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Research Article

Efficacy of Oral Protein Supplementation "PRO 360 Diabetic" on Diabetic Foot Ulcer Patients-A Pilot study

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Abstract

Foot ulcers are the main source of morbidity and a leading cause of hospitalization for persons suffering from diabetes. There is a steady increase in type 2 diabetes globally, especially among young and obese people. The main objective of the study is to assess the efficacy of oral supplementation "Pro360 Diabetic" a nutrition supplement in diabetic foot ulcers a complication predominant in diabetes. The subjects were randomly divided into two groups. Group 1 received Pro 360 coffee flavor Protein supplement and Group 2 received Pro360 Badam flavour Protein supplement daily for a period of 3 months. The following parameters CBC, HbA1c, Lipid profile, Urea, Creatinine and Total Protein were analyzed at baseline and every visit. The data obtained along with the patients' age and gender was subjected to statistical analysis by SPSS to evaluate the efficacy of supplement in foot ulcer patients. The results showed that there is statistical variation in the clinical variables of both the groups and badam flavor is found to be better than coffee flavor. It can be inferred that p value <0.05 is statistically significant for total protein on 0^{th} day and 90^{th} day related to age. In conclusion Pro 360 diabetic with micronutrients can be implemented as oral protein supplement in diabetic foot ulcer patients but further studies need to be conducted.

Keywords: PRO 360 Diabetic; Nutraceuticals; Diabetic

Foot Ulcer; Triple protein; Wound Healing

1. Introduction

The International Diabetes Federation (IDF) estimates approximately 463 million adults (20-79 years) were living with diabetes; by 2045 this will rise to 700 million. The percentage of people with type 2 diabetes is increasing in most countries and 79% of adults with diabetes were living in low- and middle-income countries [1]. India is the second largest contributor to the world's diabetic load after China. The complications due to diabetic foot affects >30% of the diabetic population over 40 years of age [2]. Diabetic foot ulcer is one of the most common diabetic complications associated with major morbidity, mortality, and reduced quality of life [3]. It is a challenging problem of diabetes mellitus affecting up to 25% to 35% of patients over their lifetime. Diabetic people often progress hard-to-heal diabetic foot ulcers secondary to neuropathy, peripheral vascular disease with ischemia, or both [4]. Also recurrent infection, wound depth, size and duration has negative impact on healing which can lead to amputation.

Wound healing is a multifaceted process and any interruption in the phases -hemostasis, inflammation, proliferation, and tissue remodeling has an impact on healing progression. Apart from local factors like hypoxia, infections and systemic factors, mainly age, stress, severity of diabetes, nutrition also exert a major role in wound healing [5]. In critical and post-operative care, providing early nutritional care, usually parenteral, is now considered a routine measure. Nutrition is well connected to every phase of healing, including immune function, glycemic control, weight management, and physical ability. Nutritional status is an important predictor of wound healing. A wound requires nutrients to be redirected from their normal functions to use in the various stages of the healing process [6]. Malnutrition is a well-known nutritional risk factor that can lead to the development of impaired wound healing. The elderly population is excessively burdened with risk of nutritional deficiency due to medical, psychological, physiological, social, and economic difficulties associated with increased age [7]. Micronutrients also play a vital role in the form of trace elements and vitamins, since they influence the course followed by the healing wound.

GMN Healthcare Pvt. Ltd. manufacturer of Pro360 Nutritional Supplements have specially formulated an ultimate health drink that will address all your macro and micronutrient needs. PRO360 products are specialized for various age groups, sex and health conditions. A huge range of products for diabetics, kids, pregnancy and lactation, orthopedic, weight management, liver care, renal care, oncocare, women's health and for general wellness who want protein supplements to balance their diet. The objective of the study is to introduce a nutrition supplement **"Pro360 Diabetic"** to patients suffering from diabetic foot ulcers. So we designed a Pilot study to evaluate the efficacy of oral supplement Pro360 Diabetic for 12 week period in diabetic foot ulcer patients with grade II and grade III diabetic foot ulcer based on Wagner's classification.

