

Utilizing Insulin Pump Therapy in Challenging Populations

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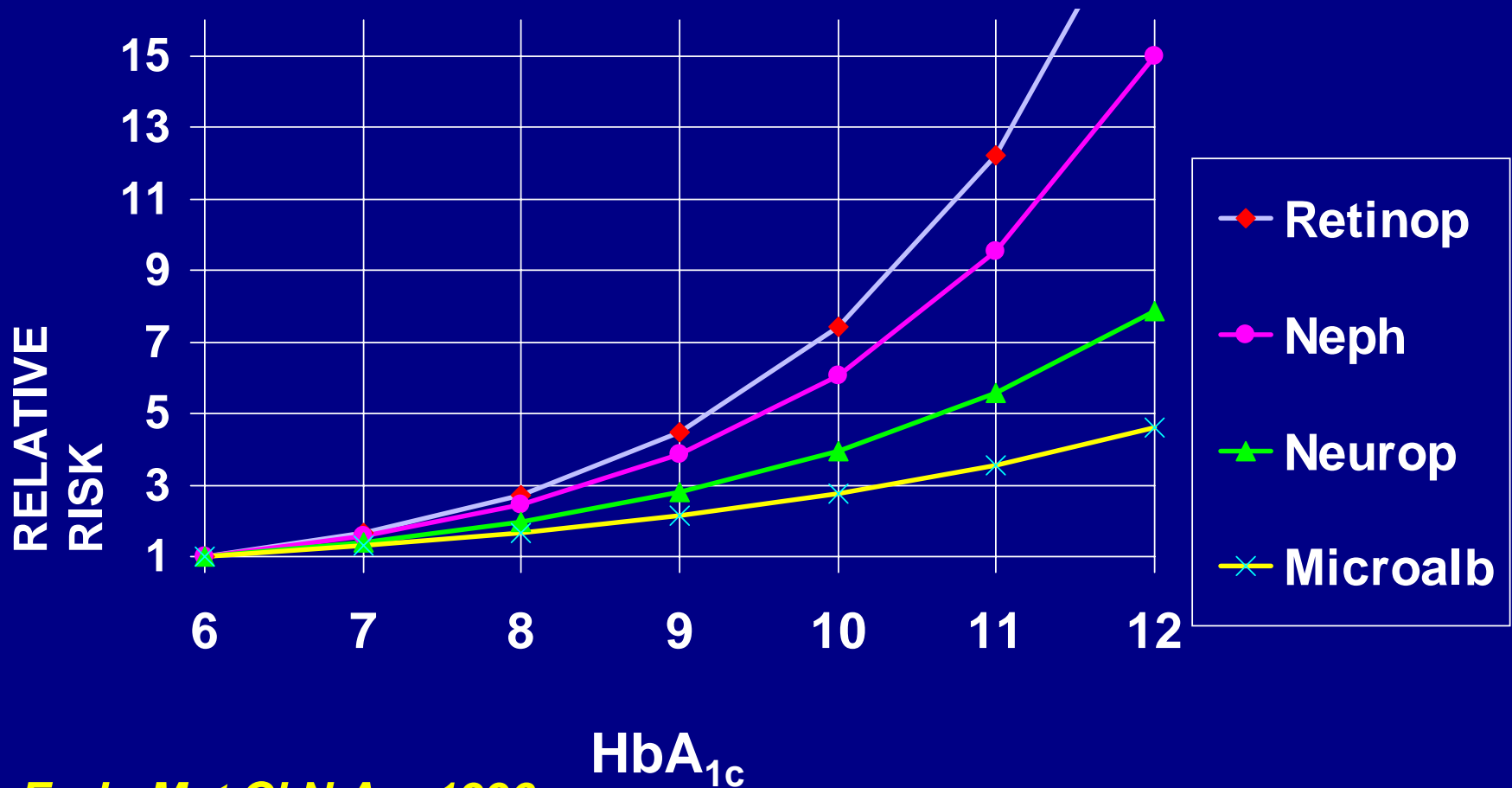
Atlanta, Georgia

ACE / AACE Targets for Glycemic Control

A1C (HbA_{1c})	< 6.5 %
Fasting/preprandial glucose	< 110 mg/dL
Postprandial glucose	< 140 mg/dL

Relative Risk of Progression of Diabetic Complications by Mean A1C

Based on DCCT Data



HbA1c and Plasma Glucose

- 26,056 data points (A1c and 7-point glucose profiles) from the DCCT
- Mean plasma glucose = $(A1c \times 35.6) - 77.3$
- Post-lunch, pre-dinner, post-dinner, and bedtime correlated better with A1c than fasting, post-breakfast, or pre-lunch

