Feiolix: Clinical Study for Blood Glucose Control

INTRODUCTION

Obesity, metabolic syndrome, and diabetes have become major global health concerns. Type-2 diabetes is the most common form of diabetes and accounts for 90% of all cases. Studies have demonstrated that Type-2 diabetes increases the risk of cardiovascular morbidity and mortality.

Maintaining blood sugar levels is important for the general population. Elevated blood glucose causes elevated triglycerides, this can lead to an increased risk of heart disease, storing of unwanted fat, and increases the rate of aging. Weight loss also becomes easier when blood glucose levels are controlled.

Feiolix is a high quality, polyphenolic-rich feijoa fruit extract made entirely from New Zealand feijoa. In clinical and pre-clinical studies, Feiolix extract has been shown to:

- Significantly decrease glycated haemoglobin A1c (HbA1c) in humans;
- Significantly decrease fasting blood glucose, triglyceride, and cholesterol in humans and *in vivo*;

This document summarises the clinical studies on Feiolix extract for blood glucose control, weight management and metabolic syndrome to date.

It is expected that the Feiolix whole fruit powder containing equivalent levels of bioactives plus the cell wall xyloglucans which increase Bacteroides levels and activity, producers of the postbiotic propionate which reduces liver fatty acid synthesis gene expression, will maintain or exceed this activity. Unpublished preclinical data using STZ diabetic mice support this hypothesis.

CLINICAL STUDY

EFFECT OF FEIOLIX FEIJOA EXTRACT CONSUMPTION BY PATIENTS WITH TYPE 2 DIABETES

Summary Notes

- In a randomised, double-blind, placebo-controlled trial, patients with type-2 diabetes received a daily dose of either feijoa extract or placebo for 12 weeks.
- The subjects were 34 men and women, 40-75 years old with type-2 diabetes. There were no significant differences between the 2 groups regarding age, height and body weight.

	Placebo	Feijoa extract (Feiolix)
Number of participants	14	20
Male : Female ratio	7: 7	4 : 16
Age (years)	52.6	55.0
Weight (kg)	77.6	77.2
Height (cm)	164.4	158.6

Mean years of diabetes treatment is the same for both groups. 19 of the 20 subjects supplemented with feijoa extract used additional medication: 95% use a combination of Metformin and Glibenclamide with two participants using insulin. 13 of the 14 subjects in the placebo group used additional medication: 55% use Metformin and Glibenclamide, insulin (1 subject) or Atenolol.

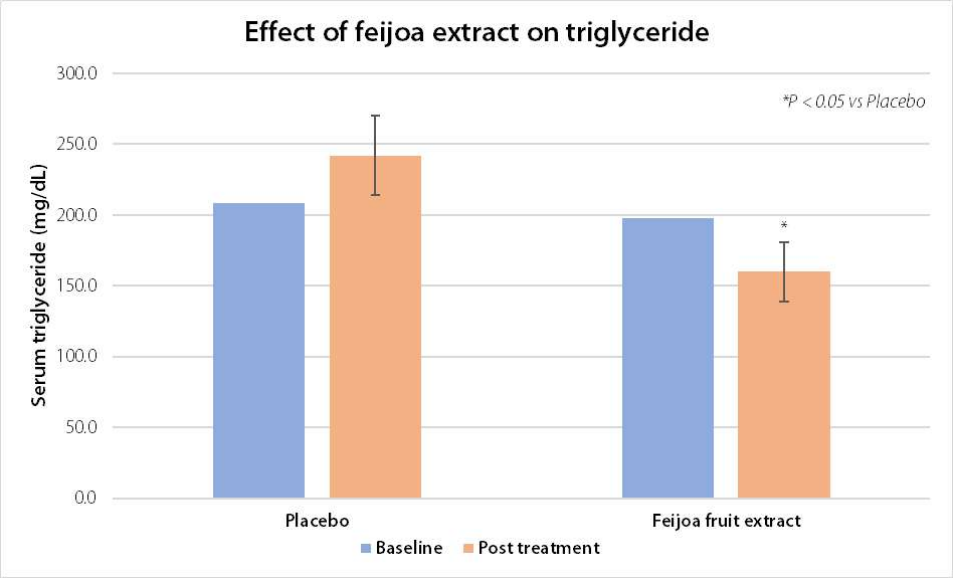
- Blood pressure, serum level of fasting blood sugar, total cholesterol, LDL, HDL, triglycerides, glycosylated haemoglobin, were measured and compared at the beginning and after 12 weeks treatment.
- After 12 weeks, patients in the feijoa group had significant decreases ($p < 0.05$) in fasting blood glucose and haemoglobin A1c (HbA1c).
- The magnitude of change seen with HbA1c (decrease by 0.86) is considered by FDA as clinically significant as pharmaceuticals for diabetes treatment are approved with changes of greater decrease than 0.5.
- Cholesterol and triglycerides also decreased significantly in the feijoa group in comparison to the placebo group ($p < 0.05$), and trending decrease for systolic blood pressure ($p < 0.08$)
- Trial participants in the feijoa group showed no significant changes in the standard liver enzyme, serum creatine, albumin, and urea. These data suggest no toxicity is observed in the feijoa extract.
- This study showed that feijoa fruit extract can improve diabetes control, reduce antihypertensive medicine use, and may favour a reduction in cardiovascular disease risk in individuals with Type-2 diabetes.

