How pen needles influence compliance and wellbeing of the diabetic patient

Thessaloniki, November 13 2015
• Intro – key facts

• Factors influencing compliance and wellbeing:
  
  o Innovation
  
  o Technology
  
  o Quality
KEY FACTS

- **Headquarter:** Grandate (Como)
- **Turnover 2014:** 1.218 Mio €
- **Branches:** 24 worldwide, 15 in Europe and 4 in emerging countries
- **Distributors:** over 100 worldwide
- **Business units:** 6 in Europe
- **Points of Sale:** over 400 worldwide
- **Employees:** 6,600
OUR BRANDS

Baby care

Health & beauty

chicco
the original Boppy

PiC solution
LYCIA

Prenatal
CONTROL
MARKET SHARES - ITALY

1. Diabetes (32%)
2. BPMs (14%)
3. Woundcare (20%)
4. Thermometers (28%)
5. Nebulizers (24%)
6. Venipuncture (77%)
7. Health Care (26%)

Source: IMS sep 15
Insupen
• Intro – key facts

• Factors influencing compliance and wellbeing:
  
  o Innovation
  o Technology
  o Quality
Pen needle technical terminology

1. Primary container
2. Needle shield
3. Cannula
4. Transparent glue
5. Needle hub
6. Medical paper
Pen needle technical terminology

Tip

Bevels

Heel
Pen needle technical terminology

Patient tip:
- enters patient’s skin
- entirely covered of silicone to ensure smooth sliding

Cartridge tip:
- enters the cartridge piercing its rubber lid
Insupen innovation

1. Extr3me triple sharpening
2. External diameter
3. Internal diameter
4. Length
1) Triple sharpening

The top of the cannula (patient tip) undergoes 3 grinding treatments:
- one central sharpening (A)
- two side sharpening (B)

All main Insupen pen needles are sharpened according to the new Extr3me technology, ensuring a more comfortable penetration.

**NEW**

**Insupen EXTR 3 ME**

*Designed for an Extr3me comfort*
1) Triple sharpening – Extr3me

*Designed for an Extr3me comfort*
1) Extr3me: thinner profile

The new PiC’s Extreme 3 needle geometry makes the needle profile thinner, thus *reducing the material that penetrates into the skin.*

Insupen «traditional» vs. new Insupen Extreme: **less material** penetrates into the skin.

1) Extr3me: longer bevels

The new geometry makes the tip even sharper: bevels are longer and less inclined while the length of the cannula doesn’t change. This leads to a reduced penetration force.
1) Extr3me: penetration force

Tip penetration force -21%

Heel penetration force -10%

31G
1) Extr3me: penetration force

Tip penetration force -20%

Heel penetration force -12%
1) Triple sharpening – The new Extreme range

All Insupen 32G and 31G pen needles feature the new Extreme sharpening.
2) External diameter of the needle

External diameter (GAUGE)
2) External diameter: patient’s attitude

Fear and pain of injections:

- 94% of insulin users show symptoms of anxiety, distress or phobia around blood and injury from injections (1)
- 33% of insulin users are afraid of their injections (2)
- 75% of newly diagnosed children < 9 years old have a fear of injections (3)
- 47% of people with diabetes say they would be more likely to follow their prescribed insulin regimen if a product easing pain and discomfort of injections was available (4)

(4) AADE Injection Impact Survey, 2007
2) External diameter: more comfortable injections

There is a significant correlation between needle diameter and frequency of painful injections.

Pain following controlled cutaneous insertion of needles with different diameters. Lars Arendt-Nielsen, Henrik Egevist & Peter Bjerring. Somatosensory and Motor Research, March/June 2006; 23(1/2) : 37-43 (from page 3-4)
2) External diameter

The first 32G pen needle on the market (2007).
2) External diameter: Insupen 32G customer survey

Main results of a customer satisfaction survey* involving 350 patients who tried Insupen 32G

Does Insupen 32G make injections more comfortable and less painful?

- Strongly agree: 52%
- Agree: 40%
- Partly agree: 8%

Would you recommend Insupen 32G to another diabetic patient?

