

*Injection Techniques Questionnaire (ITQ)  
WorldWide Results*

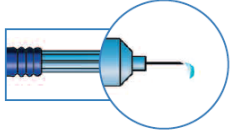
*2014-2015*

**Leakage from Site**



# What do patients mean by leakage?

Patients often confuse different kinds of leakage:

- **Leaking from the pen** due to a **poor seal** between the needle and the cartridge in the pen
- **Dripping from the needle** (on the pen): 
  - because the **plunger** was not held down correctly or
  - because the **needle** was taken out of the skin too soon
- **Reflux out of the injection site**
  - because the **needle** was taken out too soon
  - even though the **injection** was done correctly
  - or for some **other reason** (obese patient)

# Factors that Help Prevent Leakage

- **Horny cells** in the epidermis
- The **basement membrane** in the dermis
- The **elasticity** of the dermis (closing the track)

# HORNY CELLS



## **The Epidermis as Barrier**

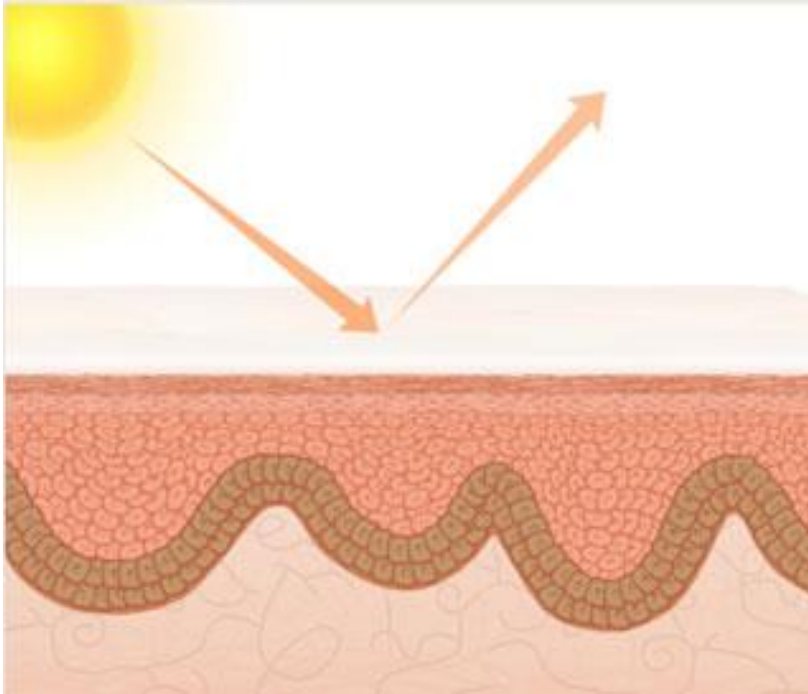
Layers of horny cells (stratum corneum)  
with their tight intercellular  
junctions (ICJ)

These cells are packed with lipids

This prevents water loss and  
dehydration

**It also blocks injected substances  
from leaking out**

# BASEMENT MEMBRANE



## The Dermis as Barrier

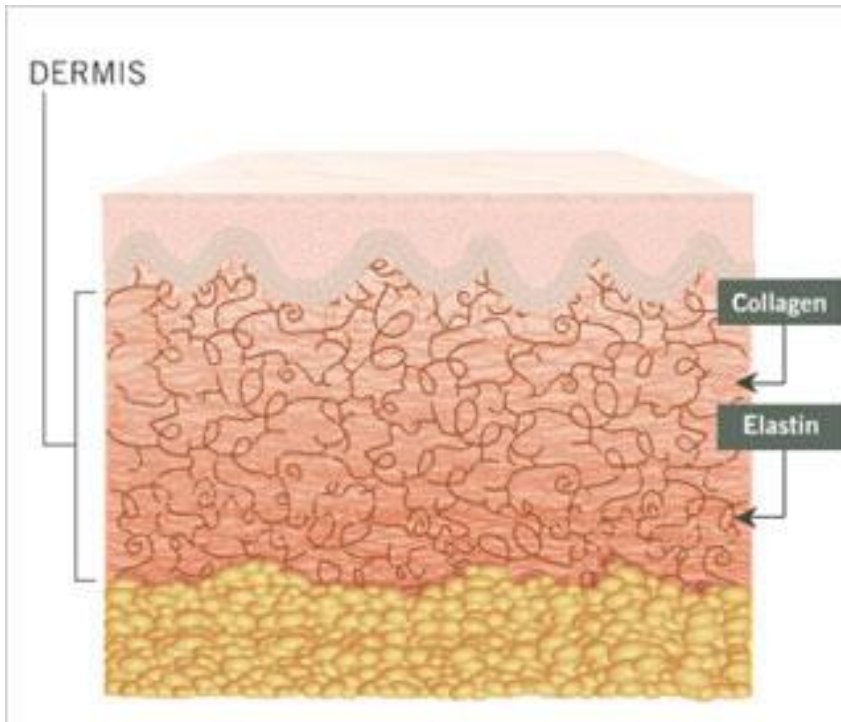
Thick layer of barrier cells

Separates Dermis from SC

Elastic properties of Dermis:

1. Closes off injection tracks
2. Resists backflow from SC

# Elastic Dermis



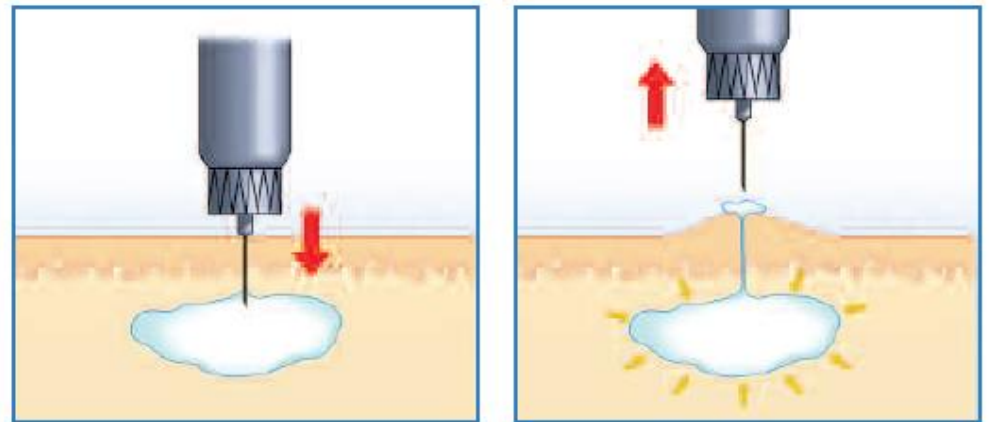
## The Dermis as Elastic Jumpsuit

Collagen gives it strength

Elastin gives it flexibility

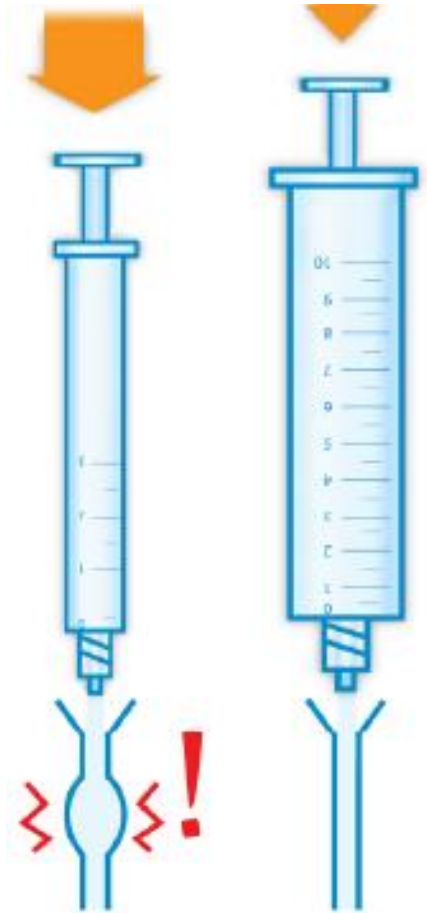
## Issue: Oozing from the Skin

- **Higher volumes** create higher pressures and more leakage
- **Obese patients** have more oozing for unknown reasons
- Not related to the **needle length**



## Preventing Oozing from the Skin

- **10 seconds rule important**
- Injections given **rapidly** are more likely to leak
- Not enough time for the injected drug to **spread out** through the tissue planes and/or to cause the tissue to **expand and stretch**





## Issue: Oozing from the Skin

- Another factor in the risk of leakage is the **size of the puncture hole**
- Larger holes lead to **more leakage**
- **Thinner needles/TW** have a role



# What do we know already about leakage?

- 4 mm leaks no more than any other length
- Obese subjects have more reports of leakage....*regardless* of needle length...we don't yet know why
- Volume of leakage is generally <0.1 IU (or < 1% of insulin total) and hence clinically insignificant

# **DESCRIPTIVE STATISTICS**

# Do patients see leakage from injection sites? If so, how frequently?

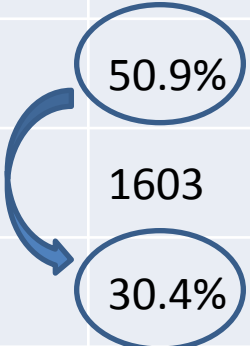
Site leakage?	N	%
Yes	3611	<b>36.9</b>
No	6188	<b>63.1</b>

