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New frontiers in osteoarthritis treatment: An expert consensus on evolving role of nutraceuticals

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Abstract
Osteoarthritis (OA) is a leading cause of pain and disability worldwide, with its prevalence expected to rise due to aging populations and lifestyle factors. Traditional pharmacological treatments primarily offer symptomatic relief without addressing the underlying causes of cartilage degradation, often accompanied by adverse effects. Nutraceuticals, particularly Undenatured Collagen Type II: UC-II®, sourced from Lonza, Switzerland, Mobilee®, sourced from Bioberica, Spain, and Curcumin from *Curcuma longa*, have emerged as promising alternatives, demonstrating disease-modifying effects with a strong safety profile. This expert opinion paper, based on sessions with 49 top Indian orthopedics, explores the efficacy and tolerability of these nutraceuticals in OA management. The combination of UC-II®, Mobilee®, and Curcumin has shown significant improvements in pain, mobility, and overall quality of life in OA patients, particularly in early-grade OA. Clinical evidence supports the role of these nutraceuticals in reducing inflammation, enhancing cartilage regeneration, and improving synovial fluid properties. Moreover, their safety and efficacy make them suitable for long-term use across diverse patient populations. The paper highlights the importance of appropriate dosing and the potential for these nutraceuticals to improve patient adherence and satisfaction, offering a viable alternative to conventional therapies. The findings advocate for the integration of evidence-based nutraceuticals into standard OA treatment protocols.

Keywords: Collagen type ii, sodium hyaluronate, osteoarthritis, uc-ii, nutraceuticals

Introduction
Osteoarthritis (OA) is the most common musculoskeletal disorder globally, associated with pain, disability, and quality-adjusted life-year losses. Years Lived with Disabilities (YLD) in OA grew by 75% between 1990 and 2013, positioning OA as the third most quickly increasing condition after dementia and diabetes [1]. In 1990, there were about 23.46 million cases of OA in India; by 2019, that number had risen to 62.35 million [2]. The prevalence of OA is anticipated to rise further in the near future due to an aging population, an increase in obesity, and a rise in physical inactivity [3].
Current guidelines recommend three types of modalities for OA management including pharmaceutical, lifestyle/non-pharmacological, and surgical, which can be combined when necessary. Pharmacological therapy, including NSAIDs, opioids, and cyclooxygenase (COX)-2-specific drugs, merely serves as a "palliative" measure, alleviating symptoms without addressing the underlying cause of the cartilage disorder. Furthermore, the efficacy of conventional medicines is limited, with a potential risk of side effects including gastrointestinal, and cardiovascular effects, and others, particularly with prolonged usage [4, 5].

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Even though lifestyle interventions (LIs), a non-pharmacological strategy, have been shown to be successful, evidence-practice gaps show that their implementation is still insufficient [6]. If medicine and lifestyle change are inadequate, the third approach is surgery [4]. Nevertheless, there has been a lot of interest in nutritional supplements and nutraceuticals recently. These comprise a diverse class of compounds that can significantly lower pain, inflammation, oxidative stress, and stiffness in the joints, and promote the development of cartilage [4, 5]. Furthermore, human clinical trials have demonstrated their potential to relieve OA pain (Liu, *et al*. 2017; Mobasheri, 2012; Ragle & Sawitzke, 2012; Senftleber *et al*., 2017) and are appealing for the treatment of chronic illnesses and disorders like OA because of their safety profile [4].

Among the most used nutraceuticals in OA, collagen and hyaluronic acid have demonstrated remarkable effects in reducing inflammatory markers and improving clinical symptoms in OA patients [4]. Curcumin is also another potent anti-inflammatory and antioxidant agent with strong evidence in OA treatment [7]. However, insufficient awareness among physicians and patients of the potential benefits of evidence-based nutraceuticals still exists. Hence, the aim of this expert opinion paper is to provide the first attempt at recommendation on the management of OA and to generate guidance on the evidence-based use of nutraceuticals, with a special focus on the combination of Undenatured Collagen Type II: UC-II® from Lonza, Switzerland, Mobilee®, and curcumin.