- Yes: 90%
- No: 10%
3) Internal diameter: the wall of the cannula
3) Internal diameter: the wall of the cannula

According to the ISO norm, the cannula can be:

**NORMAL WALLED**

or

**THIN WALLED.**
3) Internal diameter: ISO Norm

Table 2 — Dimensions of tubing

<table>
<thead>
<tr>
<th>Designated metric size</th>
<th>Gauge size</th>
<th>Range of outside diameters</th>
<th>Inside diameter of tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>min.</td>
<td>max.</td>
</tr>
<tr>
<td>0.2</td>
<td>33</td>
<td>0.203</td>
<td>0.216</td>
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<tr>
<td>0.23</td>
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<tr>
<td>0.25</td>
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<td>0.4</td>
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<td>0.400</td>
<td>0.420</td>
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<tr>
<td>0.45</td>
<td>26</td>
<td>0.440</td>
<td>0.470</td>
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<tr>
<td>0.5</td>
<td>25</td>
<td>0.500</td>
<td>0.530</td>
</tr>
<tr>
<td>0.55</td>
<td>24</td>
<td>0.560</td>
<td>0.580</td>
</tr>
<tr>
<td>0.6</td>
<td>23</td>
<td>0.600</td>
<td>0.673</td>
</tr>
<tr>
<td>0.7</td>
<td>22</td>
<td>0.698</td>
<td>0.730</td>
</tr>
</tbody>
</table>
3) Internal diameter: thin wall cannula

THIN WALL BENEFITS*:

• less pain
• less bleeding
• less skin irritation
• less injection strain
• less residual insulin leakage from the patients skin after injection
• less needle occlusion

The whole Insupen range is **thin walled** according to ISO 9626.

3) Internal diameter: High Flow Thin Wall

Inupen 32G 4mm goes even beyond:

1. drug flows easier through the needle, for a faster injection
2. more comfortable injection

Super thin wall features a wall thickness of 0.045 mm, still complying with the ISO Norms requirements (such as cannula stiffness).
3) Internal diameter: High Flow

32G
inner diameter = 0,12 mm

32G HIGH FLOW
inner diameter = 0,14 mm

Inner diameter 16% increased
3) Internal diameter: High Flow

The equation below describes the flow rate of liquids inside any tube.

Flow rate is highly affected by inner diameter ($R^4$). This means that a slight increase in the inner diameter allows a big increase in the flow rate.

Hagen-Poiseuille equation

\[ Q = k \frac{R^4}{L} \Delta P \]

- $Q =$ flow rate
- $\Delta P =$ pressure
- $R =$ cannula inner radius
- $L =$ cannula length
- $k =$ constant
3) Internal diameter: High Flow Thin Wall technology

Insupen 32G 4mm normal wall

Insupen 32G 4mm High Flow Thin Wall

VS.

+70% insulin flow

Insupen 32Gx4 High Flow vs Insupen 32Gx4 traditional. Data on file.
3) Internal diameter: High Flow

ISO 11608-2:2012 ➔ minimum flow rate expected

PiC G32x4
Minimum flow rate expected = 2.2 [ml/min]

PiC G32x4 HIGH FLOW
Minimum flow rate expected = 4.3 [ml/min]
3) Internal diameter: the Insupen range

**HIGH FLOW THIN WALL**

- 32G: 0.23mm
  - 4mm
  - 6mm
  - 8mm

- 31G: 0.25mm
  - 5mm
  - 6mm
  - 8mm

Thin Wall
4) Length: pain and ease of use

- In a 2004 study, blinded assessments of pain showed no significant difference in pain scores for the 2 needle lengths tested (6mm and 12.7mm). This observation would indicate that, at least under the conditions of needle testing in this clinical trial, the discomfort of puncturing dermal tissues did not differ materially for the 2 lengths.

- The questions specifically comparing patient perception toward the 2 needles showed however a marked preference for the shorter, finer needle: when specifically asked about needle preference, patients indicated that they considered the shorter needle (6mm) easier to use.
4) Length: dermis thickness

The thickness of the dermis is unrelated to BMI and fluctuates, on average, between 1.8 and 2.5 mm according to the injection site*.