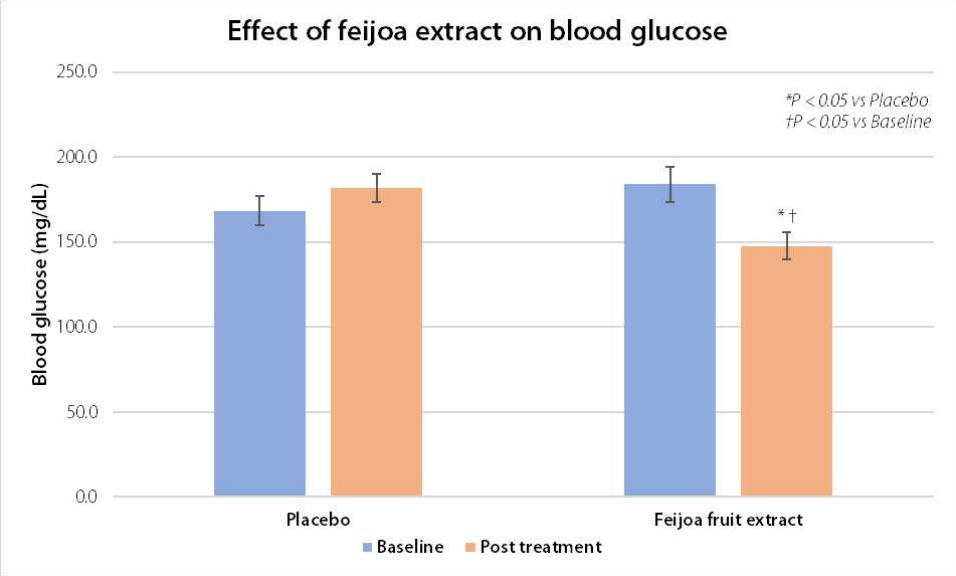
Results

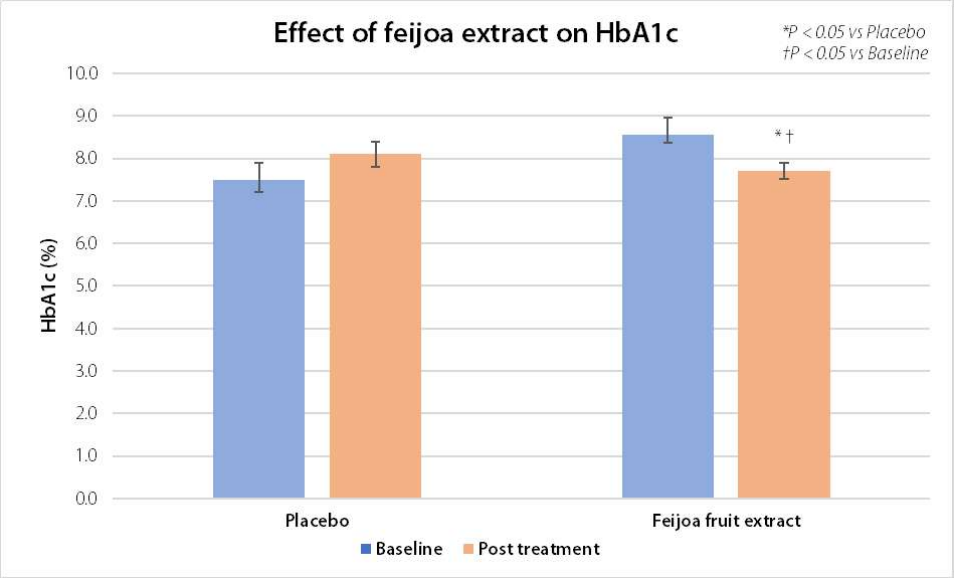
	Placebo			Feijoa fruit extract		
Variables	**Baseline**	**Post Treatment**	**Change**	**Baseline**	**Post Treatment**	**Change**
Triglyceride (mg/dL)	208.2 ± 23.5	241.9 ± 29.7	+33.6 ± 12.6	197.9 ± 28.1	159.8 ± 20.8*	-38.1 ± 20.9

