Getting to the Point of Injection Recommendations

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Objectives



- Apply the evidenced based global injection recommendations to your practice
- Describe the benefits of BD Needle Technology
- Apply the "one-handed, straight in" no pinch technique for all your patients
- Describe the issues with needle reuse



New Evidence Based Findings are Changing Best Injection Practices

Last Decade....



DCCT 1983 - 1993

- Type and dose of insulin delivered
- Selection of appropriate device
- Education

International Injection Technique Workshop 1998

- Insulin injection approached in a scientific way
- Suggested performing the injection correctly is equally important to good glycemic control



mg/dl



Post-

prandial

capillary

plasma

glucose



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Questionnaire Survey

- Over 8 months
- More than 4300 insulin-injecting patients participated
- One of the largest multi-centered studies of its kind

Survey results and initial draft of recommendations presented at Third Injection Technique Workshop in Athens (TITAN)

- Group of dedicated injection experts
 - > 127 doctors, nurses, educators and psychologists
 - From 27 countries
- Met to discuss and debate these proposals

Diabetes & Metabolism. 2010;36 (suppl.): S1-S29.

Global Injection Recommendations

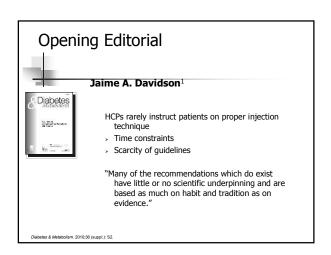


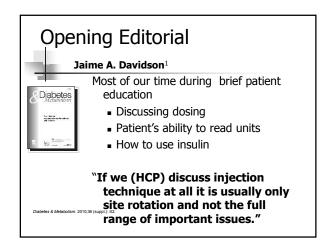
- Consensus document
- Thoroughly evidenced based given our current state of knowledge
- Published, September, 2010

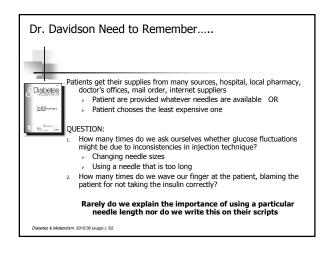
Recent years – major shift toward shorter length needles New Injection Recommendations:

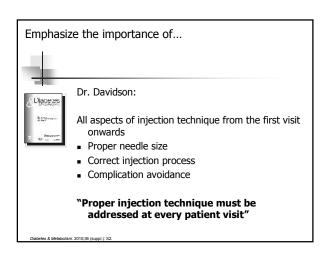
- 1. Provide clear recommendations in specific patient populations
- 2. Stress the need for correct technique in every injection
- 3. Technique is critical for achieving optimal control of diabetes

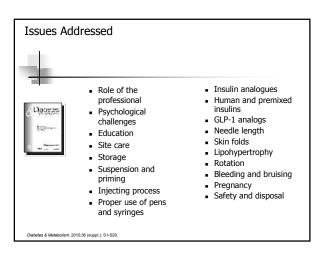
Diabetes & Metabolism. 2010;36 (suppl.): S1-S29.





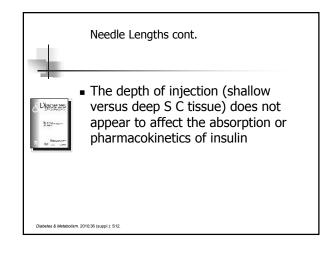


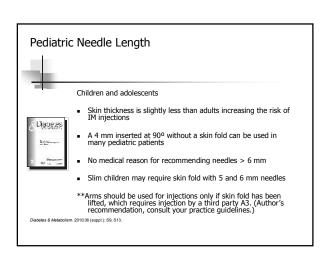


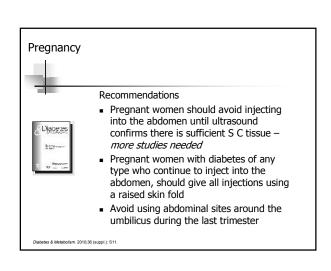


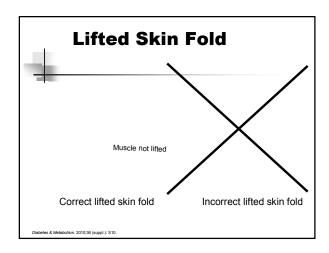
Needle Lengths No medical rationale for using needles >6mm Diabetes No consistent evidence to date in patients using short needles of increased: leakage of insulin poor diabetes management other complications Needle Lengths "Shorter needles are safer and often better tolerated" Djagggs • "Even in obese patients, studies have confirmed equal efficacy and safety/tolerability with shorter length needles as compared to longer ones" • "Randomized, controlled clinical prospective trials demonstrate the lack of any change in overall glycemic control when using shorter length needles."