Methodology

This expert opinion paper is the result of five committee sessions held on June 22nd, July 7th, July 13th, July 20th, and August 10th, 2024, featuring 49 of India's leading orthopedic specialists. The committee aimed to discuss the current management challenges with OA, while comprehending the emerging role of nutraceuticals like UC-II®, a patented Undenatured Collagen Type II, sourced from Lonza, Switzerland; Mobilee® (60-75% Hyaluronic acid, >10% Polysaccharides, >5% collagen), a patented sodium hyaluronate, sourced from Bioberica, Spain, and curcumin. The objectives outlined for the expert meeting were as follows:

1. To comprehend the evolution of nutraceuticals in the management of OA, with a focus on advancements and differences in collagen supplements.
2. To analyze and determine an optimal combination with the right dose of nutraceuticals for achieving maximal therapeutic benefits in joint health.
3. To determine factors influencing adherence to cartilage therapy and identify safe, efficacious strategies that enhance the quality of life for OA patients within the context of nutraceutical advancements.

Results

1. What is the effectiveness of different collagen supplements in managing osteoarthritis (OA)?

Collagen supplementation is an emerging area of interest with its preventive and therapeutic role in OA [8]. However, all collagens reported in the literature differ not only in terms of physicochemical qualities or biological activities but also in terms of molecular structure and amino acid composition. These differences occur because of distinct raw materials as well as manufacturing processes [9]. Hence, different collagen-derived products can have completely different structures, compositions, and properties depending on how they are made. For example, there are three types of collagen-derived products: undenatured native collagen (insoluble) or soluble native collagen, both of which maintain the triple helical structure; gelatin (denatured collagen) and hydrolyzed collagen (peptides/amino acids), produced through hydrolysis. Undenatured Collagen Type II, made from chicken sternum, is a recently discovered unique nutraceutical ingredient that has garnered significant attention in the treatment of OA [7]. Animal studies have demonstrated that undenatured collagen type II stimulates specific regulatory T cells (Tregs) within the gut. These Tregs migrate to inflamed areas, where they control local immune responses in a specific, targeted manner, enhancing cartilage microstructure, reducing degeneration, and improving surface organization in OA [10, 11]. Undenatured collagen type II contains active epitopes capable of interacting with Peyer's patches, thereby inducing oral tolerance. On interacting with Peyer's patches, immune cells are activated, thus converting naive T-cells into regulatory T cells (Tregs), that specifically target type II collagen. Upon recognizing type II collagen in joint cartilage, these Tregs secrete anti-inflammatory cytokines, including transforming growth factor-beta (TGF-β), interleukin 4 (IL-4), and interleukin 10 (IL-10). This activity aids in reducing joint inflammation and promoting cartilage repair [12] *(Fig. 1. Mechanism of action of UC-II®)*. Various clinical studies have proven the efficacy of Undenatured Collagen Type II in OA. Moreover, it is common for both practitioners and consumers to assume that ingredients with the same name are identical, but this is not always the case [13].