2. Materials and Methods

This Pilot study was conducted at Hycare Super Speciality Hospital, a tertiary Wound care center in Chennai, Tamil Nadu, India. The study protocol was approved by the Ethics committee of the Hycare Super Speciality Hospital. The patients were fully informed regarding the composition of Pro360 Diabetic supplement. All the study participants gave written informed consent. Total 30 patients were enrolled for the study and were randomly divided into 2 groups.

2.1 Composition of Pro360

Pro360 Diabetic's Composition is as follows:

NUTRIENTS	UNIT	Per 100g serving	Per 25g serving
Protein	g	27	6.75
Carbohydrates	g	52	13
Fat	g	1.6	0.4
Dietary Fibre	g	12	3
Ash & Moisture	g	2	0.5
VITAMINS			
Vitamin A	mcg RE	1000	250
Vitamin E	mg	20	5
Vitamin K2	mcg	40	10
Vitamin B1	mg	2	0.5
Vitamin B2	mg	2	0.5
Vitamin B3 (Niacin)	mg	12	3
Vitamin B5 (Pantothenic acid)	mg	8	2
Vitamin B6	mg	4	1
Biotin	mcg	60	15
Vitamin C	mg	120	30
Vitamin D3	mcg	8	2
Vitamin B12 (Methylcobalamin)	mcg	2	0.5
Folic acid	mcg	600	150
MINERALS			
Calcium	mg	1200	300
Phosphorus	mg	600	150
Iron	mg	20	5
Magnesium	mg	160	40
Zinc	mg	6	1.5
Copper	mcg	600	150
Manganese	mg	1	0.25
Sodium	mg	300	75
Potassium	mg	1200	300
Iodine	mcg	60	15
Selenium	mcg	20	5
Chromium Picolinate	mcg	80	20
Molybdenum	mcg	36	9

Curcumin	mcg	100	25
DHA	mg	200	50
Chloride	mg	700	175

Table 1: Composition of Pro360.

2.2 Study design

2.2.1 Grouping:

Group 1- Pro 360 Diabetic Coffee Flavor

Group 2- Pro 360 Diabetic Badam Flavor

2.2.2 Selection Criteria

2.2.2.1 Inclusion Criteria:

- Subject is diagnosed with Type II diabetes
- Diabetic patients with grades II/III-foot ulcer.

2.2.2.2 Exclusion Criteria:

- Non diabetic ulcer
- Subjects who are currently receiving Dialysis.
- Patients with chronic kidney disease (CKD)
- Liver diseases.
- Subjects with Protein Inborn Error Metabolic Disorder.
- Wagner's grade I, IV and V ulcer.
- Lost to follow-up.

All participants were stratified for gender, type and duration of DM. The subjects were randomly divided into two groups, group 1 received Pro 360 coffee flavor Protein supplement and Group 2 received Pro360 Badam flavor Protein supplement daily for a period of 3 months. Subjects were reminded daily by telephone calls to take after food every day.

2.2.3 Dosage: 25 grams twice a day after food.

2.2.4 Preparation:

- Take 1 mug of Luke warm water (200ml).
- Add two heaped tablespoons of PRO360 Diabetic powder and stir well.
- Drink it.

2.3 Intervention

Patient received supplement every day for a period of 3 months and was followed-up every month. The data was collected from 30 patients with diabetic ulcers satisfying all the inclusion criteria mentioned above. Selection of patients was prepared and randomized grouping was done. Informed written consent was obtained from all participants. A detailed clinical history, including age, sex, duration of diabetes, grade of the wound was taken on baseline and anti-diabetic medications were recorded on a preset proforma.

2.4 Ethical consideration

Informed and written consent was taken from each subject before collecting data and blood sample. Subjects who volunteer to participate in the study were included. The proposed study was undertaken after receiving approval by Institutional Ethical Committee of Hycare Super Specialty Hospital. Blood samples were collected and following parameters like HbA1 C, CBC, Lipid Profile FBS, PPBS Total Protein, Urine Albumin, Creatinine and Urea were analyzed at the start of the Pilot study and every visit for period of 3 months. Data collected was entered into Microsoft Excel Worksheet and statistically analyzed by using SPSS (Statistical Package for Social Sciences) version 2.0. For quantitative data mean, standard mean, standard deviation, standard error and t-test were calculated. P value <0.05 (0.01) will be considered as statically

significant (highly significant) at 95% confidence interval.