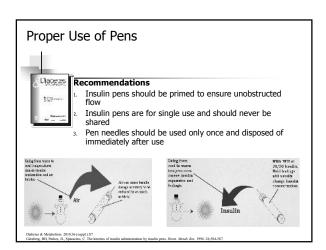
Skin thickness is constant averaging 1.9-2.4mm across injection sites, ages, races, BMI and gender; 4 mm pen needle shown to be safe and efficacious in adults of all sizes including the obese Injections with shorter needles should be given in adults straight in (at 90°) to the skin surface* Slim individuals and those injecting into a limb may need to lift a skin fold, especially when using a 5 or 6 mm needle Initial therapy should begin with shorter length needles Daletee & Melabolim. 2010.36 (kuppl.) S. 8, S. 51.3.

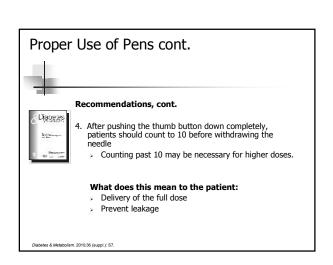






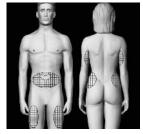






Injection Sites





- Best way to safeguard normal tissue is to properly and consistently rotate injecting sites
- Absorption rates differ

Best practices:

- Rotate injection sites
 - > Move the injection by a finger's width from the last injection point
 - > Change site every week

Insulin Analogues and GLP-1 Agents



Rapid acting insulin analogues

May be given at any site absorption rates do not appear to be site specific

- Avoid IM injections rapid absorption serious hypoglycemia Thigh and buttocks are preferred sites as a basal insulin
- Should be given at bedtime to avoid risk of nocturnal hypoglycemia

Regular Insulin:

Abdomen is preferred site

Premixed Insulins

- Morning -- abdomenPM thigh or buttock

GLP-1 agents

May be given at any injection site as the pharmacokinetics do not appear to be site specific

IM injections of long acting insulin analogues must be avoided



Needle Lengths

No medical rationale for using needles >6mm

No consistent evidence to date in patients using short needles of increased:

- leakage of insulin

■ poor diabetes management

other complications

Needle Lengths



- "Shorter needles are safer and often better tolerated"
- "Even in obese patients, studies have confirmed equal efficacy and safety/tolerability with shorter length needles as compared to longer ones"
- "Randomized, controlled clinical prospective trials demonstrate the lack of any change in overall glycemic control "When using shorter length needles."

Adult needle length



- Skin thickness is constant averaging 1.9-2.4mm across injection sites, ages, races, BMI and gender;
- 4 mm pen needle shown to be safe and efficacious in adults of all sizes including the obese
- Injections with shorter needles should be given in adults straight in (at 90°) to the skin surface*
- Slim individuals and those injecting into a limb manified បែនាក្សាន្ត្រាស់ស្កើនទីនូវវិទៀប when uswith និងចក់ចេះខែងថ្មាំង needles

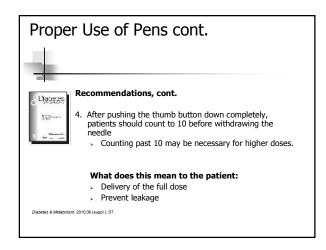
Diabetes & Metabolism. 2010;36 (suppl.): S8, S9, S13. * Tested with adults of BMI 20-49.

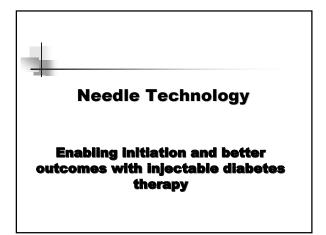
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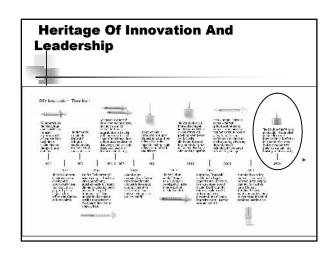
Needle Lengths cont.

