Topical Edge Sports Lotion Study
Conducted by Dr. Mark Kern, PhD, RD of San Diego State University's Exercise & Nutritional Sciences Department

Background

Muscles generate acid under exertion and for decades it has been proposed that muscle acidosis is associated with muscle fatigue and reduced exercise performance. Acidification of muscle is known to negatively affect several steps in the excitation-contraction in the muscle cells including effects on myosin ATPase, Ca2++ ATPase, Na+-K+ ATPase, potassium channel activity and the activity of metabolic enzymes.[1]

Sodium bicarbonate supplementation, which alkalinizes blood, has been shown to lower intramuscular acidosis (H+ concentrations) [2] and the induced alkalosis decreases metabolic acidosis and improves pH recovery.[3] Through this mechanism, sodium bicarbonate (baking soda) supplementation has been used safely and effectively for decades to improve exercise performance. Over 30 studies in scientific literature support this, including the following examples:

• Metabolic alkalosis following sodium bicarbonate ingestion increased muscle fiber conduction velocity following prolonged submaximal cycling.[4]
• Mean power output during high intensity cycling performance (3km time trial) was significantly higher with the use of oral bicarbonate.[5]
• Ingestion of sodium bicarbonate (NaHCO₃) improved sprint performance during prolonged intermittent cycling[6]
• Both acute and serial sodium bicarbonate loading significantly improved 4-minute cycling performance when compared with that in a placebo trial.[7]
• Douroudos et al found that performance improvement in anaerobic exercise was dose-related.[8]

Current research also suggests that strenuous exercise contributes to muscle damage, inflammation, and resulting delayed onset muscle soreness (DOMS). During intense exercise, mitochondria, which comprise 60% of a muscle’s mass, generate energy (ATP) by oxidative phosphorylation and its by-products, reactive oxygen species (ROS) and acidosis (ROS in the presence of oxygen and acidosis in the absence of oxygen). These by-products lead to mitochondrial fatigue and damage as well as inflammation. Both damage and inflammation are thought to cause DOMS. Research has recently shown that alkalinization reduces muscle mitochondrial damage from oxidative stress. Additionally, research has shown that mitochondrial function in trained muscle is higher with bicarbonate use versus control. Together, these findings suggest that alkalinization with sodium bicarbonate protects muscle mitochondria from damage due to oxidative stress and that the resulting reduction in damage and inflammation may be the link between sodium bicarbonate use and a reduction of DOMS. Theoretically, protecting mitochondria from the damage of oxidative stress and acidosis may preserve the pool of mitochondria allowing an athlete to better consolidate gains from high intensity exercise.[9]

Side effects limit the amount of bicarbonate that can be taken and for most athletes, these side effects are intolerable. When sodium bicarbonate reacts with stomach acid it forms CO₂ and HCO₃, resulting in gastric pain, nausea, vomiting, and diarrhea. Therefore, a route of
administration that bypasses the gastrointestinal tract would be desirable and allow for more widespread use.

Topical Edge is an innovative topical analgesic that combines menthol, sodium bicarbonate, and a patented drug delivery technology, shown to deliver molecules through the skin. With Topical Edge sports lotion, it is now possible for athletes to deliver sodium bicarbonate directly to working muscles while bypassing the stomach.

Methodology
Dr. Mark Kern, PhD, RD of San Diego State University’s Exercise & Nutritional Sciences Department was sponsored to conduct a rigorous institutional review board (IRB) approved, double-blind, randomized, placebo controlled, cross-over study of Topical Edge in elite professional and semi-professional cyclists (N=20). Study participation was limited to 18-50 year-old highly trained athletes with category 1-3 professional cycling licenses, training for their racing season. The cyclists included 17 men and 3 women. 50% (n=10) of the subjects were USA Cycling certified Category 1 cyclists. 20% (n=4) were Category 2 and 30% (n=6) were Category 3 cyclists.

The study design was a cross-over study where each subject was tested while using Topical Edge lotion then tested again at least 4 days later while using a Control lotion (containing all ingredients in Topical Edge except the sodium bicarbonate) with the order of product testing randomized. The product was applied 15 minutes before exercise testing began. Subjects and investigator were blinded to which product was being tested (Topical Edge or Control) at each study visit. Study visits 1 and 2 involved three short high intensity exercise tests. Visits 3 and 4 were one hour exercise tests.

<table>
<thead>
<tr>
<th>Visits 1 and 2 – Short Intensity</th>
<th>Visits 3 and 4 – Long Intensity</th>
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<tr>
<td>• Ramp test with workload increased by 20 watts every 3 minutes until rate of perceived exertion reached 17+ of 20</td>
<td>• 1 hour time trial of maximum work over duration</td>
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<td>• 30 second sprint at maximum effort</td>
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<td>• 5 minute time trial where subjects were instructed to cycle as hard as possible for the duration</td>
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<td>• 5 minute recovery between each stage</td>
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Table 1. Exercises performed at each study visit.

Subjects were blinded to revolutions per minute (RPM) and heart rate throughout testing. Performance during each form of exercise test was measured by average watts, peak watts (in the sprint) and total work done (kJ). Blood lactate and pH during exercise testing was obtained by testing blood collected by finger stick. Oxygen consumption (VO₂), respiratory exchange ratio (RER), hemoglobin saturation, rate of perceived exertion (RPE), and heart rates were also collected throughout exercise testing. A venous blood draw was also collected at visits 1 and 2 to compare bicarbonate, potassium, sodium, calcium, creatinine, albumin, and glucose between Topical Edge and Control. After each exercise test visit, subjective reports of DOMS were collected using a 0-100 scale at 1 day and 2 days post-exercise testing. Results were analyzed with a mixed effects linear model and paired t-tests. Significance was set at p≤0.05. Trends were considered to be 0.05<p<0.10.
Results and Discussion
The following are the significant findings observed in this trial and discussion of these findings.

