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Boom Time for BOTANICALS

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NEW FORM OF CHONDROITIN IMPROVES KNEE FUNCTION IN OA PATIENTS

WHILE CHONDROITIN SULFATE has a long history of use in joint health, concerns around sourcing are leading to innovations in this ingredient. Xavier Berger, marketing manager for mobility and joint health at Gnosis by Lesaffre (Lille, France), says consumer concerns around animal welfare and cross-contamination have prompted formulators to source chondroitin from plants. Gnosis's branded chondroitin product Mythocondro is one example of this trend.

"Mythocondro helps reduce the risk of osteoarthritis and joint degeneration," Berger says. "Additional benefits include pain relief, anti-inflammatory activity, and increased articular function."

One recent clinical trial²⁰ on Mythocondro found that a 600 mg/day dose reduced inflammation, WOMAC scores, and C-reactive protein levels in obese adults with moderate knee osteoarthritis after eight weeks.

postmenopausal women for 14 days. The women received either 500 mg of NEM per day (n=30), or a placebo (n=30), while doing step exercises (50-100 steps per leg) on alternating days. NEM administration resulted in faster recovery from exercise-induced joint pain and stiffness, as well as reduced discomfort, relative to placebo.

MSM—A Flexible Option

While the joint health benefits of methylsulfonylmethane (MSM) have been established for some time, recent clinical trials examining MSM in combination with other joint health ingredients have found that MSM has a synergistic effect.

Tim Hammond, vice president of sales and marketing for Bergstrom Nutrition

Another rich source of emerging joint health botanicals is the world of traditional Chinese medicine.

(Vancouver, WA), says Bergstrom's branded OptiMSM is ideal for new products because of its relative affordability, strong safety profile, and proven efficacy.

"Extensive research has shown that MSM decreases joint pain, improves stiffness and swelling, and increases the range of motion and physical function of individuals with osteoarthritis," Hammond says. "OptiMSM's likely mechanism stems from its ability to decrease pro-inflammatory cytokines, reduce oxidative damage, and supply a rich source of sulfur."

One 2017 randomized, double-blind, placebo-controlled trial¹⁰ examined the performance of a glucosamine-chondroitin sulfate product both with and without MSM in relieving symptoms of osteoarthritis. The subjects, all of whom had either grade I or grade II osteoarthritis according to the Kellgren-Lawrence scale, received either 1) 1,500 mg of glucosamine and 1,200 mg of chondroitin sulfate (n=49), or 2) 1,500 mg of glucosamine, 1,200 mg of chondroitin sulfate, and 500 mg of MSM (n=50), or 3) a matching placebo (n=48) daily for three months. The subjects were assessed for joint pain on the WOMAC and VAS scales at baseline and after 4, 8, and 12 weeks. By the end of the study, the group that received the combination of glucosamine, chondroitin sulfate, and MSM exhibited the most significant improvements in WOMAC and VAS scores.

Botanicals

Various botanicals are showing promise as joint health supplements in clinical trials. Several of these products may present considerable advantages over legacy ingredients. Steve Fink, vice president of marketing for PLT Health Solutions (Morristown, NJ), says botanical ingredients like *Boswellia serrata* take effect faster and require a lower dosage than some of the established ingredients in the market.

"If we look at the most commonly used natural solutions for mobility support, two things stand out: they require relatively large doses, and they require a long time to show efficacy," Fink says.

In contrast, Fink says *Boswellia* extracts and other botanicals have been found to take effect in as little as five days and to be effective with doses as low as 100 mg. PLT's branded *Boswellia serrata*, Dynagenix Muscle+Joint Formula, is a low-dose joint health ingredient that can be formulated in RTD products, powders, and more. One 2019 randomized, double-blind, placebo-controlled clinical trial examined the effects of Dynagenix Muscle+Joint Formula in 50 healthy, active men aged 25 to 40. In this unpublished study, subjects received 60 mg of *Boswellia serrata* per day (n=25), or a matching placebo (n=25), for 10 days. Subjects underwent an eccentric exercise regimen, which involves muscles contracting and lengthening in quick succession, on day 7. The subjects were assessed for muscle and joint soreness via the VAS, knee range of motion, overall stiffness, and biomarkers of inflammation like IL-6 and cytokines at baseline and once daily on days 7 through 10. The subjects who received *Boswellia serrata* experienced a reduction in joint soreness and a faster recovery of knee range of motion relative to the control group.

