CHAPTER 4

RESULTS

Subjects were recruited from the Out Patient Diabetes Clinic, King Chulalongkorn Memorial Hospital, which cares for more than 3000 adults with type 2 diabetes during March 2002 - October 2002. All subjects meeting selection criteria were asked by an investigator to participate in this study during a routine diabetes clinic visit. Most of them were using Human premixed insulin injection twice daily. All gave written, informed consent for inclusion in the study, which was approved by the Faculty of Medicine, Chulalongkorn University's Ethical Committee. Clinical data on entry into the study are shown in Table 17. A total of 80 subjects were recruited from the beginning. Four subjects were withdrawn because of HbA1c >10.5% and one subjects was withdrawn because of HbA1c <6.0%. Five subjects did not complete the study. Two subjects form the pre-prandial group and two subjects from the post-prandial group were withdrawn from the study because of non-compliance. One subject form the post-prandial group were withdrawn because of hospital admission for surgery from car accident. A total of 75 subjects completed the study. The age of the subjects ranged from 28 to 72 year-old with mean age of 55.5 years. Most of the subjects were female with the ratio of female : male approximately 2:1. The majority of subjects were non-obese with the mean body mass index of 23.6 and 24.5 kg/M2. The mean duration of having diabetes was 5.4 -5.6 years. The duration of insulin use was 4.5 years for both groups. There was no significant difference in body weight, BMI, duration of diabetes and duration of insulin therapy between both groups.

Table 17   Demographic data of the subjects

		Pre-prandial Monitoring	Post-prandial Monitoring
Number		38	37
Age	(Years)	56.5 ±11.2	54.5 ±11.3
Gender	Male:Female	12:26	13:24
Height	(M)	1.62 ± 0.14	1.64 ± 0.16
Weight	(kg)	64.4 ± 13.2	63.5 ± 11.8
Body mass index	(kg/M^2)	24.5± 4.2	23.6± 3.8
Duration of diabetes	(Years)	5.6 ± 2.4	5.4 ± 1.8
Duration of insulin treatment	(Years)	4.4 ± 1.9	4.5 ± 1.8
Daily dose of insulin	(units)	34.8 ± 14.6	35.6 ± 13.4

Data shown as Mean ± SD

The mean fasting plasma glucose was 134.5 mg/dl for pre-prandial group and 138.6 mg/dl for post-prandial group. The mean fructosamine level of both groups were 312.5 uM/L and 310.8 uM/L respectively. The HbA$_{1c}$ ranged from 6.6% to 9.9% with a mean level of 7.8% and 7.9% respectively. There was no significant difference in fasting plasma glucose, fructosamine and HbA1c levels between pre- and post-prandial monitoring group at the beginning of the study (Table 18).

Table 18   Baseline Laboratory Data

		Pre-prandial Monitoring	Post-prandial Monitoring
Fasting plasma glucose	(mg/dl)	134.5 ± 18.2	138.6 ± 17.2
Fructosamine	(uM/L)	322.5 ± 45.2	330.8 ± 40.8
HbA1c	(%)	8.2 ± 1.2	8.4 ± 1.1
Total cholesterol	(mg/dl)	228.3 ± 58.4	224.3 ± 51.9
Triglycerides	(mg/dl)	195.4 ± 66.1	188.4 ± 67.2
HDL-cholesterol	(mg/dl)	44.5 ± 11.0	45.1 ± 12.6
LDL-cholesterol	(mg/dl)	115.4 ± 31.0	112.4 ± 29.7

Data shown as mean $\pm$ SD

Table 19   Compliance of SMBG at 8th week

	Pre-prandial Monitoring (n=38) %	Post-prandial Monitoring (n=37) %
Before randomization	93.5 ± 2.8	92.6 ± 3.4
0 - 8 week period		
fasting	91.5 ± 4.5	91.2 ± 4.5
breakfast		90.5 ± 4.5
lunch	92.5 ± 4.5	89.5 ± 4.5
dinner	90.5 ± 4.5	91.5 ± 4.5
bedtime	89.5 ± 4.5	88.5 ± 4.5

