OBJECTIVES

To evaluate the short term pain-relief effect of ANTI-OX-VS in patients suffering from knee osteoarthritis

Study design

Prospective, open-label 26 weeks study 29 outpatients fulfilling the American College of Rheumatology clinical criteria for the diagnosis knee OA.

Inclusion criteria

- ✓ Patients fulfilling the American College of Rheumatology clinical criteria for the diagnosis knee OA and considered by the physician as requiring viscosupplementation
- ✓ 85 ≥ Age ≥ 30 years
- ✓ Kellgren-Lawrence grade (KL) II to IV on standing AP view, Lyon-schuss view, profile, skyline view of the patella

Main exclusion criteria

- ✓ Flare and / or significant effusion at any joint
- ✓ VS of any knee within 6 months prior to the initiation of treatment
- ✓ Intra-articular steroid injection of any knee within 3 months prior to the initiation of treatment
- ✓ Known hypersensitivity to sodium hyaluronate and/or sorbitol
- ✓ History of autoimmune disease or abnormal physiological condition
- ✓ Skin disorder or infection at the site of the injection
- ✓ Pregnant women or under the age of 18 years.

Treatment procedure

Three 2mL intra-articular injections of Synolis V-A™ were performed 1 week apart by an experienced rheumatologist.

Authorized treatments

• Paracetamol < 4 g/jour
• NSAIDs if taken before inclusion
• SYSADOAs *(chondroïtin sulfate, diacerhein, avocado/soja unsaponifiables, glucosamin , diacerhein)* if taken at stable doses at least 3 months before inclusion and during the whole follow-up period.

Evaluation

At baseline (W0), W1, W2, W13 and W26; common assessment by patient and physician using a Likert 5 points scale:

- ✓ Walking pain and global assessment of the knee
- ✓ WOMAC A,
- ✓ WOMAC stiffness.

At W1, W2, W13 and W26: Percentage of improvement since the first injection were obtained (figure 4).
Treatment satisfaction was also evaluated at the end of the follow up period (Likert 3 points scale).

Primary end-points

- ✓ Variation of walking pain (WP) between W0 and W26.

Secondary end-points

- ✓ Variation of WP, WOMAC A, WOMAC Stiffness, Patient global assessment (PGA) between W0 and W1, W2, W13 and W26. Percentage of improvement between W0 and W1,W2,W13 and W26
- ✓ Safety and tolerance quantitative assessment (nb of side effects / nb of treatments)

RESULTS

Mean age 68 +/- 9
KL (grade /N): II/12; III/14; IV/1
At baseline:

- ✓ Mean WP = 2.9
- ✓ Mean WOMAC A = 10.5
- ✓ Mean WOMAC stiffness : 4.4

At week 1:

- ✓ Mean WP = 2.1 (p< 0.0020)
- ✓ Mean WOMAC A = 6.7 (p< 0.0000)
- ✓ Mean WOMAC stiffness : 3.1 (p< 0.0002)

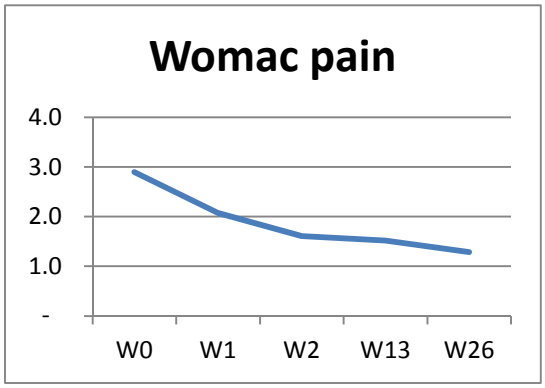
At week 13:

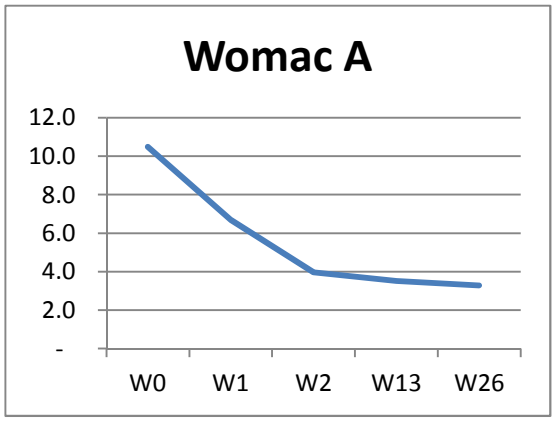
- ✓ Mean WP = 1.5 (p< 0.0000)
- ✓ Mean WOMAC A = 3.5 (p< 0.0000)
- ✓ Mean WOMAC stiffness : 2.1 (p< 0.0000)

At week 26:

- ✓ Mean WP = 1.3 (p< 0.0002)
- ✓ Mean WOMAC A = 2.3 (p< 0.0000)
- ✓ Mean WOMAC stiffness : 2.1 (p< 0.0001)

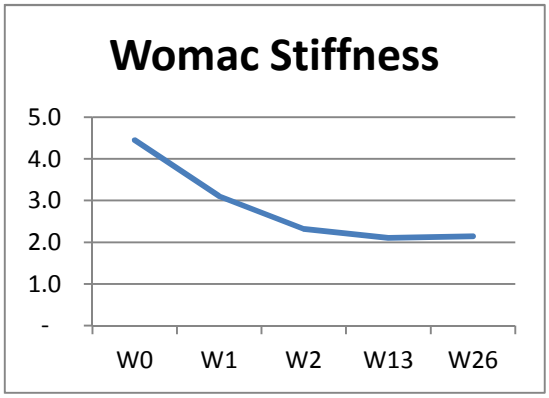
- ✓ Variation of WP between baseline and W1, W2, W13 and W26 was respectively -0.8, -1.3, -1.4 and -1.6



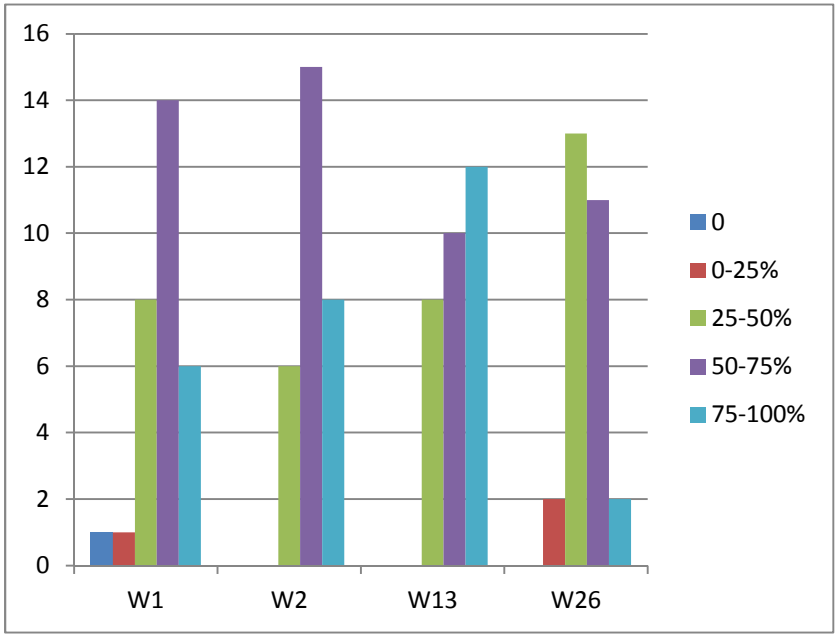


- ✓ Variation of WOMAC A between baseline and W1, W2, W13 and W26 was respectively -3.8, -6.5; -7.0 and -8.2.

- ✓ Variation of WOMAC Stiffness between baseline and W1, W2, W13 and W26 was respectively -1.3, -2.1, -2.3 and -2.3.



At W26, 100% of the patients considered SYNOLIS V-A effective to extremely effective. 59% considered it extremely effective.



No device-related adverse event was reported.

Responding patients:

Considering a success criteria such as minimum 1 point reduction in Womac pain between W0 and W26, 26 patients out of 29 have improved for at least more than 1 point, meaning **90%** responding patients at W26 time point.