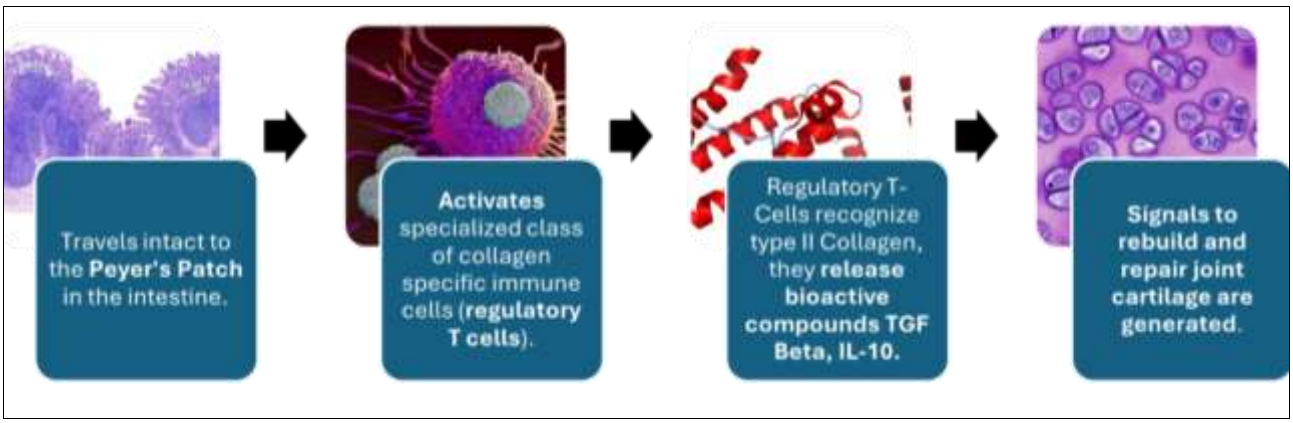

Fig 1: Mechanism of action of UC-II®

A study evaluating the functional characteristics of different undenatured collagen type II supplements available on the market revealed that the undenatured collagen type II: UC-II® obtained from Lonza contained 71 times more undenatured collagen compared to other supplements. The variance in undenatured content influences the efficacy and health benefits of the product. Additionally, UC-II® maintained the triple helical structure typical of type II collagen, unlike other products *(Fig. 2. TEM micrographs showing a difference in the appearance of collagen supplements* [13]. Significant differences were observed in the presence of antigenic epitopes, which are believed to be the active components of type II collagen supplements in establishing oral tolerance. Thus, the clinical effects of various supplements will differ as well. Thus, not all products labeled as undenatured (native) type II collagen are interchangeable, and practitioners should not assume their equivalence [13].

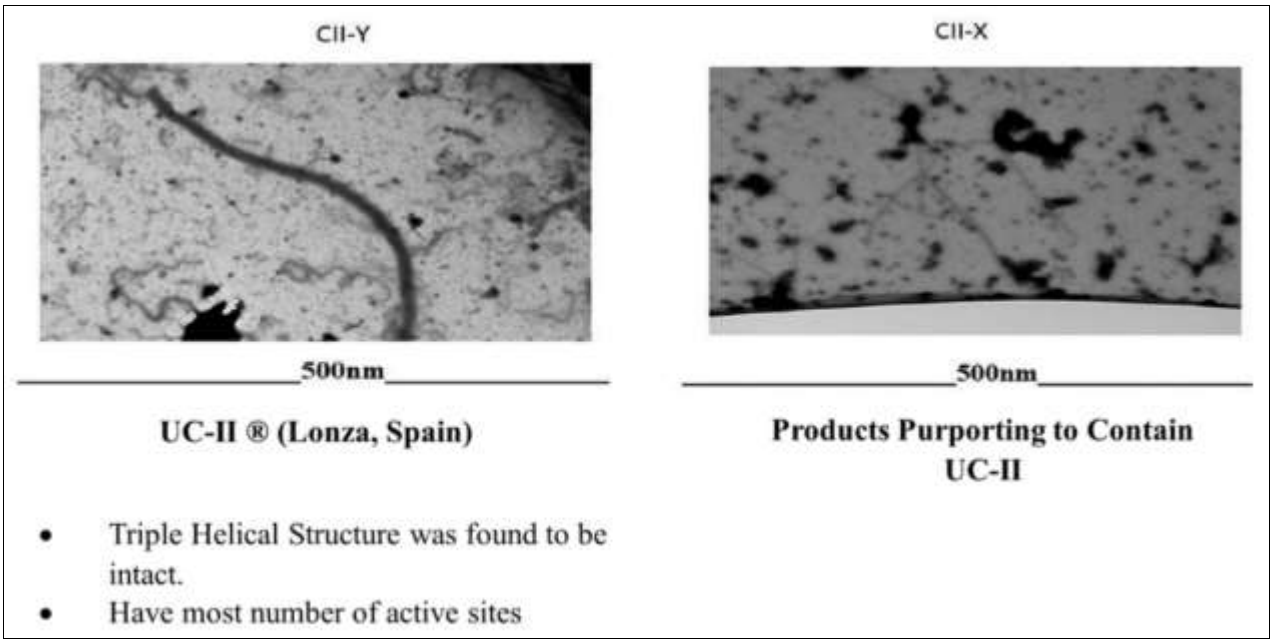

Fig 2: TEM micrographs showing a difference in the appearance of collagen supplements (Source: Harris *et al*., J Diet Suppl) [13]

1.1 Expert Opinion

UC-II® has demonstrated positive effects with amelioration of OA symptoms. Importantly, the efficacy of UC-II® remains unaffected by the quantity of Peyer's patches, which are crucial to its pharmacological action. For instance, in patients with inflammatory bowel disease, the use of UC-II® showed consistent efficacy, with positive patient feedback and symptom alleviation. Furthermore, UC-II® can be safely prescribed alongside NSAIDs, as no adverse drug reactions have been reported, and the two do not exhibit antagonistic effects due to their differing mechanisms of action. The robust clinical data supporting UC-II®, coupled with expert endorsement, underscores its superiority as a therapeutic option, offering enhanced efficacy and safety compared to older treatments. However, a significant challenge exists in prescribing animal-derived collagen products to vegetarian patients, even though it is acknowledged that animal-sourced collagen peptides are more effective. Thus, UC-II, sourced from Lonza, Switzerland has proved to be an efficacious and superior collagen for the management of OA.

