Guy's and St Thomas' NHS
NHS Foundation Trust

BACK TO BASICS
INSULIN PUMP INFUSION SETS (IIS)

SMALL BITS OF KIT HAVE BIG EFFECTS ON THE SAFETY AND SUCCESS OF PUMPING

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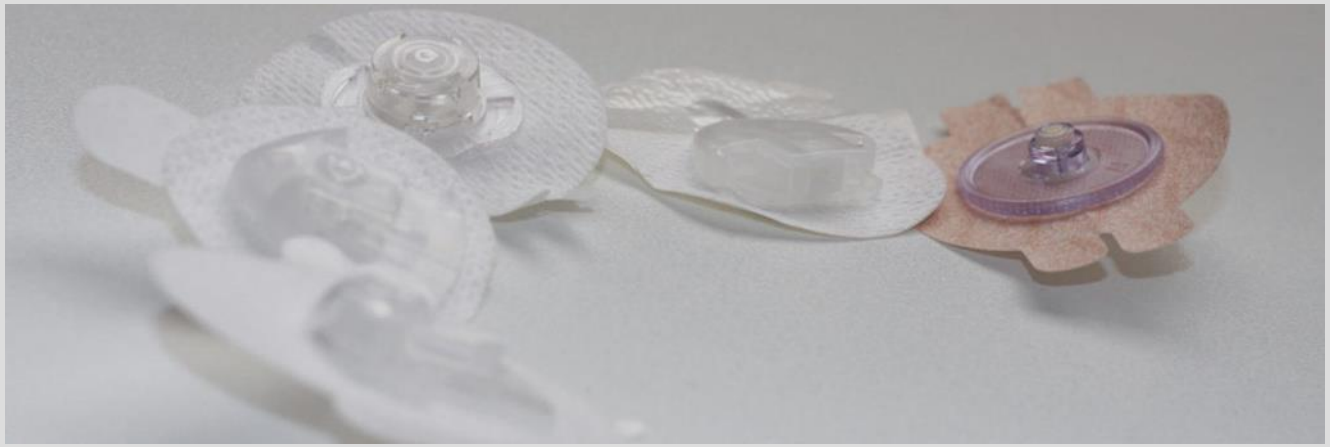
Advanced nurse practitioner

Diabetes

Guy's & St Thomas' Hospital



KING'S HEALTH PARTNERS

CONTENT

- What are the real life issues Insulin Pump users and Educators need to consider ?
- What is an Insulin Infusion System ?
- What factors to consider when choosing IIS ?
- IIS complications reported in practice
- IIS Case Studies
- Recommendations to reduce IIS complications

ISSUES TO CONSIDER

- High rates of reported blocked cannulas/dislodgement
- Unpredictable variability in insulin absorption
- Silent occlusions - no alarm
- Skin complications
- Demands on the patient of frequent set changes & site rotation
- Reduced trust and confidence in pump therapy if the IIS fails
- Essential component to more precise insulin delivery & emerging closed loop insulin pumps
- New challenges with a long duration & an ageing pump population
- Neglected topic in research

WHAT IS AN IIS ?

- **Cannula -** One end of this tubing is attached to a needle that goes through the skin into the subcutaneous (SC) adipose tissue. The needle is either a steel needle or a thicker plastic cannula of Teflon which stays in the skin after its insertion, while a metal mandarin is removed.
- **Hub -** the plastic piece and adhesive dressing that sits on top of the skin, that holds the cannula in place
- **Tubing** - flexible tube that carries the insulin from the pump to the infusion site
- **Connector** - The other end of he tubing is connected to the pump's insulin cartridge via a Luer-lock or proprietary connector.

