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Effects of a novel hops extract & undenatured collagen combination in an open case series of subjects with arthritis[1]

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Introduction

- According to the National Health Interview Survey, 30% of US adults have reported experiencing some type of joint pain during the preceding 30 days.[2]
- The most common types of arthritis in which the main feature is joint pain are osteoarthritis (OA) and rheumatoid arthritis (RA).[3]
- Common underlying causes such as synovial inflammation, immune-cell infiltration, and chondrocyte pathophysiology have contributed to the pathogenesis of both conditions.[4-7]
- Hops-derived tetrahydro iso-alpha acids (THIAA) – a mixture of co-, n-, and ad- congeners – have been shown to exhibit anti-inflammatory properties in vitro and to reduce bone cartilage degradation in a mouse model of RA.[8-11]
- The n-congener has demonstrated higher anti-inflammatory activities in vivo than the other two congeners.[12] A THIAA mixture with a higher content of the n-congener is termed n-enriched THIAA (nTHIAA).
- Undenatured type-II collagen (UC-II), derived from chicken cartilage, has been shown to ameliorate symptoms in individuals with RA, OA and in normal participants who had joint discomfort after exercise.[13-15]

Objective

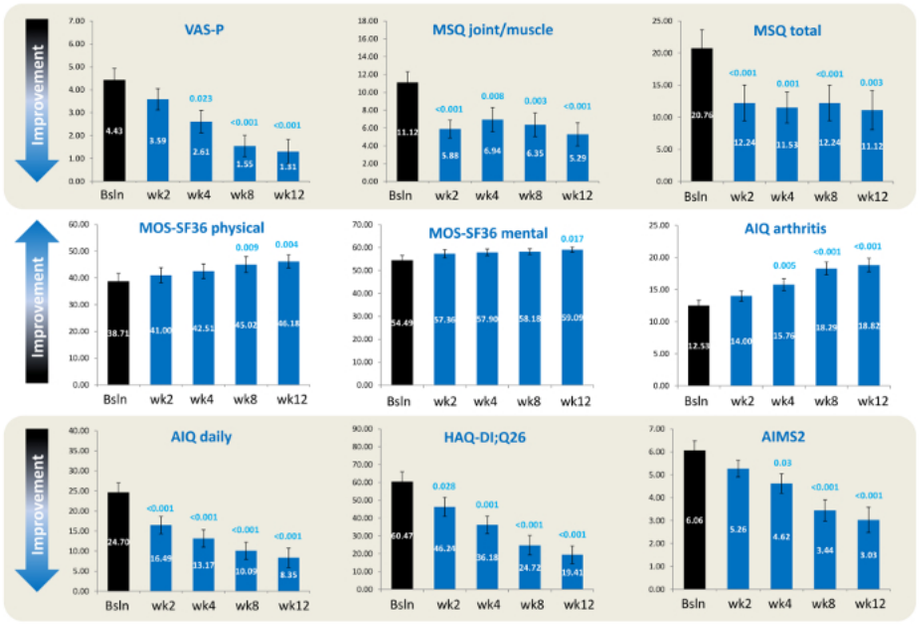
To evaluate the efficacy and safety of nTHIAA and UC-II combination in patients with chronic joint pain, probably secondary to OA and/or RA.

Methods

- **Patients**
  N=17; 12 women and 5 men (39 – 69 y/o); 13 with probable OA and 4 with possible RA
- **Study design**
  Open case series
- **Treatment**
  2 tablets twice daily; each tablet contains nTHIAA (150 mg) + UC-II (10 mg)
- **Follow-ups**
  Baseline to 12 weeks
- **Assessments**
  At each clinic visit, patients were assessed by the following:
  - **VAS-P**: Visual Analog Scale for Pain
  - **MSQ**: Medical Symptoms Questionnaire, including joint/muscle score and total score
  - **MOS-SF36**: Health and Wellness Outcome Questionnaire, including physical component and mental component
  - **AIQ**: Arthritis Impact Questionnaire, including arthritis symptoms score and daily living score
  - **HAQ-DI**: Health Assessment Questionnaire; Q26 indicates overall pain over previous week
  - **AIMS2**: Arthritis Impact Measurement Scales 2
  - **VAS-E**: Visual Analog Scale for Efficacy
  - **Analgesic use by patients**
- **Statistical analysis**
  Two-sided paired t-tests comparing with baseline; data expressed as mean ± standard error

Results

Overall: All subjects completed the 12-week evaluation and all reported improvements; some improvements were seen as early as 2 weeks.



VAS-E:
At Week 12, participants rated product efficacy at 7.8 ± 0.47 out of 10.

Analgesics use:
At baseline, 13 of the 17 participants were using analgesics for joint pain. At Week 12, Only 4 were using analgesics; 2 of the 4 had reduced dosages.

Safety and tolerability:
The product was well tolerated and no serious side effects.

Study limitations:
- lack of a randomized control arm to compare efficacy
- potential placebo effect and seasonal effect
- selection bias
- small sample size and short study duration.

Illustrative case report

- The case is a 39 y/o white male with a 5-year history of chronic joint pain (diagnosed with OA in 2008), who uses acetaminophen for pain relief.
- Began taking nTHIAA (600 mg/d) and UC-II (40 mg/d) in 02/2013 with no changes to diet or exercise.
- Patient noted continued improvement and pain relief during the next 6 months.
- Patient has stopped taking analgesics as a result.

Questionnaire	Baseline (2/12/13)	Week 2 (2/27/13)	Week 5 (3/20/13)	Week 8 (4/11/13)	3 Months (5/02/13)	6 Months (8/14/13)
VAS-P	7.5	6.9	2.0	0.4	0	0
MSQ joint/muscle	10	8	6	10	3	2
MSQ total	49	32	23	36	14	11
MOS-SF36 physical	25.2	32.4	37.3	44.6	48.8	48.3
MOS-SF36 mental	48	44	52.5	48.8	52.8	54.4
AIQ arthritis symptoms	14	15	17	20	24	24
AIQ daily living	43	28	18	19	8.2	6.2
HAQ-DI;Q26	65	65	35	20	10	5
AIMS2	5.0	5.0	4.5	2.5	0.5	0.5

Conclusion

This case series provides preliminary evidence that nTHIAA and UC-II combination is safe and efficacious in management of participants with chronic joint pain and that improvement in most participants was experienced within 2 weeks.

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