2. What constitutes the optimal dose and combination of nutraceuticals for effective osteoarthritis (OA) management?

OA arises from an imbalance between cartilage synthesis and breakdown, leading to cartilage damage and synovial inflammation. Several complex biochemical and inflammatory mechanisms are involved in the pathogenesis of disease. The breakdown of cartilage in OA is one of the principal mechanisms in OA pathogenesis. It is primarily driven by proteolytic enzymes, with metalloproteinases (MMPs) being the key enzymes involved in this destructive process. MMPs play a crucial role in degrading the extracellular matrix of cartilage, contributing significantly to the disease's pathogenesis. Additionally, endogenous substances in the articular cartilage may act as antigenic stimuli, triggering immune responses that contribute to inflammatory arthritis. Thus, both mechanical and immunological pathways appear to be involved in the pathogenesis of OA [10].

Studies of joint biology and clinical investigations using MRI have identified numerous structural and molecular targets that show potential for alleviating pain and slowing OA progression. However, none of these targets has yet led to the development of newly approved treatments that both modify the disease process and effectively relieve osteoarthritic joint pain caused by pain sensitization or other biological factors like inflammation [11]. Pharmacological treatments, involving analgesics such as paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs) provide only symptomatic relief and do not have disease-modifying effects. Moreover, they are associated with several adverse effects, prompting clinicians and patients to seek alternative options that offer joint protection without major side effects [10]. A combination of nutraceutical supplements including UC-II®, Mobilee®, and curcumin has shown promise in addressing both the mechanical and immunological pathways involved in OA while being safe with no reported adverse effects. UC-II®, a collagen derivative, has demonstrated disease-modifying effects in OA while clinical studies have demonstrated the anti-inflammatory action of Mobilee® and curcumin to relieve OA pain and improve joint stiffness.

UC-II acts by oral tolerance to induce repair and support joint cartilage regeneration [12]. In a study evaluating cartilage

thickness, UC-II showed an increase in cartilage thickness of 17.6% [14]. Hyaluronic acid (HA), present in synovial fluid and the extracellular matrix of cartilage, contributes to the viscoelastic and lubricating properties of synovial fluid. When administered orally, HA has shown anti-inflammatory effects and improvement in knee OA symptoms. Oral HA binds to an intestinal receptor (Toll-like receptor-4; TLR-4), which promotes the production of the anti-inflammatory cytokine interleukin-10 (IL-10) and up-regulates suppressor of cytokine signaling 3 (SOCS3), while down-regulating pleiotrophin expression. These actions lead to anti-inflammatory effects in arthritis [15]. Mobilee® is a synergistic and proprietary composition of hyaluronic acid (60-75%), polysaccharides (>10%), and collagen (>5%) [16]. Mobilee® has demonstrated a multimodal mechanism of action that improves joint health by reducing synovitis and synovial effusion through the inhibition of prostaglandin E2 (PGE-2), strengthening synovial muscles by stimulating myoblast proliferation and reducing catabolism via IL-6 inhibition, and stimulating synovial cells to increase endogenous hyaluronic acid production, thereby enhancing joint lubrication. Mobilee® has been shown to stimulate a tenfold increase in endogenous HA secretion [17]. Curcumin, a potent anti-inflammatory and antioxidant agent, has demonstrated efficacy in treating OA by reducing pain, improving physical function, and enhancing the quality of life among OA patients. Its effects are primarily due to its ability to prevent chondrocyte apoptosis caused by inflammation and oxidative stress [7].

2.1 Expert Opinion

Clinicians should focus on identifying treatments supported by robust scientific data, such as UC-II®, Mobilee®, and Curcumin which they can trust. The synergistic action of UC-II®, Mobilee®, and Curcumin has been most beneficial for patients of grade 1 and 2 OA. However, most patients seek treatment only when they reach grade 3 or 4, where treatment becomes particularly challenging. No single drug universally benefits all patients at this stage, despite the use of various treatments such as PRP and intra-articular injections. Among these, the combination of UC-II®, Mobilee®, and Curcumin stands out as a promising option with superior results observed when compared to others. With UC-II®, Mobilee®, and Curcumin patients often experience improvements in movement, range of motion, and reduced pain, as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score. Another significant advantage of UC-II® is its long-term safety, making it suitable for use regardless of a patient's underlying comorbidities, thus ensuring high patient acceptability.

