

## OPTIMIZATION OF AEROBIC EXERCISE PROTOCOLS IN DIABETES MELLITUS: A RANDOMIZED TRIAL

Jaspreet Kaur<sup>1,✉</sup>, Shailendra Kumar Singh<sup>1</sup>, Jaspreet Singh Vij<sup>2</sup>

<sup>1</sup> Department of Physiotherapy, Guru Jambheshwar University of Science & Technology, Hisar, India

<sup>2</sup> College of Physiotherapy, Baba Farid University of Health Sciences, Faridkot, India

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### Abstract

**Background and Aims:** diabetes mellitus one of the non-communicable disorders which is spreading globally irrespective of nation being developed or developing. The aim of this study was to optimize the exercise protocols and to find the efficacy of these protocols on glucose control, balance, gait and proprioception in patients suffering from type 2 diabetes mellitus. **Material and Methods:** 40 individuals with type 2 DM with age 35 to 60 were randomly allotted to four groups with 10 subjects in each. Cycle ergometer based aerobic exercises were given with duration of 20 or 30 minutes twice or thrice weekly for 6 weeks. Pre and post intervention was collected using Fullerton Advanced Balance scale for balance, spatiotemporal gait parameters for gait, Continuous passive motion for Proprioception and High Performance Liquid Chromatography in the laboratory. **Results:** data was analysed using Design Expert software. Full factorial design was used to compare role of duration and frequency of exercise on each patient. The results showed significant effect of exercises on balance, gait, proprioception and glycated haemoglobin (HbA1c). **Conclusion:** Aerobic exercises if given for 30 minutes and thrice weekly can show a significant improvement in complications in Diabetics.

**key words:** Optimization, Aerobic Exercises, Balance, Gait, HbA1c, Diabetes Mellitus.

### Background and Aims:

Diabetes mellitus (DM) is one of the non-communicable diseases which is fast becoming a global menace especially in low and middle income countries. Lack of physical activity, faulty food habits, luxurious lifestyle, overweight and obesity has led to rapid rise of this metabolic disorder [1,2]. India has become global capital of diabetes as every fifth diabetic in world is Indian. India alone contributes around 41 million diabetic patients, which are

assumed to be 87 million by year 2028. DM is characterised by increase in glucose levels in blood and insulin sensitivity [2]. This leads to complications like retinopathy, renal failure, cardiorespiratory disorder and peripheral neuropathy [1]. Moreover, patients suffering from DM also have balance deficits, altered spatio-temporal gait parameters and impaired proprioception, which often results fall related injuries in such patients [3-5]. These impairments are usually related to peripheral neuropathy but Allet L. reported that these

✉ Jaspreet Kaur, Department of Physiotherapy, Guru Jambheshwar University of Science and Technology, Hisar, India 125001. Tel: 09466092657, 01662-263517; *corresponding author e-mail:* jaspreet\_malik16@yahoo.co.in

complications develop well before the development of clinical symptoms of peripheral neuropathy and, therefore they go unseen or overlooked by the physicians [3].

The treatment of DM includes physical exercise, healthy diet along with proper medication [6]. “Exercise” is defined as “planned or structured physical activity” which improves one of the components of physical fitness [7-9]. Although there are many types of exercises but only aerobics, resistance and combination of aerobics and resistance have been extensively studied [7,8-10]. Aerobic exercise (AE) helps in reducing weight and controlling factors in glycaemia besides improving cardiorespiratory fitness, therefore considered useful in treatment of T2DM [11]. Exercising regularly should be part of various practice guidelines which has been suggested by American Diabetes Association. Although guidelines elaborate the method and procedure but the debate still exists on the duration, frequency and type of exercise [7]. The literature shows lot of studies on finding effect of aerobic exercises on glucose control and related physiological parameters. But the role of AE on balance, spatiotemporal gait parameters and proprioception have not been studied.

Therefore, purpose of the present study was first to define relationship between factors (duration and frequency of exercises) and responses followed by optimization of exercise protocols to maximize its efficacy in improving gait, balance, proprioception and to minimize the HbA1c levels as effective control of sugar levels

in diabetic patients . Secondly to find efficacy of AE on these responses.

## Materials and Methods

The procedure of the study was approved by institutional ethics committee (03/11/2015 vide letter no PTY/2015/800) which was in accordance with guidelines laid down by Indian Council of Medical Research. Informed written consent was obtained from all the participants in English and regional language.

### Participants

The study protocol was carried out on patients with type 2 diabetes mellitus. Patients were recruited through referrals from hospitals and outpatient clinics or reported directly to University Health Centre and OPD of Physiotherapy department, GJUS&T. The study was performed from May 2016 to July 2017. The patients were randomly selected if they met T2DM diagnostic criteria established by American Diabetes Association 2010 [12]. Patients were excluded if they had foot ulcers, orthopaedic and neurological problems, recent surgeries which may directly or indirectly influence outcome measures. A total of 40 individuals (both males and females) were randomly allocated to four groups. Subjects in all the groups received cycle ergometer based Aerobic Exercise with different duration and frequency of exercises. Exercise duration and frequency of each session for different groups is shown in (Table 1).