Frequency	%
<b>Always</b>	<b>2.2</b>
<b>Often</b> (several times a week)	<b>13.3</b>
<b>Sometimes</b> (several times a month)	<b>46.4</b>
<b>Almost never</b> (several times a year)	<b>38.1</b>

# **COMPARATIVE STATISTICS**

# Is there an association between leakage and type of DM?

Type of DM	Leakage		Total
	Yes	No	
T1DM	1375	1325	2700
	50.9%	49.1%	100.0%
T2DM	1603	3678	5281
	30.4%	69.6%	100.0%
GDM	20	63	83
	24.1%	75.9%	100.0%



**p < 0.000**

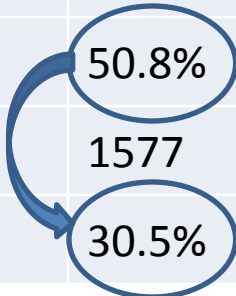
# Is there an association between leakage and type of insulin?

Type of insulin	Leakage		Total
	Yes	No	
Rapid-acting human	44	112	156
	28.2%	71.8%	100.0%
Fast-acting analogues	82	189	271
	30.3%	69.7%	100.0%
NPH	121	331	452
	26.8%	73.2%	100.0%
Basal analogues	288	676	964
	29.9%	70.1%	100.0%
Premixes	440	1104	1544
	28.5%	71.5%	100.0%

**p = 0.062**

# Is there an association between leakage and LH?

		Leakage		Total
		Yes	No	
LH	Yes	1179	1140	2319
	%	50.8%	49.2%	100.0%
	No	1577	3588	5165
	%	30.5%	69.5%	100.0%

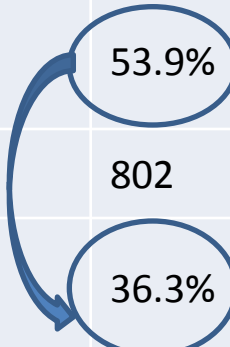


**p < 0.000**



# Is leakage reduced by not injecting into LH?

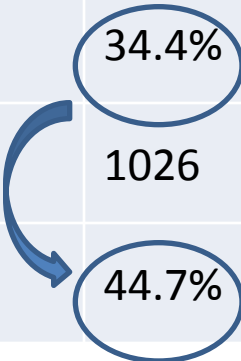
		Leakage		Total
		Yes	No	
Injecting	Yes	940	804	1744
	%	53.9%	46.1%	100.0%
	No	802	1409	2211
	%	36.3%	63.7%	100.0%



**p < 0.000**

# Is there an association between leakage and correct rotation?

		Leakage		Total
		Yes	No	
Correct rotation	Yes	1901	3620	5521
	%	34.4%	65.6%	100.0%
	No	1026	1269	2295
	%	44.7%	55.3%	100.0%



**p < 0.000**

# Is leakage associated with needle reuse?

		Leakage		Total
		Yes	No	
Reuse	Yes	1527	2471	3998
	%	38.2%	61.8%	100.0%
	No	1462	2582	4044
	%	36.2%	63.8%	100.0%

**p = 0.523**

# Is there an association between leakage and total daily dose (TDD) of insulin?

Leakage	TDD	SD	N
Yes	51.8	32.2	2819
No	46.6	32.5	4777
Total	48.5	32.4	7596

$\Delta = 5.2 \text{ IU}$

$p < 0.000$

# Is there an association between leakage and HbA1c?

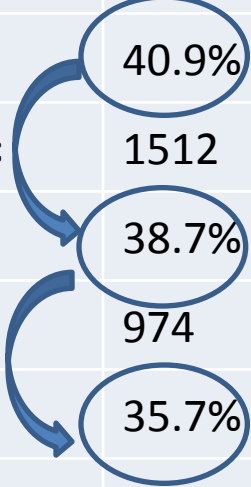
Leakage	HbA1c	SD	N
Yes	8.60	1.9	2847
No	8.39	2.3	4643
Total	8.47	2.1	7490

$\Delta = 0.21$

$p < 0.000$

# Is leakage associated with dwell times of pen needles under the skin?

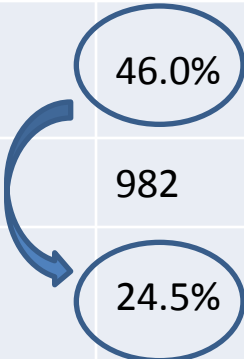
Dwell Times	Leakage		Total
	Yes	No	
< 5 sec	649	936	1585
	40.9%	59.1%	100.0%
5–10 sec	1512	2394	3906
	38.7%	61.3%	100.0%
> 10 sec	974	1751	2725
	35.7%	64.3%	100.0%
I'm not aware of how long	142	189	331
	42.9%	57.1%	100.0%