Insulin

**The most powerful agent we
have
to control glucose**

The Miracle of Insulin

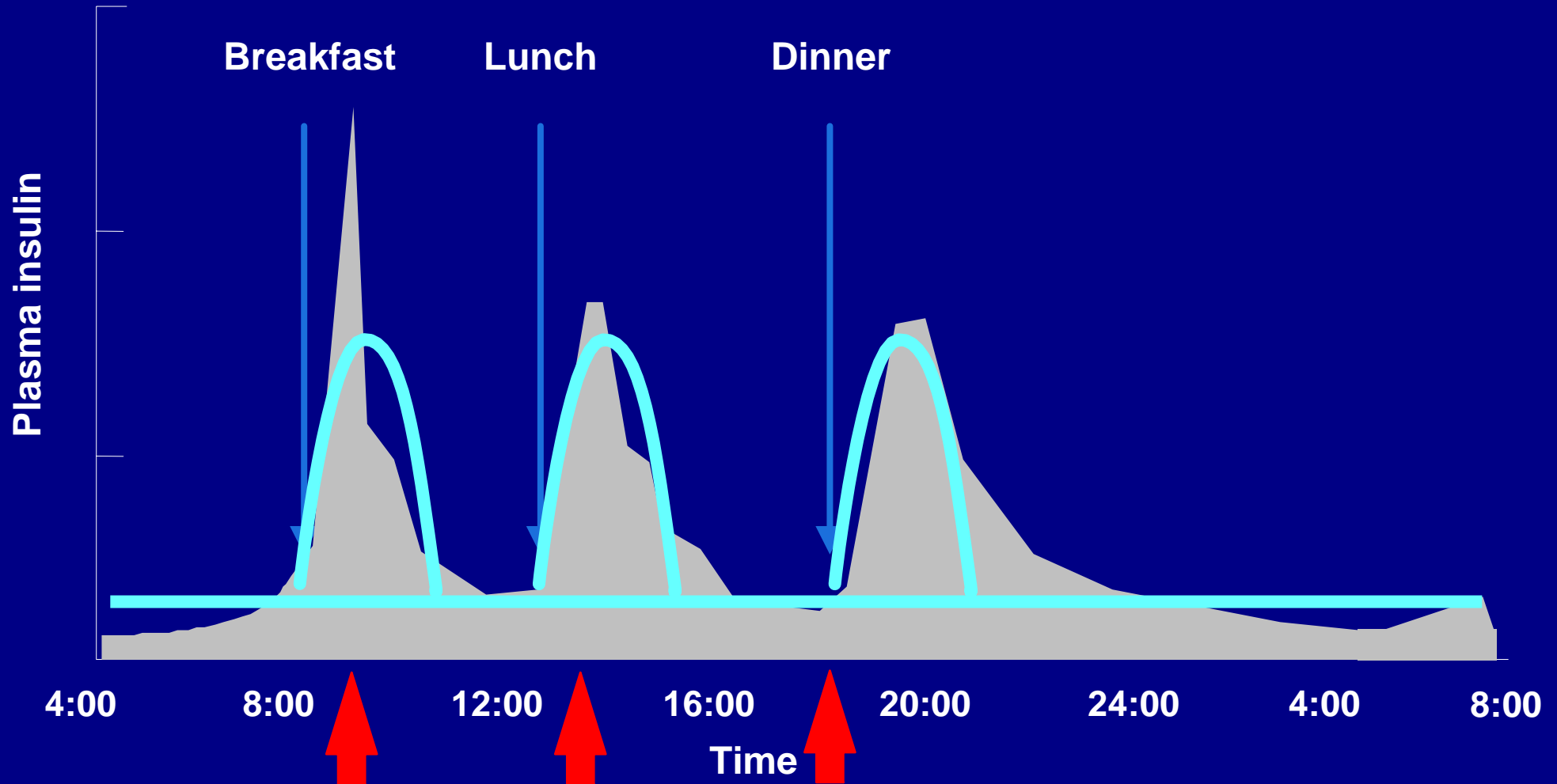


Patient J.L., December 15, 1922

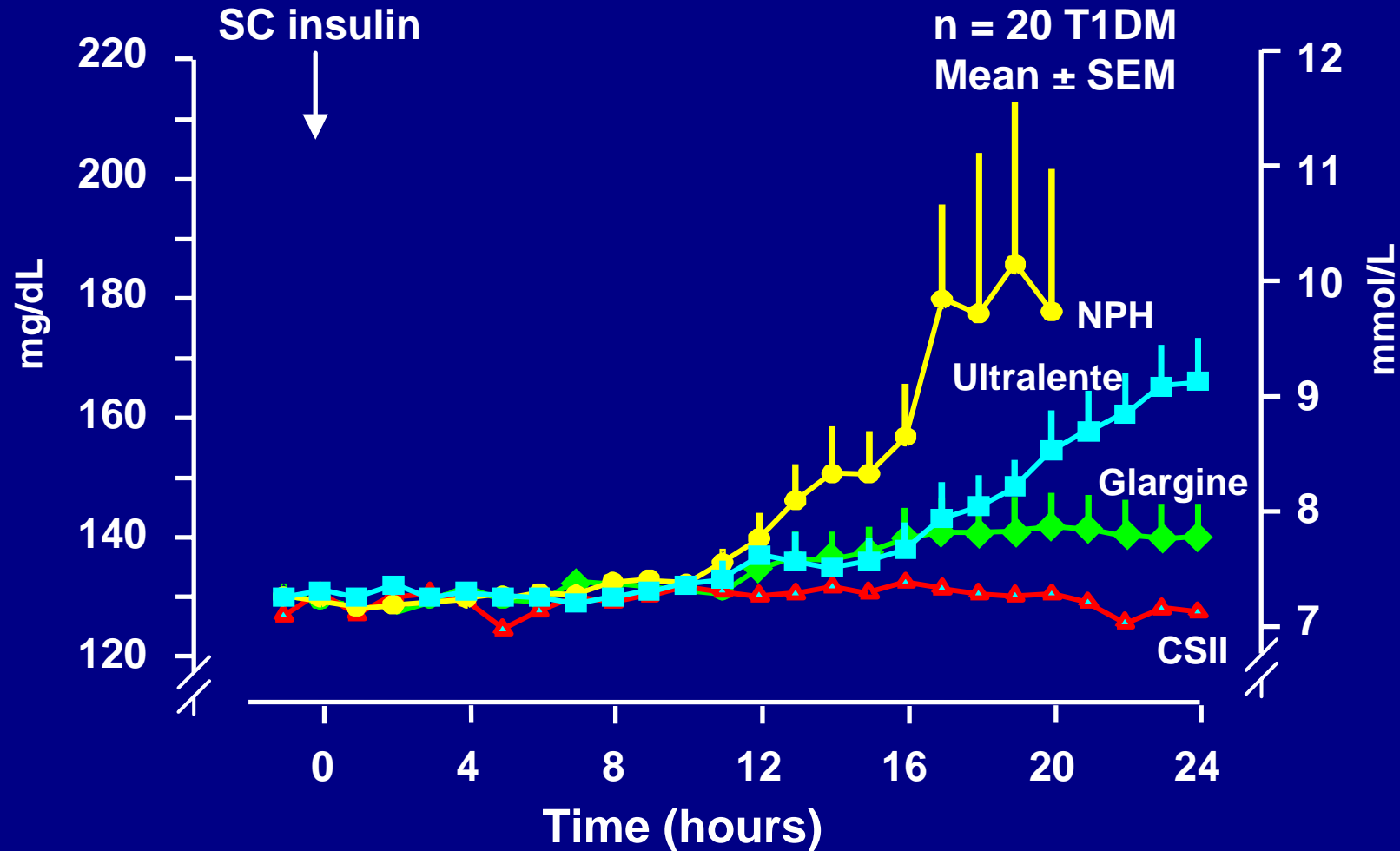


February 15, 1923

Ideal Basal/Bolus Insulin Absorption Pattern



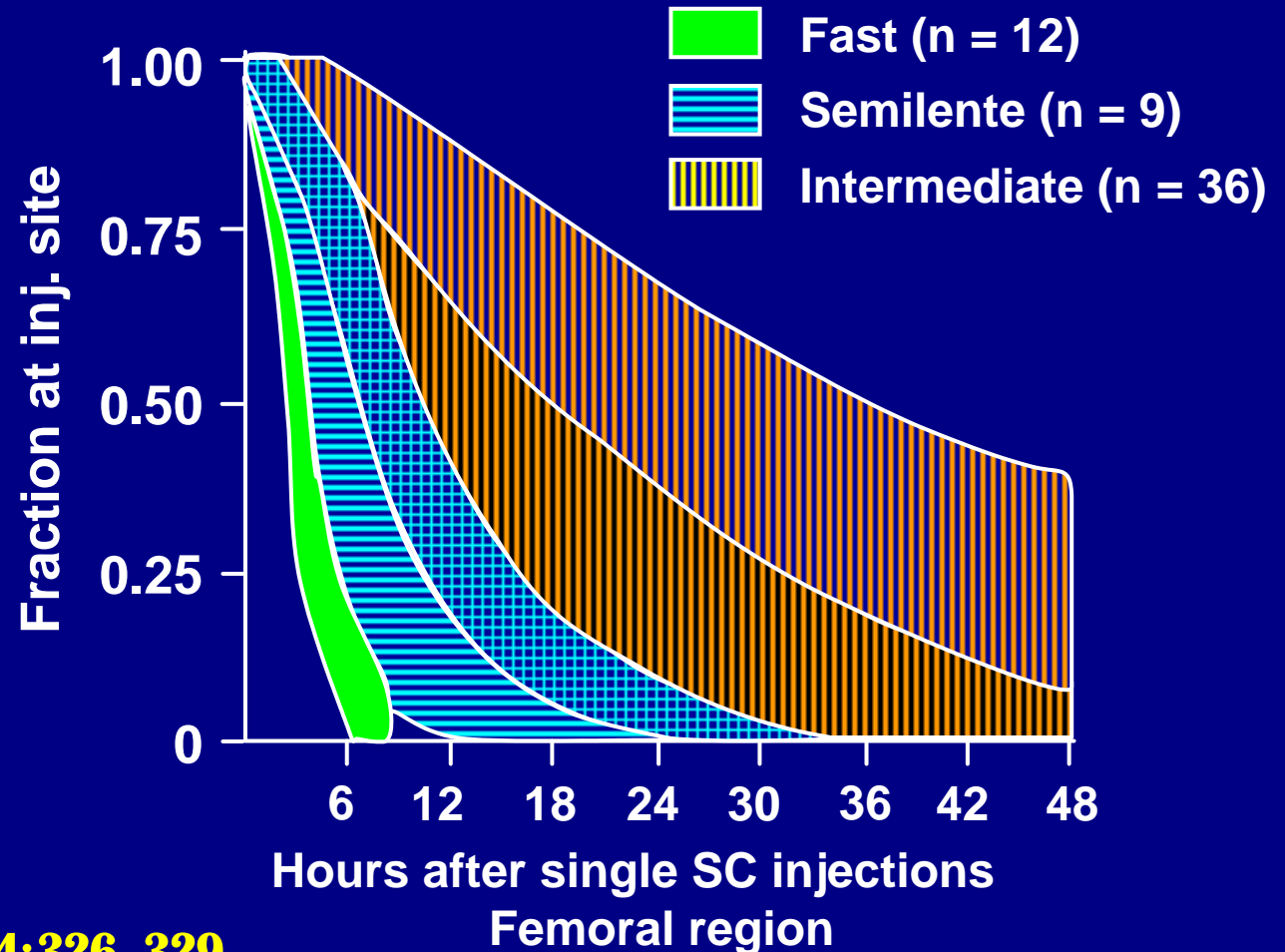
Plasma Glucose



Variability of Insulin Absorption

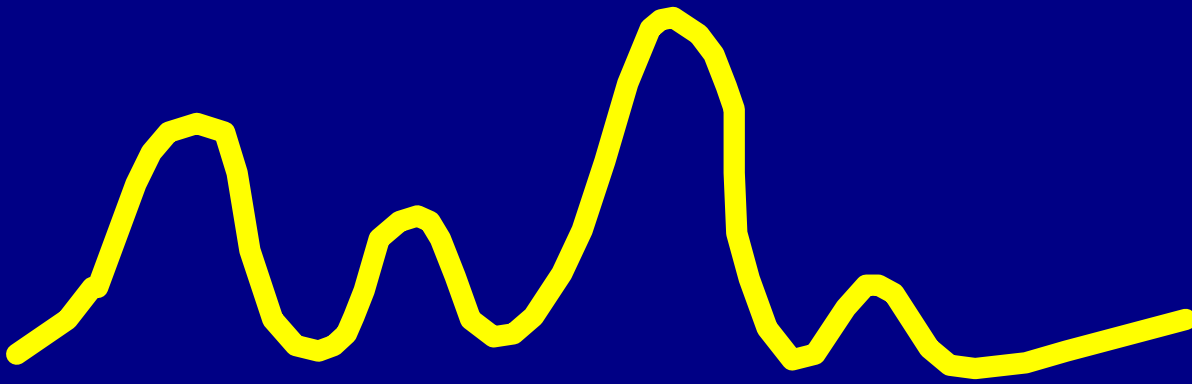
CSII <2.8%

Subcutaneous
Injectable
10% to 52%