**Table 1.** Six week exercise protocol for different groups

Group	Code	No. patients (n)	Duration	Frequency	Completion period
Group 1	G1	10	20 minutes	Twice weekly	6 weeks
Group 2	G2	10	20 minutes	Thrice weekly	6 weeks
Group 3	G3	10	30 minutes	Twice weekly	6 weeks
Group 4	G4	10	30 minutes	Thrice weekly	6 weeks

### *Intervention*

Pre and post intervention data was collected with interval of 6 weeks. Exercises were carried out after routine morning meal in a room equipped with mats and static cycle and cycle ergometer. Session started with 5 minutes of warm up followed by 30 or 20 minutes of Cycle Ergometer Based aerobic exercise with 5 minutes of break. The session ended with cool-down with mild stretching and relaxation. This was continued thrice or twice weekly for 6 weeks with progression of resistance on weekly intervals. After 6 weeks patients were encouraged to continue the exercise sessions at their own.

### *Outcome measures*

Balance was measured by using *Fullerton advanced balance tests*. This scale was chosen as it is easy to imply and patients do not get tired while performing the given ten items in test. This scale incorporates 0 to 4 marks each to ten items which constitutes to 40 marks in total but in present study patient scoring  $\leq 25$  points were included. *Gait* was assessed by measurement of gait parameters that is stride length, step length, cadence, gait velocity. The step length (cm) was measured from the geometrical heel centre of the current footprint to the same of the previous footprint on the opposite foot, and the stride length (cm) from the line of progression between the heel points of two consecutive footprints of the same foot. The walking velocity (m/s) was obtained after dividing the recorded distance by the ambulation time. The cadence was calculated by asking the patient to walk for one minute through a straight pathway with self-selected speed and then calculating the number of steps taken for one minute. *Proprioception* was measured by joint reposition error. Average of three readings was taken using continuous passive motion (CPM). Patient's dominant leg

was placed in CPM and was asked to memorise position of three angles 15, 45 and 60 degrees. The position at each angle was maintained for five seconds. Then patient was then asked to stop the CPM at the same angle. HbA1c was measured using High Performance Liquid Chromatography in the laboratory

### *Statistical analysis*

In order to optimize efficacy of Aerobic exercise protocols in diabetes mellitus and associated complications 2 level full factorial design was selected taking two factors 1) Duration (at two levels 30 minutes and 20 minutes with 5 min interval in both), 2) frequency (at two levels twice and thrice a week) and there effect on responses was measured. The seven responses selected were Balance, Gait Parameters (step length, stride length, velocity and cadence), proprioception, glycated Haemoglobin (HbA1c).

### **Results**

The experimental design suggested by Design Expert software version 10.0.6 is shown in [Table 2](#) along with value of observed responses measured. A total 40 trial runs were suggested with four groups and ten blocks (data obtained from patients were evaluated for each group). Further the descriptive analysis of the responses has been elaborated in [Table 3](#). The equations were generated for effect of factors on different responses in terms of actual factor ([Table 4](#)).

It can be observed from polynomial equation (i) ([Table 3](#)) that increase in frequency and duration of aerobic exercises results in improvement of balance in patients suffering from Diabetes Mellitus. Further efficacy of frequency and duration are depicted with the help of 3- D plots ([Figure 1](#)) it has been observed that the frequency and duration of aerobic exercises results into improvement of balance. It

also reflects that increase in duration of exercises produce more pronounced effects on balance as compared to frequency of exercises. The equation (ii) shows that as the duration of aerobic exercise is increased there is improvement in step length whereas no effect was found with frequency.