**p = 0.001**

# Is there an association between leakage and pain?

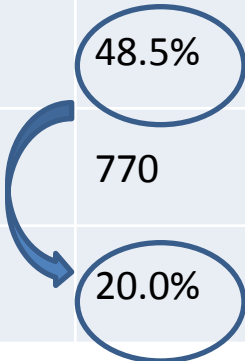
		Leakage		Total
		Yes	No	
Pain	Yes	2296	2700	4996
	%	46.0%	54.0%	100.0%
	No	982	3021	4003
	%	24.5%	75.5%	100.0%



**p < 0.000**

# Is there an association between leakage and bleeding?

		Leakage		Total
		Yes	No	
Bleeding	Yes	2823	3000	5823
	%	48.5%	51.5%	100.0%
	No	770	3075	3845
	%	20.0%	80.0%	100.0%




**p < 0.000**



# Is there an association between leakage and hypoglycemia?

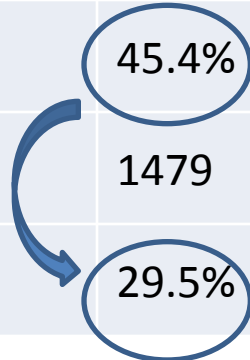
		Leakage		Total
		Yes	No	
Hypo	Yes	2438	3074	5512
	%	44.2%	55.8%	100.0%
	No	1119	2989	4108
	%	27.2%	72.8%	100.0%



**p < 0.000**

# Is there an association between leakage and hyperglycemia?

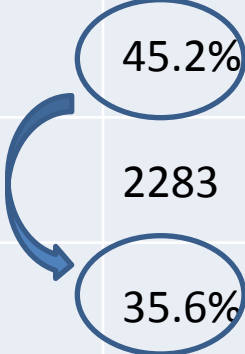
		Leakage		Total
		Yes	No	
Hypers	Yes	2021	2430	4451
	%	45.4%	54.6%	100.0%
	No	1479	3529	5008
	%	29.5%	70.5%	100.0%



**p < 0.000**

# Is there an association between leakage and unexplained hypos?

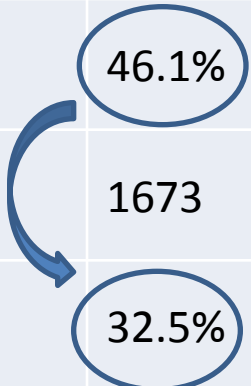
		Leakage		Total
		Yes	No	
Unexplained hypo	Yes	690	835	1525
	%	45.2%	54.8%	100.0%
	No	2283	4137	6420
	%	35.6%	64.4%	100.0%



**p < 0.000**

# Is there an association between leakage and glucose variability?

		Leakage		Total
		Yes	No	
Glucose variability	Yes	1286	1504	2790
	%	46.1%	53.9%	100.0%
	No	1673	3467	5140
	%	32.5%	67.5%	100.0%



**p < 0.000**

# Is there an association between leakage and lifting a skin fold?

		Leakage		Total
		Yes	No	
Skin fold	Yes	1949	3200	5149
	%	37.9%	62.1%	100.0%
	No	1044	1879	2923
	%	35.7%	64.3%	100.0%

**p = 0.056**

# Is there an association between leakage and angle of insertion?

		Leakage		Total
		Yes	No	
Angle	Yes	489	774	1263
	%	38.7%	61.3%	100.0%
	No	2543	4309	6852
	%	37.1%	62.9%	100.0%

**p = 0.279**

# Is there an association between leakage and BMI?

Leakage	BMI	SD	N
Yes	27.1	6.8	3382
No	27.8	6.5	5981

**p = 0.736**

# Conclusions (1)

- Just over 1/3 of patients report leakage of insulin from the skin.
- Of these, 5 out of 6 say it occurs rarely (several times a month or a year).
- Leakage occurs more frequently in T1DM patients than T2DM.
- Leakage appears to be more frequent if patients have LH or inject into LH, do not leave the pen needle under the skin for 10 seconds after injecting or do not rotate injections correctly.



# Conclusions (2)

- The longer pen users leave the needle under the skin after the plunger is pushed in (and especially if they reach the 10-second goal) the less leakage is reported.
- Of patients who weren't aware how long they left the needle in, almost half had leakage.

# Conclusions (3)

- Leakage is associated with pain, bleeding, hypo- and hyperglycemia, unexplained hypoglycemia and glucose variability.
- Leakage is not associated with needle reuse, the type of insulin used, lifting a skin fold, the angle of insertion or BMI.
- Patients with leakage used on average 5 more units of insulin a day and had slightly higher HbA1c.