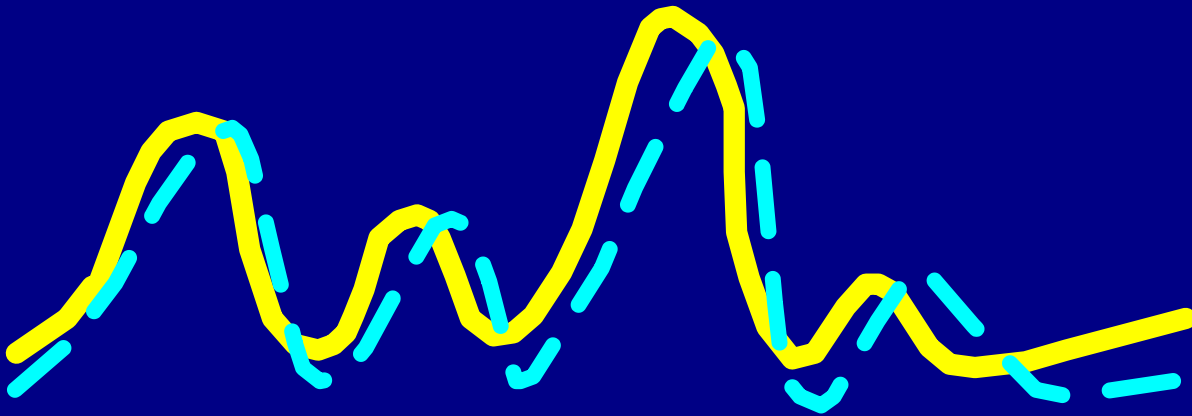
Pump Therapy

Basal & Bolus Short-Acting Insulin



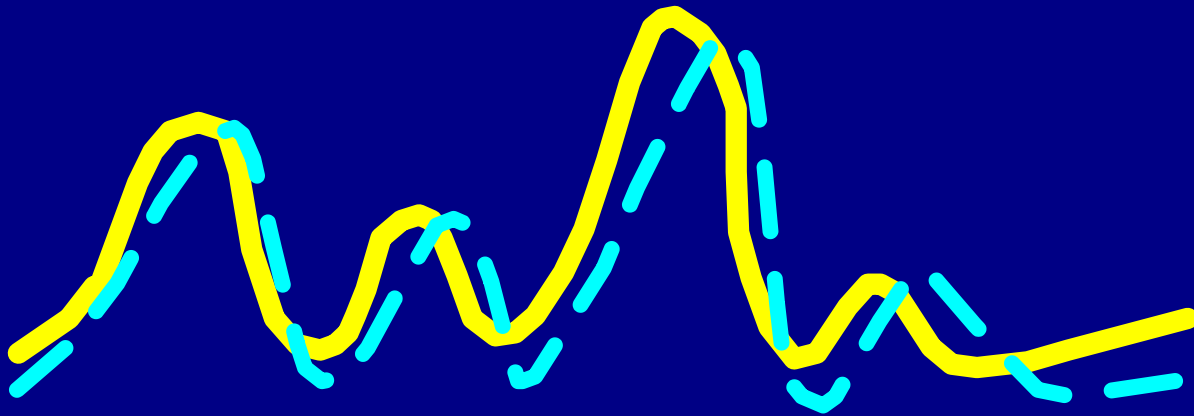
Pump Therapy

Basal & Bolus Short-Acting Insulin



Pump Therapy

Basal & Bolus Short-Acting Insulin

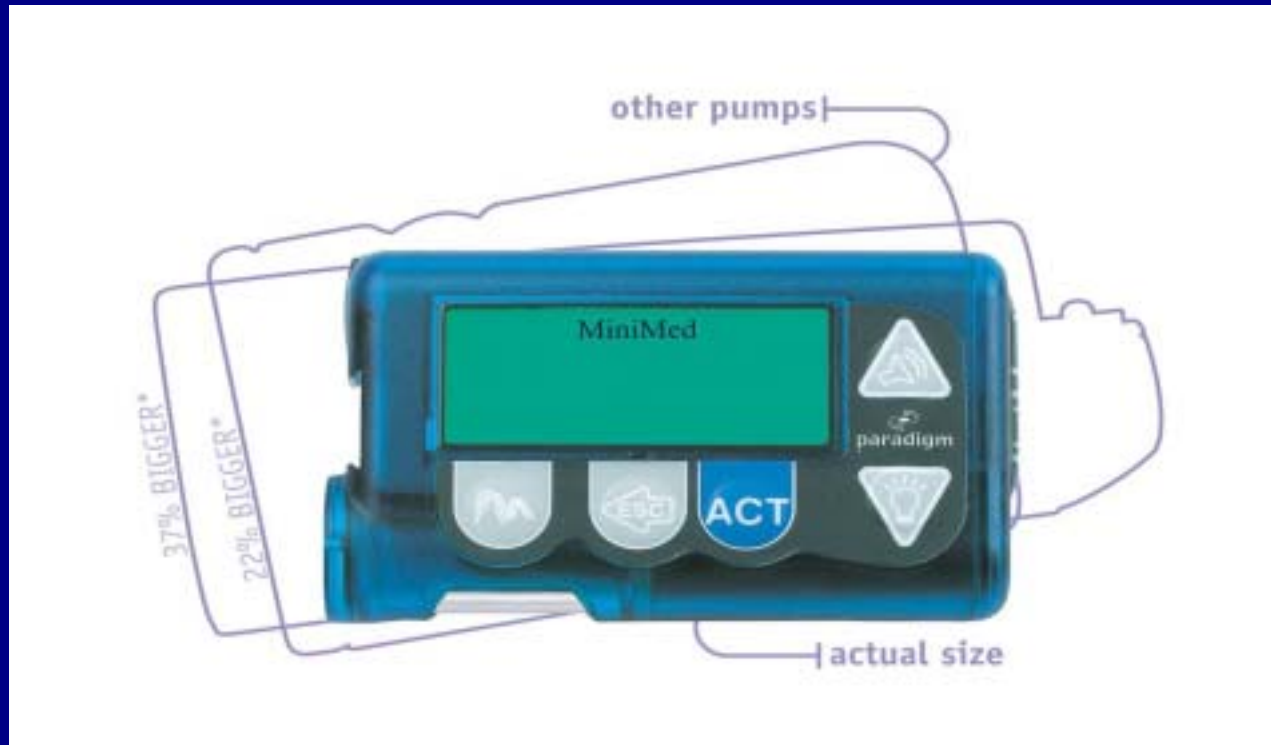


- Combined with SMBG, physiologic insulin requirements can be achieved more closely
- Flexibility in lifestyle

History of Pumps



PARADIGM PUMP



Paradigm.
Simple. Easy.

