

Report on Comparative Lung Capacity of Marathon Runners

before and after the intake of PCSO-524®.

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Abstract

The Stabilised lipid oil from the New Zealand Green Lipped Mussel (PCSO-524®) and Fish oil; are considered beneficial for the treatment of inflammatory conditions including asthma and arthritis. Sports medicine practitioners often witness the occurrence of Exercise Induced Bronchoconstriction (EIB). This condition is thought to be due to the flow of air in a lung pipe (with living cells bordering it) whereby these cells react and release variable amounts of inflammatory mediators, as "protection". We were interested in understanding why we observed better lung efficiency in endurance athletes using PCSO-524®. In Germany, the largest group of purchasers of PCSO-524® are endurance athletes. It is hypothesised that PCSO-524's anti-inflammatory action helps increase the air flow by protecting the airways against inflammatory mediators. This is particularly observable for athletes undergoing extreme exercise. In order to learn if PCSO-524® does improve lung function for athletes, we have monitored the lung capacity of a small group of sub elite athletes and found that uploading of PCSO-524® resulted in increases in lung capacity. To better understand this phenomenon, we have also searched the literature on Exercise Induced Bronchoconstriction and Asthma.

Background

The Maoris who live in New Zealand have claimed for centuries that consuming local green-lipped mussels helps them maintain good health. To investigate its reported anti-inflammatory activity, researchers in the United Kingdom, Korea, Scandinavia, Germany, Hong Kong, Australia and Japan have studied the effects of various oral preparations of the New Zealand green lipped mussel, *Perna canaliculus*.

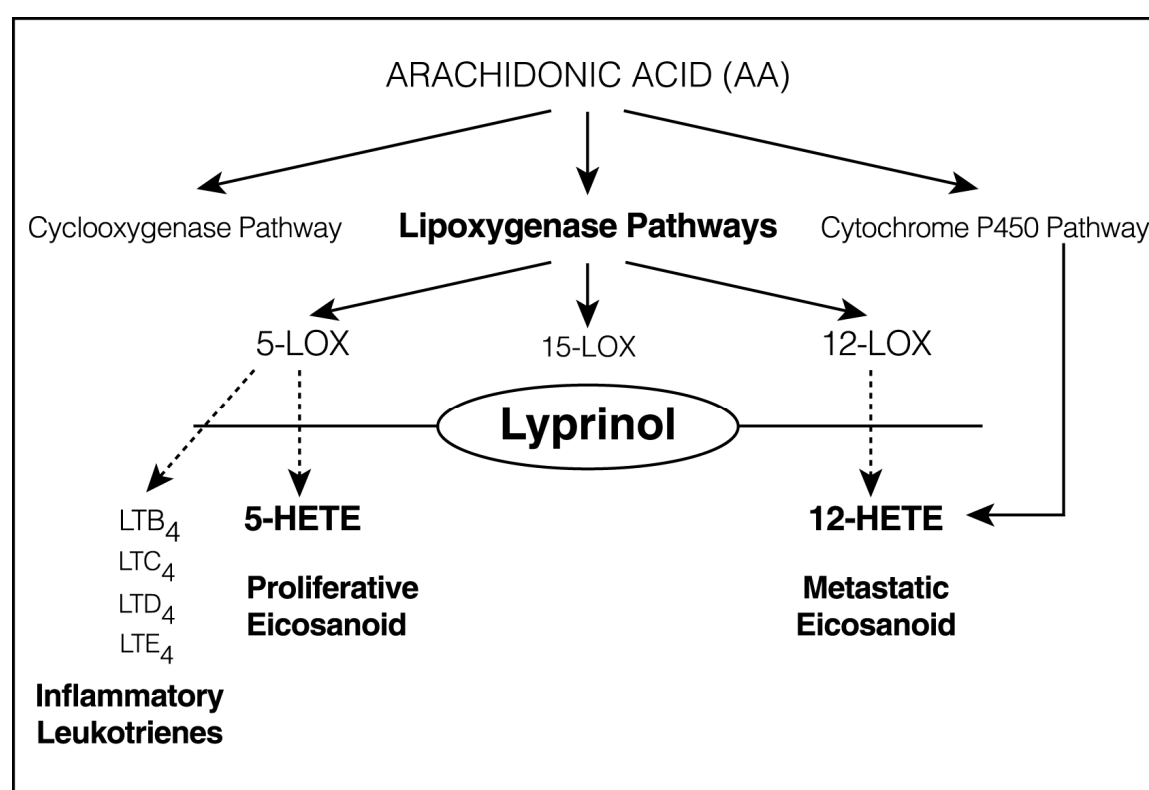
Dr Georges Halpern¹ has comprehensively documented the clinical studies since 1980, demonstrating that a stabilised lipid extract of *Perna canaliculus* is effective and safe in relieving symptoms of arthritis and asthma. Most clinical trials have used a product trademarked PCSO-524®², capsules containing 50 mgs of patented stabilised mussel oil in a 100 mg olive oil carrier. The numerous animal and human trials have shown that PCSO-524® exhibits significant anti-inflammatory effects and has been shown to down-regulate the lipoxygenase and possibly cyclooxygenase-2 pathways responsible for production of pro-inflammatory leukotrienes, some prostaglandins, and other eicosanoids. More recent studies conducted at the Hong Kong Polytechnic University (Prof. Samuel CL Lo, PhD and his group) demonstrate that PCSO-524 has a unique and complex anti-inflammatory activity: it does regulate the production of cytokines (decreasing pro-inflammatory ones, while