3. Results

Thirty subjects were included for the study and distribution of the subjects in 2 groups is represented in Figure 1. 24 males and 6 females were enrolled in the study with a gender distribution percentage as 80% males and 20% females with male to female ratio 4:1 as shown in Figure 2. The mean age of the subjects included for the study was 86.26 years, ranging from 40-80 year as represented in Figure 3. Figure 4 demonstrates the distribution of subjects based on Wagner's classification nearly 90% of patients were in Grade 2, 10% in Grade 3. Table 2 and Table 3 represents the Hb A1C, FBS, PPBS FBS, CBC, Urea, Creatinine, Total Cholesterol, Triglycerides, HDL Chol, LDL Chol, VLDL Chol, HDL Ratio and Total Protein in the subjects supplemented with coffee flavor and badam flavor of P360 Diabetic respectively. These determinations were performed at baseline and at 3 months in both coffee flavor and badam Flavor of Pro360. From the Table 2 and Table 3 it is clear that there is a statistical variation in the clinical variables of both the groups and badam flavor shows better result than coffee flavor. It can be inferred that p value < 0.05 is statistically significant for total protein on 0 day and 90 days related to age as depicted in the Table 4a and 4b.

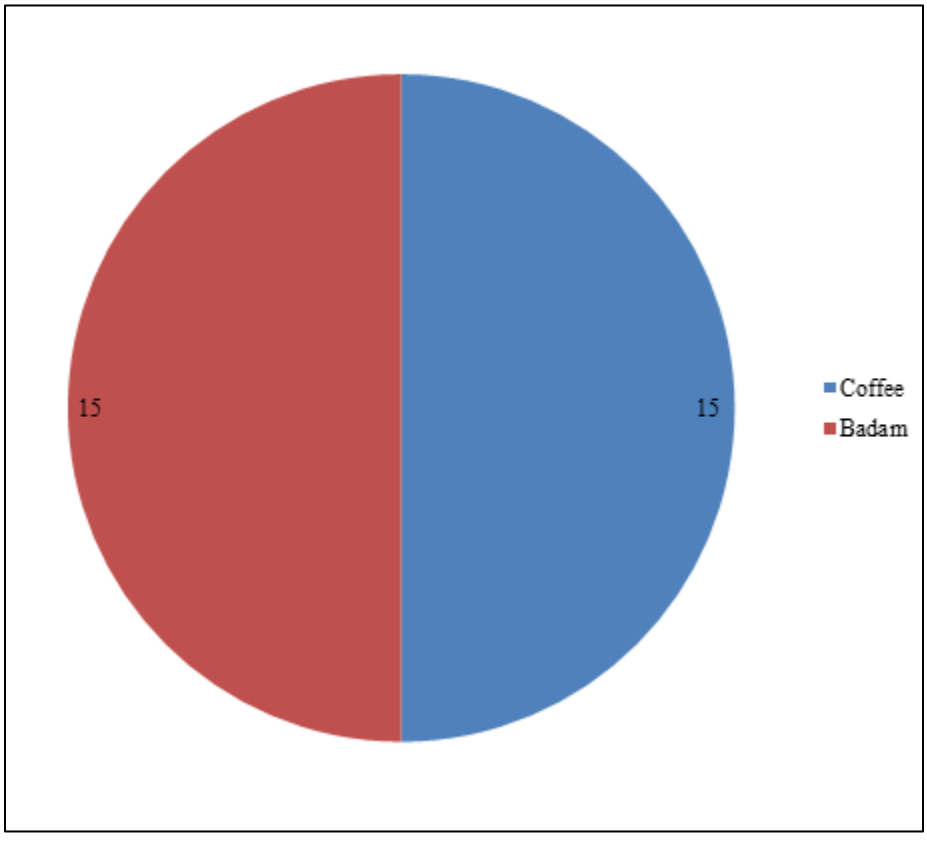

Figure 1: Distribution of Subjects in 2 groups.

