



UNIBAR

CORPORATION

White Paper

**Modulating Exercise Recovery with a soothing composition
of CURCUMIN & EKTIBAFLEX®**



Modulating Exercise Recovery with a soothing composition of CURCUMIN & EKTIBAFLEX®

Health and exercise are the two sides of the same coin, absolutely inseparable from each other. Individuals who are physically active have strong bones, muscles and connective tissues like tendons and ligaments. Exercise also leads to an increase in lean muscle mass which helps the human body burn more calories. Increased lean muscle mass thus helps to maintain a healthy weight and better quality of life.

Why People are giving up Exercise?

Many people start an exercise regimen on the advice of their doctors. Most people will continue a good program for a week or a month. It's also common to make a New Year's Resolution to work out, be fit and lose weight. According to Huffington Post, out of the 45% of people who make New Year's resolutions each year, only 8% actually succeed. Of the most popular types of resolutions, the two highest involve some level of fitness or healthy lifestyle adoption, with 47 percent of people making vows to self-improve and another 38% making weight-related goals. There are several reasons listed for quitting fitness goals like a hectic lifestyle, having no consequences of quitting, unenjoyable workouts etc. but according to recent studies the hidden reason many people quit is due to Post Exercise Recovery.

According to *LANCE C. DALLECK, PH.D.*, American Council on Exercise (ACE), much contemporary research has explored numerous tactics for augmenting the recovery process, including various nutritional strategies (e.g., when, why and how much to consume of various nutrients and combinations of nutrients), cold-water immersion, stretching and compression garments but still the recovery process is delayed due to muscle soreness. Also, when people begin an exercise program they are likely to do too much, too soon, which creates soreness that negatively impacts their desire to continue exercising.

Delayed onset muscle soreness (DOMS) is the pain and stiffness felt in muscles several hours to days after unaccustomed or strenuous exercise. The soreness is felt most strongly 24 to 72 hours after the exercise. ^{[1][2]} It is thought to be caused by eccentric (lengthening) exercise and/or oxidative stress, which causes small-scale damage (micro trauma) to the muscle fibers. After such exercise, the muscle adapts rapidly to prevent muscle damage, and thereby soreness, if the exercise is repeated. ^{[1][2]} **Delayed onset muscle soreness (DOMS)** prevents people from achieving their fitness goals.

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What about Pain Killers?

It's proven that exercise and pain killers are a lethal combo. According to a recent article published in NY Times, taking ibuprofen and related over-the-counter painkillers could have unintended and worrisome consequences for people who vigorously exercise. These popular medicines, known as nonsteroidal anti-inflammatory drugs, or NSAIDs, work by suppressing inflammation. But according to two new studies, in the process they potentially may also overtax the kidneys during prolonged exercise and reduce muscles' ability to recover afterward. Also, NSAIDS are not part of a long-term healthy lifestyle strategy.

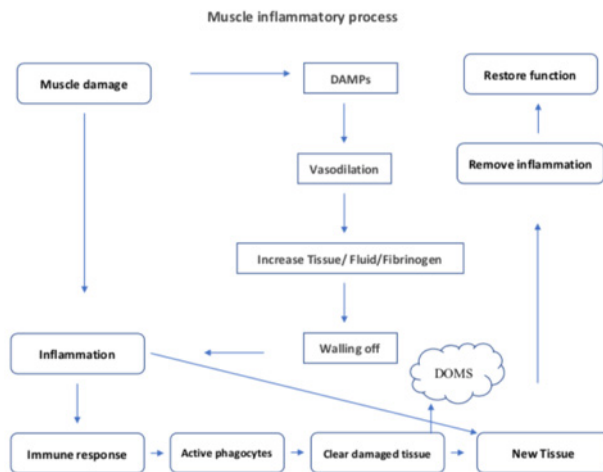
Achieving Fitness goals with CURCUMIN & EKTIBAFLEX®, a clinically verified composition

Individuals who exercise on a regular basis or work in physically demanding occupations are prone to regular muscle damage. Depending on the nature of the exercise or work protocol, this damage and the resultant muscle soreness can range from mild to extreme. Once muscle damage occurs, the body initiates a series of biological processes that eventually lead to the restoration of muscle tissue and function (see pathway image I). One step in this process is the accumulation of localized inflammation. Unfortunately, the body often overshoots the quantity of inflammation needed for healing and the net effect is reduced physical functioning during the recovery period. Thus, excessive inflammation results in lost practice, performance, and work days. One method commonly used to counter post-exercise inflammation and soreness is regular ingestion of nonsteroidal anti-inflammatory drugs (NSAID). Unfortunately, NSAID use prevents the body from healing properly because NSAIDs completely block inflammation. Also, given the serious negative health side-effects associated with habitual use of NSAIDs, such use cannot be considered a viable long-term treatment option.

