symptoms. Only 17.3 % of patients from the PF subgroup and 19.5% of those of the NoPF group 19.5 % had no change in pain ratings at W26.
Conclusions: Viscosupplementation with HA+ sorbitol is as effective in patients with patello-femoral symptoms, than in those without.

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HYALGAN DRIVES CELL ENGRAFTMENT TO CARTILAGE MODULATING TISSUE REPAIR IN AN OSTEOARTHRITIS MODEL

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Purpose: The lack of a disease- modifying treatment for Osteoarthritis (OA) moved lately the field of research in considering cell therapy and biological compounds as new therapeutic strategies. Recently, the entire bone marrow niche received great attention by clinicians and researchers since its use enables to overcome the drawbacks related to culture-expanded cells.On the basis of these biological and clinical needs, we designed this study to assess the effectiveness of Mesenchymal Stem Cell (MSC) and Bone Marrow Concentrate (BMC), alone and/or combined with Hyalgan (HA) in counteracting OA progression in a rabbit model as well as their local bio-distribution at short-term follow-up. Moreover, we considered what was the impact of HA and of some typical OA features in modulating cell homing.
Methods: Post-traumatic OA was induced bilaterally by Anterior Cruciate Ligament Transection. After OA onset, intra-articular injections of: i) HA; ii) MSC; iii) MSC-HA; iv) BMC; and v) BMC-HA were carried out and evaluated after 2 months in synovial membrane , cartilage and meniscus through histological and immunohistochemical analyses. A group of animals, designed to assess local bio-distribution of both labelled-cells with and without HA combination, was evaluated at 7 and 14 days from their delivery. Kruskal–Wallis test followed by the post-hoc Dunns test, were used to assess the regenerative potential of treatments. Spearman's rank-order correlation method analyzed the relationships between the percentages of bio-distribution and the histological features observed in joint tissues.
Results: A beneficial contribution of HA in reducing OA changes was noticed in cartilage, meniscus and synovial membrane showing different degrees of repair. In particular, the greatest effect of HA was observed when combined with BMC in synovial membrane displaying a