Data shown as mean ± SD

A review of the patients' records of home blood glucose monitoring during the eight weeks period of monitoring (average of 112 glucose samplings) revealed similar degrees of compliance at different time points (>90 percent) . Comparing the data from patient's records and the glucometer's memory showed a good consistency of the results.
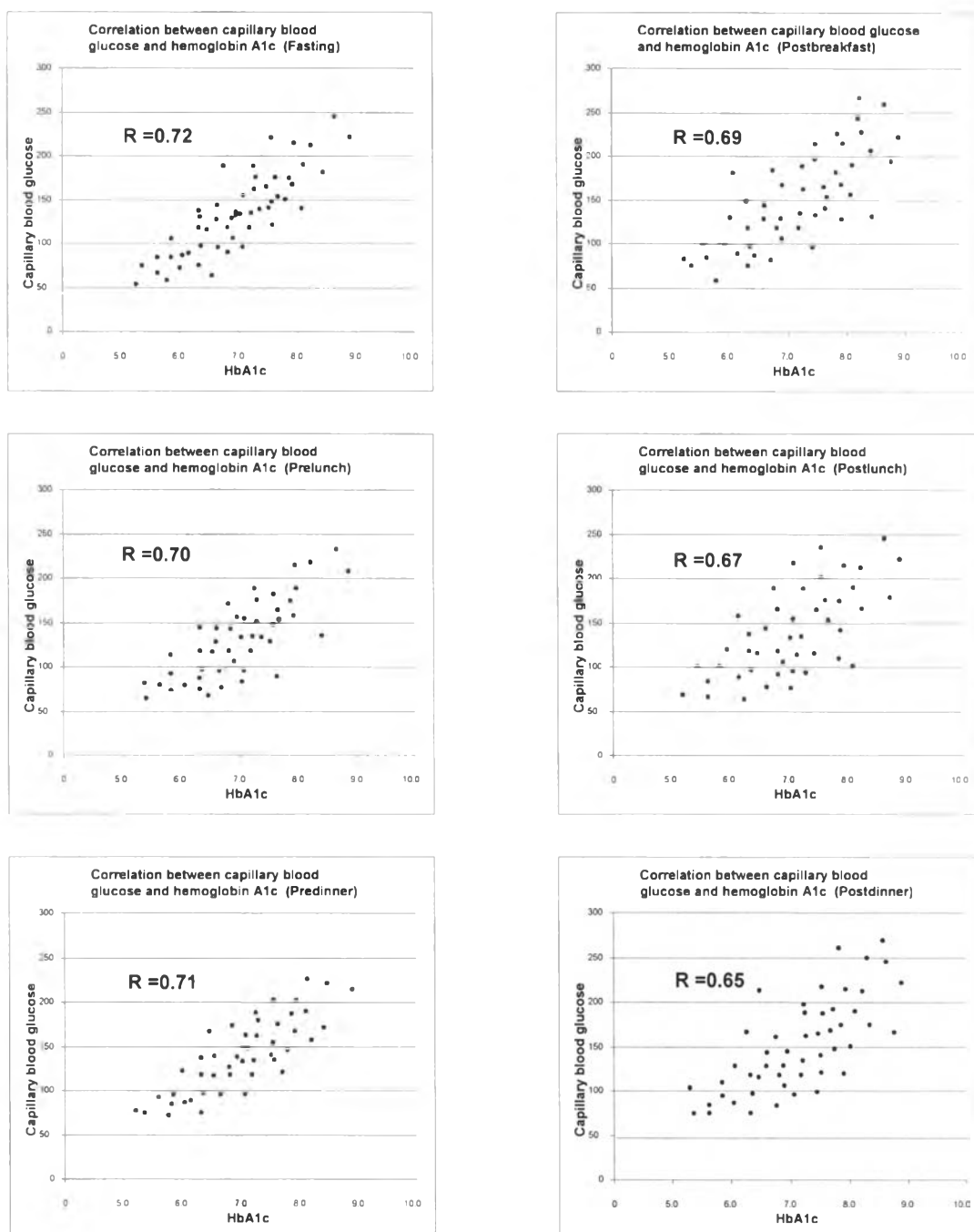
Figure 9 Correlation between capillary blood glucose and HbA1c at 8th week

