



# DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED, CROSSOVER PILOT STUDY EVALUATING THE IMPACT OF SODIUM BICARBONATE IN A TRANSDERMAL DELIVERY SYSTEM ON DELAYED MUSCLE ONSET SORENESS (DOMS)

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## ABSTRACT

Sodium bicarbonate/alkalinization may reduce muscle mitochondrial damage caused by reactive oxygen species during intense exercise. Such damage can induce post-exercise inflammation and pain, which may be linked to delayed onset muscle soreness, or DOMS. However gastrointestinal side effects limit the use of oral sodium bicarbonate.

**PURPOSE:** This study evaluated the efficacy of a commercially available, topical transdermal sodium bicarbonate (TSB) lotion (Topical Edge™), which is claimed to be delivered through the skin using a novel patent-pending transdermal delivery system for impacting DOMS.

**METHODS:** 20 trained cyclists (Category 1-3) and professional triathletes participated in this randomized, cross-over, double-blinded, placebo-controlled study. After application of TSB or a placebo, subjects completed a variety of exercise and performance tests varying in duration. On one day, subjects completed a series of high-intensity exercises which included a ramped protocol to a rating of perceived exertion (RPE) of 17 out of 20, a 30-sec sprint performance test, and a 5-min time trial with 5 minutes of recovery between tests. On a separate day, subjects completed a 1-hr time trial. Subjects completed DOMS questionnaires 24- and 48-hours after exercise sessions. Muscle soreness was rated on a scale of 0-100 where 0 = “no soreness”, 25 = “mild pain”, 50 = “moderate pain”, 75 = “severe pain” and 100 = “the worst pain you can imagine”.

**RESULTS:** DOMS was reduced following the high-intensity series with TSB compared to placebo. Similar effects were not observed following the 1-hr exercise bout. From the first to second day following the high-intensity exercise series, subjects using TSB experienced a 54% reduction in DOMS versus an increase in DOMS of 34% with placebo (p=0.007).

**CONCLUSIONS:** Findings from this study suggest that TSB can significantly shorten recovery from DOMS following high-intensity exercise. Findings also support the effectiveness of the transdermal system in delivering sodium bicarbonate topically and may allow athletes to achieve these results while avoiding the side-effects of oral bicarbonate. Furthermore, we believe this study is the first to provide a direct link between sodium bicarbonate use and DOMS in athletes. Additional research is underway to further substantiate these findings.

## INTRODUCTION

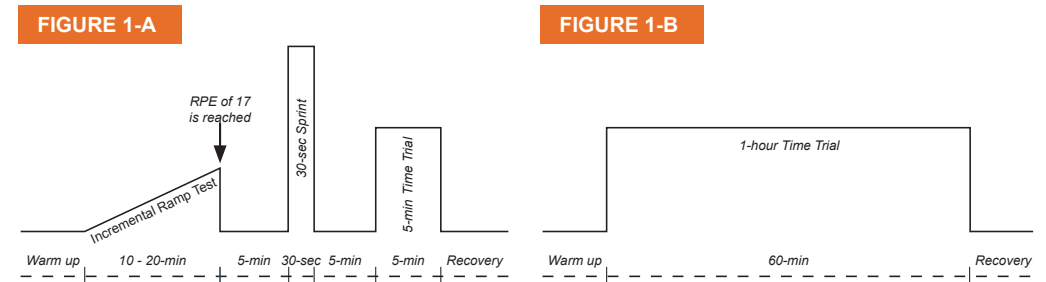
DOMS is characterized by discomfort of muscles peaking 24-48 hours following exercise. A body of evidence is mounting that suggests that generation of reactive oxygen species (ROS) after strenuous exercise may be involved in DOMS. The significant increase in ROS (superoxide, nitric oxide, hydrogen peroxide and hydroxyl radical) release, following muscle contractions, leads to oxidative stress. Research has recently shown that alkalization reduces ROS release. Therefore, theoretically, since oxidative stress-related muscle damage may be a key contributor to DOMS, the use of sodium bicarbonate may reduce DOMS following intense exercise. However gastrointestinal side effects limit the use of oral sodium bicarbonate.

**HYPOTHESIS:** We hypothesized that the topical transdermal sodium bicarbonate (TSB) lotion (Topical Edge PR™) would positively impact DOMS. Specifically it would lower the DOMS score at ~24 hours after exercise and would result in faster recovery from DOMS as observed by a larger decrease in DOMS scores from ~24 hours to ~48 hours after exercise.

## METHODS

- 20 trained cyclists (Category 1-3) and professional triathletes with an average VO<sub>2</sub> Peak (VO<sub>2</sub>mL/kg/min) of 58.9+/-7.2 participated in this randomized, cross-over, double-blinded, placebo-controlled study.
- After application of Transdermal Sodium Bicarbonate (TSB) or placebo lotions, subjects completed a variety of exercise and performance tests (Figure 1).
- Subjects completed delayed-onset muscle soreness (DOMS) questionnaires ~24 and ~48 hours after exercise sessions. Muscle soreness was rated on a scale of 0-100 where 0 = “no soreness”, 25 = “mild pain”, 50 = “moderate pain”, 75 = “severe pain” and 100 = “the worst pain you can imagine”.
- Statistical analyses were performed using a mixed effects linear model with subject as a random effect and DOMS as a fixed effect. DOMS results are reported as least-squares means ± SE. Post hoc analyses were completed to analyze DOMS results for the subset of subjects reporting scores >0 at day 1 after exercise. Significant differences are p≤0.05.