FACTORS TO CONSIDER WHEN CHOOSING THE IIS
NUMBER 1 – THE CANNULA

BENEFITS OF A FIXED STEEL

- It will not kink – Removes a variable
- Good choice for small children where reliability is essential
- Option in people with low BMI
- Option when sensitivity to Teflon

DISADVANTAGE

- Uncomfortable if knocked
- Requires changing after 48 hrs
- Requires anchoring

BENEFIT OF FLEXIBLE CANNULA

- Comfort and not feeling it once it is in
- The inserter helps place the tip of the needle in the SC tissue consistently
- Longer duration of wear – 3 days
- Change the angle – penetration depth
- Widely available – most used IIS
- 6mm needle appropriate for most children, teens and adult
- Above 6mm for > BMI or very large boluses

DISADVANTAGE

- Can bend when inserted
- Or kink when it contacts muscle
- Interruption of insulin flow leading to hyperglycaemia and ketosis

THE SITE, INSERTION TECHNIQUE AND ANCHORING

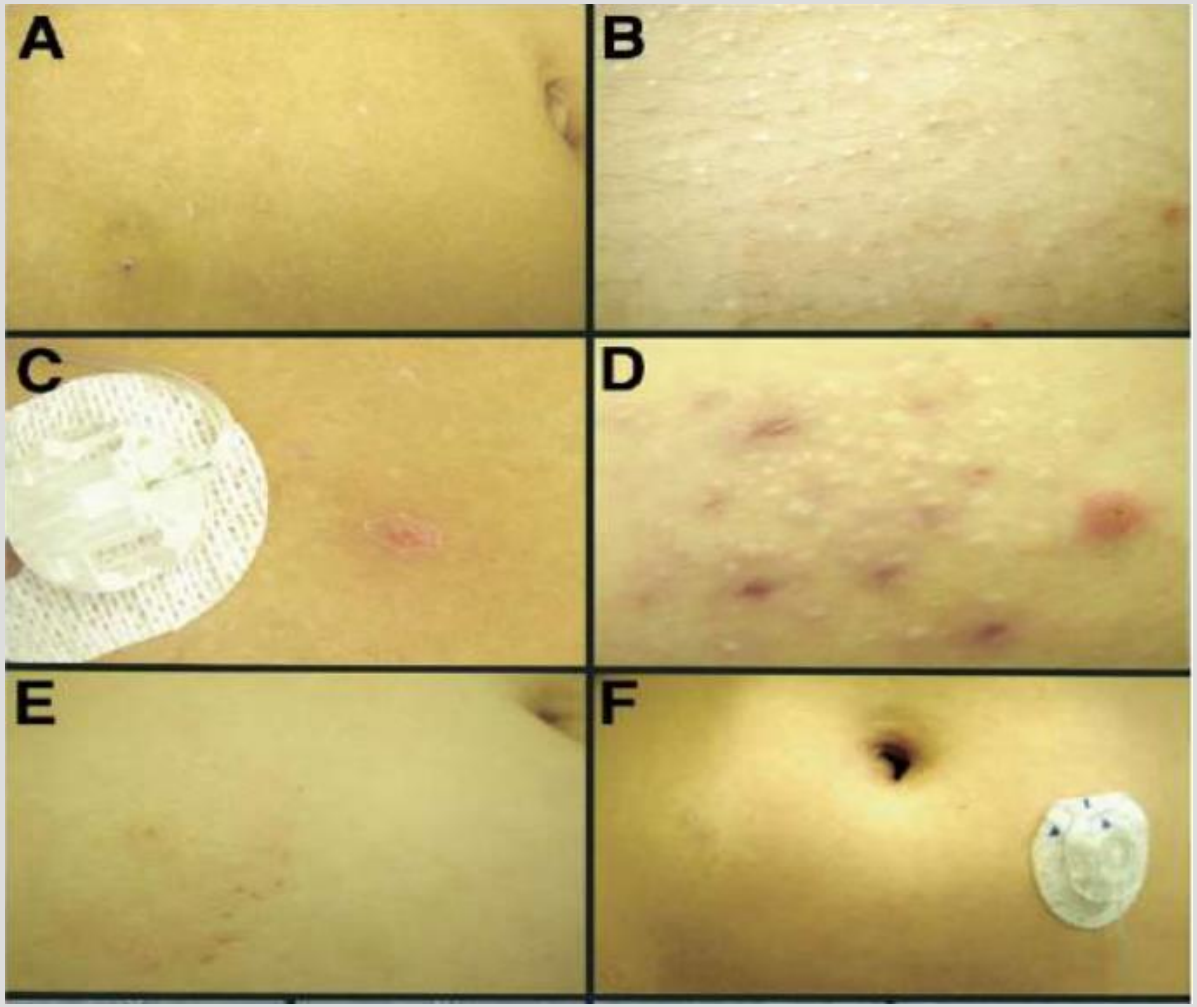
FACTOR NUMBER 2

Personal choice

<u>Variables to consider</u>

- Rates of absorption differ by site
- Patient dexterity and visual acuity
- Physical activity
- Disinfecting the infusion site
- Getting the Insertion technique right
- Anchoring the tubing
- Keeping pump stable with clips, belts, bra pouches

SKIN COMPLICATIONS



A + B: Hypopigmented scars and bruise. C + D: erythematous nodule, E: Epidermal abrasion, F: Bilateral lipohypertrophy.

CHANGING THE IIS AS INSTRUCTED

FACTOR NUMBER 3

EVIDENCE

DELAYING IIS USE BEYOND 2-3 DAYS

- Late blockage by insulin precipitation
- Insulin absorption deterioration
- Increases skin complications
- Lipohypertrophy

CHALLENGES

- Hyperglycemic response following IIS change
- Fearful the next IIS will not work as well as the last one
- Uncomfortable, difficult process
- Environmental waste of consumables and insulin
- Routine disrupted by life