Given the need to manage excessive inflammation during recovery from muscle injury, there is a need to identify naturally occurring substances that have anti-inflammatory potential, yet are less potent than NSAIDs and without the negative health side-effects of NSAIDs. A combined treatment with Curcumin and Boswellia represent the potential to provide such benefit. **EKTIBAFLEX®, Boswellia serrata extract which is standardized for 3-O-Acetyl-11-keto-β-boswellic acid (AKBA) 90%, is 8X more bioavailable than regular 30% AKBA.**

Curcumin, is a widely researched natural ingredient. Current database indicates more than 9,000 publications on curcumin. At the molecular level, this multi targeted agent has been shown to exhibit anti-inflammatory activity through the suppression of numerous cell signaling pathways including NF-κB, STAT3, Nrf2, ROS and COX-2. Numerous studies have indicated that curcumin is a highly potent antimicrobial agent and has been traditionally used to improve health. To date, over 100 different clinical trials have been completed with curcumin, which clearly show its safety, tolerability and its effectiveness against various chronic diseases in humans⁵.

Boswellia serrata has been traditionally used in folk medicine for centuries to treat various chronic inflammatory diseases. The resinous part of *Boswellia serrata* possesses monoterpenes, diterpenes, triterpenes, tetracyclic triterpenic acids and four major pentacyclic triterpenic acids i.e. β -boswellic acid, acetyl- β -boswellic acid, 11-keto- β -boswellic acid and acetyl-11-keto- β -boswellic acid, responsible for inhibition of pro-inflammatory enzymes. Out of these four boswellic acids, acetyl-11-keto- β -boswellic acid is the most potent inhibitor of 5-lipoxygenase, an enzyme responsible for inflammation.⁶



Clinical study on CURCUMIN & EKTIBAFLEX®⁷

The clinical study is blinded, randomized and seven-day treatment of CURUMIN & EKTIBAFLEX® or Placebo conducted on Healthy, physically active subjects. This study is sponsored by Unibar Corporation.

Subjects & Screening

Prior to participating, all subjects are provided written informed consent; subject procedures are approved by the University of North Texas (UNT) Institutional Review Board and completed in accordance with the latest version of the Declaration of Helsinki. Physically active men and women (N=14) recruited to participated in the study. Subjects are Screened with an aerobic capacity test (bike test), a standard whole body dual-energy x-ray absorptiometry (DXA) test (GE Lunar Prodigy), and a medical history questionnaire. Individuals with contraindications to exercise or who present with medical conditions that might affect inflammatory markers are excluded from the study. Due to the nature of the exercise protocol, subjects should be physically active. This protocol has been designed to challenge the subject's ability to recover from exercise on repeated days. Jacob's ladder climbing and Stationery cycling create an oxidative stress and fatigue component that may exacerbate the anticipated muscle soreness while downhill running creates strong muscle soreness via eccentric muscle contraction. Thus, this model is ideal for testing treatment with Curcumin &EKTIBAFLEX® vs placebo.

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Supplementation Period

Subjects are provided with their assigned supplement 7-d prior to the first intensified exercise session (Curcumin & EKTIBAFLEX® or placebo). After each intensified exercise session, subjects will be asked to consume a “booster dose” of the supplement (2 capsules of Curcumin & EKTIBAFLEX®) or placebo. Placebo capsules consists of rice flour. In order to increase subject compliance, supplements are provided in a daily blister pack. Subjects are encouraged to consume capsules at about the same time each day and are asked to promptly report any missed doses to the investigators. Subject compliance with the supplement protocol was >90%.

Experimental Design

Following a 7-day supplementation with either active (Curcumin & EKTIBAFLEX®) or placebo compounds subjects were asked to complete an intensified exercise protocol on 3 consecutive days. The exercise protocol consists of Jacob’s Ladder Climbing, Maximal Effort cycling and downhill running and each of the above repeated 3 times on each of three consecutive days (45-min total activity per day). The recovery of each subject is monitored prior to and after each session via subjective and biological measures. Final measurements are made at 24-h after the final exercise session.

Subjective Muscle Pain and Soreness Measures

Three unique tests are used to assess each subject’s perception of muscle soreness and pain in a variety of lower leg muscles. Each of the measurements are completed before and after each exercise protocol and at 24-h after the final protocol. Change over time are compared and evaluated.

Palpated Visual Analog Pain Scale (VAS)-Pain

This test is designed to assess muscle soreness/pain in three distinct anatomical locations (proximal, middle, and distal) of the thigh and of the calf. After application of a standardized force (using a digital force compression meter), subjects are asked to rate their soreness/pain using a 10-point visual analog scale (VAS) at each measurement site (insertion and middle). This test is completed on the right and left vastus lateralis (main thigh muscle) and gastrocnemius (main lower leg muscle). VAS is a routine measure for the assessment of delayed onset muscle soreness (DOMS).