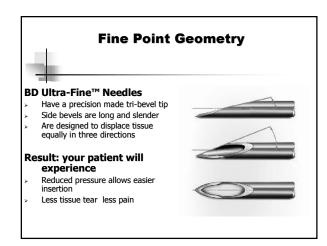
 The depth of injection (shallow versus deep S C tissue) does not appear to affect the absorption or pharmacokinetics of insulin

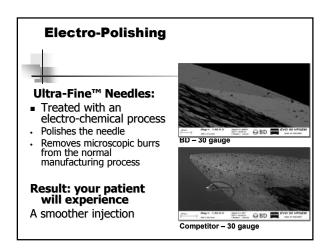
Diabetes & Metabolism. 2010;36 (suppl.): S12

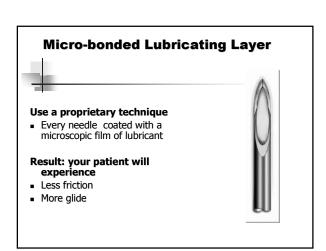












Thin Wall Technology



Ultra-Fine™ Needles:

- Have a wider, increased inner diameter
 - ✓ Same outer diameter with bigger inner diameter



What does this mean to your patient?

- Improved insulin flow rate
- Lower force required to push plunger down

Benefits Of Technology



- Greater comfort
- Less pain
- Consistency
- Convenience
- Helps patient make an easier transition to injection therapy

47% of Patients With Diabetes (PWD) would be more likely to administer their injections regularly if a product was available that would ease the pain and discomfort of injections¹

1. 2007 AADE Injection Impact Survey

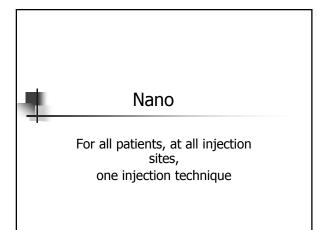
One Pen Needle For All Diabetes Pens One Brand For Life

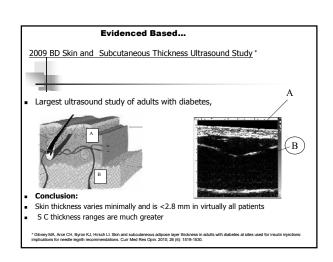


Tested in accordance with The International Standards Organization for connectivity and dose accuracy

- Guaranteed to fit all insulin pens and dosers sold in the U.S.*

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Take a closer look.....



- Type 1 and type 2 for \ge 1 yr
- 350 subjects
- BMIs of 18 50
- Male and females
- **3** age groups: 18-39, 40-59, and 60-85
- All races/ethnic groups: White, Black, Asian, Hispanic
- Insulin users and non- insulin users

Take a closer look....



At the four common insulin injection sites (arm, abdomen, thigh, buttock)

Objectives:

- Measure skin thickness (epidermis-dermis) using high frequency 2D ultrasonography
- Measure S C adipose tissue
- Determine impact of BMI on skin thickness and S C tissue
- Determine the impact of other demographic factors on skin and S C thickness

Analysis of Key Findings



Skin thickness

- Statistically significant effects:
 - Body site: thigh thinnest, buttocks thickest (difference ~ 0.6 mm)
 - Gender: male > female ~ 0.3 mm
 - BMI: ∆ 10 BMI units accounts for ~ 0.2 mm change

S C thickness

- Statistically significant effects:
 - \bullet Body site: arm thinnest, buttocks thickest (difference ~5.2 mm)
 - Gender: female > male ~ 5.1 mm
 - $_{\bullet}$ BMI: $~\Delta$ 10 BMI units ~accounts for \sim 4.0 mm change

Summary



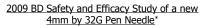
- Skin Thickness
 - 95% Confidence Interval for all subjects and sites Skin = 2.8mm
 - Does not differ by clinically significant degrees in different demographic groups
- S C Thickness
 - Ranges are much greater than for skin thickness; 95% Confidence Interval for all subjects and sites
 - > Arm = thigh < abdomen < buttocks

Conclusions



- Needles ≥8 mm, when inserted perpendicularly (90°) may enter the muscle, especially in the thigh, arm and abdomen in thin persons (BMI < 25)
- In adults with diabetes, needles 4-5 mm are long enough to penetrate the skin and enter the S C tissue, assuming perpendicular insertion, with minimal risk of IM injection

Evidenced Based...