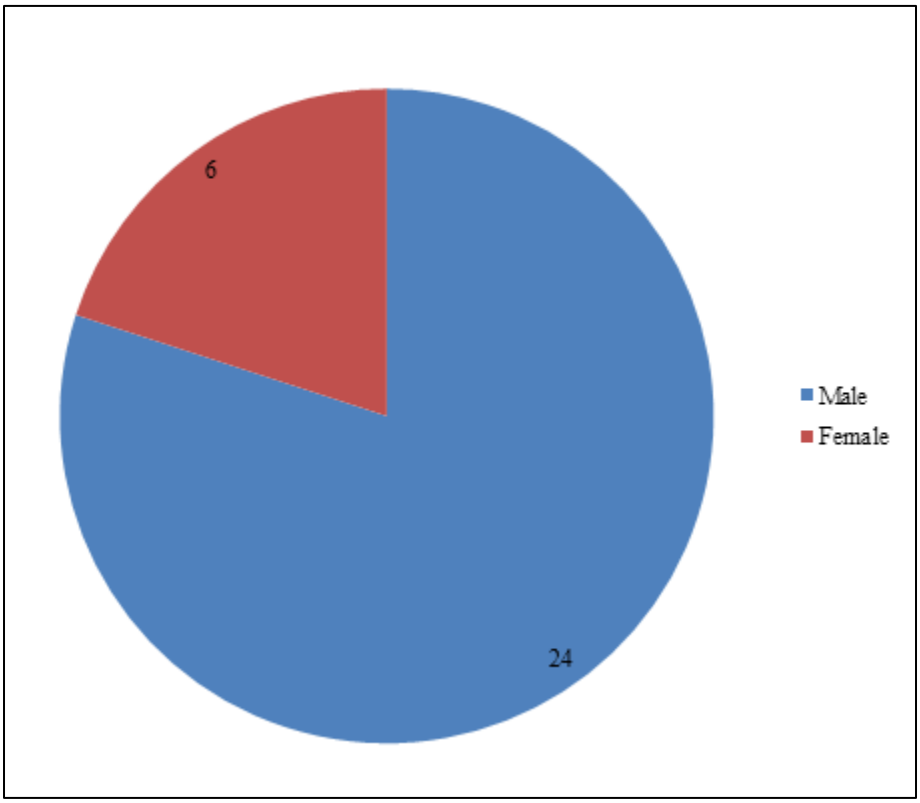

Figure 2: Gender distribution pattern.