Pain Threshold/Tolerance Tests-Soreness

This test is designed to assess a subject’s pain threshold/tolerance, which have considerable individual variation. In order to complete the pain threshold test, the subject’s muscle is pressed with a force meter until they indicate experiencing the onset of pain. The force required to elicit pain is recorded. After a brief rest, the same spot is pressed with the force meter until the pain is uncomfortable. The force required to elicit discomfort is recorded as the pain tolerance. These tests are completed on the right and left vastus lateralis (main upper leg muscle) and gastrocnemius (main lower leg muscle).

Isometric Quadriceps Strength (Muscle strength)

Subjects are allowed to sit with their right and left knees bent to 90° and asked to physically contract their muscle as hard as they can against a fixed force arm. The maximal force generated are recorded for each leg. These measurements are made in triplicate and the highest force generated for each leg are used.

Biological Muscle Pain and Soreness Measures

Blood samples are collected from subjects at baseline (prior to onset of supplementation), exercise Session 1 pre-and post-exercise Session 2 pre-and post-exercise Session 3 pre-and post, and 24h after the final exercise session (Session 3). Venous blood is collected and serum is isolated and frozen for subsequent analysis. In order to complement the subject measurements described above, we measured a series of blood biomarkers that have been previously linked to muscle pain, inflammation, injury and regeneration.

Muscle Damage Biomarker Analysis - Serum Creatine kinase (CK)

This is a classic measure of muscle injury in the blood. The change relative to pre-exercise reflects the current state of injury in the muscle via a simple blood test. Creatine kinase (CK) and Myostatin serum activity are determined in duplicate by using an enzymatic assay run on an automated chemistry analyzer.

Muscle Damage Biomarker Analysis - Serum Cytokine Analysis

Measuring a set of pro- and anti- inflammatory cytokines help us to track muscle injury and muscle health. These cytokines are also used to provide context to the other muscle injury measurements. Cytokines IL-2, MIP-1 beta and IL-6 are measured using a multiplex, bead-based assay system. All serum samples are analyzed in duplicate.

Clinical study outcome

The total no of subjects expressed interest to participate in this study are N= 195. After initial screening N=105 are rejected due to not meeting the Inclusion criteria. The laboratory screening allowed to randomize N=56. Active (Curcumin & EKTIBAFLEX®) N=10 and Placebo N=7 completed the study. Reduction in Pain threshold at Day 4 with Curcumin & EKTIBAFLEX® Supplementation when compared to Placebo (Image 2). Subjective soreness is reduced at Day 3 and Day 4 with Curcumin & EKTIBAFLEX® Supplementation when compared to placebo (Image-3). The muscle functional recovery (knee force) for both legs significantly improved with Curcumin & EKTIBAFLEX® Supplementation when compared to Placebo (Image 4 and 5).

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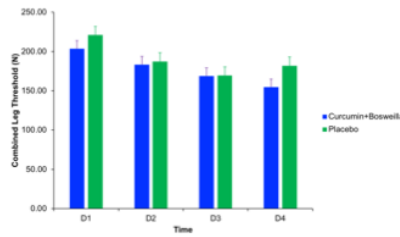
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Subjective Muscle Pain Threshold

Combined Leg Threshold



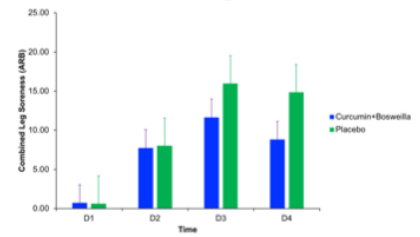
Biological Action
Subject measure of muscle injury

Interaction Effect
P = 0.33

Interaction Effect Size
0.33

Subjective Muscle Soreness

Combined Leg Soreness



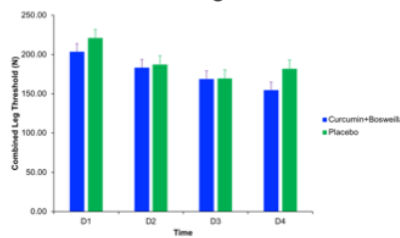
Biological Action
Subject measure of muscle injury

Interaction Effect
P = 0.10

Interaction Effect Size
0.38

Subjective Muscle Pain Threshold

Combined Leg Threshold



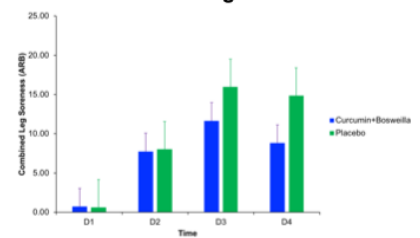
Biological Action
Subject measure of muscle injury