- Reminder of burden of diabetes

SUPPORTING THE RIGHT CHOICE

Patient Factors	IIS selection
Age	90˚ insertion angle and consider shorter IIS tube, young children – steel
Lean/Muscular Physical activity	30-45˚ reduce kinking and dislodging Steel needle eliminates kinking
Pregnancy	30-45˚ option when abdominal tissue becomes stretched
Dexterity and visual impairments	90˚ Steel stops kinking Audioclick sideway pull disconnect/reconnection, colour cannulae, longer tubing Simplicity. 90˚ insertion device – for example: Mio Advance
Susceptibility to occlusions	Steel stops kinking IIS with side-ported cannula may reduce risk of sub-alarm flow interruptions due to in-line rises in pressure
Insulin dose	Longer-length catheter for large insulin boli ≥ 25 units and basal rates ≥ 2.5 units/hr
Allergies and infections	Reaction to Teflon or nickel in steel needle
Skin redness/tape allergies	30-45˚ angle viewing window allows monitoring Adhesive barriers – skin prep-Cavlon, hydrocolloid tapes
Lipohypertrophy/Scarring	Rotation of site 2-3 days, longer length catheter

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 16, Number 3, 2014

DOI: 10.1089/dia.2013.0192

DTT
Diabetes Technology & Therapeutics

ORIGINAL ARTICLE

Nonmetabolic Complications of Continuous Subcutaneous Insulin Infusion: A Patient Survey

John C. Pickup, BM, DPhil,[1] Nardos Yemane, BSc, SRD,[2] Anna Brackenridge, MD,[2] and Siobhan Pender, MSc[2]

TABLE 2. INFUSION SET AND INFUSION SITE PROBLEMS

Problem	*%*
Infusion set	
Kinking	64.1
Frequent kinking	12
Blockage	54.3
Frequent blockage	9.8
Leakage	16.3
Infusion site	
Lipohypertrophy	26.1
Site infection	17.4
Bleeding or bruising	14.1
Pain or soreness	9.8
Adhesion problems	5.4
Irritation or itchiness	5.4

Data are percentages of all subjects reporting problem at some time during pump treatment.