* Skin and subcutaneous adipose layer thickness in adults with diabetes at sites used for insulin injection: implication for needle length recommendation, Michael A. Gibney, Christina H. Arce, Karen J. Byron, Laurence J. Hirsch*.
4) Length: suitable needle

The new guidelines for insulin injections recommend to use **short needles (4 to 6mm) for all patients**, including those with a sturdy physical build, because they can pass through the dermis layer and reach the subcutaneous tissue.
4) Length: Insupen’s choice

We have decided however to have a wide 32G range in order to let freedom of choice:

• to the patient, who can choose a comfortable pen needle (32G) in a variety of lengths matching his/her own favorite injection technique (90°, 45°, with pinch etc)

• to the professional, who –according to his/her own experience- may prescribe a specific pen needle for each patient

The above injection techniques are recommended in the Clinical Study “New injection recommended for patients with diabetes”, Anders Frid, Ruth Gaspar, Debbie Hicks, Larry Hirsch, Gillian Kreugel, Jutta Liersch, Corinne Letondeur, Jean-Pierre Sauvanet, Nadia Tubiana-Rufi, Kenneth Strauss - Vol.36 – 2010, Diabetes & Metabolism.”
4) Length: the Insupen range

A larger range

for a wider choice.
• Intro – key facts

• Factors influencing compliance and wellbeing:
  o Innovation
  o Technology
  o Quality
Insupen technology

1. Anti-coring
2. Electrochemical polishing
3. Silicon
4. Compatibility
1) Anti-coring treatment: purpose & process

In order to get the heel surface smooth, tiny glass microspheres are “shot” at the heel to round off its surface and remove all eventual spikes/burrs left after the sharpening.

Closer look
500x magnifying

Comparative scanning microscope examination (Breda Scientific Institute – Milan)
1) Anti-coring treatment: benefits

PATIENT TIP:
- smoother sliding into the skin
- no risk of abrasions/grazes
- further reduction of discomfort

CARTRIDGE TIP:
- effective piercing of the cartridge rubber lid
- prevention of fragments fall into insulin ➔ no cannula obstruction

NO ANTICORING: POSSIBLE FRAGMENTS

ANTICORING: NO FRAGMENTS
2) Electrochemical polishing

Both tip and bevels are treated in an electrochemical acid bath giving a final finishing that:
- removes any remaining spikes
- gets a surface finish (absence of micro-imperfections on the tip)

**INSUPEN needle**

**Untreated needle**

*Comparative scanning microscope examination (Breda Scientific Institute – Milan)*
3) Silicone

Special Medical grade silicone is laid evenly all over the entire needle surface.

In combination with a precise sharpening and polishing of the needle, this ensures its smooth sliding into the skin.
4) Compatibility

The updated ISO 11608 norm (ISO 11608-2:2012) prescribes that the compatibility between pen needles and pen injector has to be assessed through testing the needles with every single pen.

The list of the compatible pens is listed on the packs and it’s **periodically updated**.

The previous revision (EN ISO 11608-2:2000) instead stated that each “Type A” pen needle was compatible with each “Type A” pen injector.

<table>
<thead>
<tr>
<th>Sanofi</th>
<th>ClikStar, SoloStar, Lyxumia Pen, JuniorStar, AllStar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lilly</td>
<td>KwikPen, HumaPen Memoir, HumaPen Savvio, HumaPen Luxura, HumaPen Luxura HD,</td>
</tr>
<tr>
<td>Novo Nordisk</td>
<td>FlexPen, Novopen 3, Novopen 4, Novopen Echo, Novopen Junior, Victoza Pen, InnoLet,</td>
</tr>
<tr>
<td>Amylin Pharmaceutical</td>
<td>Byetta 5 mcg, Byetta 10 mcg</td>
</tr>
</tbody>
</table>
Single use device

Using a needle more than once may cause:

- Inaccurate dosage 1
- Insulin crystallization 2
- Lipodystrophies 3
- Sterilisation 4
- Damage of needle tip 5
- Lubricant removal 6

6. The Importance of Good Insulin Injection Practices in Diabetes Management - Richard Dolinar, MD, 2009
These data suggest that if participants reuse pen needles, they have just as much chance of having lipohypertrophy as not, but if they do not reuse pen needles they have a modest (and significant) reduction in the risk of lipohypertrophy, even though many of those who do not reuse pen needles still develop lipohypertrophy.
• Intro – key facts

• Factors influencing compliance and wellbeing:
  o Innovation
  o Technology
  o Quality
Quality levels