**Table 2.** Experimental design two factor two level full factorial along with responses.

Run	Factor 1	Factor 2	Response 1	Response 2	Response 3	Response 4	Response 5	Response 6	Response 7
	A:Duration	B:Frequency	Balance	Step Length	Stride Length	Velocity	Cadence	Proprioception	HbA1c
1	-1	1	2	1.6	3.3	-0.08	2	2	-0.8
2	-1	-1	2	2	2	0	3	0	-0.2
3	1	1	5	2	4	0.1	1	-0.8	1.2
4	1	-1	1	0	1	0.1	3	-1	0.6
5	1	-1	1	2	0	0	2	-2	0
6	1	1	4	2	3	0.1	1	-1.4	-0.3
7	-1	1	1	2	2	0.1	4	2	-0.3
8	-1	-1	4	3	2	-0.1	2	-0.6	-0.4
9	1	-1	2	2	1	0	3	2	0
10	1	1	1	2	2	0.1	1	0.6	-0.4
11	-1	-1	4	0	2	0.3	2	-0.8	-4
12	-1	1	2	2	4	0	2	-1	-0.8
13	-1	-1	0	0	0	0.02	2	1	0
14	-1	1	2	1	2	-0.03	-1	2	-0.3
15	1	1	-2	1	4	0	1	0.5	-1.5
16	1	-1	3	2	4	0.2	5	-2	0
17	1	-1	3	3	7	0.13	4	2	0
18	1	1	5	3	6	-0.1	1	-2.7	-0.3
19	-1	-1	2	3	0	0.1	2	4	-0.4
20	-1	1	3	2	3	0.1	3	0	0
21	-1	1	2	0	2	0.06	2	2	0.4
22	-1	-1	0	2	2	0	-2	-1	-0.2
23	1	1	1	0	2	-0.19	2	1	-1.4
24	1	-1	6	2	5	0.1	3	2	-0.5
25	-1	-1	1	2	5	0.03	2	1	-0.2
26	-1	1	2	2.2	0.6	0.1	4	2	-0.2
27	1	1	2	1	3	-0.1	3	-0.4	-2.3
28	1	-1	2	2	5	0.14	2	-0.4	-0.3
29	1	1	1	0	1.6	0	1	3	-1.1
30	1	-1	1	3	4	0.2	3	1	-0.5
31	-1	-1	1	0	4	-0.1	2	1	-0.2
32	-1	1	3	2	4	0	2	0	-0.1
33	-1	1	3	2	2	0	4	-1	0
34	-1	-1	0	1	3	0.06	2	-0.1	0
35	1	1	2	1	2	0.2	2	0.1	0.3
36	1	-1	3	4	5	0.2	6	1.4	-0.6
37	-1	-1	2	3	2	0.14	1	0.7	0.3
38	-1	1	2	1	4	0	3	2	0.6
39	1	-1	4	1	3	0	3	0	0
40	1	1	4	2	4	-0.06	2	2.4	-0.6

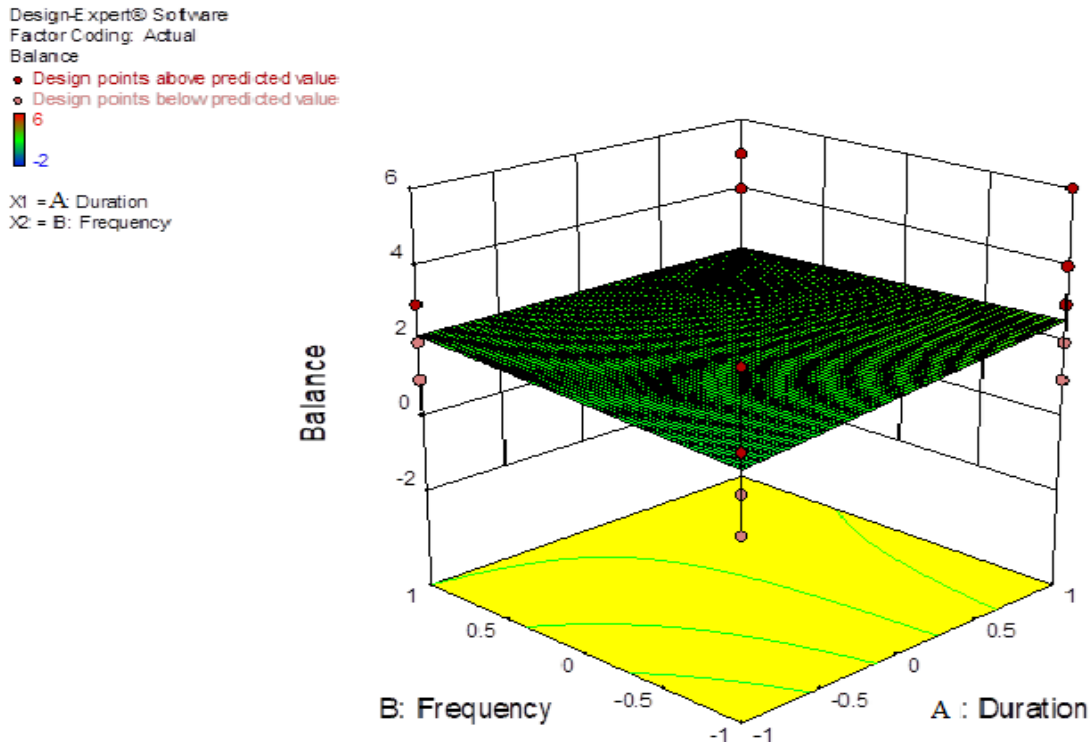
**Table 3.** Descriptive analysis of responses.

