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Real-world clinical experience with FreeFlex™ emulgel in osteoarthritis: Insights from a cross-sectional survey of orthopedician specialists

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Abstract
Background: Osteoarthritis (OA) is the most common form of arthritis, significantly impacting quality of life due to chronic pain and reduced mobility. Although oral medications and intra-articular injections are commonly used, their long-term application is often limited by systemic side effects. Topical formulations offer a targeted approach with fewer adverse effects. FreeFlex™ Emulgel, incorporating VesiFuze™ technology, is designed to enhance skin penetration and deliver effective anti-inflammatory and analgesic benefits for localized pain relief. This survey-based study was conducted to evaluate healthcare professionals' preferences and perceptions regarding the topical use of FreeFlex™ Emulgel, which incorporates VesiFuze™ technology.
Methods: A paper-based survey was conducted among orthopedicians to assess their experience with FreeFlex™ Emulgel. The questionnaire covered key aspects such as symptom relief, onset of action, safety profile, and patient adherence in comparison to other topical agents.
Results: The survey revealed that 85.71% of orthopedicians prescribe FreeFlex™ Emulgel regularly, while 14.29% use it occasionally. In terms of effectiveness, 92.85% of respondents rated it as very good to excellent. Regarding patient outcomes, 78.57% observed significant pain relief, 54.29% noted improved mobility, and 51.43% reported enhanced patient satisfaction. Compared to other topical formulations, 55.71% rated it as significantly better, and 45.71% as superior. Furthermore, 95.71% of respondents indicated they would recommend FreeFlex™ Emulgel to their colleagues, citing its positive impact on patient care.
Conclusion: FreeFlex™ Emulgel was highly regarded by orthopedicians for its effectiveness in pain relief and improving patient mobility and satisfaction.

Keywords: Osteoarthritis, FreeFlex™ Emulgel, VesiFuze™ technology, pain relief, patient satisfaction, clinical effectiveness

Introduction
Osteoarthritis (OA) is a chronic, degenerative joint disorder that affects over 500 million individuals worldwide [1]. It is characterized by articular cartilage degradation, osteophyte formation, subchondral bone remodeling, and synovial inflammation. Chronic pain remains the primary cause of disability in affected individuals, making OA the fourth leading cause of disability globally [1, 2].
Effective topical therapy for OA remains challenging, as most therapeutic agents struggle with poor skin penetration and are rapidly cleared from the application site. Additionally, while topical NSAIDs have been shown to reduce pain and improve function over short periods (typically two weeks), these benefits tend to diminish after four weeks. Moreover, there is no robust evidence to support the long-term use of topical non-steroidal anti-inflammatory drugs (NSAIDs) in OA. Therefore, topical NSAIDs are recommended to be reserved for short-term use, particularly during acute flare-ups. Given these risks, nutraceuticals are gaining increasing recognition in the management of OA, largely due to their favorable safety profile. They present a safer alternative with minimal side effects, offering both preventive benefits and symptom relief, making them a promising option for long-term disease management [3, 4].

Nutraceuticals are a category of bioactive dietary compounds that play a crucial role in regulating cartilage metabolism while balancing the anabolic and catabolic signaling pathways that lead to cartilage degeneration [5]. Current research has explored the broad utility of Emulgels in topical drug delivery, demonstrating their superiority over other topical formulations [6].

FreeFlex™ Emulgel is one such advanced topical formulation developed for OA management, containing glucosamine sulfate, chondroitin sulfate, curcumin, Boswellia serrata, ginger, wintergreen oil, and menthol. It is formulated using VesiFuze™ Emulgel technology, which consists of lipid vesicles embedded within an aqueous gel matrix, designed to enhance transdermal absorption and joint permeability. The combination of glucosamine and chondroitin sulfate suppresses IL-1-induced gene expression of inflammatory mediators, Inducible Nitric Oxide Synthase (iNOS), Cyclooxygenase-2 (COX-2), Microsomal Prostaglandin E Synthase (mPGEs), and nuclear factor-κB (NF-κB) in cartilage explants. This leads to reduced production of Nitric Oxide (NO) and Prostaglandin E_2 (PGE2), two mediators responsible for chondrocyte cell death and inflammatory reactions [7]. Curcumin is a potent anti-inflammatory and antioxidant compound that functions as an NF-κB suppressor. It has demonstrated significant efficacy in reducing pain, improving physical function, and enhancing quality of life in OA patients across multiple clinical trials [8]. Boswellia serrata extract (BSE), particularly 5-Loxin (30% acetyl-11-keto-boswellic acid (AKBA) content, has shown promising results in reducing pain and improving physical function in OA patients. Its mechanism of action involves modulating inflammatory pathways and inhibiting enzymatic cartilage degradation, with a favourable safety profile [9]. Ginger extracts exert anti-inflammatory effects by targeting arachidonic acid metabolism, inhibiting cyclooxygenases (COX) and lipoxygenases (LOX), and reducing leukotriene synthesis [10]. Wintergreen oil, rich in methyl salicylate, provides analgesic, anti-inflammatory, and counterirritant effects by triggering mild irritation or cutaneous pain to mitigate pain of subdermal origin [11]. Menthol has demonstrated pain reduction and functional improvements in OA patients. It also has antinociceptive and counterirritant properties [12]. While clinical studies have evaluated the efficacy of FreeFlex™ Emulgel in OA patients, existing research remains limited and does not comprehensively capture physicians' real-world observations, clinical experiences, and patient responses.