Innovative features & quality controls

- **HIGH FLOW THIN WALL**
- NO USE OF ALLERGENS IN MANUFACTURING

Voluntary technical Standards

- COMPLIANCE WITH UNI EN ISO PRODUCT STANDARDS (e.g. UNI EN ISO 7886)
- COMPLIANCE WITH UNI EN ISO PROCESS STANDARDS (e.g. UNI EN ISO 13485)

Compulsory Standards

- COMPLIANCE WITH DIR. 93/42
- ESSENTIAL SAFETY AND MARKET SUITABILITY REQUISITES
- PHARMACOPOEIA REGULATIONS

Excellence

High Quality

Minimum Quality
Quality Control process: stiffness test

The ISO 9626 Stiffness Test is made in order to verify that the normal bending of the needle stays inside the parameters set by the ISO.
Quality Control process: cannula pull test

The ISO 7864 pull test, consisting in pulling the cannula with a certain force, is performed to verify that it does not detaches from the hub.
Quality Control process: cannula breakage test

The ISO 9626 Breakage Test, consisting in bending right and left several times a cannula, is performed to verify that it does not break.
Quality Control process: dislocation test

This test verifies that the cannula is straightly mounted onto the hub (ISO 11608)
Quality Control process: torque test

This test, performed according to ISO 11608, verifies that the strength necessary to screw and unscrew a pen needle on a pen stays inside ISO parameters.
Quality Control process: cannula length

This test, performed according to ISO 11608, verifies that the real length of the needle stays inside ISO tolerances.
Quality Control process: length and tolerance

4.3.2 Type A needles

Type A needles shall fit the test apparatus specified in 7.2 and function with pen-injectors designated and labelled to be used with Type A needles.

The length \( l_2 \) of the cartridge-end of the needle shall be within 3.50 mm to 7.25 mm (see Figure 1).

The tolerance on the length \( l_1 \) of the patient-end of the needle shall be \( \pm 1.25 \text{ mm} \) of the length specified by the manufacturer (see Figure 1).

The tolerance set as a goal by Insupen is narrower: 
\[ +/\!-\!0.5\text{mm} \]
A ray of light enters the cannula on one side; if the «quantity of light» coming out the other side is smaller it means that the cannula is not straight and it’s discarded.

Additional voluntary quality control, not required by ISO standard.
Quality Control process: cannula obstruction

Three different checks are performed to ensure that cannulas are not stuck:

1. Automatic control during cannula manufacturing
2. Random control at the end of the cannula manufacturing stage
3. Automatic control during assembly stage (100% of the production)

Additional voluntary quality control not required by ISO standard.
We check the penetration force of Insupen pen needles using a special polyurethane film that reproduces as closely as possible the features of the human skin. The output is then compared with our internal database to verify that it stays inside the established parameters. Additional voluntary quality control not required by ISO standard.
## Main needle controls

<table>
<thead>
<tr>
<th></th>
<th>Reference Standard</th>
<th>Aim of Test</th>
<th>Impact on Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shear Resistance</strong></td>
<td>UNI EN ISO 7864 (validation control – internal procedure no. 10.05.01.00 no. 6)</td>
<td>Check cannulas’ shear resistance under cyclic stress</td>
<td>Guarantee maximum needle quality</td>
</tr>
<tr>
<td><strong>Needle Dimensions</strong></td>
<td>ISO 7864 (routine control - internal procedure no. 10.05.01.00 no. 3)</td>
<td>Check cannula and needle dimensions (internal/external diameter - wall/angle/tip thickness)</td>
<td>Ensure most painless penetration possible</td>
</tr>
<tr>
<td><strong>Flexing</strong></td>
<td>ISO 9626 (routine control - internal procedure no. 10.05.01.00 no. 4)</td>
<td>Check needle’s flex resistance</td>
<td>Ensure utmost needle quality and safety during use</td>
</tr>
<tr>
<td><strong>Internal/External Cannula Cleanliness</strong></td>
<td>ISO 7864 – ISO 8537 (routine control - internal procedure no. 10.05.01.00 no. 5)</td>
<td>Exclude contamination by foreign bodies</td>
<td>Ensure maximum patient health and safety</td>
</tr>
</tbody>
</table>