Response	Name	Units	Observations	Analysis	Minimum	Maximum	Mean±SD
R1	Balance	-----	40	Factorial	-2	6	2.17±1.56
R2	Step length	cm	40	Factorial	0	4	1.67±1.02
R3	Stride length	cm	40	Factorial	0	7	2.88±1.63
R4	Velocity	m/sec	40	Factorial	-0.19	0.3	0.04±0.10
R5	Cadence	Steps/1 min	40	Factorial	-2	6	2.25±1.42
R6	Proprioception	degree	40	Factorial	-2.7	4	0.51±1.49
R7	Hba1c	%	40	Factorial	-4	1.2	-0.36±0.84

**Table 4.** Numerical relationship between factors and responses.

Responses With The Equation Generated (factors #A & #B)	
BALANCE	$= 2.18+0.28*A+0.075*B-0.22*AB$ .....(i)
STEP LENGTH	$= 1.67+0.08*A-0.18*B-0.17*AB$ .....(ii)
STRIDE LENGTH	$= 2.89+0.44*A+0.037*B-0.21*AB$ .....(iii)
VELOCITY	$= 0.045+0.011*A-0.03*B-0.02*AB$ .....(iv)
CADENCE	$= 2.25+0.20*A-0.25*B-0.70*AB$ .....(v)
PROPRIOCEPTION	$= 0.51-0.25*A-0.10*B-0.14*AB$ .....(vi)
HbA1c	$= -0.36-0.02*A-0.03*B-0.22*AB$ .....(vi)

#A= Duration of exercise, #B= Frequency of Exercise



**Figure 1.** 3-D Plot showing interaction between Duration and Frequency for Balance

This has been again depicted in [Figure 2](#) that duration of exercise is playing important role as compared to Frequency. The improvement in step length could be found when individual effect of the factor was observed but combined effect of both the factors did not show any improvement. The equation (iii) shows that there was improvement in step length with both the factors that is duration and frequency of exercises improves stride length but when factors were analysed together it did not show any improvement.

It is also depicted in [Figure 3](#) that both duration and frequency are showing improvements but duration of exercise resulted in more improvement when compared to frequency. but combined effect of both the factors did not show any improvement. The equation (iv & v) shows role of duration and frequency of aerobic exercises on velocity and cadence in patients suffering from DM. here duration of exercises improved velocity and cadence, but frequency did not show any improvement. When combined effect of both the factors was observed it was found that together

they do not show any noticeable change in both increased improves velocity and cadence. the responses, it is only duration which when

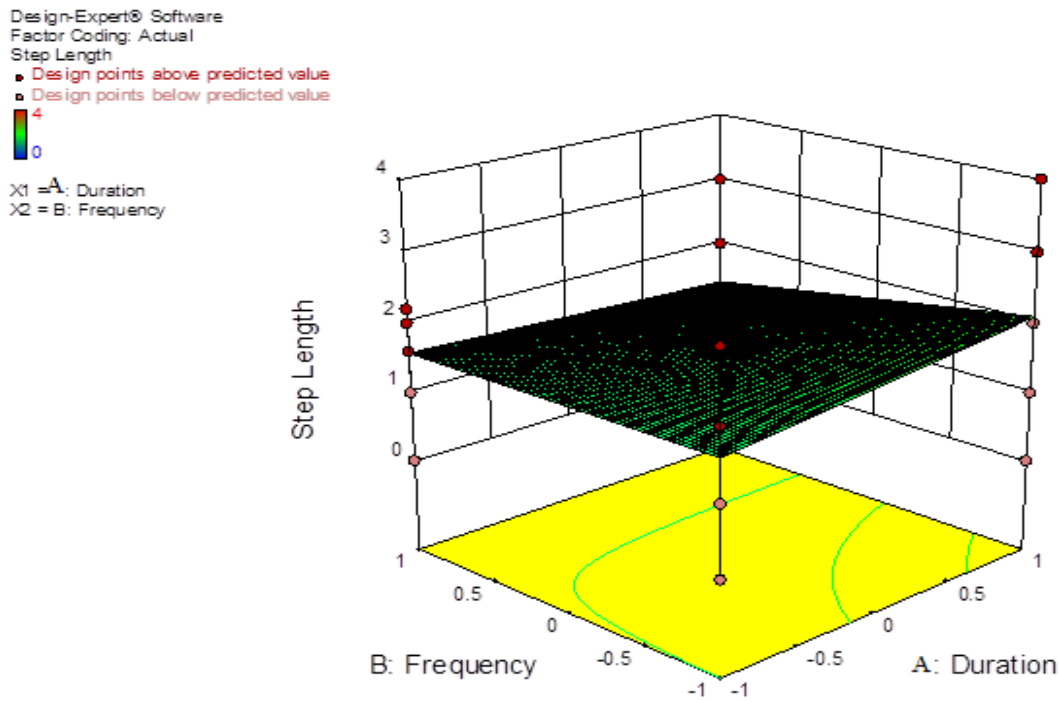


Figure 2. 3-D Plot showing interaction between Duration and Frequency for Step length.