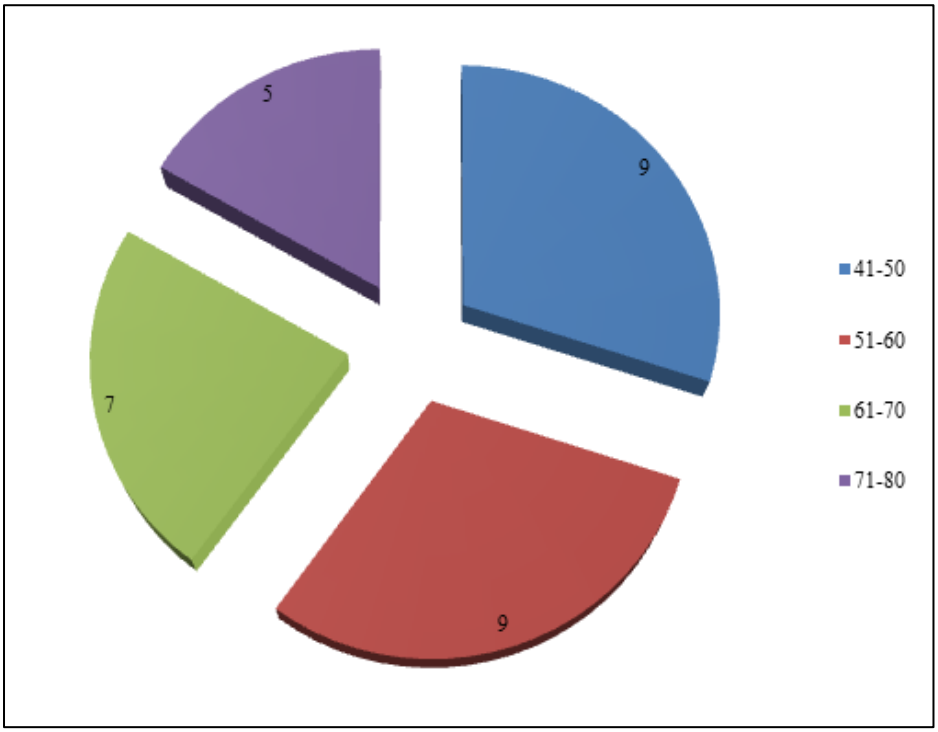

Figure 3: Age Distribution of subjects based on age (in yrs).

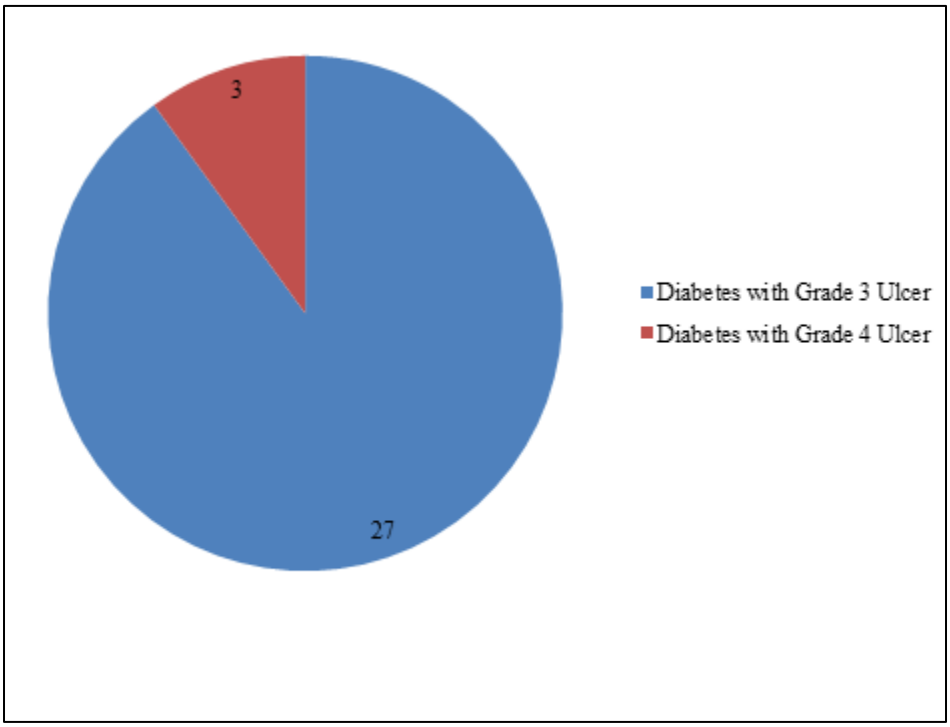

Figure 4: Distribution of subjects based on Wagner's classification.