*Technical file available on demand*
## Main product controls

<table>
<thead>
<tr>
<th></th>
<th>REFERENCE STANDARD</th>
<th>AIM OF TEST</th>
<th>IMPACT ON QUALITY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CANNULA/BARREL TRACTION</strong></td>
<td>ISO 7864 - ISO 8537 (routine control - internal procedure no. 10.05.01.00 no. 10)</td>
<td>Check force needed to detach cannula from its support</td>
<td>Ensure perfect needle-support (barrel) adhesion and maximum device safety</td>
</tr>
<tr>
<td><strong>NEEDLE COVER/NEEDLE TRACTION</strong></td>
<td>routine control - internal procedure 10.05.01.00 no. 11</td>
<td>Check force needed to detach needle cover from its support</td>
<td>Ensure adequate needle protection and sterility</td>
</tr>
<tr>
<td><strong>PLASTIC MATERIAL ACCEPTANCE</strong></td>
<td>(acceptance control - internal procedure 10.05.02.00 no. 4)</td>
<td>Check plastic product properties (cleanliness, transparency)</td>
<td></td>
</tr>
<tr>
<td><strong>SILICONE OIL ACCEPTANCE</strong></td>
<td>correspondence with specifications</td>
<td>Check silicone polymer properties</td>
<td>Ensure user’s maximum safety</td>
</tr>
</tbody>
</table>
## Main biochemical controls

<table>
<thead>
<tr>
<th>CHEMICAL/BIOLOGICAL TEST</th>
<th>REFERENCE STANDARD</th>
<th>AIM OF TEST</th>
<th>IMPACT ON QUALITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>FARMACOPEA-REQUIRED TESTS</td>
<td>Farmacopea (routine control - internal procedure 10.05.02.00 no. 13)</td>
<td>Check parameters such as syringe non-pyrogenicity and non-toxicity</td>
<td>Ensure product safety</td>
</tr>
<tr>
<td>QUANTITATIVE SILICONE</td>
<td>Farmacopea (routine control - internal procedure 10.05.02.00 no. 1)</td>
<td>Check lubricant content</td>
<td>Prevent excess of silicone, which is not broken down if introduced into body</td>
</tr>
<tr>
<td>RESIDUAL ETHYLENE OXIDE CONTENT</td>
<td>Farmacopea (routine control - internal procedure 10.05.02.00 no. 2)</td>
<td>Check that EO content is less than 10 ppm as per standard</td>
<td>Check that residual EO is below Artsana standard of 2 ppm (less than Farmacopea limit) to ensure greater patient safety.</td>
</tr>
<tr>
<td>BACTERIAL ENDOTOXIN DETECTION (GEL-CLOT METHOD)</td>
<td>Farmacopea (routine control - internal procedure 10.05.03.00 no. 7)</td>
<td>Exclude risk of pyrogen contamination</td>
<td>Respect patient’s health and avoid irritation</td>
</tr>
<tr>
<td>BACTERIAL ENDOTOXIN QUANTIFICATION (LAL TEST)</td>
<td>Farmacopea (routine control - internal procedure 10.05.03.00 nos. 5 and 8)</td>
<td>Exclude risk of pyrogen contamination</td>
<td>Respect patient’s health and avoid irritation</td>
</tr>
<tr>
<td>ELASTOMER CLOSURES</td>
<td>Farmacopea (routine control - internal procedure 10.05.02.00 no. 22)</td>
<td>Evaluate conformity of closures for aqueous preparations for parenteral use</td>
<td>Ensure product safety</td>
</tr>
<tr>
<td>STERILITY</td>
<td>Farmacopea (routine control - internal procedure 10.05.04.00 no. 1)</td>
<td>Correspondence with safety requisites</td>
<td>Ensure product safety</td>
</tr>
</tbody>
</table>

*Technical file available on demand*
Assembling process: quality controls

Automatic, 100% check stations during assembly, impacting onto product quality:

- Vision system checking useful length of the cannula
- Vision system checking presence of the glue
- Vision system checking patient tip integrity (absence of hooks)
- Vision system checking patient tip bending after placing shield
- Vision system checking cartridge tip bending
- Vision system checking printing of data on the box
- Sensor checking non-obstruction of the cannula
- Sensor checking integrity of primary container
- Sensor checking correct positioning of needle shield
- Sensor checking box weight (100 pen needles per box)