Figure 10 Correlation between combination of combination of fasting and pre-meal or post-meal capillary blood glucose and HbA1c at 8th week
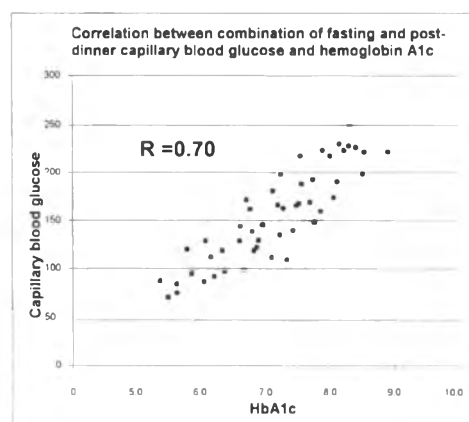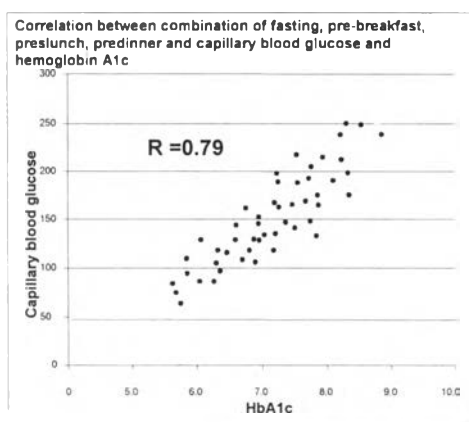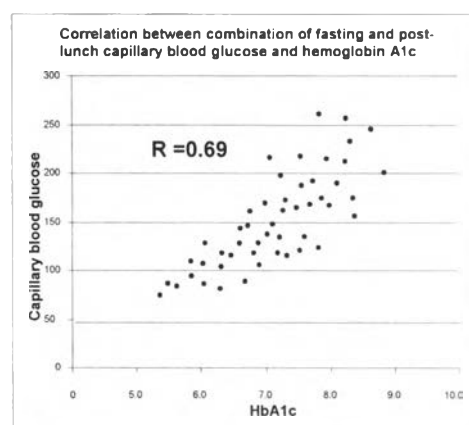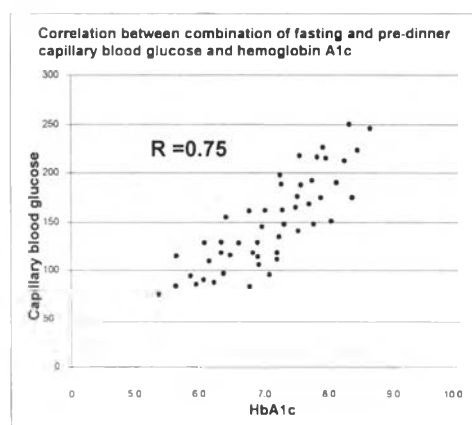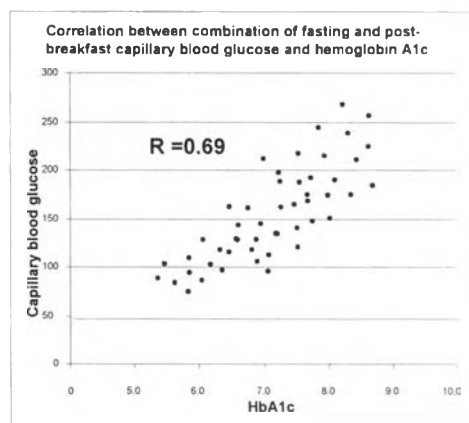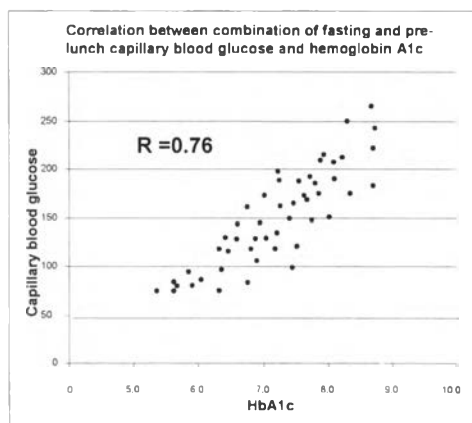
Table 20 Glycemic control at the end of 8th week

		Pre-prandial Monitoring (n=38)	Post-prandial Monitoring (n=37)
Fasting plasma glucose	(mg/dl)	114.5 ± 18.5	118.6 ± 17.4
Pre-prandial plasma glucose	(mg/dl)	130.5 ± 22.2	-
Post-prandial plasma glucose	(mg/dl)	-	168.6 ± 40.2
Bedtime plasma glucose	(mg/dl)	134.5 ± 18.5	138.6 ± 23.7
Fructosamine	(uM/L)	302.5 ± 55.2	310.8 ± 50.8
Reduction from baseline*	(uM/L)	20.5 ± 10.0*	20.1 ± 10.8*
HbA1c	(%)	7.7 ±1.3	7.8 ±1.5
Reduction of HbA1c from baseline*	(%)	0.48 ±0.08*	0.51 ±0.08*
Number of hypoglycemic episodes	(/week)	1.9 ±1.1	1.4 ±1.1
Number of hyperglycemic episodes	(/week)	4.9 ±1.5	7.6 ±1.8

Data shown as mean ± SD

The mean fasting plasma glucose of both group were significantly reduced from baseline as well as the mean pre- and post-prandial plasma glucose level in both groups. The mean fructosamine levels of both groups were reduced significantly with mean reduction of ~20 uM/L in both groups. The mean HbA_{1c} levels were reduced significantly by approximately 0.5% in both groups. There was no significant difference in fasting plasma glucose, fructosamine and HbA1c levels between pre- and post-prandial monitoring group at the 8th week of the study.

