

# CASE STUDY

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## ADIPOSANO® OBSERVATIONAL STUDY PRELIMINARY STATISTICAL REPORT

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### RESULTS SUMMARY

Data from 32 patients treated with Adiposano® has been received and processed. Data included body weight and composition as well as analytical parameters (adipokines, biomarkers of inflammation, basic biochemical profile). All patients had data at 3 months of treatment while 23 patients had data at 6 months. However there are differences in the type of data collected from different patients.

All statistical tests have been applied with a  $\alpha=0.05$  two-sided significance level. The analysis was conducted to evaluate absolute change from baseline to 3 and 6-month visit, using oneway repeated measures analysis.

The results obtained show a numerical reduction of body mass index associated to a change in body composition: lean body mass increased numerically (132 vs. 135 lbs at 0 and 6 months;  $P>0.05$ ) while body fat mass tended to decrease (119 vs.104 lbs;  $P=0.07$ ).

The decrease in body fat has been parallel to a significant decrease in plasma leptin concentration (69.41 vs. 53.74 ng/mL at 0 and 6 months;  $P=0,0010$ ) and consequently to a decrease in the leptin/adiponectin ratio (7.19 vs. 5.23;  $P=0.00120$ ).

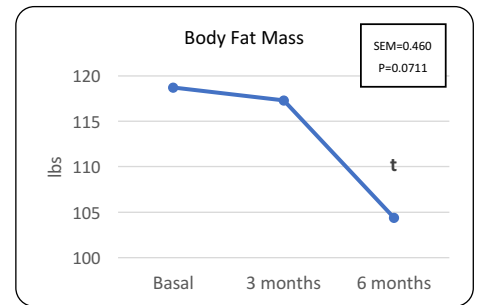
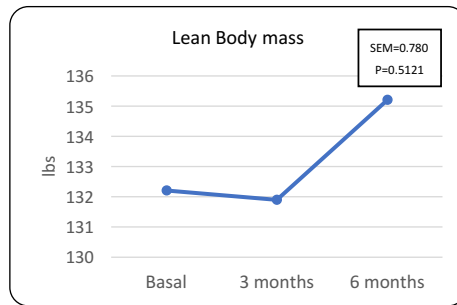
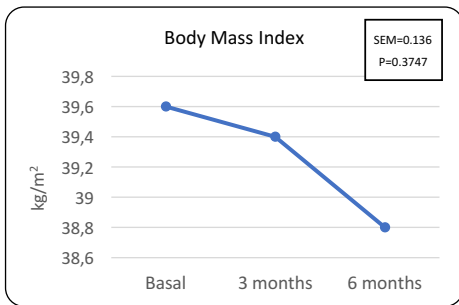
In addition a significant decrease on total cholesterol has been detected at 6 months of treatment as compared to baseline ( $P=0.0163$ ), accompanied with a trend towards a reduction in plasmatic tryglyceride levels ( $P=0.0899$ ). Besides this, insulin and HOMA-IR score have been reduced numerically although differences didn't reach statistical significance.

The overall results show that Adiposano® administration during 6 months has an impact on body fat mass, associated to a reduction in plasmatic leptin concentration. This effect tends to repercute in insulin sensitivity and specially on normalization of dyslipidemia.

# Table 1 – Body mass index and composition\*

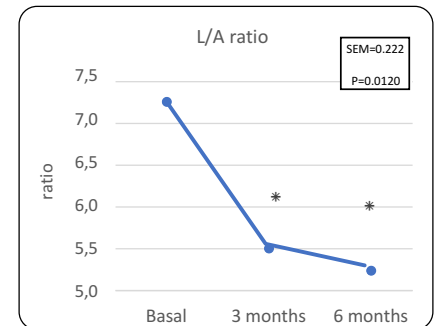
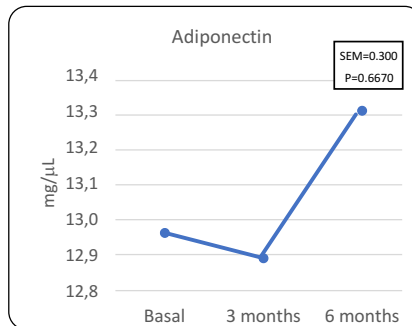
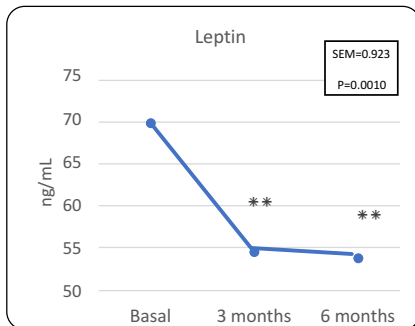
|                 | Basal | 3 months | 6 months | ANOVA (0-3 months) |         | ANOVA (0-6 months) |               | % responders |          |
|-----------------|-------|----------|----------|--------------------|---------|--------------------|---------------|--------------|----------|
|                 |       |          |          | sem                | p-value | sem                | p-value       | 3 months     | 6 months |
| Body Mass Index | 39.6  | 39.4     | 38.8     | 0.183              | 0.6727  | 0.136              | 0.3747        | 45           | 62       |
| Lean Body Mass  | 132.2 | 131.9    | 135.2    | 0.527              | 0.7755  | 0.780              | 0.5121        | 54           | 75       |
| Body Fat Mass   | 118.7 | 117.3    | 104.4    | 0.897              | 0.4493  | 0.460              | <b>0.0711</b> | 44           | 100      |
| % Body fat      | 47.3  | 47.0     | 44.0     | 0.190              | 0.4199  | 0.203              | 0.1077        | 56           | 100      |
| Trunk fat       | 56.8  | 56.4     | 50.9     | 0.420              | 0.6187  | 0.306              | 0.3535        | 67           | 75       |