Paradigm Pump: Advantages

- 29% smaller, water resistant
- Menu driven:
bolus, suspend, basal, prime, utilities
- Reservoir based (easier to fill)
- Silent motor
- AAA batteries

Paradigm Pump: Advantages

- Various bolus options

normal, square, dual, and “easy bolus”

- Enhanced memory

- Enhanced safety features

(low reservoir alarm, auto off, etc.)

Pump Infusion Sets



Softset QR



Silhouette

Pharmacokinetic Advantages

CSII vs MDI

- Uses only regular or very rapid insulin
 - More predictable absorption than modified insulins (variation 3% vs 25 to 52%)
- Uses 1 injection site
 - Reduces variations in absorption due to site rotation
- Eliminates most of the subcutaneous insulin depot
- Programmable delivery simulates normal pancreatic function

Metabolic Advantages with CSII

- Improved glycemic **control**
- Better pharmacokinetic **delivery** of insulin
 - Less hypoglycemia
 - Less insulin required
- Improved **quality** of life

Case 1: DM 1 not at goal A1C

- 35 year old female physician presents with Type 1 Diabetes since age 7
- Control suboptimal (A1C 8.7%) on MDI with Regular AC and NPH HS.
- SMBG 5/day with CHO counting
- Complications: mild retinopathy and neuropathy, and hypoglycemia induced migraines

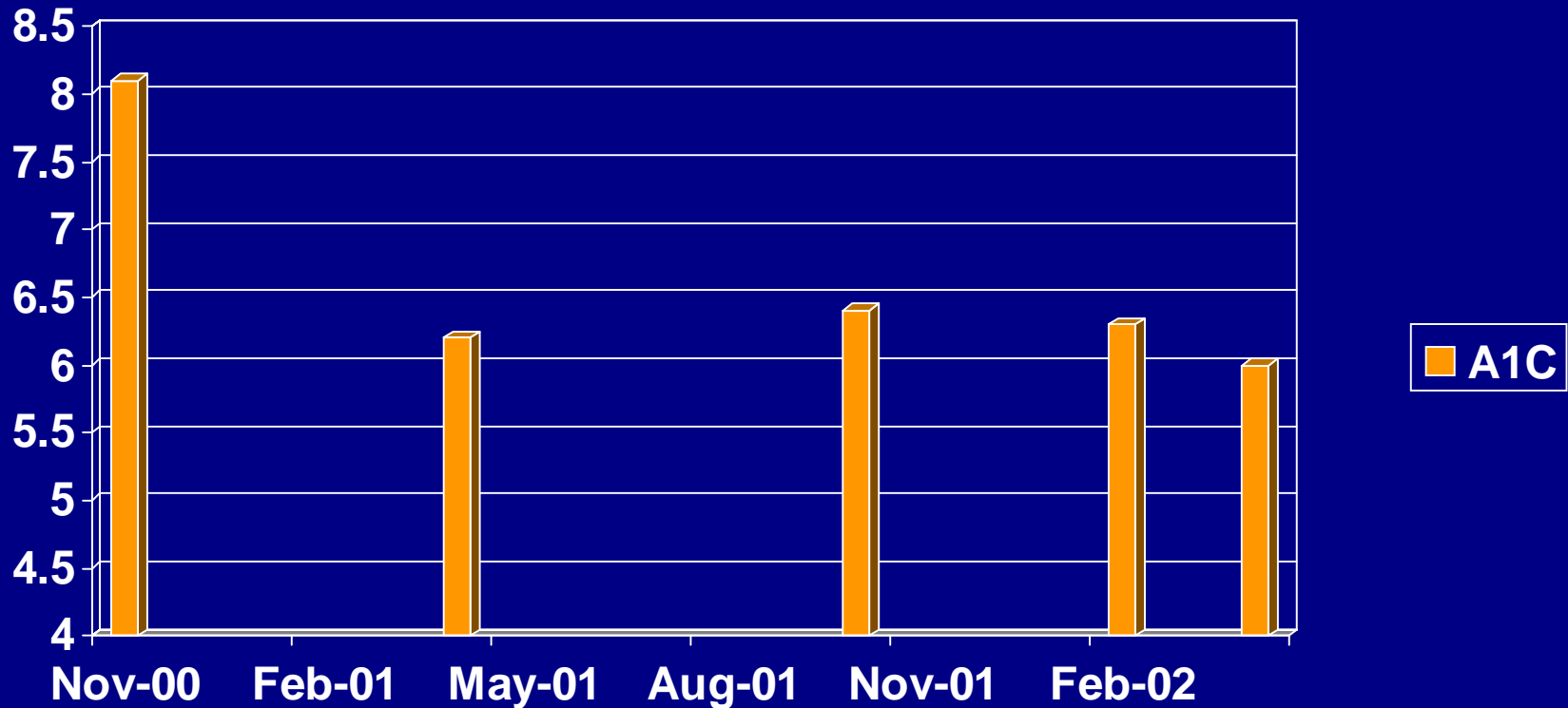
Case 1: DM 1 not at goal A1C

- Recommend CSII but refuses; Does not want to be attached to something
- Ask her to record, monitor 6 to 7 times per day, fax readings, and try lispro
- She complies with minimal change in A1C falling to 8.4% at 3 months and 7.7% at 6 months
- Still refuses CSII
- Recommend a sensor (CGMS)

Case 1: DM 1 not at goal A1C

- CGMS confirms a dawn rise
- Try giving NPH later but no help; Try lente and ultralente but no help; Glargine only available in Germany
- Patient gets married and desires children
- Attempt to get Glargine from Germany but my contacts say no one uses glargine in pregnancy. Put her on a pump

