## Introduction

In the World, alcohol is used to help us celebrate and socialize, and is an intricate part of many of our religious ceremonies. According to a report from the Department of Health and Human Services of the Center for Disease Control and Prevention data from the 2009 National Health Interview Survey indicate that 52% of Americans and 60% of the rest of the people in the world report consuming alcohol on a regular basis. Alcohol consumption is, however, engrained into the American culture, and even modest consumption of alcohol can have a negative impact upon the body (NIAAA, 2007). Alcohol affects every organ in the body. It is a central nervous system depressant that is rapidly absorbed from the stomach and small intestine into the bloodstream. Alcohol is metabolized in the liver by enzymes; however, the liver can only metabolize a small amount of alcohol at a time, leaving the excess alcohol to circulate throughout the body. The intensity of the effect of alcohol on the body is directly related to the amount consumed. Alcohol abuse can damage organs, weaken the immune system, and contribute to cancers. To complicate things further, alcohol affects different people differently. Genes, environment, and even diet can play a role in how a person metabolizes alcohol and whether a person will develop analcohol - related disease.

Moreover, many people drive vehicles while under the influence which leads to erratic driving, accidents and arrest. The cost of holding a person in the “drunk tank” until a person is sober is significant as it generally takes from 4-8 hours before a person can be released.

Allowing the body to metabolize alcohol faster, may help to alleviate some of the negative factors associated with alcohol consumption. It may also benefit society in general by reducing the number of accidents, or reducing the amount of time a person has to spend in a “drunk tank” when arrested for DUI, this providing a cost savings to police departments around the country.

## Methods

The study utilized a repeated measures design with each participant providing basal alcohol elimination rate without taking **Fluppy** and then alcohol elimination rate after taking **Fluppy**.

### Participants

A volunteer sample of participants (22 males and 26 females) was recruited through the recruiting network of Anaheim Clinical Trials group. To be eligible to be the in the study participants had to:

- Be between 25-36 years of age,
- African American, Hispanic, or white.
- In good physical health, with no known health conditions.
- Not taking any prescription medications (exception: birth control pills for women)
- Not taking any over-the-counter medications for gastrointestinal issues such as gastroparesis, acid reflux, or other metabolic processing issues, pain relievers, cold or allergy medications
- No family history of alcoholism or depression
- Willing to adhere to the study protocol.

Two female participants were lost to follow-up because they experienced vomiting at the Baseline Trial and one male was a no show at the Dosing Trial. One additional female participant did not complete the Dosing Trial because she experienced nausea and/or lightheadedness and refused to continue the trial. All results presented in this report are based on the 44 participants who completed the protocol.

Table 1. Demographic Characteristics of the Participants

| | All n=44 | Male n=21 | Female n=23 |
|---|---|---|---|
| Age | | | |
| Ethnicity: | | | |
| White | 36% | 43% | 30% |
| African American | 07% | 09% | 04% |
| Hispanic/Latino | 47% | 48% | 65% |
| Average Weight | 172 lbs Range (115-265) | 191 lbs Range(125-265) | 152 lbs Range (115-208) |

Protocol (Original)

Participants were brought into a testing facility on two separate occasions after completing a 12 hour fast. At the beginning of each trial, participants' basal Breath Alcohol Content (BrAC), Pulse/Heart Rate, and Percent of Oxygen in the blood were collected. Participants were then provided a meal of cheese pizza (approximately 520 calories) with a bottle of water prior to ingesting any alcohol.

Twenty minutes after the participants ate their meal they were served 1.5 ounces of 80 proof vodka neat and cold, at 20 minute intervals. BrAC, Pulse/Heart Rate, Blood Pressure and percent of Oxygen in their blood (SpO2 were measured 20 minutes post vodka until their BrAC reached 0.10 g/100 ml or the trial was stopped because of an adverse event.

Data collection was broken into three phases: 1) alcohol dosing phase, in which vital signs were monitored 20 minutes after the participant took a shot of vodka, 2) absorption phase, in which vital signs were monitored at 10 minute intervals beginning after the participants' BrAC reached .085 to.10to capture maximum absorption, 3) Alcohol Elimination phase, in which vital signs were monitored at 30 minute intervals to capture alcohol elimination rates.

Heart rate, pulse and SpO2 were monitored as a safety precaution using the same monitoring schedule as was used for BrAC.