The non-complying pieces are automatically discarded.
KEY FACTS

• More than **50 years of experience** in cannula and needles manufacturing

• More than **5.500 millions** pen needles manufactured so far

• **Integrated, made in Italy** production (ISO and FDA compliant)

• **Innovation** (32G, Extr3me sharpening, High Flow Thin Wall)

• 32G pen needle in **3 lengths**

• Over **60 quality control** tests

• **Additional quality restrictions** and quality level parameters
Ευχαριστώ!
means:

**Expertise**

**Innovation**

**Technology**

**Quality**

**MADE IN ITALY**
Injection techniques: the latest guidelines

New injection recommendations for patients with diabetes

A. Frid, L. Hirsch, R. Gaspar, D. Hicks, G. Kreugel, J. Liersch, C. Letondeur,
J.P. Sauvanet, N. Tubiana-Rufi, K. Strauss

- These new recommendations come from a 2-steps process:
  - the results of the second Injection Technique Questionnaire (ITQ) survey (2008-2009), involving more than 4,300 insulin-injecting patients with diabetes from 171 centers in 16 countries, making it one of the largest multi-center studies of its kind in diabetes. The outcomes were then presented for review and revision to 127 experts from 27 countries at the TITAN workshop in September 2009.
  - a systematic literature analysis conducted for all peer-reviewed studies and publications on injections in diabetes: an international group of experts met regularly over a two-year period to review this literature and draft the recommendations. Of 292 articles reviewed, 157 were found to meet the criteria of relevance to the recommendations.
Where to inject: site rotation

- Many studies show that to safeguard normal tissue one must properly and consistently rotate sites.
- Patients should be taught an easy-to-follow rotation pattern from the onset of injection therapy.
- The below scheme with proven effectiveness involves dividing the injection site into quadrants (or halves when using the thighs or buttocks), using one quadrant per week and moving always clockwise, as shown by figures below.
- Injections within any quadrant or half should be spaced at least 1cm from each other in order to avoid repeat tissue trauma.

Abdominal rotation pattern by quadrants

Thigh and Buttocks rotational pattern by halves
Where to inject: absorption speed

The choice of the injection site is an essential element for the glycaemia control, since there is (especially with fast insulin) a relevant variability of the absorption speed (= passage into blood) for non-analogue insulins.

From fastest to slowest:

abdomen, shoulder, buttock, thigh

Absorption speed depends also on the type of insulin (human, analogues, rapid- or slow-acting). For example, soluble human insulins may have a slower absorption profile than rapid-acting analogs. The most rapid absorption of soluble human insulins is in the abdomen, which should be the preferred site.
How to inject: the appropriate technique

Clinical evidences and literature varies onto this subject.

Several healthcare professionals suggest to make the skinfold in order to reduce the risk of IM injections, which can lead to a too fast insulin absorption and therefore hypoglycaemia.

Here below general recommendations for adults.
How to inject: the skin fold

• Lifting a skin fold and/or injecting at a 45-degree angle are especially important in slim or normal weight patients and in those injecting into the limbs or into slim abdomens, particularly when using needles ≥8 mm.

• Skin folds are essential when the distance from skin surface to the muscle is less than the length of the needle.

• Lifting a skin fold is an easy and effective means for ensuring SC injections.

• A proper skin fold is made with the thumb and index finger (possibly with the addition of the middle finger). Lifting the skin by using the whole hand risks lifting muscle with the SC tissue and can lead to IM injections.

• The skin fold should not be squeezed so tightly that it causes skin blanching or pain.
Lipohypertrophy

- Lipohypertrophy is a thickened, ‘rubbery’ lesion that appears in the SC tissue of injecting sites in up to 50% of patients who inject insulin.
- Patients **should not inject** into areas of lipohypertrophy since insulin absorption can be delayed or made erratic.
- Detection of lipohypertrophy requires both visualization and palpation of injecting sites, as some lesions can be more easily felt than seen.
- Figure 1 illustrates **visible lipohypertrophy** in a woman who had injected in the same two locations below the umbilicus for twelve years.
- Figure 2 illustrates the detection of **palpable lipohypertrophy** by comparing a fold of normal skin (left) with lipohypertrophic tissue (right). Normal skin can be pinched tightly together, while lipohypertrophic lesions cannot.