\* oneway repeated measures analysis



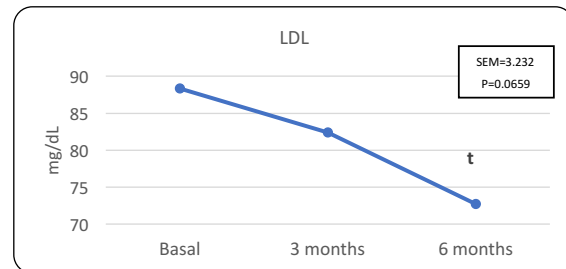
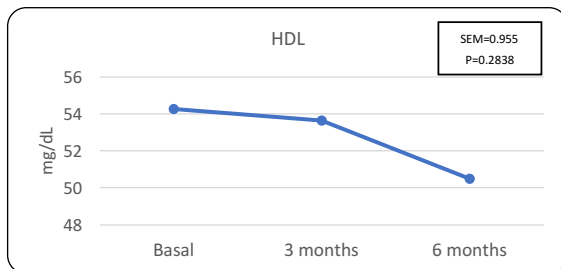
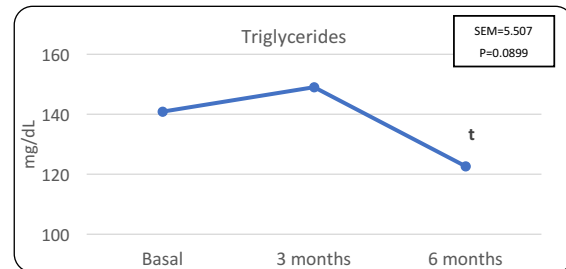
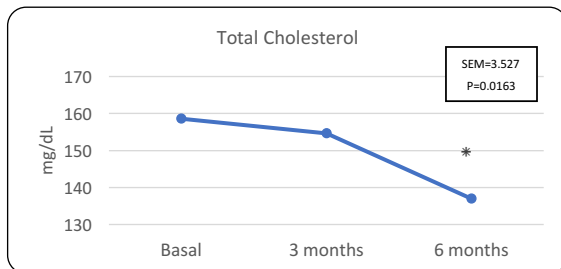
# Table 2 – Adipokines

|             | Basal | 3 months | 6 months | ANOVA (0-3 months) |               | ANOVA (0-6 months) |               | % responders |          |
|-------------|-------|----------|----------|--------------------|---------------|--------------------|---------------|--------------|----------|
|             |       |          |          | sem                | p-value       | sem                | p-value       | 3 months     | 6 months |
| Leptin      | 69.41 | 54.49    | 53.74    | 1.725              | <b>0.0060</b> | 1.136              | <b>0.0010</b> | 100          | 88       |
| Adiponectin | 12.96 | 12.89    | 13.3     | 0.417              | 0.9354        | 0.300              | 0.6670        | 75           | 65       |
| L/A ratio   | 7.19  | 5.49     | 5.23     | 0.292              | <b>0.0112</b> | 0.222              | <b>0.0120</b> | 88           | 94       |



## Table 3 – Lipid metabolism

|                   | Basal | 3 months | 6 months | ANOVA (0-3 months) |         | ANOVA (0-6 months) |               | % responders |          |
|-------------------|-------|----------|----------|--------------------|---------|--------------------|---------------|--------------|----------|
|                   |       |          |          | sem                | p-value | sem                | p-value       | 3 months     | 6 months |
| Total Cholesterol | 158.7 | 154.7    | 136.9    | 4.370              | 0.6539  | 3.527              | <b>0.0163</b> | 59           | 82       |
| Triglycerides     | 140.8 | 149.0    | 122.7    | 4.700              | 0.3980  | 5.507              | <b>0.0899</b> | 35           | 71       |
| HDL               | 54.3  | 53.6     | 50.5     | 0.681              | 0.2074  | 0.955              | 0.2838        | 71           | 59       |
| LDL               | 88.4  | 82.4     | 72.7     | 3.740              | 0.4387  | 3.232              | <b>0.0659</b> | 53           | 71       |



## Table 4 – Glucose metabolism

|         | Basal | 3 months | 6 months | ANOVA (0-3 months) |         | ANOVA (0-6 months) |         | % responders |          |
|---------|-------|----------|----------|--------------------|---------|--------------------|---------|--------------|----------|
|         |       |          |          | sem                | p-value | sem                | p-value | 3 months     | 6 months |
| Glucose | 127.4 | 131.7    | 130.5    | 7.270              | 0.7685  | 5.455              | 0.3165  | 71           | 60       |
| Insulin | 22.0  | 20.0     | 15.6     | 1.570              | 0.5238  | 1.974              | 0.1038  | 67           | 60       |
| HOMA-IR | 7.2   | 6.7      | 5.2      | 0.593              | 0.6993  | 0.609              | 0.2938  | 62           | 50       |