• Evaluated the safety, efficacy and patient ratings of the 4mm by 32G Pen Needle

Conclusion:

- > Clinically proven as effective as longer pen needles for patients of ALL sizes (20-49 BMI)
- > No difference in insulin leakage compared to 5mm and 8mm pen needles
- > Less intimidating
- > Proven less painful
- > Preferred by patients

Take a closer look....



Objective: evaluate the safety, efficacy and patient ratings of the new 4mm x 32G BD Pen Needle, Nano

Research design:

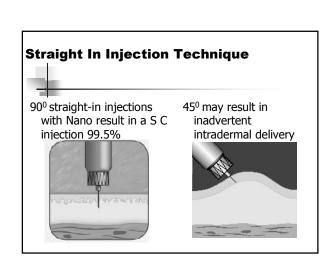
- Type 1 and type 2 PWDs,
 A1Cs of 5.5% to 9.5%
 18 to 75 years of age

 - BMIs 18 to 50 kg/m²
 - 173 PWDs randomized, 168 completed study
- Subjects were either
- > "Low dose" group ≤ 20 units
 > "Regular" dose group 21 40 units
 Randomized crossover design , 4mm x 32G BD Pen Needles and either
 - 5mm x 31G BD Pen Needle 8mm x 31GBD Pen Needle
- Primary endpoint percent absolute change in serum fructosamine

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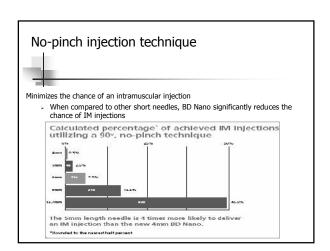
For all patients 4mm pen needle was shown to be safe and efficacious in adult patients of all sizes* Nano proven effective for all patients Clinically proven effective in maintaining glycemic control for patients of all sizes (20-49 BMI) No increased leakage when compared to the 8mm and 5mm Proven less painful Preferred by 72% of patients Shown to be less intimidating 88% of patients were "not at all anxious"

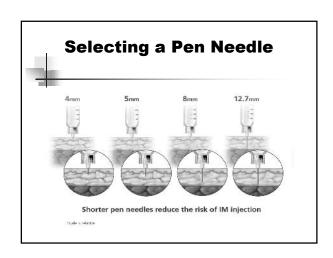
One injection technique Single handed, straight in, no pinch for all of your patients: Simple for patients to do Simple to remember Opens up more sites allowing patients more discrete injections with greater convenience What does this mean to your Patients? Increased site flexibility



All injection sites Best way to safeguard normal tissue is to properly and consistently rotate injecting sites BD Nano -- Single handed, straight in, no pinch technique Allows greater site flexibility

Result: more robust site rotation regimen which improves skin health





Computerized Tomography

Injecting with an 8 mm needle in the thigh:

• <u>Without</u> a lifted skin fold

() results in an intramuscular (IM)

- injection:
 <u>With</u> a lifted skin fold (...)
 the injection is in the S C tissue.

- A higher risk of intramuscular injection in sites where the subcutaneous tissue is thin
- Needle length and skin fold determine if the injection will be in the subcutaneous or intramuscular tissue.

Misconception



We need longer needles to go deeper for larger BMI patients

• 8 and 12.7 mm needles have frequently been used to "ensure" S C medication delivery

Global injection recommendations show this is a fallacy.

The depth of injection does not affect the absorption or pharmacokinetics of insulin



- For nearly all patients, no matter what size, skin thickness is no more than 2.8mm thick
- Depth of injection into S C has no impact on the efficacy of the insulin
- Longer needles increase likelihood of IM injections

Insurance Coverage



- Insulin Syringes and Pen Needles are covered by virtually all insurance plans at the preferred co-pay
- For your patients on Medicare Part D:

Insulin Syringes, BD Pen Needles and Alcohol Swabs are "Covered Drugs" under the Medicare Part D Prescription Drug Benefit

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One final thought	
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In summary, The BD Nano	
an earning, the BB Halle	
For all patients, at all injection sites, one injection technique	
 The "single handed, straight in" no pinch injection technique is the best technique for all your patients 	
Simple for you to teach; simple for the patient to remember Increases site flexibility	
 Less intimidating Significantly reduces the chance of IM injections 	
Clinically proven as effective as longer pen needles for nations of ALL sizes.	