Parameters	Zero day	30 days	60 days	90 days
FBS (mg/dl)	159.8 ± 26.715	148.6667 ± 21.224	118.7333 ± 15.243	127.5333 ± 17.111
PPBS (mg/dl)	220.8667 ± 30.37	200.2667 ± 27.074	173.6667 ± 17.877	160.0667 ± 15.386
TWC (cells/cumm)	10,686.6667 ± 1,330.969	10,820 ± 1,176.653	10,700 ± 1,137.09	10,786.6667 ± 1,100.607
Neutrophils (%)	73.2 ± 4.099	71.3333 ± 4.533	66.5333 ± 4.991	64.0667 ± 5.033
Lymphocytes (%)	51.5333 ± 11.551	51.3333 ± 11.138	41.0667 ± 9.894	40.4 ± 10.376
Eosinophils (%)	3.6667 ± 0.312	3.9333 ± 0.776	3.5333 ± 0.324	3.3333 ± 0.312
Monocytes (%)	2.2 ± 0.342	2.2 ± 0.342	2.2667 ± 0.3	2.2667 ± 0.404
Basophills (%)	0	0	0	0
Haemoglobin (g/dl)	12.9553 ± 0.621	12.9667 ± 0.497	12.2867 ± 1.344	12.0667 ± 1.298
RBC (millions)	4.208 ± 0.228	4.0713 ± 0.201	4.17 ± 0.479	4.006 ± 0.487
Platelet (Laks cumm)	3.3533 ± 0.454	3.2387 ± 0.417	3.3333 ± 0.683	3.2627 ± 0.683
Urea	30.4 ± 9.345	29.6 ± 9.056	25.4 ± 1.741	24.2667 ± 1.789
Creatinine (mg/dl)	1.1333 ± 0.123	1.1133 ± 0.111	1.02 ± 0.133	1.0667 ± 0.14
Hba1c (%)	8.1667 ± 0.995	7.8933 ± 0.928	7.7933 ± 0.923	7.7067 ± 0.909
Total Cholestrol (mg/dl)	156.8 ± 9.539	156.2667 ± 19.043	151.1333 ± 17.567	147.4 ± 7.084
Triglycerides (mg/dl)	86 ± 14.824	101.5333 ± 27.975	98.6 ± 26.097	86.4 ± 14.612
HDL Chol. (mg/dl)	57.2 ± 9.566	57 ± 8.755	55 ± 8.37	54 ± 10.536
LDL Chol. (mg/dl)	69.2 ± 18.162	92.0667 ± 24.952	88.8 ± 23.871	61.6667 ± 13.951
VLDL Chol. (mg/dl)	45.1333 ± 14.52	33.4 ± 11.962	32.4 ± 11.641	42.8333 ± 13.503
HDL Ratio (mg/dl)	3.3733 ± 0.401	3.2353 ± 0.402	3.1133 ± 0.403	3.3327 ± 0.507
Total Protein (g/dl)	7.2333 ± 0.239	6.9533 ± 0.453	6.822 ± 0.485	6.8813 ± 0.223

Values are expressed as mean ± SEM for 15 subjects in each group

Table 2: Clinical variables in subjects supplemented with Pro360 Diabetic Coffee flavor.

Parameters	Zero day	30 days	60 days	90 days
FBS (mg/dl)	130.0667 ± 20.082	148.6667 ± 21.224	118.7333 ± 15.243	110.6 ± 13.876
PPBS (mg/dl)	194.2667 ± 25.703	190.2 ± 27.825	173.6667 ± 17.877	160.0667 ± 15.386
TWC (cells/cumm)	11,020 ± 1,102.157	10,766.6667 ± 1,219.628	10,700 ± 1,137.09	10,786.6667 ± 1,100.607
Neutrophils (%)	70.0667 ± 4.434	67.8667 ± 4.626	66.5333 ± 4.991	64.0667 ± 5.033
Lymphocytes (%)	42.4667 ± 10.387	42.6667 ± 10.28	41.0667 ± 9.894	40.4 ± 10.376
Eosinophils (%)	3.8667 ± 0.422	4 ± 0.541	3.5333 ± 0.324	3.3333 ± 0.312
Monocytes (%)	2.3333 ± 0.366	2.2667 ± 0.404	2.2667 ± 0.3	2.2667 ± 0.404
Basophills (%)	0	0	0	0
Haemoglobin (g/dl)	12.3533 ± 1.173	12.5467 ± 1.355	12.2867 ± 1.344	12.0667 ± 1.298
RBC (millions)	4.314 ± 0.396	4.276 ± 0.476	4.17 ± 0.479	4.006 ± 0.487
Platelet (Laks cumm)	3.538 ± 0.695	3.378 ± 0.693	3.3333 ± 0.683	3.2627 ± 0.683
Urea	25.1333 ± 2.551	26.0667 ± 2.218	25.4 ± 1.741	24.2667 ± 1.789
Creatinine (mg/dl)	0.9733 ± 0.0886	0.9533 ± 0.0786	0.9333 ± 0.0563	0.8973 ± 0.0454
HbA1c (%)	8.06 ± 0.889	7.8933 ± 0.928	7.7933 ± 0.923	7.722 ± 0.939
Total Cholestrol (mg/dl)	166.2667 ± 23.359	156.2667 ± 19.043	151.1333 ± 17.567	149 ± 15.913
Triglycerides (mg/dl)	111.6 ± 40.206	101.5333 ± 27.975	98.6 ± 26.097	93 ± 21.795
HDL Chol. (mg/dl)	57.8 ± 8.966	57 ± 8.755	55 ± 8.37	52.6667 ± 8.877
LDL Chol. (mg/dl)	96.4 ± 26.677	92.0667 ± 24.952	88.8 ± 23.871	88.2 ± 23.316
VLDL Chol. (mg/dl)	33.4667 ± 12.27	33.4 ± 11.962	32.4 ± 11.641	31.4667 ± 11.372
HDL Ratio (mg/dl)	3.3527 ± 0.459	3.2353 ± 0.402	3.1133 ± 0.403	2.9973 ± 0.392
Total Protein (g/dl)	6.9867 ± 0.463	6.9533 ± 0.453	6.822 ± 0.485	6.7687 ± 0.496