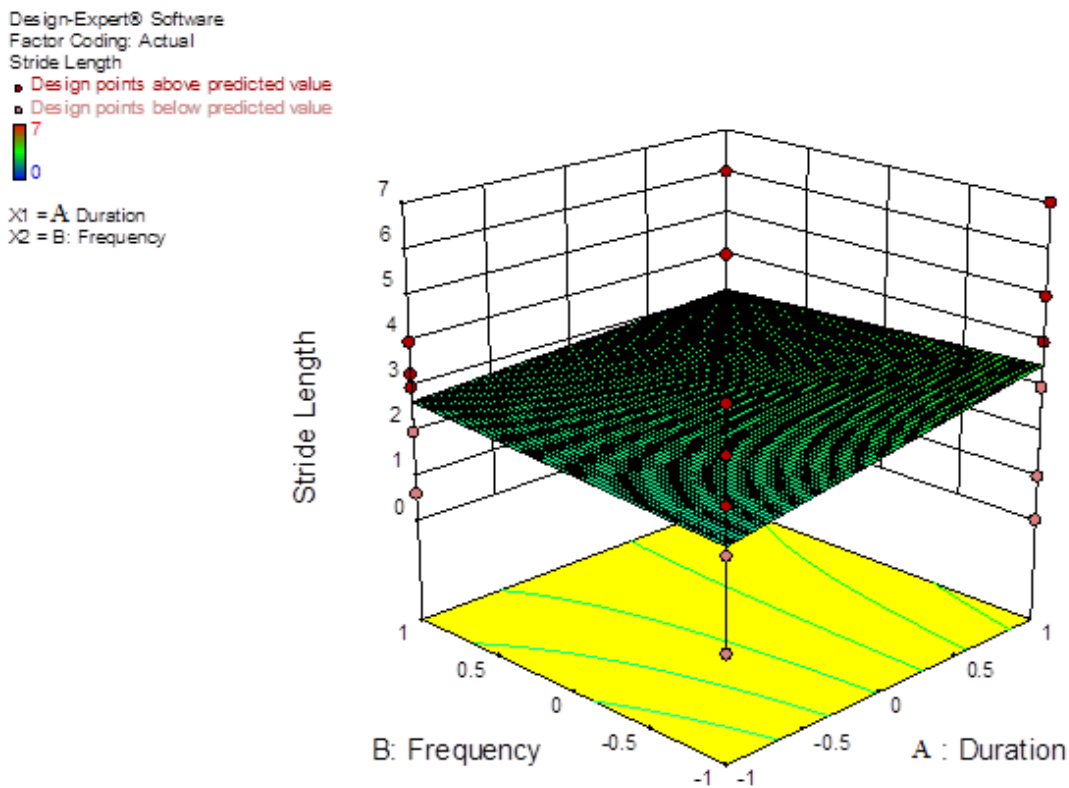
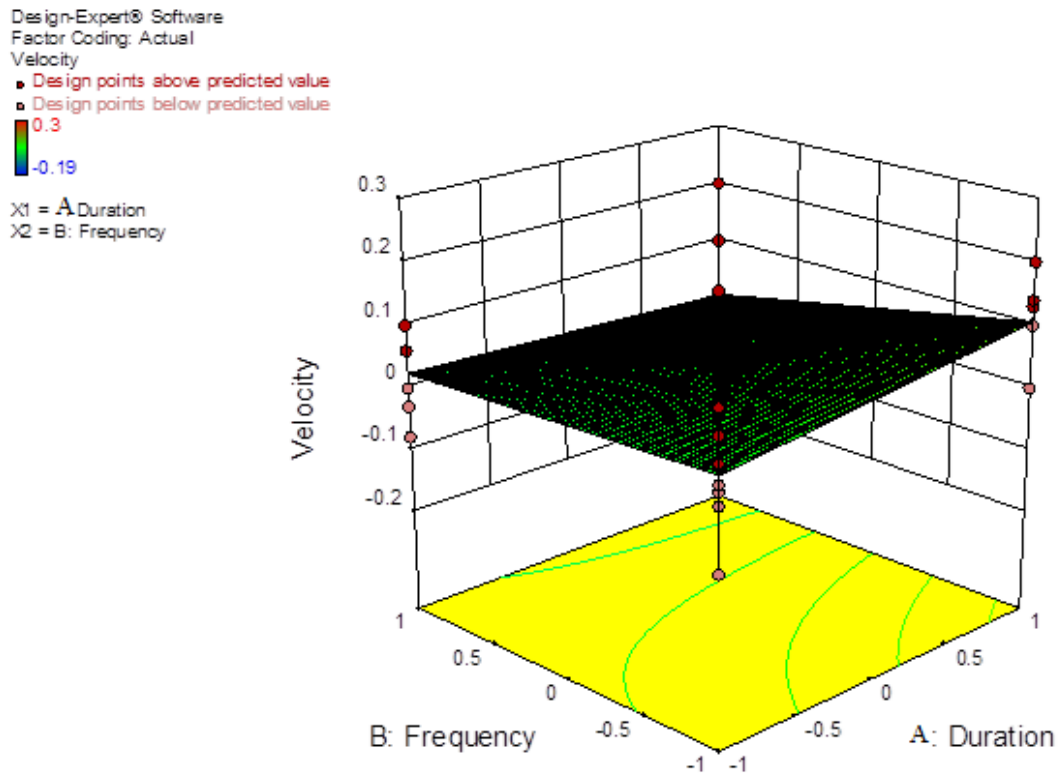