¹ See Georges Halpern MD, PhD.,: *The Inflammation Revolution*, Square One Publishing, NY 2005

² PCSO-524®, the original and first stabilised Greenshell Mussel Oil, sold in 23 countries since 1996 see 8/07/2008

increasing the anti-inflammatory) of the immune response, and controls the synthesis of some inflammation-associated proteins while promoting the synthesis and release of an anti-inflammatory enzyme (articles in press). This report also notes recent asthma research using free fatty acids from fish oil as well as from mussel oil showing reduced inflammatory responses.

One mode of action was initially described by Dr. Henry Betts (Adelaide, Australia)³. Dr. Betts (as referenced in³) reminded us that the metabolism of arachidonic acid via the 5-lipoxygenase pathway in leukocytes leads to the formation of leukotriene B₄ (LTB₄) and leukotrienes C₄, D₄ and E₄ (LTC₄, LTD₄ and LTE₄) as shown in Figure below. LTB₄ is a potent chemotactic agent and is responsible for the increased number of leukocytes at sites of inflammation. LTC₄, LTD₄ and LTC₄ are very potent broncho-constricting agents produced by eosinophils in the lung, and whose production is increased in asthma and during intense sports activities.



Improvement of Asthma in Adults with PCSO-524

The first link between asthma and the anti-inflammatory potential of PCSO-524® was commenced in 1999 and published in the European Respiratory Journal in 2002. 60 patients with mild-to-moderate atopic asthma were enrolled in an IRB-approved double blind random study conducted at Pavlov Medical University Hospital, St. Petersburg, Russia⁴.

PCSO-524®, daily dosage of mussel oil 200 mgs, had a significantly positive effect beginning at day 28 and confirmed at day 56. Results included improvement in clinical symptoms of

³ See Georges Halpern; *Anti-inflammatory effects of a stabilised lipid extract of Perna Canaliculus (PCSO-524®)*. *Allergy et Immunologie* 2000; 32:272-278

⁴ Emelyanov, A., G Fedoseev, O. Krasnoschekova, PJ Barnes et al. *Treatment of Asthma with Lipid Extract of New Zealand Green-Lipped Mussel: A Randomised Clinical Trial.* *European Respiratory Journal* 2002;20:596-600,

chest tightness and nocturnal attacks, 50% reduction in use of rescue medication, significant increased peak expiratory flow and 65% reduction in concentration of H₂O₂ in exhaled air (an objective evidence of reduced inflammation). There was no improvement in the placebo treated group. No side effects were reported in either group. Investigators concluded, "This study has revealed some beneficial effects of PCSO-524 in mild asthmatic patients. These findings provide evidence that PCSO-524 may have anti-inflammatory activity on airways."

In 2006, Dr Timothy Mickleborough⁵ published an exercise induced bronchoconstrictive study showing that high daily dosages of fish oil containing EPA (3,2 gm) and DHA (2,0gm) improved breathing under induced exercise stress. On the normal and placebo diet, subjects exhibited EIB. However, the fish oil diet improved pulmonary function to below the diagnostic EIB threshold, with a concurrent reduction in bronchodilator use. Induced sputum differential cell count percentage and concentrations of LTC₄-LTE₄, PGD₂, IL-β, and TNF-alpha were significantly reduced before and following exercise on the fish oil diet compared to the normal and placebo diets. There was a significant reduction in LTB₄ and a significant increase in LTB₅ generation from activated PMNLs on the fish oil diet compared to the normal and placebo diets. Mickleborough concluded that fish oil supplementation could provide a potentially beneficial non pharmacological intervention treatment for asthmatics with EIB.