Figure 1

Figure 2

Other recommendations

• Inject slowly and ensure that the plunger (syringe) or thumb button (pen) has been fully depressed.
• When using a pen, wait another 10 seconds after dose delivery before removing the needle in order to avoid leakage/reflux; this ensures full delivery of the injected dose.
• Massaging the site before or after injection may speed up absorption and is generally not recommended.
• Tips for making injections less painful include:
  o Keeping insulin in use at room temperature, since cold insulin can be more painful when injected;
  o If using alcohol, injecting only when the alcohol has dried out;
  o Not injecting at hair roots;
  o Using a new needle at each injection.
Insulin injection and patient’s compliance

Fear and pain of injections:
• 94% of insulin users show symptoms of anxiety, distress or phobia around blood and injury from injections (1).
• 75% of newly diagnosed children < 9 years old have a fear of injections (3).
• 47% of people with diabetes say they would be more likely to follow their prescribed insulin regimen if a product easing pain and discomfort of injections was available (4).
• 33% of insulin users are afraid of their injections (2).

(4) AADE Injection Impact Survey, 2007
### Insulin injection and patient’s compliance

**Table 1—**Attitudes about insulin therapy, unwilling vs. willing subjects

<table>
<thead>
<tr>
<th>Attitude</th>
<th>Unwilling</th>
<th>Willing</th>
<th>Total</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected harm: Insulin therapy can cause problems, such as blindness</td>
<td>16.7</td>
<td>8.0</td>
<td>10.1</td>
<td>0.005</td>
</tr>
<tr>
<td>Illness severity: Taking insulin means my diabetes will become a more serious disease</td>
<td>46.7</td>
<td>35.4</td>
<td>38.1</td>
<td>0.000</td>
</tr>
<tr>
<td>Restrictiveness: Insulin therapy would restrict my life, it would be harder to travel, eat out, etc.</td>
<td>36.1</td>
<td>41.6</td>
<td>44.8</td>
<td>0.000</td>
</tr>
<tr>
<td>Lack of fairness: I’ve done everything I was supposed to; if I had to do insulin therapy, it just wouldn’t be fair</td>
<td>41.5</td>
<td>21.9</td>
<td>26.8</td>
<td>0.000</td>
</tr>
<tr>
<td>Anticipated pain: I couldn’t take the needle every day; it would be just too painful</td>
<td>50.8</td>
<td>30.2</td>
<td>34.7</td>
<td>0.000</td>
</tr>
<tr>
<td>Problematic hypoglycemia: Insulin therapy might cause serious problems with low blood sugar</td>
<td>49.3</td>
<td>37.9</td>
<td>40.6</td>
<td>0.021</td>
</tr>
<tr>
<td>Low self-efficacy: I’m not confident I could handle the demands of insulin therapy</td>
<td>58.1</td>
<td>39.7</td>
<td>43.9</td>
<td>0.000</td>
</tr>
<tr>
<td>Personal failure: Insulin therapy would mean I had failed, that I hadn’t done a good enough job taking care of my diabetes</td>
<td>55.0</td>
<td>33.6</td>
<td>38.4</td>
<td>0.000</td>
</tr>
<tr>
<td>Permanence: Once you start insulin, you can never quit</td>
<td>53.1</td>
<td>42.6</td>
<td>44.9</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Data are percentages of subjects who agree (either mildly, moderately, or strongly) with each barrier. *P* values compare differences between willing and unwilling subjects.


“Willing” and “unwilling” refer to patients’ willingness to begin insulin therapy.
The importance of the education: patients’ mistakes

UK data from the 2009 Injection Technique Questionnaire (ITQ) survey of people with diabetes using insulin (*) showed that:

• 75% did not follow any site rotation routine.
• 60% had not changed their needle size since starting therapy.
• 54% reported lipohypertrophy at some time in their life.
• 45% experienced bleeding or bruising.
• 43% released the skin fold too soon.
• 41% failed to re-suspend their cloudy insulin adequately.
• 28% admitted injecting into areas of lipohypertrophy.
• 17% were using an incorrect technique for lifting a skin fold.
• Only 41% reported frequent and adequate inspection of their injection sites.

D. Hicks, The UK & Ireland experience, TITAN 2009 congress
The importance of the education: information retention

A 2010 survey* asked participants about the education and training they had received relating to injection technique. Many did not remember receiving any education on particular topics.