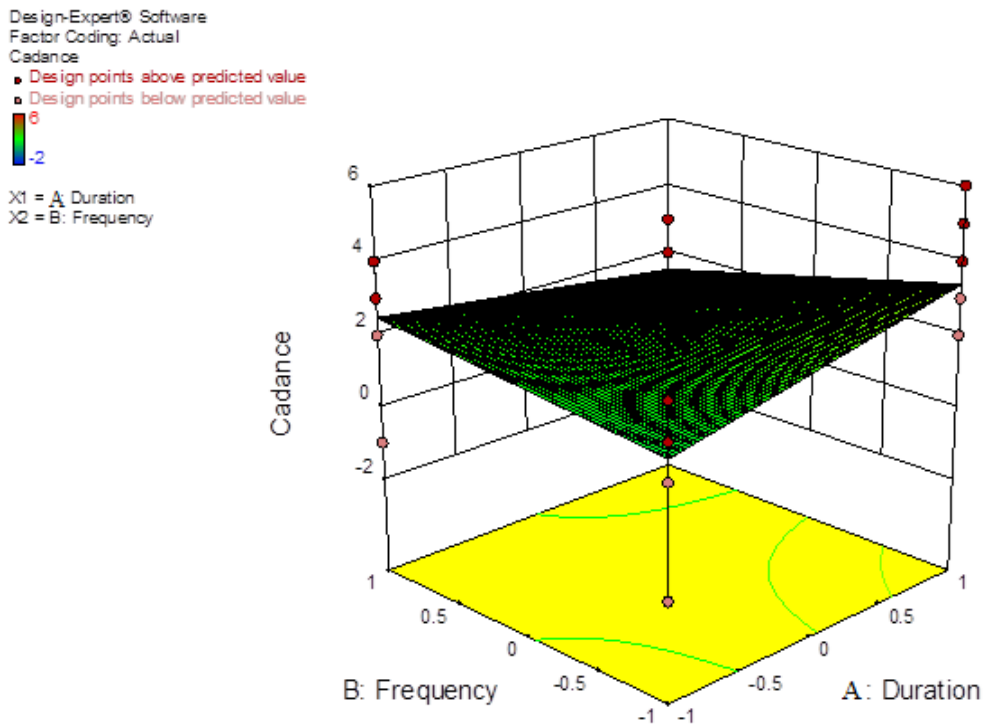
Figure 3. 3-D Plot showing interaction between Duration and Frequency for Stride length.

Similar results have been depicted in [Figures 4](#) and [5](#). Further it is evident from equation vi that proprioception decreases significantly with increase in duration of AE.

However frequency alone was increasing proprioception. Although interaction term of duration and frequency of AE decreases proprioceptive error.



**Figure 4.** 3-D Plot showing interaction between Duration and Frequency for Velocity.



**Figure 5.** 3-D Plot showing interaction between Duration and Frequency for Cadance.

These mathematical equations supported our hypothesis that both duration and frequency of AE improves proprioception. Further the 3-D plot (Figure 6) has also depicted the similar finding that increasing duration of exercise

improves proprioception as compared to frequency of exercises. Further proprioceptive error is calculated on post intervention minus pre intervention. Therefore the negative value suggests decrease in proprioceptive error.