Protocol (Modification)

During the course of the study the study team noted that over 50% of participants had longer than anticipated absorption rates for the alcohol. Several female participants required 6-7 shots of vodka to reach a BrAC of 0.10 g/ml (acceptable range .095 to .110) using the timeframe of a 20 minute interval between shots, but at 30 and 60 minutes post alcohol dosing their BrAC had continued to climb reaching levels between .15 g/ml and .19 g/ml. Because of the high levels of BrAC observed and the potential harm from ingesting this much alcohol the protocol was modified as follows:

Participants were given shots based on their body weight according to the following table:

Table 2. Alcohol Dosing Schedule by Body Weight*

| Weight in lbs | Expected Max Number of Drinks | Timeframe |
|---|---|---|
| 90 -115 | 2 | 1 and 2 at 20 min intervals then drink 3 at 30 minutes if needed to reach BrAC =.10 |
| 116-145 | 3 | 1 and 2 at 20 min intervals then drink 3 at 40 minutes if needed to reach BrAC= .10 |
| 146-185 | 4 | Shots 1 and 2 at10minutes intervals shots 3 and 4 at 30 minute intervals if needed to reach BrAC=.10 |
| 186- 225 | 5 | Shots 1 - 3 at 10 minutes intervals shots 4 and 5 at 30 minute intervals if needed to reach BrAC = .10 |
| 226- 245 | 6 | Shots 1- 3at 10minutes intervalsshots4-6at30 minute intervals if needed to reach BrAC=.10 |

To verify maximum absorption, participants' BrAC were monitored at 10 minute intervals until 2 readings at the same BrAC were obtained or there was evidence that the participant's BrAC was beginning to decline. The 30 minute monitoring of vital signs and BrAC then began.

Example:

Table 3. Example of Monitoring for Male weighting 185 lbs.

| Shot Number | Time Drank | Time and BrAC 20 min | Time and BrAC 30 Min | Time and BrAC 40 min | Time and BrAC 50 Min | Time Fluppy Taken | Time 30 min monitoring began |
|---|---|---|---|---|---|---|---|
| 1 | 12:00 | | | | | | |
| 2 | 12:10 | | | | | | |
| 3 | 12:20 | 12:40 (.065) | | | | | |
| 4 | 12:50 | 13:10 (.080) | 13:20 (.088) | 13:30 (BrAC .088) | | | |
| 5 | 13:31 | 13:51 (.104) | 14:01 (.107) | 14:11 (.112) | 14:21 (.112) | 14:21 | 14:51 |

Protocol Deviations

The following protocol deviations were noted:

- Participants were given gum to chew after their BrAC reach the specified .10 or the trail was stopped because of an adverse event.
- During the dosing trial, 1 Female participant asked a question regarding the **Fluppy** product and revealed a family history of alcoholism.

Equipment

BrAC was measured using a LifeLok F10 breathalyzer. Additional it was chosen because it uses BAC standard as the unit of measure. The LifeLok F10 has immediate response on negative results, and <10 seconds on positive results. It also has immediate recovery on negative results, and <30 seconds on positives results. It has a range of 0 to .600 BAC with accuracy of ±.005 BAC to .100 BAC. ±5% above .100 to .400 BAC.

Outcome Measure

Alcohol Elimination Rate Attributable to **Fluppy** (AERAF):

The primary outcome measure AERAF was the percent reduction in BrAC above what would normally be expected for the time period observed after dosing with **Fluppy** minus the observed % reduction in BrAC without **Fluppy**. AERAF measured using the most distal interval from maximum BrAC. This interval varied from 60 to 120 minutes depending upon the time that the highest BrAC reading was taken. AERAF, was calculated by subtracting the expected reduction in BrAC based on forensic data (.0075 at 30 minutes, .015 at 60 minutes, .0225 at 90 minutes and .03 at 120 minutes; Jones, 2010) from the observed BrAC at the respective time points and then dividing the maximum BrAC observed to obtain the % reduction in BrAC. The difference between % reduction at Baseline and % reduction at Dosing was then calculated to provide the estimate of AERAF.

Example: Max BrAC minus 90 minute BrAC divided by expected 90 minute reduction in BrAC.

Baseline Max BrAC= .148 – 90 Minute BrAC = .128 / .0225 = .89 or 89% of expected.

Dosing Max BrAC=.134 – 90 minute BrAC = .097 / .0225 = 1.64 or 164% of expected.

AERAF= 1.64 - .89 =.76 or a 76% greater reduction in BrAC with **Fluppy** than without **Fluppy.**

## Results

The data were double entered into a database and checked for outliers and deviations from the assumptions of a normal distribution. The data were analyzed using Minitab 16.