In 2005, Pharmed International Ltd, the owners of the PCSO-524® trademark, initiated a Juvenile Asthma Study. This is a clinical study being conducted in cooperation with the New Zealand Asthma Foundation to investigate if PCSO-524 can alter the pathogenesis of moderate to severe asthma as demonstrated by the reduction in the use of reliever medication, and minimization of the use of inhaled corticosteroids in children. This study is a single centre, randomized, double blind, placebo controlled comparative study on 60 children between 6 and 13 years old, with persistent asthma evaluating the effect of PCSO-524 in minimizing the requirement for inhaled corticosteroids (IHC) and the use of short acting beta2 agonists (SABAs) as reliever medication. Estimated completion date October 2008.

Dr Halpern concludes that studies in humans and animals have demonstrated that PCSO-524 lipid extract of *Perna canaliculus* is safe and effective in the management of arthritis and other inflammatory disorders. It has been found to be non-toxic and free of significant side effects. Unlike most non-steroidal anti-inflammatory drugs that have adverse gastrointestinal side effects, the lipid extract of green-lipped mussel demonstrates protective gastrointestinal effect. Its ability to safely down-regulate 5-lipoxygenase, and possibly 12-lipoxygenase and cyclooxygenase-2 pathways, plus the new data from Hong Kong Polytechnic University (in press) indicates that PCSO-524 is likely to have significant benefit in a broad range of inflammatory disorders and other conditions in humans.

Preliminary Observatory Study Design

Andreas Rehn, Nutritionist and Elite Triathlon Athlete, has observed steadily increasing sales over the past 3 years of PCSO-524® to endurance athletes competing in marathon, triathlon and cycling events. Athletes who purchase PCSO-524® report significantly reduced muscle soreness after competition, faster recovery and easier breathing during competition and heavy training. In conjunction with Andrea Jacobs, Natural Therapist and Phytochemical expert, an ~~exploratory study was designed~~ to measure changes in lung capacity possibly related to the intake of PCSO-524®.

Study Design Details

Andreas Rehn recruited 8 sub elite athletes (marathon runners) who had completed pre season training and were entering their peak fitness phase in preparation for the summer marathon season. Each marathon runner agreed to participate in the preliminary study. None of the Marathon Runners had previously taken PCSO-524® nor regularly used fish oil capsules.

The Forced Vital Capacity (FVC) and the Forced Expiratory Volume (FEV) in 1 second were measured in 6 marathon runners in the middle of April 2008 and then again after 3 weeks of intake of 12 PCSO-524 capsules per day. The measurements were carried out with the Schiller Spirometric Sensor SP-250.

Results

The measurements showed an increase in lung capacity in 80% of the marathon runners. The increase was between 5 and 10%. This applied to FVC as well as FEV1. Details are presented in the appendix.

Some of the runners showed a slight bronchial constriction in the first test. The bronchial constrictions were absent after 3 weeks of taking PCSO-524. All Athletes reported general improvements in recovery and less muscle soreness.

Conclusion

The preliminary study conducted by Andreas Rehn showed the potential link between increased lung capacity and the regular intake of PCSO-524®. Previous studies with PCSO-524® and Fish Oil on Asthma and Exercise Induced Bronchoconstriction have also shown improved lung efficiency. The results are statistically significant from this small study to warrant further research into the benefits that Athletes accrue from PCSO-524®.

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Appendix

Lung Capacity Tests

Before and after the intake of 12 Capsules of Lyprinol per day/ 4 Weeks

April – May 2008, Bonn, Germany

Test Persons: Marathon Runners

Average Results	23.04. FVC	15.5. FVC	in %	23.04. FEV 1.0	15.5. FEV 1.0	in %
Andrea	3,24	3,58	110%	2,91	3,2	110%
Udo	3,92	4,17	106%	3,31	3,55	107%
Harry	5,12	5,27	103%	3,86	4,16	108%
Thomas	4,19	4,31	103%	4	3,7	93%
Joachim	6,65	8,14	122%	6,07	6,28	103%
Andreas	5,83	6,38	109%	5,03	5,4	107%
Average Total			109%			105%
Maximum Results	23.04. FVC	15.5. FVC	in %	23.04. FEV 1.0	15.5. FEV 1.0	in %
Andrea	3,31	3,66	111%	2,96	3,22	109%
Udo	4,02	4,27	106%	3,36	3,57	106%
Harry	5,59	5,62	101%	3,95	4,19	106%
Thomas	4,29	4,45	104%	4,03	3,97	99%
Joachim	6,91	9,01	130%	6,07	6,53	108%
Andreas	6,04	6,52	108%	5,06	5,48	108%
Average Total			110%			106%
Average (excluding lowest and highest result)	FVC	FVC	in %	FEV 1.0	FEV 1.0	in %
Andrea	3,24	3,58	110%	2,91	3,2	110%
Udo	3,92	4,17	106%	3,31	3,55	107%
Harry	5,12	5,27	103%	3,86	4,16	108%
Andreas	5,83	6,38	109%	5,03	5,4	107%
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