Values are expressed as mean ± SEM for 15 subjects in each group.

Table 3: Clinical variables in subjects supplemented with Pro360 Diabetic Badam flavor.

	0 days	**90 days**
Mean	7.233333333	6.881333333
Variance	0.223809524	0.194369524
Observations	15	15
Pearson Correlation	0.692924686	-
`Hypothesized Mean Difference	0	-
Df	14	-
t Stat	3.793781507	-
P(T<=t) one-tail	0.000987456	-
t Critical one-tail	1.761310115	-
P(T<=t) two-tail	0.001974912	-
t Critical two-tail	2.144786681	-

t-Test: Paired Two Sample for Means

Table 4a: Coffee Flavor.

	0 days	**90 days**
Mean	6.986667	6.768666667
Variance	0.838381	0.962440952
Observations	15	15
Pearson Correlation	0.975503	-
Hypothesized Mean Difference	0	-
df	14	-
t Stat	3.8422	-
P(T<=t) one-tail	0.000897	-
t Critical one-tail	1.76131	-
P(T<=t) two-tail	0.001795	-
t Critical two-tail	2.144787	-

t-Test: Paired Two Sample for Means

Table 4b: Badam Flavor.

4. Discussion

The results of our Pilot study indicate that there is a possibility of introducing this nutritional supplementation with additional protein (Tri Protein) and micronutrients to Diabetic Foot ulcer Patients to enhance the immune system therefore to accelerate the healing Process. Collagen synthesis is required for repair of soft tissue injuries and to accelerate wound healing. Adequate protein is essential for function of platelet, proliferation of fibroblast and wound remodeling and deficiency can prolong the

inflammatory phase which eventually delays wound healing [8]. Intolerance issues such as nausea, vomiting, bloating, abdominal pain, and diarrhea were not observed in any of the subjects and there were no dropouts due to intolerance. Oral Protein nutrition supplementation Pro360is a nutritionally complete supplement that can provide the essential proteins, vitamins, and minerals needed to meet the nutritional requirements. It can also provide selected micronutrients such as vitamin C, vitamin D and zinc which can play a key role as antioxidant and immune boosters. Recent studies have shown that the nutrition formulations rich in protein, vitamin C, and zinc are effective in significantly improving healing [9]. Zinc contributes to protein and DNA synthesis, immune function, and cellular proliferation. Vitamin C is involved in collagen synthesis, fibroblast proliferation, and cellular immunity. The potential mechanism involved could be due to the synergistic effect of components present in the supplement especially the micronutrients –vitamins and minerals. In conclusion, oral Protein supplementation Pro360 diabetic of dosage 25 gm twice a day for a period of 12 weeks in addition to the normal diet in diabetic foot ulcer patients may improve plasma glucose (FBS) and lipid profile in patients with type 2 diabetes. Further clinical studies may be conducted to validate the results in larger population.

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