Table 21   Clinical profiles and biochemical profiles at the end of pre/post-prandial monitoring (8th week)

		Pre-prandial Monitoring	Post-prandial Monitoring
Changed in body weight	(kg)	1.3 ± 0.3	1.6 ± 0.4
	(%)	+2.0%	+2.5%
insulin dosage	(units/d)	36.8 ± 10.2	43.6 ± 10.4
changes in insulin	(units/d)	$+ 2.0 \pm 0.1$	$+8.0 \pm 0.4$
Total cholesterol		218.1 ± 55.4	212.7 ± 48.9
changes from baseline	(%)	-4.5	-5.2
Triglycerides		178.2 ± 64.0	176.5 ± 54.2
changes from baseline	(%)	-8.8	-6.3
HDL-cholesterol		46.8 ± 11.3	47.6 ± 11.4
changes from baseline	(%)	+5.2	+5.5
LDL-cholesterol		110.4 ± 30.4	111.4 ± 24.6
changes from baseline	(%)	-4.3	-1.2

Data shown as mean $\pm$ SD

Table 22   Compliance of SMBG at 16th week

	Pre-prandial Monitoring (n=38) %	Post-prandial Monitoring (n=37) %	All (n=75) %
8 - 16 week period			
fasting	91.5 ± 4.0	92.2 ± 4.5	91.8 ± 3.9
breakfast	-	89.5 ± 5.9	89.5 ± 5.9
lunch	91.0 ± 4.9	87.5 ± 4.5	89.2 ± 4.2
dinner	90.5 ± 5.2	91.5 ± 4.1	91.0 ± 4.0
bedtime	88.5 ± 4.0	87.5 ± 5.5	87.8 ± 4.0

Data shown as mean $\pm$ SD

A review of the patients' records of home blood glucose monitoring during the 8-16-week period of monitoring (average of 84.5 glucose samplings/patient) revealed a lower degree of compliance (<90 percents) compared to the first 8-week period.

Table 23 Glycemic control at 16th week

		Pre-prandial Monitoring	Post-prandial Monitoring	All
Fasting plasma glucose	(mg/dl)	113.8 ± 20.3	116.6 ± 18.4	114.4 ± 18.1
Pre-prandial plasma glucose	(mg/dl)	123.8 ± 21.2	128.6 ± 19.9	126.1 ± 17.4
Post-prandial plasma glucose	(mg/dl)	163.8 ± 40.3	157.6 ± 38.4	160.6 ± 34.4
Bedtime plasma glucose	(mg/dl)	136.8 ± 20.2	143.6 ± 20.4	139.8 ± 19.1
Fructosamine	(mM/L)	299.5 ± 45.2	298.8 ± 40.8	298.4 ± 38.8
HbA1c	(%)	7.6 ±1.4	7.5 ±1.5	7.5 ±1.3
Number of hypoglycemic episodes	(/wk)	1.8 ±1.1	1.5 ±1.1	1.7 ± 0.9
Number of hyperglycemic episodes	(/wk)	4.4 ±1.4	6.5 ±1.7	5.5 ±1.4

Data shown as mean ± SD

Table 24   Clinical profiles and biochemical profiles at 16th week

		Pre-prandial Monitoring	Post-prandial Monitoring	All
Changed in body weight	(kg)	0.8 ± 0.3	1.0 ± 0.4	0.9 ± 0.4
	(%)	+1.8%	+2.0%	+1.9%
Insulin dosage	(units/d)	36.8 ± 10.2	43.6 ± 10.4	40.2 ± 8.4
Changes in insulin	(units/d)	+ 3.4 ± 0.3	+4.0 ± 0.4	+3.7 ± 0.4
Total cholesterol	(mg/dl)	212.1 ± 48.4	210.1 ± 44.9	211.7 ± 38.2
Triglycerides	(mg/dl)	170.2 ± 54.0	168.5 ± 50.2	169.5 ± 48.2
HDL-cholesterol	(mg/dl)	47.5 ± 11.3	47.9 ± 11.4	47.7 ± 10.0
LDL-cholesterol	(mg/dl)	111.4 ± 31.4	112.4 ± 34.6	111.6 ± 25.6

Data shown as mean ± SD

Table 25   Comparison of 7 points plasma glucose profiles at 8th and 16th week between pre- and post-prandial group

