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People with Type 2 Diabetes See Considerable HbA1c Improvement in 1 Month Using Lysulin

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Diabetes mellitus is a leading and increasing cause of morbidity and mortality worldwide [1]. The causes of type-2 diabetes are multi-factorial, and supplements can play an important role on its' incidence, severity and management [2]. Hence studies have frequently focused on dietary components beneficial in the prevention and treatment of diabetes. Recent studies have demonstrated that numerous herbal and nutraceutical products have beneficial effects in patients by improving glucose and lipid metabolism, antioxidant status, disease progression and capillary function [3].

Lysulin™ is a new, patent pending nutritional supplement for people with Type 2 diabetes and prediabetes and those at risk of developing diabetes and metabolic syndrome [4]. Lysulin is manufactured in the USA and contains 3 active ingredients: Lysine (essential amino acid), Zinc (micronutrient) and Vitamin C (plus other standard excipients) and is manufactured by Lysulin Inc, San Diego, CA (www.lysulin.com). All three of the active ingredients have been shown (in more than 20 years of R&D and clinical studies) to lower blood glucose, lower glycated proteins and improve the lipid profile by lowering triglycerides, cholesterol and LDL and raising HDL. Daily use of Lysulin™ may slow or halt the progression of prediabetes to diabetes and slow or halt the progression of diabetes complications by lowering protein glycation [5,6].

A recent double-blind, placebo-controlled study of Lysulin intervention in 67 Type 2 diabetes patients demonstrated a significant improvement in HbA1c of 1.4% in 6 months and noted that HbA1c drops were first seen in as little as 1 month after initiation of Lysulin [7]. The number of subjects receiving 3 servings per day of Lysulin in this study was 18, 11 of which showed an improvement in their HbA1c. For these 11 subjects, the HbA1c drop in 6 months was 1.91% [7].

In addition to this double-blind study, we have also studied volunteers who started using Lysulin and self-measured their HbA1c using the A1cNow home test kit at baseline and then one month after starting Lysulin [8]. In addition to 37 subjects with Type 2 diabetes, we also observed 4 subjects with Type 1 diabetes, all of whom were using a DexCom continuous glucose monitor (CGM) with a hypoglycemia alarm. This precaution was sufficient to alleviate our concern about potential hypoglycemia for people with Type 1 diabetes using insulin, in combination with Lysulin, as both reduce blood glucose [9].

The results for the 37 volunteers are shown in the following **Tables 1-3**. Improved HbA1c required an improvement of at least 0.2%. No change in HbA1c meant that the HbA1c changes were plus or minus 0.1%. For the group labeled Increase in HbA1c, this group had an elevation of at least 0.2% after 1 month.

Baseline HbA1c	Month One HbA1c
7.4	6.1
6.5	5.4
7	6.1
6.2	5.8
5.7	4.9
12.8	7.9
8.4	7.8
6.3	6.1
6.8	6
12	11.4
5.6	5.2
6.2	5.8
8.6	7.2
6.9	6.5
7.1	6.9
5.8	5.6
5.9	5
6.8	6
6.5	6.2
6.1	5.9
7.4	6.9
10.5	9.5
7.8	7.2
6.4	5.8
6.4	5.5
Average 7.324	**Average 6.508**

Table 1: Improved HbA1c.

Baseline HbA1c	Month One HbA1c
6.1	6.1
5.9	6
5.6	5.6
6.3	6.2
5.3	5.4
7.1	7.1
5.9	5.9
Average 6.029	**Average 6.042**

Table 2: No Change in HbA1c.

Baseline HbA1c	Month One HbA1c
7.7	8.1
5.1	5.4
7.8	8.2
6.5	6.9
6.7	7.2
6.9	7.8
6.1	7
9.5	10.7
6	6.7
Average 6.92	**Average 7.56**

Table 3: Increase in HbA1c.

As seen in the above tables, 25 (61%) of Lysulin users had an improvement in their HbA1c in just one month of use. Their average HbA1c improved 0.816%.

Another 7 (17 %) had no increase in their HbA1c with an average HbA1c of 6.029 going to 6.042.

Another group of 9 volunteers (22%) saw an increase in their HbA1c after 1 month, with the average HbA1c going from 6.92 at baseline to 7.56 at 1 month.

Using all 41 volunteers, the average HbA1c went from 7.015% to 6.658% in just 1 month. An average drop of 0.357 in just one month.

None of the volunteers reported any side effects or other problems which could be ascribed to Lysulin. Ideally, of course, all volunteers would see an improvement in their HbA1c. However, it is noteworthy that Pharmaceutical executives have openly admitted that prescription medications only work in 30 to 50% of patients taking them [10]. Accordingly, our results revealing that 61% see an improvement is in line with this observation. In addition, nearly 20% saw no change in their HbA1c. This result allows for the possibility that, had they not taken Lysulin, that they may have seen an increase in HbA1c. To be clear, this possibility is speculative but a point worth considering nonetheless. There are at least two possible reasons for an increase in HbA1c seen in Lysulin users in this study. The first is that these individuals may have been having a large increase in HbA1c and that Lysulin effectively tempered the rise in HbA1c, which would have occurred in the absence of Lysulin. Another possible reason is that these individuals experienced a difficulty in absorbing Lysulin from their stomach and into their bloodstream. Further investigations are in progress to examine both of these possibilities and find a solution to further improve the effectiveness in Lysulin in lowering HbA1c.

These results confirm the excellent results observed in the double-blind study reported earlier [7]. In addition, these results also confirm that home testing for HbA1c on a monthly basis may lead to more effective diabetes management, especially after a change in treatment [7].

Further clinical studies are underway to firmly establish the usefulness of Lysulin in bettering the health of people with diabetes by lowering glucose toxicity and improving glycemic control.

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