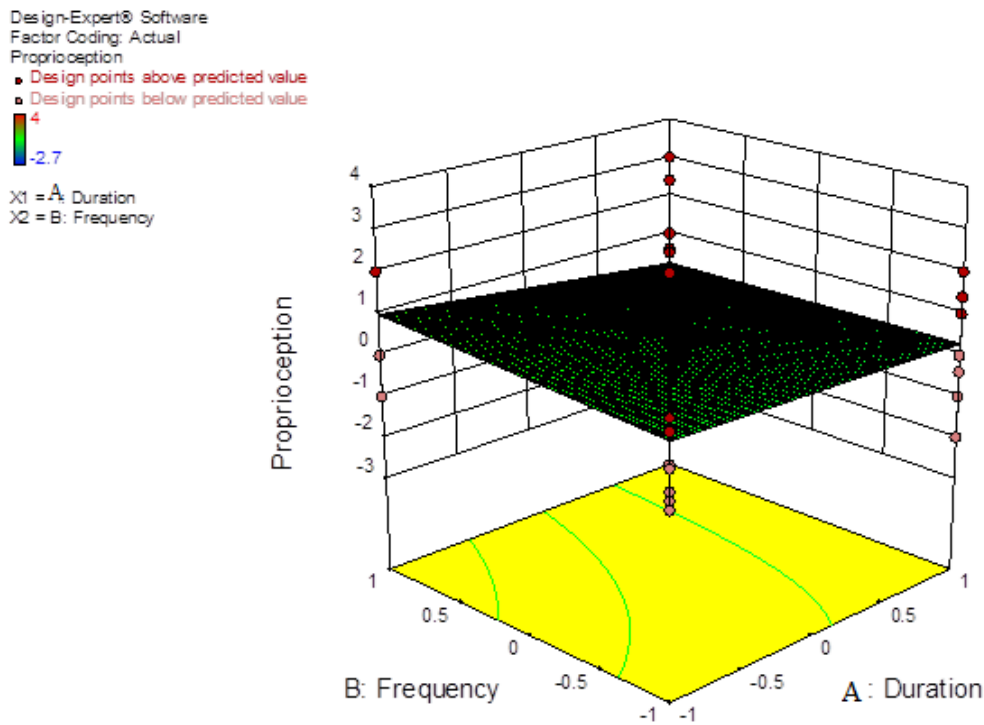


Figure 6. 3-D Plot showing interaction between Duration and Frequency for Proprioception.

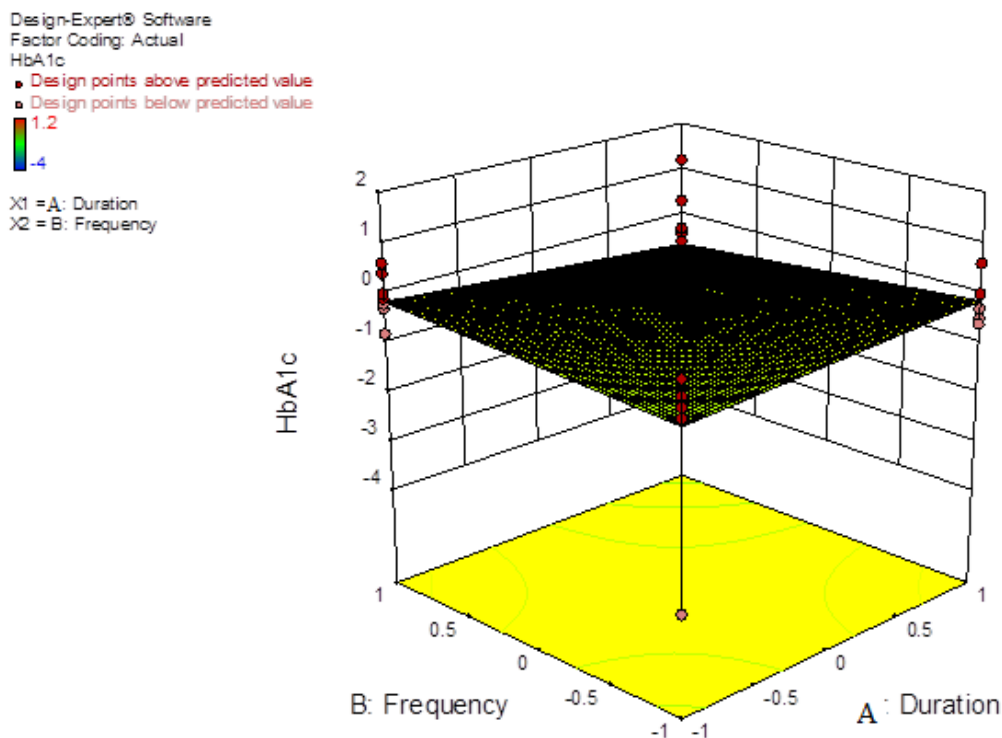


Figure 7. 3-D Plot showing interaction between Duration and Frequency for HbA1c.

In case of level of HbA1c which indicated better control over sugar levels in patients. It was observed that both the factors that is Duration and Frequency as well as their interaction term resulted in decreasing the level of HbA1c (factor 0.3625). This was also observed in 3-D plot

(Figure 7) that HbA1c falls with frequency and duration that is interaction between both the factors have approximately equable effects. As improvement is calculated on post intervention minus pre-intervention. Therefore the negative value suggests decrease in HbA1c.