	Pre-prandial Monitoring (n=7)	Pre-prandial Monitoring (n=7)	All (n=14)
0-8th week period			
fasting	98.5 ± 11.0	101.5 ± 14.2	99.8 ± 10.2
postbreakfast	180.5 ± 25.2	188.5 ± 24.0	184.1 ± 20.8
prelunch	148.5 ± 24.0	155.0 ± 24.9	152.1 ± 21.3
postlunch	180.5 ± 25.2	178.5 ± 25.2	179.5 ± 23.1
predinner	148.5 ± 24.0	137.5 ± 24.0	142.8 ± 21.5
postdinner	170.5 ± 25.2	180.5 ± 25.2	175.4 ± 21.8
bedtime	138.5 ± 24.0	133.5 ± 24.0	136.1 ± 21.9
8-16th week period			
fasting	92.5 ± 15.1	100.5 ± 18.2	95.4 ± 14.1
postbreakfast	177.5 ± 25.0	168.5 ± 24.0	173.3 ± 21.2
prelunch	128.8 ± 24.1	131.0 ± 23.9	130.0 ± 21.6
postlunch	166.5 ± 22.0	170.4 ± 25.2	168.5 ± 21.1
predinner	158.5 ± 24.0	154.5 ± 27.0	156.5 ± 22.4
postdinner	192.5 ± 29.2	188.5 ± 31.2	190.4 ± 30.0
bedtime	116.8 ± 22.5	119.5 ± 24.1	117.8 ± 21.1

Data shown as mean ± SD

Table 26   Mean number of blood glucose testing at 16th weeks

		Pre-prandial Monitoring (n=38)	Post-prandial Monitoring (n=37)	Both
Mean number of blood glucose testing/week		16.6 ± 3.8	17.5 ± 3.5	16.5 ± 3.4
Distribution of number of testing				
<5	times/week	4	3	7
5-10	times/week	11	10	21
10-20	times/week	14	15	29
20-30	times/week	6	7	13
30-40	times/week	2	2	4
>40	times/week	2	0	2
Time of testing	(% total)			
Fasting/prebreakfast		42.3	40.5	41.4
Postbreakfast		9.4	10.4	9.9
Prelunch		5.8	5.4	5.6
Postlunch		6.2	5.2	5.7
Predinner		10.2	10.5	10.3
Postdinner		11.0	12.6	11.8
Bedtime		12.7	13.2	12.9
Others		2.4	2.2	2.3
Mean changes in insulin dosage	(% from baseline)	+ 6.8	+ 8.8	+7.8

Data shown as mean ± SD

Table 27   Frequency of SMBG according to patient characteristics (n =75) and clinical outcomes

		Frequency of blood glucose testing			
		< 5/week	5-15 /week	15-25/week	>25/week
n		7	36	21	11
Age	(years)	58.5 ± 15.5	56.8 ± 11.2	55.5 ± 10.5	53.5 ± 12.3
Fructosamine	(mM/L)	333.5 ± 58.5	326.8 ± 41.7	325.5 ± 40.2	312.5 ± 42.1
HbA1c	(%)	7.8±1.6	7.7±1.1	7.6±1.1	7.4±1.4
Frequency of hypoglycemia	(/wk)	1.2±0.9	1.5±0.8	1.6±0.8	1.9±0.8
Frequency of hyperglycemia	(/wk)	3.2±1.9	3.6±1.8	4.6±2.8	6.9±2.8

Data shown as mean ± SD

Table 28   Cost of self-monitoring**

Cost associated	Cost (Baht)		
	Portable blood glucose meter	Test strips per box of 25 tests	per single test
Precision (Medisense)	4,200.00	619.00	24.76
Medisafe (Terumo)	4,300.00	495.00	19.80
One touch (Johnson&Johnson)	4,800.00	830.00	33.20
Surestep (Lifescan)	4,900.00	396.00	15.84
Advantage (Roche)	4,350.00	560.00	22.40
Average	4,510		23.20

Cost per one-year (meter+strips) for the first year (Baht)* from average cost

Frequency of testing

Once daily (7 tests/week)	$4,510 + (7 \times 22.68 \times 52)$	=	12,765.52
Twice daily (14 tests/week)	$4,510 + (14 \times 22.68 \times 52)$	=	21,021.04
Four times daily (28 tests/week)	$4,510 + (28 \times 22.68 \times 52)$	=	37,532.08

*Cause of accessories (eg. alcohol, cotton, lancet, etc.) is not included

**Data from Chulalongkorn Hospital Pharmacy, Feb 2003