Thus, this study aims to evaluate the clinical experiences and perceptions of orthopedicians regarding the effectiveness, safety, and patient outcomes of FreeFlex™ Emulgel in OA management compared to other topical treatments.

Materials and Methods

The Flexpert Survey, a structured paper-based questionnaire developed by Universal NutriScience (UNS) was designed to evaluate the clinical experience of orthopedicians with the use of FreeFlex™ Emulgel while comparing its effectiveness to other topical gels. This cross-sectional survey was approved by the Institutional Ethics Committee (ECR/644/Inst/MH/2014/RR-20), dated 20th April 2024.

The survey consisted of 5 multiple-choice questions (Table 1) assessing the clinical effectiveness, patient satisfaction, and safety profile of FreeFlex™ Emulgel in OA management. Survey responses were collected between May 2024 to October 2024. Written informed consent was obtained from orthopedicians before conducting the survey.

A total of 70 orthopedicians from across the country participated in the survey, representing a variety of clinical settings, including hospitals and private practices.

Table 1: Survey consisted of 5 multiple-choice questions assessing the clinical effectiveness, patient satisfaction, and safety profile of FreeFlex™ Emulgel in OA management

Questions
How frequently do you prescribe or recommend FreeFlex™ Emulgel to your Patients?
• Regularly
• Occasionally
• Rarely
• Never
How would you rate your overall experience with FreeFlex™ Emulgel?
Excellent
• Very Good
• Good
• Poor
Do you notice any positive changes in the following parameters among your patients after using FreeFlex™ Emulgel?
Improved Pain relief
• Improve mobility
• Increased patient satisfaction
• Other (Please Specify)
How does FreeFlex™ Emulgel compare to other topical gels you've used in terms of effectiveness?
• Much Better
• Better
• About the Same
• Worse
Would you recommend FreeFlex™ Emulgel to your colleagues based on your experience?
• Yes
• Probably
• No

Results

A total of 70 orthopedicians were included in the survey. The results are presented below, focusing on key areas such as frequency of prescription, overall experience, observed patient improvements, and comparison with other topical treatments.

Frequency of Prescription/Recommendation

A significant portion of the surveyed doctors (85.71%) reported prescribing FreeFlex™ Emulgel regularly. 14.29% prescribed it occasionally, while none reported prescribing it rarely or never**.**

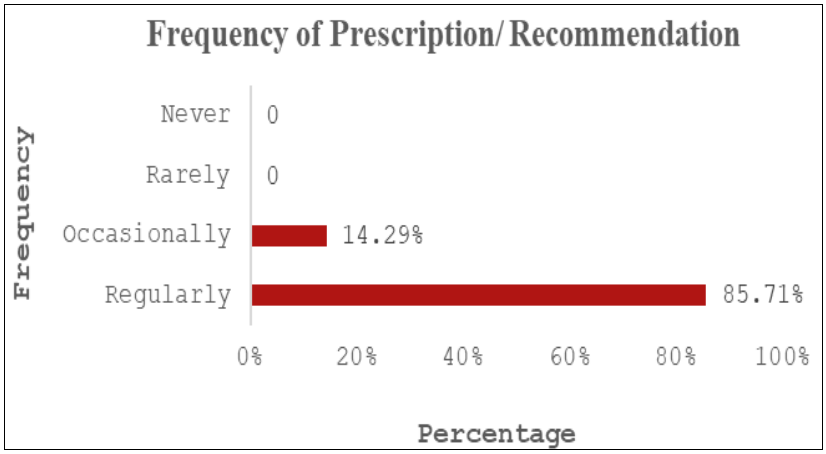

Fig 1: Graphical distribution of replies to question 1

This indicates that **FreeFlex™ Emulgel** is commonly recommended by orthopedicians suggesting that it is well-integrated into their practice and a preferred topical treatment option.