Number of subjects	92
Age (years)	45.3 ± 12.8
Mean (range) diabetes duration (years)	28.8 ± 12.8 (2.0–67.0)
Median (range) duration of CSII (years)	3.3 (0.5–32.0)
Mean (range) duration of infusion set use (days)	3.2 ± 0.7 (2.0–6)
Pump manufacturer (% of subjects)	
Medtronic	84.8
Roche	9.8
Animas	5.4
Pump insulin (% of subjects)	
Aspart	55.8
Lispro	40.7
Glulisine	3.5
Infusion set (% of subjects)	
Medtronic Quick-Set[a]	72.0
Medtronic Mio[a]	6.5
Animas Inset[b]	5.4
ACCU-CHEK FlexLink[b]	4.3
Medtronic Silhouette[a]	4.3
Medtronic Sure-T[b]	3.2
ACCU-CHEK Tender[a]	3.2
ACCU-CHEK Rapid-D[b]	1.1

[a]Teflon.
[b]Metal.

Occlusion Detection Time in Insulin Pumps at Two Different Basal Rates

Journal of Diabetes Science and Technology
2018, Vol. 12(3) 608–613

DOI: 10.1177/1932296817750404
journals.sagepub.com/home/dst
SAGE

Guido Freckmann, MD[1], Ulrike Kamecke, MEng[1], Delia Waldenmaier, MSc[1], Cornelia Haug, MD[1], and Ralph Ziegler, MD[2]

Abstract

Background: The detection of insulin infusion set (IIS) occlusions is an important feature of insulin pumps with regard to patient safety. However, there are no requirements for a time limit until an alarm has to be triggered after an occlusion occurred. The standard IEC 60601-2-24 is applicable for insulin pumps and describes test settings and procedures to determine occlusion detection time (ODT).

Methods: In this study, ODT of six different insulin pump models with different IIS (in total 10 different insulin pump systems) was tested for two basal rates (1.0 U/h and 0.1 U/h).

Results: Differences were seen between the tested pump systems. At a basal rate of 1.0 U/h all insulin pump systems showed an acceptable ODT of less than 5 hours. However, at a basal rate of 0.1 U/h, as often used in children, the median ODT ranged from approximately 4 hours to more than 40 hours. With the lower basal rate, median ODT was longer than 6-8 hours for 9 of the 10 systems.

Conclusions: Insulin pump users should not blindly rely on occlusion alarms but perform regular glucose monitoring and manufacturers should develop mechanisms that allow an earlier detection at low basal rates.

OCCLUSION DETECTION TIME (ODT) TAKE HOME MESSAGE

- No common standard that specifies a maximum detection time for insulin pumps
- Silent occlusions may contribute to unexplained hyperglycemia
- Not all pumps or IIS respond equally when ODT is studied
- Insulin retention for up to 6 hrs is considered safe
- Very small basal rates common in children, the ODT might not be sufficient
- All pumps studied triggered an ODT alarm less than 5 hrs with a basal rate 1.0 unit hr
- IIS material, cannula & tubing length, current basal rate, bolus volume might influence the occurrence and detection of occlusions
- Users must not blindly rely on ODT alarms but perform regular glucose monitoring and check blood ketones in case of prolonged hyperglycaemia
- Remind users the pump cannot detect when the IIS is leaking or the cannula has slipped out of the infusion site
- Develop insulin pumps/IIS with robust predictive alarms for detecting occlusions

JOURNAL OF FORENSIC SCIENCES

J Forensic Sci, January 2019, Vol. 64, No. 1
doi: 10.1111/1556-4029.13841
Available online at: onlinelibrary.wiley.com

CASE REPORT

PATHOLOGY/BIOLOGY

Andrew Ziegler,[1] *B.S.*; *Timothy Williams*,[2] *M.D.*; *Nicole Yarid*,[3] *M.D.*; *Daniel L. Schultz*,[4] *M.D.*; *and Elizabeth A. Bundock*,[5] *M.D., Ph.D.*