Interaction Effect
P = 0.33

Interaction Effect Size
0.33

Subjective Muscle Soreness

Combined Leg Soreness



Biological Action
Subject measure of muscle injury

Interaction Effect
P = 0.10

Interaction Effect Size
0.38

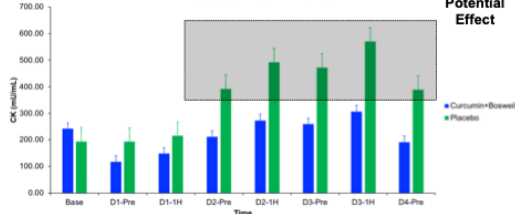
Muscle Damage Biomarker Analysis - Serum Creatine kinase (CK) and Serum cytokine

Significant reduction in Creatine Kinase, Myostatin (Index of Muscle injury/Damage), MIP-1beta (Monocyte migration to injured tissue), IL-6 (Acute Pro inflammatory) EKTIBAFLEX® Supplementation when compared to Placebo (Images-6 to 9).

Reduced Th1 and Inflammatory cell migration with Curcumin & EKTIBAFLEX® Supplementation when compared to Placebo (Image-10).

Muscle Damage

Creatine Kinase



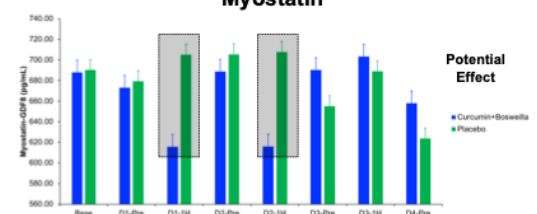
Biological Action
Index of muscle injury/damage

Interaction Effect
P = 0.30

Interaction Effect Size
0.31

Muscle Damage

Myostatin

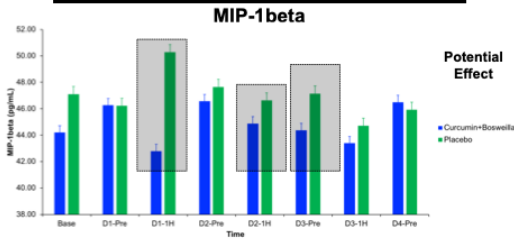


Biological Action
Index of muscle injury/damage

Interaction Effect
P = 0.49

Interaction Effect Size
0.24

Inflammatory Cell Migration

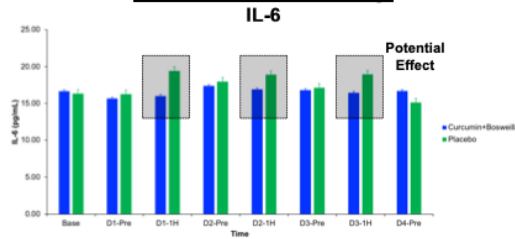


Biological Action
Monocyte Migration to Injured Tissue

Interaction Effect
P = 0.19

Interaction Effect Size
0.30

Pro-Inflammatory

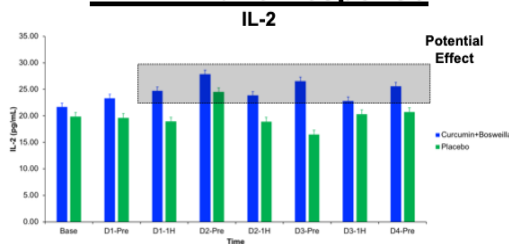


Biological Action
Acute Pro-Inflammatory

Interaction Effect
P = 0.23

Interaction Effect Size
0.29

Th1 Immune Response



Biological Action
TH1 Immune Response

Interaction Effect
P = 0.40

Interaction Effect Size
0.26

Conclusion

This clinical study of Modulating Exercise Recovery with Curcumin & EKTIBAFLEX®, Sponsored by Unibar Corporation, USA revealed that treatment with Curcumin & EKTIBAFLEX® may protect the muscle from injury as indicated by trends toward lower serum creatine kinase concentration particularly at Day 3 and 4 when compared to placebo. Treatment with Curcumin & EKTIBAFLEX® induced lowering of muscle injury translated to a trend toward a reduction in subjective muscle soreness and maintenance of muscle strength (placebo group had more subjective soreness and greater loss of muscle strength; loss of muscle strength is indicative of loss of muscle function as a result of injury from exercise).

Treatment resulted in a trend toward reduced serum IL-6 1-hour post exercise following Day 1, Day 2, and Day 3 exercise. This is directly linked to reduced muscle injury with treatment (point 1 above). All of the effects listed above are strong trends toward effects that would require more data to sufficiently power them for publication/presentation purposes. Supplementation of Curcumin & EKTIBAFLEX® attenuates Exercise Induced Muscle Damage (EIMD) and Augments Exercise Endurance.

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*The data presented here is not evaluated by the U.S. Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.



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