Overall Experience with FreeFlex™ Emulgel

The majority of the orthopedicians (93%) rated their experience with FreeFlex™ Emulgel positively, with 45.71% rating it as excellent and 47.14% as very good.

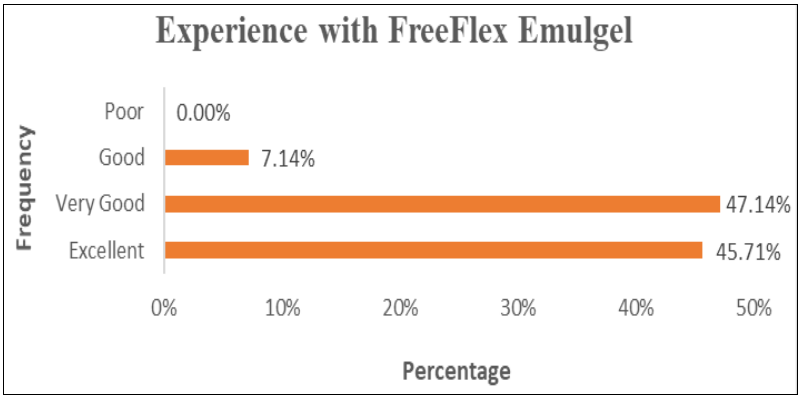

Fig 2: Graphical distribution of replies to question 2

Improvements Observed in Patients with FreeFlex Emulgel™

The most common positive changes noted by doctors were improved pain relief (78.57%), followed by improved mobility (54.29%) and increased patient satisfaction (51.43%).

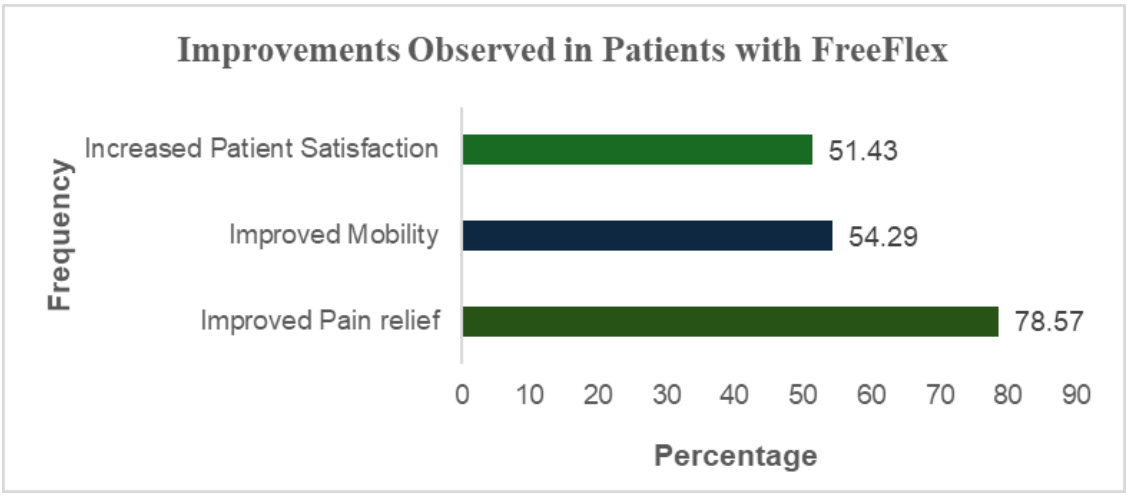

Fig 3: Graphical distribution of replies to question 3

Other Topical Gels

When comparing FreeFlex™ Emulgel to other topical gels, 55.71% of doctors considered it much better and 45.71% felt it was better. None of the participants found it worse, and no one thought it was about the same.

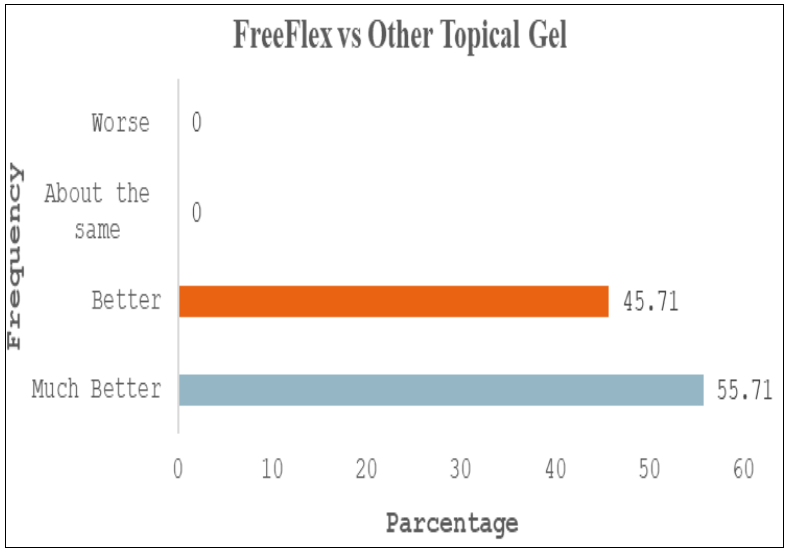

Fig 4: Graphical distribution of replies to question 4.