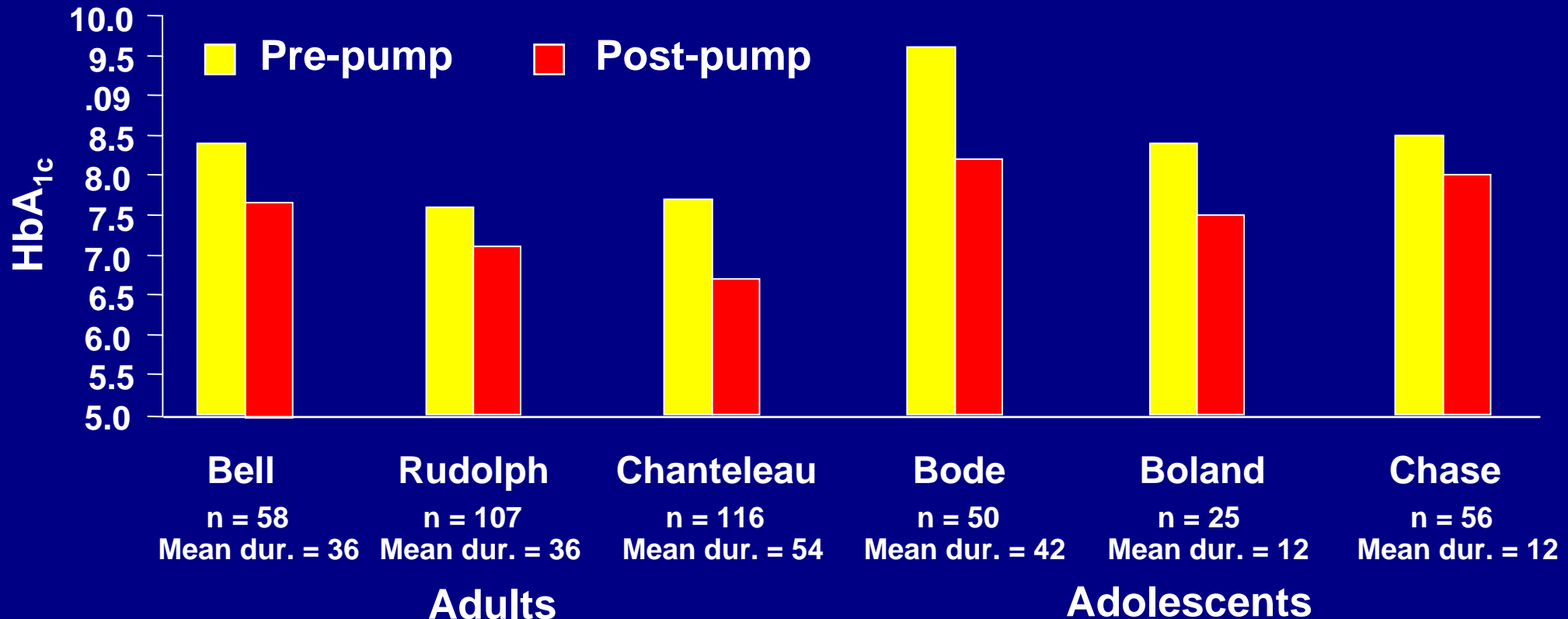
Case 1: DM 1 Agrees to CSII



Case 1: DM 1 Agrees to CSII

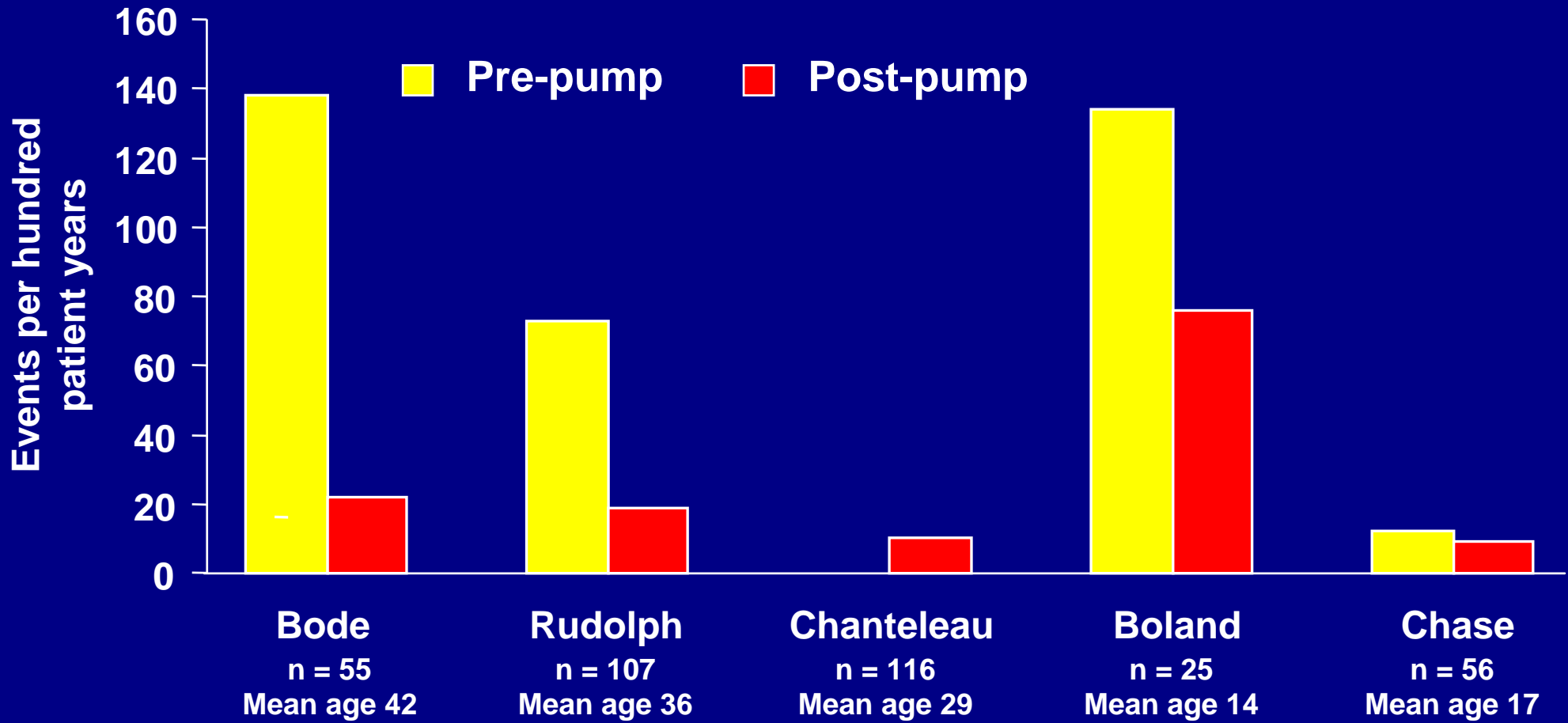
- Patient loves the pump
- No more migraines from hypoglycemia
- Patient now 13 weeks pregnant with A1C at 5.7%

CSII Reduces HbA_{1c}



Chantelau E, et al. *Diabetologia*. 1989;32:421–426; Bode BW, et al. *Diabetes Care*. 1996;19:324–327;
Boland EA, et al. *Diabetes Care*. 1999;22:1779–1784; Bell DSH, et al. *Endocrine Practice*. 2000;6:357–360;
Chase HP, et al. *Pediatrics*. 2001;107:351–356.

CSII Reduces Hypoglycemia



Chanteleau E, et al. *Diabetologia*. 1989;32:421–426; Bode BW, et al. *Diabetes Care*. 1996;19:324–327; Boland EA, et al. *Diabetes Care*. 1999;22:1779–1784; Chase HP, et al. *Pediatrics*. 2001;107:351–356.

CSII

Factors Affecting HbA_{1c}

- Monitoring
 - HbA_{1c} = 8.3 - (0.21 x BG per day)
- Recording 7.4 vs 7.8
- Diet practiced
 - CHO: 7.2
 - Fixed: 7.5
 - Other: 8.0

Case 2: New Onset Diabetes

- 45 year old male lawyer presents with polys and weight loss
- Sees internist who recommends metformin (blood glucose 500, urine ketones small, BMI 26)
- The lawyer does some internet reading and seeks a second opinion from diabetes specialist who was a high school classmate he has not seen for 27 years