Another rich source of emerging joint health botanicals is the world of traditional Chinese medicine. David Liu, PhD, is the chief technology officer for Chenland Nutritionals (Irvine, CA). Liu says the reputation of certain joint health ingredients in traditional folk medicine systems like traditional Chinese medicine and Ayurveda is prompting researchers to take a closer look at these ingredients.

"With the development and utilization of omics and bioinformatics in these research fields, the scientific implication of herbal formulas has been elucidated, which has led to a better understanding of and acceptance by the western science community," Liu explains. "Herbs like *Dioscorea nipponica*, *Andrographis paniculata*,

and *Acacia catechu* have been clinically studied for their efficacies in relieving joint discomfort related to knee osteoarthritis.”

Chenland recently completed a six-month, open-label human clinical trial on its JointAlive ingredient, which contains extracts of *Epimedium brevicornum* Maxim, *Dioscorea nipponica* Makino, and *Salvia miltiorrhiza* Bunge. Liu says that in this yet-to-be-published trial, JointAlive was 85% effective at reducing WOMAC scores. He says this trial also found that JointAlive begins to relieve joint discomfort in as little as two days.

Chenland is also actively pursuing a randomized, double-blind, placebo-controlled clinical trial¹¹ on JointAlive in partnership with KGK Science (London, ON, Canada). This study, which is currently recruiting participants, will examine the efficacy of JointAlive in alleviating joint pain and improving knee function in an otherwise healthy population with mild to moderate knee osteoarthritis. Liu says the last subject will be enrolled in September 2021, and a final report on the clinical trial is expected by the end of this year.

Formulators are also looking toward botanical ingredients that are quite well known for applications in food. Steve Holtby, president and CEO of Soft Gel Technologies Inc. (Los Angeles, CA), says one emerging joint health ingredient is better known for its role in making beer.

“Hops, the ingredient used to add a touch of bitterness to most brews, has been studied because of its joint health properties,” Holtby explains. Soft Gel Technologies’ Perluxan softgels, derived from hops (*Humulus lupulus*) “contain a unique botanical anti-inflammatory agent that has been clinically demonstrated to quickly relieve minor joint pain.”

Soft Gel Technologies exclusively markets Perluxan as a resin. Pharmachem Laboratories (Kearny, NJ), a division of Ashland (Wilmington, DE) that has performed extensive research¹² on Perluxan, owns the trademark for Perluxan as a powder.

One randomized, double-blind, parallel-design trial¹³ on 19 subjects pitted Perluxan against ibuprofen. The subjects were randomly assigned to receive either 1) 400 mg of ibuprofen once per day, 2) a softgel containing 450 mg of the hops resin once per day, or 3) a 300-mg capsule containing a powdered form of the hops resin four times per day, for 14 days. Both hops formulations inhibited COX-2 as well as ibuprofen starting nine hours after the initial dose; however, the hops formulations did not inhibit COX-1, while ibuprofen did.

“It was interesting to note that the hops resin softgel was only administered once over a nine-hour period but was as effective as ibuprofen,” Holtby says. “The Perluxan softgel had a faster onset of action and gradually reduced pain-causing enzymes over the period of the study.”

Other botanical blends are also showing promise in joint health. Indena’s (Milan, Italy) branded Mitidol, a blend of ginger (*Zingiber officinale*) and paracress (*Acmella oleracea*), underwent a pilot study that was published in 2020. This study¹⁴, a single-group pretest-posttest quasi-experimental trial, examined the effects of Mitidol on pain, inflammation, and knee function in 50 subjects aged 40 to 75 with knee osteoarthritis. All subjects received two 350-mg tablets of Mitidol daily for four weeks (n=50); there was no placebo group. The subjects were assessed for WOMAC and Tegner Lysholm Knee Scoring Scale scores at baseline and after



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