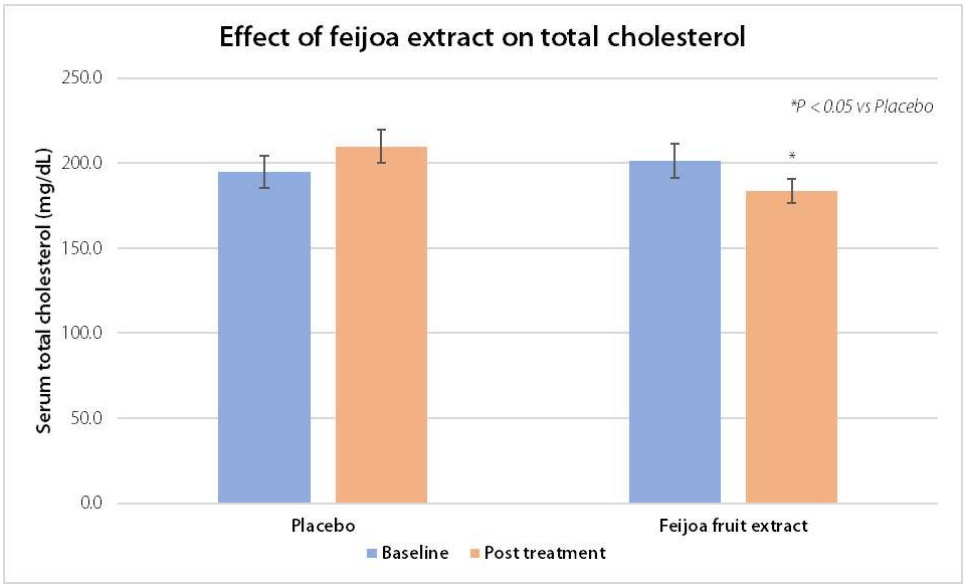
Blood glucose (mg/dL)	168.4 ± 8.4	181.9 ± 10.3	+13.5 ± 30.7	184.0 ± 8.2	147.7 ± 8.0*†	-36.3 ± 2.7
HbA1c (%)	7.5 ± 0.4	8.1 ± 0.4	+0.49 ± 0.19	8.6 ± 0.3	7.7 ± 0.2*†	-0.86 ± 0.14
Total cholesterol (mg/dL)	194.8 ± 9.6	209.8 ± 10.1	+15.0 ± 9.8	201.1 ± 9.9	183.6 ± 7.3*	-17.5 ± 6.9
LDL-cholesterol (mg/dL)	109.3 ± 37.2	116.1 ± 40.3	+6.8 ± 7.5	105.2 ± 15.2	87.2 ± 8.7†	-18.1 ± 14.4
Systolic BP (mmHg)	144.2 ± 0.2	142.9 ± 0.5	+0.36 ± 1.5	144.3 ± 1	137.6 ± 3.3	-6.7 ± 2.7