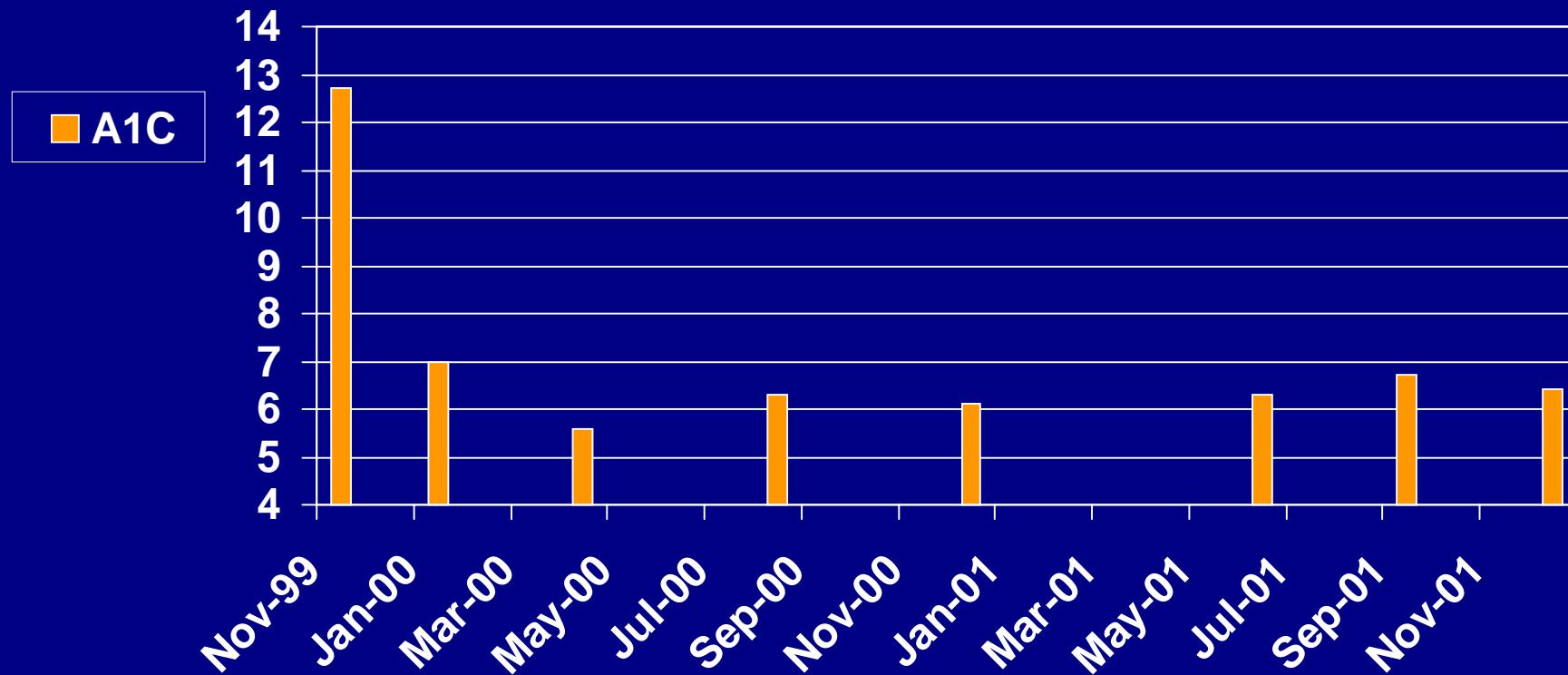
Case 2: New Onset Diabetes

- Sees myself the following am (BG 514, urine ketones small)
- I concur with him he has Type 1 Diabetes and metformin is not the treatment, insulin is.
- He asks about insulin pump therapy instead of multiple injections.
- I hospitalized him and told him I would get back to him the following am.

Case 2: New Onset Diabetes

- I see him in the am and tell him that 8 out of 10 CSII patients polled yesterday would have started CSII at onset if offered the choice.
- Dr. Pozzilli, an expert in DM 1 prevention, also recommended CSII at onset if it was him or a close relative
- Patient opted for CSII

Case 2: New Onset Diabetes on CSII: A1C Results



Case 2: New Onset Diabetes on CSII

- **Patient extremely satisfied with his care**
- **C-peptide 0.9 to 0.8 at 1 year**
- **Does not understand why everyone is not on CSII with optimal control**

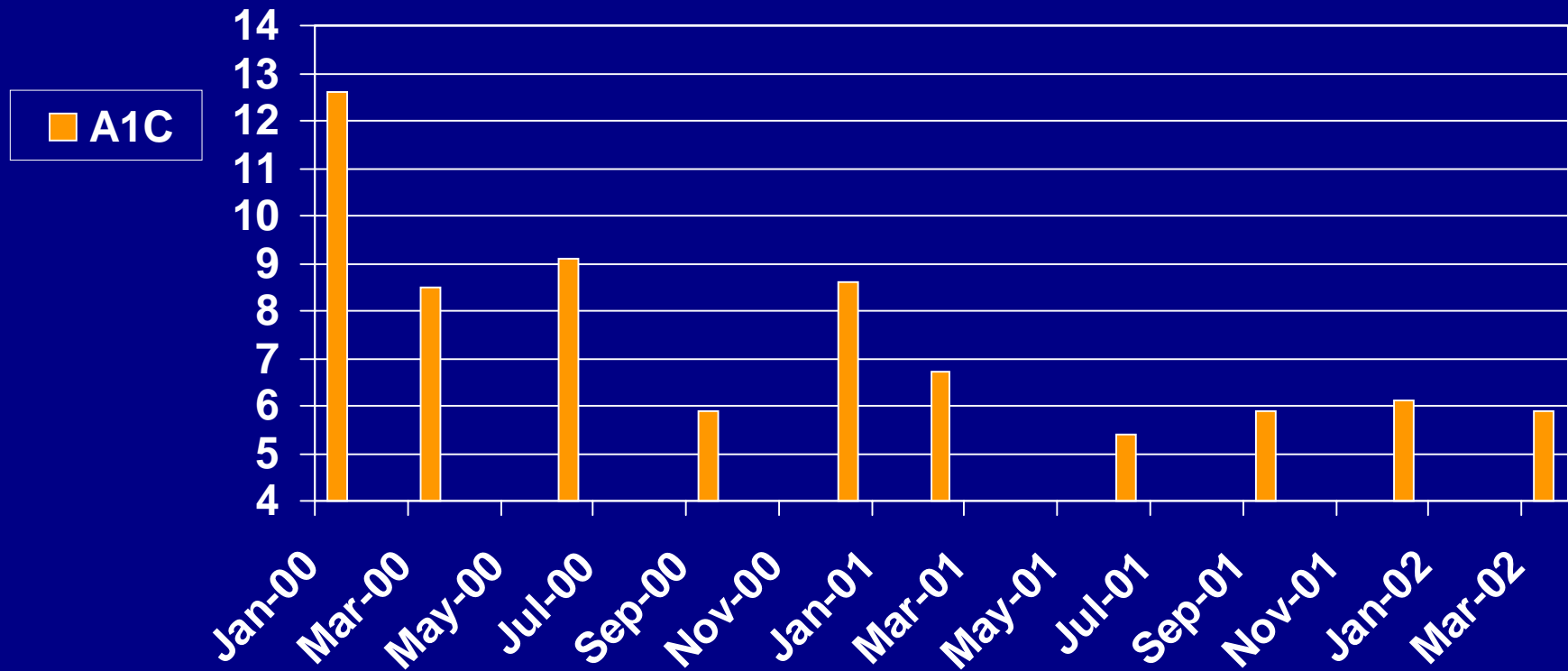
Case 3: DM 2 Poorly Controlled

- 58 year old female presented with a 12 year history of poorly controlled, insulin treated diabetes
- Ht 66", Wt 174#, BMI 28, C-peptide 2.1
- A1C 10.4% on 165 units per day (70/30 BID)
- Added troglitazone, metformin, glimepiride to MDI insulin
- A1C range 7.7 to 12.6% over 3 years

Case 3: DM 2 Poorly Controlled

- Admitted twice for IV insulin and fasting with short lived success (A1C to 7.6% but back up to 12.6%)
- Tried weight watchers and appetite suppressants; no help
- Decided to try CSII