Willingness to Recommend to Colleagues

An overwhelming 95.71% of doctors indicated they would recommend FreeFlex™ Emulgel to their colleagues.

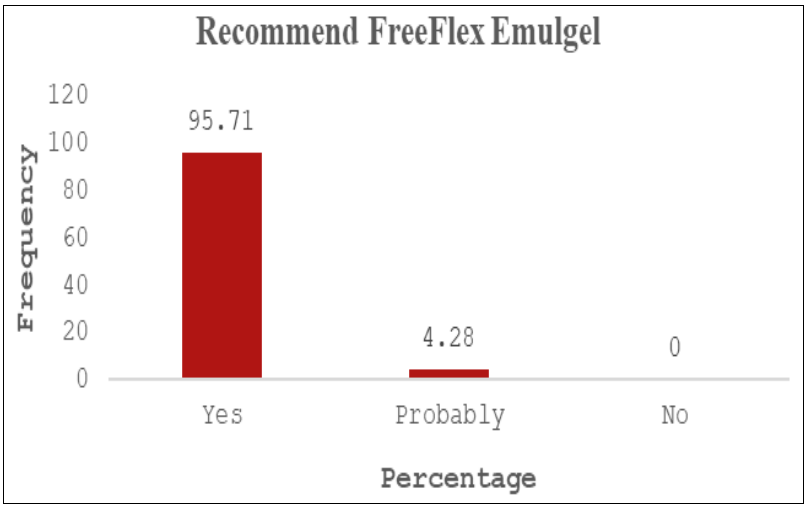

Fig 5: Graphical distribution of replies to question 5

Discussion

This study provides real-world clinical insights from 70 orthopedician, offering a diverse and representative perspective on FreeFlex™ Emulgel. By comparing it with other topical treatments, the study enhances scientific relevance and generalizability across hospital and private practice settings. When compared to other topical gels, 55.71% of doctors rated FreeFlex™ Emulgel as 'much better,' while 45.71% considered it 'better.' Importantly, none of the respondents rated it as inferior or equal to other topical treatments, suggesting its superior therapeutic efficacy. Attributing to the significant decrease in pain, an impressive 85.7% of orthopedicians reported regular use of FreeFlex™ Emulgel, indicating its strong integration into clinical practice in this study. This high prescription rate underscores its clinical acceptance, likely driven by its efficacy and ease of use.

A recent pilot study by Dr. C. Rex *et al.* (2024) assessing the global effectiveness of FreeFlex™ Emulgel based on physician feedback reported that 82% of physicians observed significant improvements in OA patients. Additionally, the study demonstrated a 49.4% improvement in Visual Analog Scale (VAS) scores [13]. Similarly, a study by Jah *et al.* reported a 44.02% improvement in total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores and a 51.11% improvement in VAS scores [14]. This survey showed similar results, supporting the positive effects of FreeFlex™ Emulgel on important outcomes like pain relief, better movement, and patient satisfaction. Notably, 78.57% of doctors observed improved pain relief, 54.29% reported better mobility, and 51.43% noted increased patient satisfaction. Furthermore, 95.7% of doctors expressed a strong willingness to recommend FreeFlex™ Emulgel to their colleagues, further reinforcing its clinical utility.

Evaluating key outcomes like pain relief, mobility, and patient satisfaction, the findings highlight strong clinical acceptance, with 95.71% of doctors recommending FreeFlex™ Emulgel. However, the study has some limitations. It relies on self-

reported data from physicians, lacking direct patient-reported outcomes. The absence of a control group limits objective comparison with other treatments.

Conclusion

Thus, FreeFlex™ Emulgel, developed with VesiFuze™ Emulgel technology, effectively alleviates OA symptoms, including pain and inflammation, leading to improved patient quality of life (QoL) and demonstrating superior clinical effectiveness compared to other topical gels.

Source of Funding

This work was supported by Universal Nutriscience, which provided funding for the study.

Conflict of Interest

Bhakti Gaonkar, Shruti Patwal and Manish R Garg, are employees of Universal NutriScience. The authors declare no other financial or non-financial conflicts of interest relevant to the subject of this manuscript.

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APPENDIX

Flexpert Study Group

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