DOMS. By reducing muscle soreness, an athlete is able to perform at a high level more consistently or simply feel better in the days following soreness inducing sports. The change in DOMS (recovery over a 2 day period) showed a significant (p=0.045) improvement for Topical Edge compared to Control after higher intensity visit 1 and 2 exercise testing, but not after visit 3 and 4. DOMS reduced by 8.7±2.38 points versus 3.4±2.44 points for Topical Edge versus Control, respectively. When looking only subjects who reported DOMS scores of >0, the reduction of DOMS from day 1 to day 2 post exercise was 13.9±2.9 points versus Control at -3.5±2.9 points (p=0.027). This significant finding was observed whether subjects reported lower or higher DOMS scores following exercise testing. In percentage terms, DOMS reduced 53.5% versus 34.3% for Topical Edge versus Control (p=0.007). Theoretically, the alkalinization of muscle tissue during strenuous/intense exercise reduces muscle cell damage and inflammation which is associated with DOMS by reducing mitochondrial oxidative damage.

Heart rate and perceived exertion. Physiologic measures were collected every 2 minutes during the ramp test, after the 5 minute time trial, and every 15 minutes during the 1 hour time trial. Immediately after the 5 minute time trial heart rates were significantly (p=0.03) lower for Topical Edge at 177±11 bpm versus 180±9 for Control. At the 15 minute mark during the 1 hour time trial, heart rate was observed to be significantly (p=0.004) lower for Topical Edge at 154±12 bpm versus 159±10 bpm for Control. In addition, at the same time point of 15 minutes the rate of perceived exertion (RPE) was significantly (p=0.054) lower for Topical Edge than Control at 13.0±1.2 versus 13.4±1.2 respectively. This is an interesting finding as it suggests that Topical Edge is allowing cyclists to work at a similar level at a lower heart rate and level of perceived exertion. The work completed in the 5 minute time trial was consistent across Topical Edge and control at 98 kJ. Total work completed in the 1 hour time trial was not significantly different either, although directionally more work was completed when using Topical Edge. These data support the findings of McNaughton et al.[10] who reported that sodium bicarbonate may be used to offset the fatigue process during high-intensity, aerobic cycling lasting 60 minutes.

Blood lactate. As expected, at baseline and at the start of the ramp test (15 minutes after application), blood lactate did not differ significantly between Topical Edge and Control. However, blood lactate was significantly (p=0.054) higher for Topical Edge versus Control by the end of the series of high intensity tests (ramp test, 30 second sprint, and 5 minute time trial), 10.80±3.2 mmol/L versus 9.74±3.1 mmol/L, respectively, showing an 11% difference. This finding corroborates with other studies.[2, 3, 8, 11-13] as a rise in reduced lactate (lactic acid with the H+ removed/buffered) is expected if increased lactic acid in the blood is buffered by bicarbonate. Increased lactate may benefit performance by providing fuel for muscles when working anaerobically.

Performance differences. Although performance differences did not reach significance when analyzed across the full population, the data was equal or directionally in favor of Topical Edge versus Control.
Table 2. Performance measures by activity for Topical Edge versus Control.

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<tr>
<th>Measure</th>
<th>Topical Edge</th>
<th>Control</th>
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<tr>
<td>Average watts during 5 minute time trial</td>
<td>326±67</td>
<td>327±61</td>
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<tr>
<td>Total work (kJ) over the 5 minute time trial</td>
<td>97±20</td>
<td>98±18</td>
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<tr>
<td>Peak power during 30 second sprint</td>
<td>769±194</td>
<td>749±195</td>
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<tr>
<td>Average watts during the 1 hour time trial</td>
<td>238±50</td>
<td>235±54</td>
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<tr>
<td>Total work (kJ) for the 1 hour time trial</td>
<td>858±183</td>
<td>846±194</td>
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<tr>
<td>Lactate threshold (VO₂ Liters/min) in the ramp test</td>
<td>2.39±0.47</td>
<td>2.36±0.47</td>
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Investigators were unable to control exercise prior to each study visit in this population since subjects were freely and actively training for a competitive season and coming into the lab for testing. This may have affected our ability to observe significant differences due to the treatment effect. Testing in a situation such as a cycling clinic where pre-test workouts are controlled would be a stronger design.

**Conclusion**
Scientific literature provides significant evidence that sodium bicarbonate can be used as a safe and effective athletic enhancement when used orally. This is the first study to elucidate the benefits of Topical Edge, a new sports lotion containing sodium bicarbonate. Topical Edge has been shown to provide statistically significant changes in athletes’ physiology. By changing the delivery route, Topical Edge supplements bicarbonate in a new way, helping athletes train harder and recover faster.

**Future Direction**
The results of this study will be submitted for publication and additional studies are currently underway. Future studies are currently being planned to optimize application dosing and timing, and to further investigate the types of training sodium bicarbonate is most effectively used with (e.g., interval training). These studies will provide better control of pre-testing workouts, which was not possible with this study population and trial setting.
References