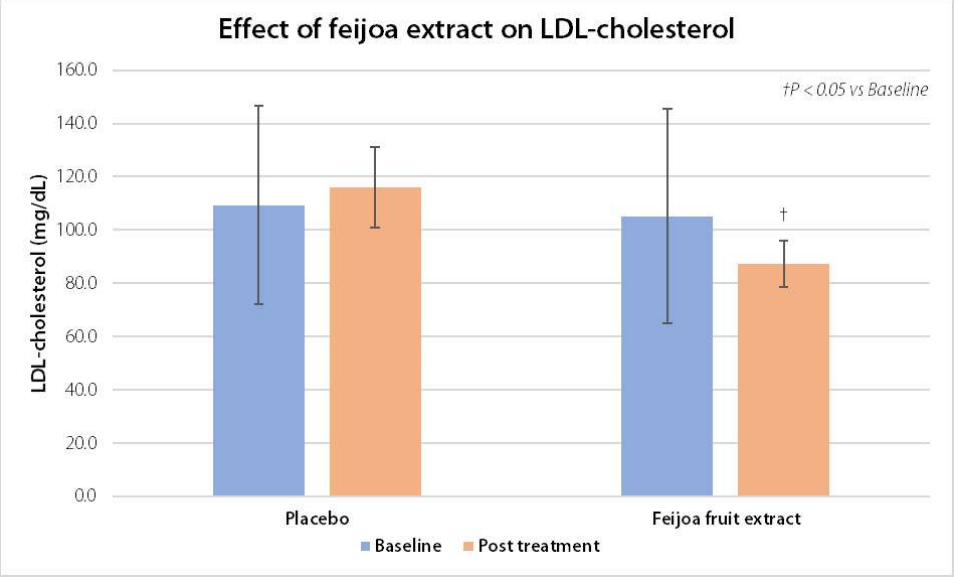
*Analysed by Student's t-test, *P < 0.05 compared with the placebo group, †P < 0.05 compared with the baseline. Measurements are performed on serum samples after 8-hours of fasting at the baseline and after 12 weeks of treatment. Values are means ± SEM (n = 20 subjects in feijoa fruit extract group and 14 in placebo except for LDL-cholesterol when both groups are 6).*

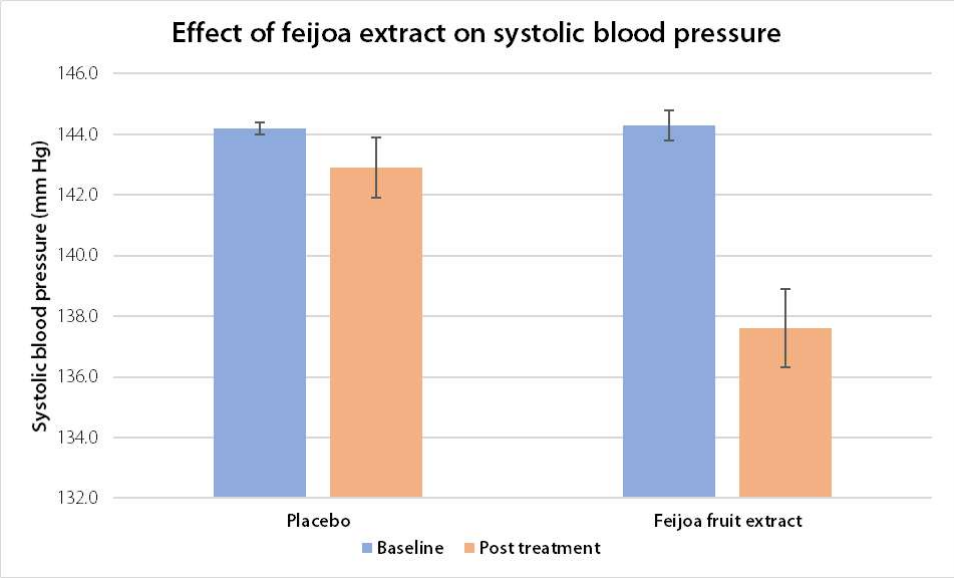





Effect of feijoa extract on HbA1c
*P < 0.05 vs Placebo
†P < 0.05 vs Baseline
HbA1c (%)
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
*†
Placebo
Feijoa fruit extract
Baseline
Post treatment


Effect of feijoa extract on total cholesterol
*P < 0.05 vs Placebo
Serum total cholesterol (mg/dL)
250.0
200.0
150.0
100.0
50.0
0.0
*
Placebo
Feijoa fruit extract
Baseline
Post treatment


Effect of feijoa extract on LDL-cholesterol
†P < 0.05 vs Baseline
LDL-cholesterol (mg/dL)
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
†
Placebo
Feijoa fruit extract
Baseline
Post treatment


Effect of feijoa extract on systolic blood pressure
Systolic blood pressure (mm Hg)
146.0
144.0
142.0
140.0
138.0
136.0
134.0
132.0
Placebo
Feijoa fruit extract
Baseline
Post treatment