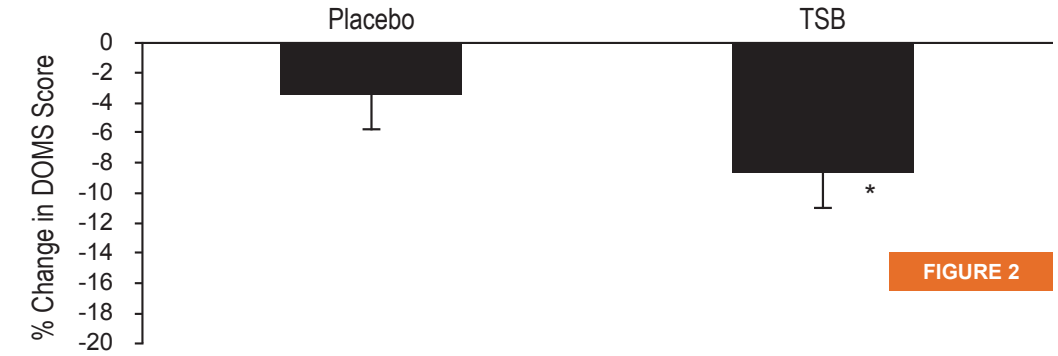
**Figure 1.** Schematic of Study Protocol. Subjects completed both tests; A) High-intensity series of exercise tests, and B) 1 hour time trial, on separate days, and for each study product (placebo or active).



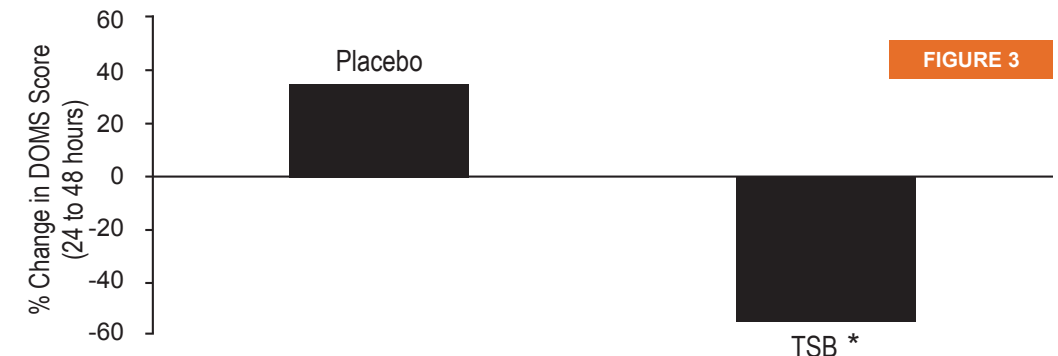
## RESULTS

- DOMS, measured over a 2-day period following exercise testing, showed faster recovery from muscle soreness with TSB lotion use versus placebo lotion after the series of high-intensity exercise tests, but not after the longer duration 1-hour time trial.
- A post hoc analysis of DOMS reporters (those who reported scores >0) and non-reporters (those consistently reporting scores of 0 points) at ~24 hours after testing, was also completed. In DOMS reporters (n=9 placebo and n=11 TSB) the reduction in DOMS was significantly greater (p=0.02) for TSB versus placebo (Figure 3).
- In this sub-population, although baseline scores were similar, there was a significantly different (p=0.02) mean (±SD) scores of 10.5 ±2.9 for TSB, and 21.0 ±3.3 for placebo at 48 hours.
- Additionally, for DOMS reporters, when evaluating % change from 24 hours to 48 hours while adjusting for ~24 hour observed values, TSB use resulted in a 54% reduction in DOMS scores versus an increase in DOMS scores of 34% when using placebo (p=0.007).

**Figure 2.** Delayed-onset muscle soreness (DOMS) was measured on a 0-100 point scale. \*Subjects had a significantly greater reduction in DOMS when using the transdermal sodium bicarbonate lotion compared to the placebo lotion (p=0.045).



**Figure 3.** Delayed-onset muscle soreness (DOMS) was measured on a 0-100 point scale. In subjects who reported scores of >0 (n=9 placebo and n=11) the % change in DOMS scores from 24 to 48 hours was had a significantly greater reduction when using the transdermal sodium bicarbonate lotion compared to the placebo lotion (p=0.007, indicated by \*).



## CONCLUSIONS

- Findings from this study suggest that TSB can significantly shorten recovery from DOMS following high-intensity exercise.
- Findings also support the effectiveness of the transdermal system in delivering sodium bicarbonate topically and may allow athletes to achieve these results while avoiding the side-effects of oral bicarbonate.
- Furthermore, we believe this study is the first to provide a direct link between sodium bicarbonate use and DOMS in athletes.
- Additional research is underway using an objective measure of DOMS to further substantiate these findings and to further elucidate the mechanisms that may be responsible for this observation.

## ACKNOWLEDGMENTS

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