Case 3: DM 2 on CSII, A1C Results

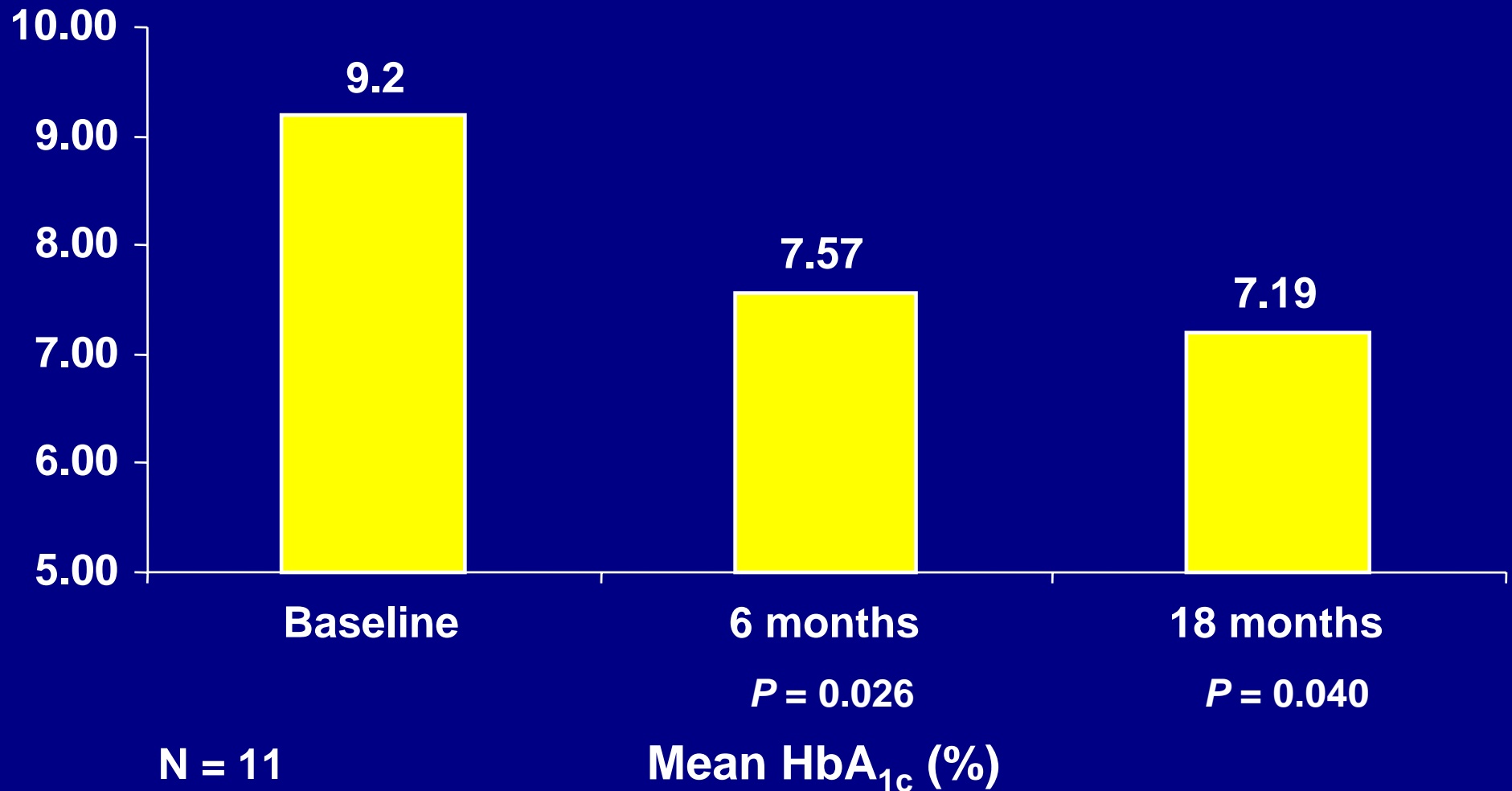


Case 3: DM 2 Poorly Controlled

- Patient loves the pump
- On 110 units per day consuming 2 meals only per day (1.4 units per kg or 0.6 units per lbs)
- Also on rosiglitazone 4 mg/day

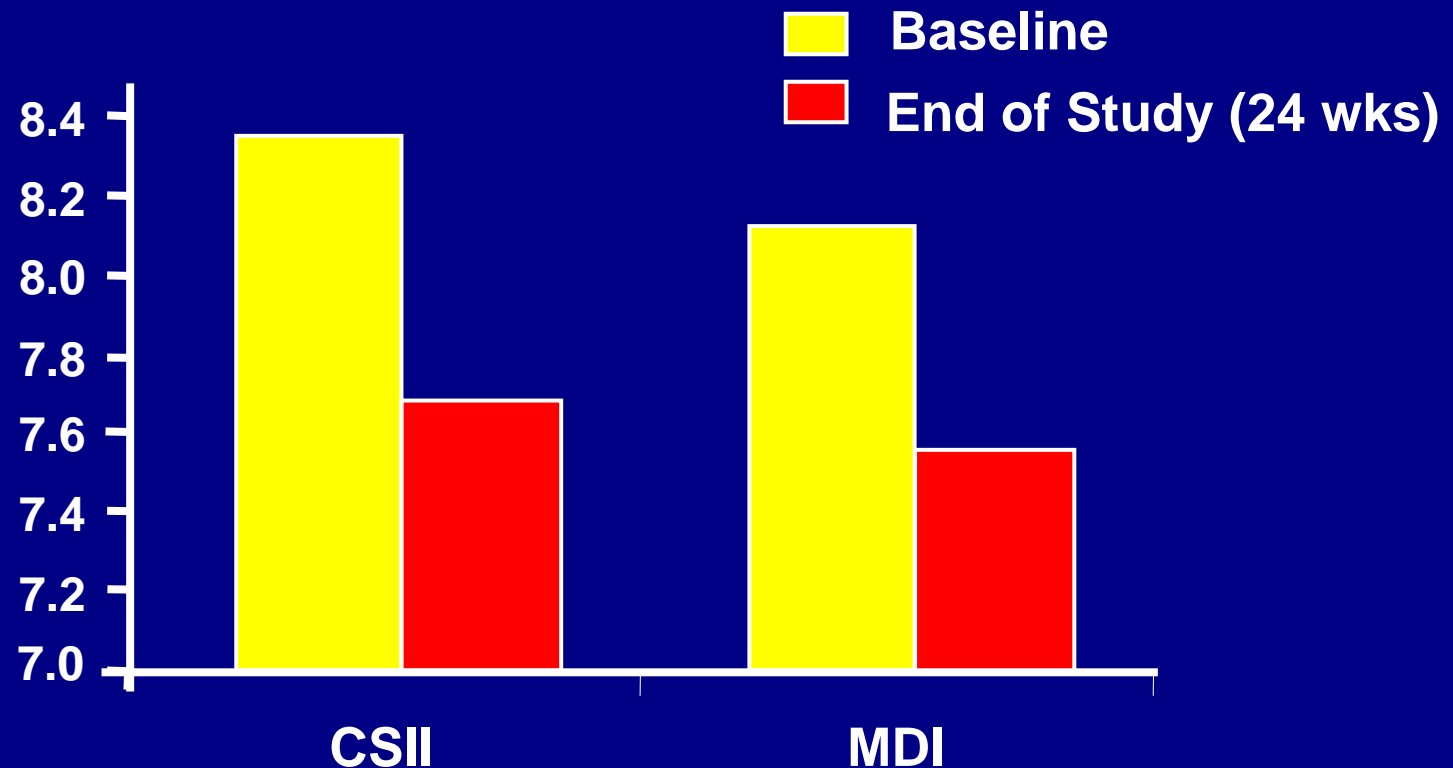
CSII Usage in Type 2 Patients

Atlanta Diabetes Experience



Glycemic Control in Type 2 DM: CSII vs MDI in 127 patients

● A1C



DM 2 Study: CSII vs MDI

- Overall treatment satisfaction improved in the CSII group: 59% pre to 79% at 24 weeks
- 93% in the CSII group preferred the pump to their prior regiment (insulin +/- OHA)
- CSII group had less hyperglycemic episodes (3 subjects, 6 episodes vs. 11 subjects, 26 episodes in the MDI group) $p < 0.01$

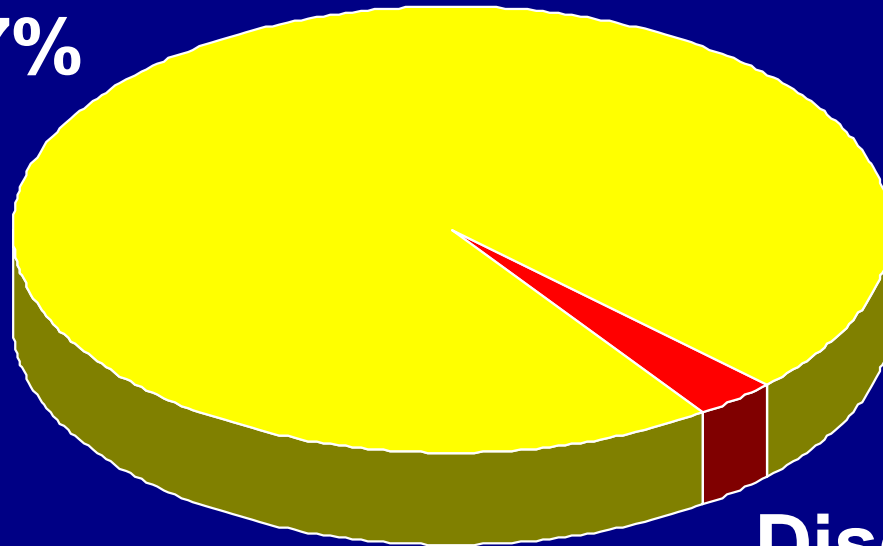
Normalization of Lifestyle

- Liberalization of diet — timing & amount
- Increased control with exercise
- Able to work shifts & through lunch
- Less hassle with travel — time zones
- Weight control
- Less anxiety in trying to keep on schedule