At the beginning of each trial BrAC was measured to verify that participants had no alcohol in their system prior to ingesting the study alcohol using a LifeLok F10 breathalyzer. The basal BrAC at the beginning of each trail was .000 for all participants. BrAC was measured 20 minutes post ingesting each shot of vodka for participants who completed the original protocol and 20 minutes post either the 2nd or 3rd shot of vodka for those participating using the modified protocol. In the original protocol, the monitoring of the Alcohol Elimination Rate (AER) began 30 minutes after the BrAC reached 0.10 or higher. In the modified protocol after BrAC reached the .10 level BrAC reading were continued at 10 minute intervals to try to Ascertain Max BrAC prior to beginning the AER monitoring phase. Because of this variation in the way data were collected, AER was calculated for all participants at 30 minute intervals post maximum BrAC observed during each of the trials. AERAF was calculated by taking the maximum BrAC observer and then subtracting the BrAC at the most distal time period. Because some participants did not reach their maximum BrAC until long as 1 hour and 30 minutes after they had consumed their last drink some AER calculations were based on as little as 30 minutes post maximum BrAC. The average amount of time between taking their last shot and reaching maximum BrAC for all participants was 43 minutes (range 19 to 90 minutes). At baseline the average maximum observed BrAC=.122 and BrAC=.129 for our study participants at baseline and dosing respectively.

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To test for significant differences in AERAF t-tests were performed to test the hypothesis that the difference between baseline AER and Dosing AER was 0 for all participants as well as for males and females separately. The means, standard deviations, Confidence intervals t and p values are presentedin Table 4. The results showed that participants had a significantly greater alcohol elimination rates with **Fluppy** than without **Fluppy**.

Table 4. Basal vs. **Fluppy** Alcohol Elimination Rates (AER)

| | N | Mean | St Dev | SE Mean | 95% CI | t | p |
|---|---|---|---|---|---|---|---|
| Baseline | 44 | 1.05 All<br>1.02 Females<br>1.08 Males | .350<br>.337<br>.369 | | | | |
| Dosing | 44 | 1.57 All<br>1.69 Females<br>1.41 Males | .522<br>.713<br>.324 | | | | |
| AERAF | 44<br>23<br>21 | .44 All<br>.71 Females<br>.32 Males | .675<br>.646<br>.692 | .102<br>.138<br>.151 | .236 - .646<br>.426 – 1.00<br>.038 - .668 | 4.33<br>5.17<br>2.34 | .000<br>.000<br>.030 |

A greater AERAF value was observed for females than for male participants, the difference, however, was not significant ($t_{(42)}$ =1.56, p=.126) in this sample.

## Discussion

Using Fluppy helped participants metabolize alcohol faster than would normally be expected. Results from the baseline trial showed that our participants did not differ significantly in their alcohol elimination rates from the expected AER of .015 g/ 100 ml per hour (Jones, 2010). The Male participants in this study, on average, had higher basal elimination rates than females, but again the rate was not significantly different from the expected AER. When the male participants took Fluppy, however, on average, they metabolized 32% more alcohol, over their basal metabolism rate observed at baseline. Female participants also show higher metabolism rates with Fluppy % higher with Fluppy than without Fluppy over basal rates.

The ingredients in Fluppy have been shown in other studies to individually have an effect on symptoms of hangover (Spince, Parker & Gonzales, 1975; Tsukamoto et al., 1990). Although not part of the analysis, participants were asked to report adverse events that were related to alcohol consumption. Participants, on average, had slightly higher BrAC levels at dosing than at baseline, however the difference was not significant. Even with having higher levels of blood alcohol content at dosing, participants reported fewer symptoms of hangover after the dosing trial than after the baseline trial. In point of fact, after drinking the vodka during the baseline trial 25% of the participants reported experiencing symptoms of hangover later in the evening or the following day, whereas only 5% of participants report hangover symptoms.

This data suggests that eliminating alcohol at a higher rate may help to prevent the negative effects associated with drinking alcohol. One limitation of the study is that although we tried to ensure that all participants had reached max BrAC before monitoring of alcohol elimination rate began, 47% of the sample did not reach maximum BrAC until after monitoring began. This suggests that we did not capture the exact amount of AER that could be attributable to **Fluppy** and that actual results may be higher if **Fluppy** is taken after the maximum BrAC is reached.

The final limitation to the study is that participants were fed an approximately 520 calorie meal. Eating prior to drinking can change the rate of absorption of alcohol as well as the elimination rate. A portion of the observed differences in dosing vs. baseline may have been a result of differences in bioavailability of the alcohol and influence of the food on the metabolism of alcohol, which could have increased or decreased the AER at either time point.

## Conclusion

Taking **Fluppy** Food Supplement really helped the participants in this study to metabolize alcohol and a significantly faster rate than would normally be expected. Additionally, overall, participants experienced significantly fewer hangover symptoms when they took the product. **Fluppy** really works.