Determining the optimal dose and duration is crucial for the success of the combination treatment as well. A minimum duration of 3-4 weeks is necessary to observe beneficial effects, with a recommended continuation of at least 3-6 months. The combination has shown a 60-80% reduction in symptoms within three months. Clinicians with more than a year of experience using the combination in the correct patient population (typically grade I, II, and III OA) have reported that patients experience long-term relief. It is essential to understand that the combination should not be used for only a week or two, as this duration may not yield any noticeable improvement. In grade III or IV OA, the combination can be preferred when surgical intervention needs to be delayed. If no improvement in symptoms is observed with the combination in early-grade OA, further investigation for a meniscal tear or other differential diagnoses using MRI is recommended. Thus, UC-II® from Lonza, Switzerland, Mobilee® from Bioberica, Spain, and Curcumin from *Curcuma longa* have proven to be an effective and synergistic combination, with the right dose to effectively manage OA.

3. What role can nutraceutical supplementation play in improving patient adherence and enhancing the quality of life in individuals with osteoarthritis (OA)?

Non-adherence to treatment regimens has become a major hurdle that can lead to various negative outcomes, including medication wastage, disease progression, reduced functional abilities, lower quality of life, and increased use of medical resources, such as nursing homes, hospital visits, and admissions [18]. In managing chronic diseases, clinical guidelines of health services increasingly prioritize quality of life, particularly emphasizing pain relief and functional improvement in OA treatment [19]. A study evaluating patient preferences for adherence to treatment for osteoarthritis (the Medication Decisions in Osteoarthritis Study - MeDos) revealed that disparity in predicted adherence with NSAIDs was primarily driven by negative preferences expressed for cardiovascular, liver, and renal side effects [20]. Another study involving 1512 surveys across six countries revealed that 42.3% of patients expressed dissatisfaction with their current OA treatment. Notably, 78% of respondents expressed a desire for access to additional non-drug/non-surgical treatments [1]. UC-II® has shown improvements in daily activities such as ascending or descending stairs, standing upright, bending to pick up objects, and squatting [21]. One of the studies conducted showed an increase in daily step count by 747 steps [22]. A study evaluating the synergistic effects of UC-II®, Mobilee, and Curcumin, demonstrated significant improvements in quality of life by reducing symptoms associated with OA. The results showed reductions in: pain on palpation (79.10%), limitation of mobility (77.05%), joint crepitus (73.54%), swelling (86.43%), redness (84.78%), and WOMAC scores, including stiffness (~77%), difficulty (~73%), and pain (~74%) [7].

3.1 Expert Opinion

Concrete evidence, such as arthroscopic studies, MRIs, or Cartigrams, in evaluating improvements in cartilage thickness is required to enhance compliance among both doctors and patients. The absence of side effects with prolonged use of UC-II®, Mobilee®, and curcumin for a year or more, supports their long-term safety. Furthermore, the capsule formulation of these nutraceuticals is more patient-compliant compared to earlier powder or sachet forms. Hence, the combination of UC-II®, Mobilee®, and curcumin can work to significantly reduce OA symptoms while increasing patient compliance and quality of life.

Table 1: A Summary of Expert Opinions

Sr No.	Expert Opinions
1.	The robust clinical data supporting UC-II®, coupled with expert endorsement, underscores its superiority as a therapeutic option, offering enhanced efficacy and safety compared to older treatments.
2.	UC-II®, sourced from Lonza, Switzerland has proved to be an efficacious and superior collagen for the management of OA.
3.	A significant challenge exists in prescribing animal-derived collagen products to vegetarian patients, even though it is acknowledged that animal-sourced collagen peptides are more effective.
4.	A minimum duration of 3-4 weeks with UC-II®, Mobilee®, and Curcumin is necessary to observe beneficial effects, with a recommended continuation of at least 3-6 months.
5.	The absence of side effects, even with prolonged use of UC-II®, Mobilee®, and Curcumin for a year or more, supports their long-term safety.

Conclusion

Despite the wide availability of collagen supplements in the market, significant differences in their composition and manufacturing processes can impact their efficacy. UC-II®, a patented undenatured type II collagen, from Lonza, Switzerland has been shown to be effective in OA management. When combined with Mobilee®, a patented Sodium Hyaluronate, from Bioberica, Spain, and Curcumin, superior results have been observed with increased tolerability, offering a reliable alternative to traditional treatments.

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