Current Continuation Rate

Continuous Subcutaneous Insulin Infusion (CSII)

Continued 97%



Discontinued 3%

N = 165

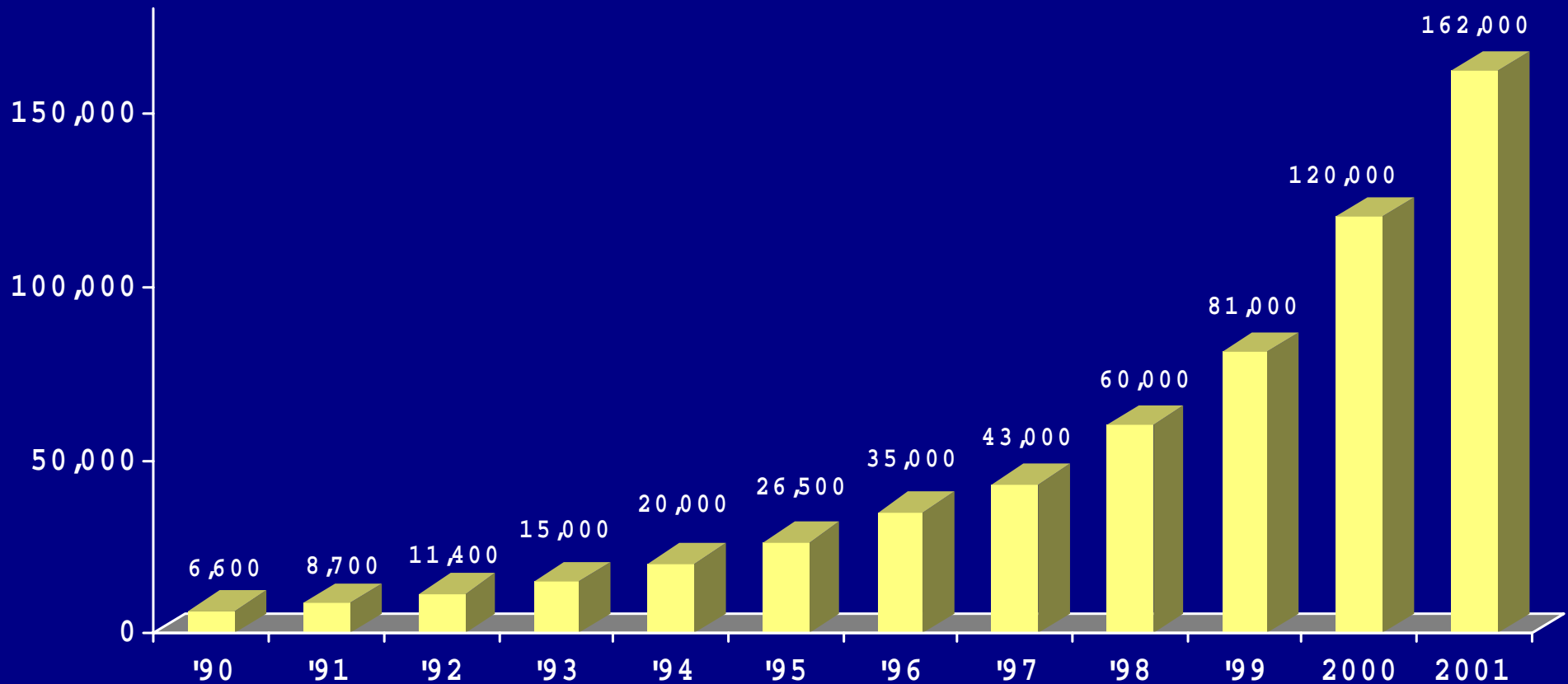
Average Duration = 3.6 years

Average Discontinuation <1%/yr

Bode BW, et al. *Diabetes*. 1998;47(suppl 1):392.

U.S. Pump Usage

Total Patients Using Insulin Pumps



Pump Therapy Indications

- HbA_{1c} >6.5%
- Frequent hypoglycemia
- Dawn phenomenon
- Exercise
- Pediatrics
- Pregnancy
- Gastroparesis
- Hectic lifestyle
- Shift work
- Type 2



Current Candidate Selection

Patient Requirements

- Willing to monitor and record BG
- Motivated to take insulin
- Willing to quantify food intake
- Willing to follow-up

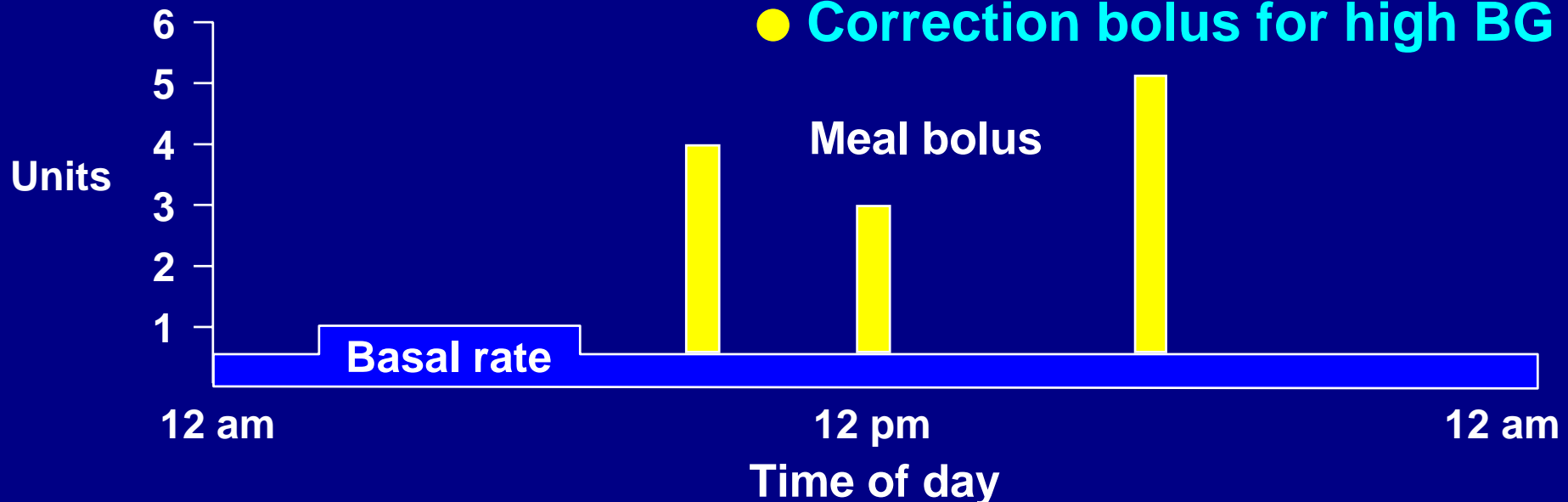
Pump Therapy

Basal rate

- Continuous flow of insulin
- Takes the place of NPH or glargine insulin

Meal boluses

- Insulin needed pre-meal
 - Pre-meal BG
 - Carbohydrates in meal
 - Activity level
- Correction bolus for high BG



If A1C Not to Goal

Must look at:

- SMBG frequency and recording
- Diet practiced
 - Do they know what they are eating?
 - Do they bolus for all food and snacks?
- Infusion site areas
 - Are they in areas of lipohypertrophy?
- Other factors:
 - Fear of low BG
 - Overtreatment of low BG

If A1C Not to Goal and No Reason Identified

- Place on a continuous glucose monitoring system (CGMS) to determine the cause

Summary

- **Insulin pump therapy offers improvement in glycemic control with less major hypoglycemia and greater flexibility in lifestyle**
- **Insulin pump therapy should be considered in all DM 1 patients and DM 2 patients failing conventional insulin therapy (basal insulin)**

QUESTIONS

- For a copy or viewing of these slides, contact

- WWW.adaendo.com