**Table 5.** Goals for Optimization of responses.

Name	Goal	Lower Limit	Upper Limit	Lower Weight	Upper Weight	Importance
A:DURATION	is in range	-1	1	1	1	3
B:FREQUENCY	is in range	-1	1	1	1	3
BALANCE	maximize	-2	6	1	1	4
STEP LENGTH	is in range	0	4	1	1	3
STRIDE LENGTH	is in range	0	7	1	1	3
VELOCITY	maximize	-0.19	0.3	1	1	3
CADANCE	is in range	-2	6	1	1	3
PROPRIOCEPTION	minimize	-2.7	4	1	1	3
HbA1c	minimize	-4	1.2	1	1	5

The constraints and goals of present optimization study are shown in table 5. The two factors duration and frequency of exercises were in range to avoid errors in data. The goal of optimization in present study was to maximize balance (importance = 4) and to maximize velocity (importance=3). Step length, stride length, cadence and proprioception were kept moderate (importance = 3). Whereas HbA1c was maximized with highest value (importance= 5).

The design expert software suggested various solutions in order to simplify goals of optimization and therefore, solution 1 with maximum desirability of 0.688 was selected. This solution indicated that duration of exercises at level +1 and frequency at 0.285 should yield balance of 2.4, step length 1.65, stride length 3.28, velocity 0.04, cadence 2.17, proprioception 0.25 and HbA1c -0.45. This result suggested that group 4 patients having been provided 30 minute thrice weekly AE showed best nearest results as suggested by the software in improvement of diabetes mellitus associated complications.

## Discussion

Even though the American Diabetes Association and the European Association for the Study of Diabetes have given guidelines regarding benefits of regular exercising on blood glucose [13,14], there is paucity of information on the exercise parameters like type, intensity, frequency, and duration. Therefore, in the present study, duration and frequency of exercise are two factors kept under consideration. In our study when aerobic exercise (AE) were performed for duration of 30 minutes and frequency of thrice per week resulted in improvement of balance, gait, proprioception and HbA1c. This result - that blood glucose (BG) decreases with AE - is in concordance with other studies [8,10,15,16]. This may be because physical activity leads to uptake of BG by the muscles which, at a time, is more than level of glucose in the blood.

Further it has also been suggested that AE can alter insulin action with duration, intensity of exercise and diet. It was also shown that a single session of AE lowers glucose levels for more

than 24 hours but less than 72 hours [10,15]. Therefore it can be attributed from our study that AE given thrice weekly on alternate days is sufficient to maintain glucose levels in blood. Other reasons could have been dietary intake as patients were advised to take low carbohydrate diet along with exercise program. As carbohydrates consumption in large quantity results in excessive glycogen storage in liver which can be lowered by decreasing intake of carbohydrate enriched diet and involving oneself in any kind of physical activity [8,17]. This may also attribute to consciousness of patients about maintenance of sugar levels as they were participating in research protocol.

The spatiotemporal gait parameters and balance are found to be impaired in patients with or without peripheral neuropathy in patients suffering from DM which have highly debilitating effects like falls and fall related injuries [3]. Joint stiffness, poor sensory perception in diabetics result in gait abnormalities, this further impairs control on movement which may reduce step and stride length [1]. In present study balance and gait parameters were found to be improved with cycle ergometer, when duration of aerobic exercises was increased. These results are in concordance with the previous studies [18-20]. This would have been due to increase in lower limb strength as the AE were leg driven. Another reason would have been that the increased resistance as the patient pedalled helps in facilitation of hamstring muscles. Moreover, due to alternate activation of agonist and antagonist muscles at regular intervals during cycling may have resulted into improved coordination [21,22].

The finding of our study that increased duration of exercises helps improve walking endurance and speed is supported by study done by Globas et al [23]. In their study aerobic

training on treadmill was found to be beneficial in improving gait velocity and walking endurance which was due to increased speed of treadmill and increased duration of session. Therefore it could be concluded that gait would have improved due to repeated cycling with increased resistance and duration.

On comparison of all four exercise protocols it was evident that when both frequency and duration of exercises is increased there is improvement in balance among patients suffering from DM. Improvement in balance can be due to strengthening of lower limb muscles and improvement in proprioception. Further it was also found that joint position sense of the patients also improved with AE. The possible reason for this could be cycle ergometer with increased resistance may have improved lower limb strength because of optimising the neuromuscular control of knee joint. These results are related to the findings of the study done by Cuixiao Wang in 2016. In their study various exercise protocols were incorporated and it was found that both balance and proprioception improved in patients who were doing exercises [4]. Further the somatosensory inputs in physically active individuals are regulated more efficiently than in sedentary individuals and this may lead to better balance and proprioceptive control [24,25].

These results can be attributed to physically active individuals to have better postural control when compared to inactive individuals. Further it has been documented that balance ability of sportive and people who started sporting later in life were not found to be different, therefore early exercises should be prescribed along with medical treatment.

## Conclusions

This study revealed that the duration and frequency of aerobic exercises are important

parameters in controlling blood sugar level as well as diabetes associated complications which includes balance, gait and proprioception. Thirty minutes exercises using cycle ergometer for at least thrice a week can result in better proprioception, balance and improved

coordination of muscles as reflected in improved gait parameters.

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