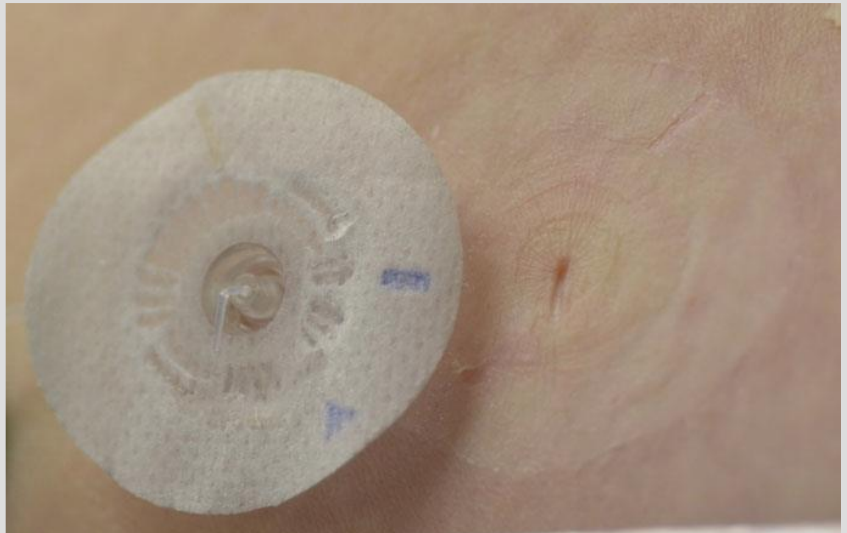
Fatalities Due to Failure of Continuous Subcutaneous Insulin Infusion Devices: A Report of Six Cases*

FATALITIES DUE TO FAILURE OF CSII DEVICES

TABLE 1—*Case characteristics, the types of insulin infusion set malfunctions, autopsy findings, and cause and manner of death for the six investigated cases.*

Case	Age	Sex	Circumstances of Death	Diabetes Diagnosis	Condition of Cannula	Cannula Insertion Style	Autopsy Findings	CSII Data Reviewed	Cause of Death	Manner of Death	Jurisdiction
1	73	F	Unwitnessed at residence	Type I	Nonpenetrating/bent	Perpendicular	No anatomical abnormalities	Yes	Complications of diabetes mellitus, type 1	Natural	VT
2	39	M	Unwitnessed at residence	Type I	Nonpenetrating/straight	Angled	No anatomical abnormalities	Yes	Diabetic ketoacidosis	Accident	King County, WA
3	52	M	Unwitnessed at residence	Unspecified	Nonpenetrating/bent	Angled	No anatomical abnormalities	No	Diabetic ketoacidosis	Accident	King County, WA
4	44	M	Unwitnessed at residence	Type II	Nonpenetrating/bent	Perpendicular	No anatomical abnormalities	No	Diabetic ketoacidosis	Accident	King County, WA
5	60	F	Unwitnessed at residence	Unspecified	Nonpenetrating/bent	Perpendicular	Subgaleal hemorrhages (consistent with fall), esophageal ulcer	No	Diabetic ketoacidosis	Natural	Erie County, NY
6	37	M	Unwitnessed at residence	Type I	Nonpenetrating/bent	Perpendicular	Cardiovascular disease	No	Diabetic ketoacidosis	Natural	District 12, FL

Case 1



Case 2

J Forensic Sci, January 2019, Vol. 64, No. 1
doi: 10.1111/1556-4029.13841
Available online at: onlinelibrary.wiley.com

OMNIPOD

The pod IS the infusion set

How to place the pod

Arms & Leg – vertically at slight angle

Back, abdomen and buttocks – Horizontally at a slight angle

Benefits

Tubeless

Hidden needle

Access to more sites

No disconnect

Have to change every 72hrs

Less steps

Challenges

Keeping the pod cannula stable – small children/contact sports

Leaking pods

Skin reactions

Anatomical positioning of the pods

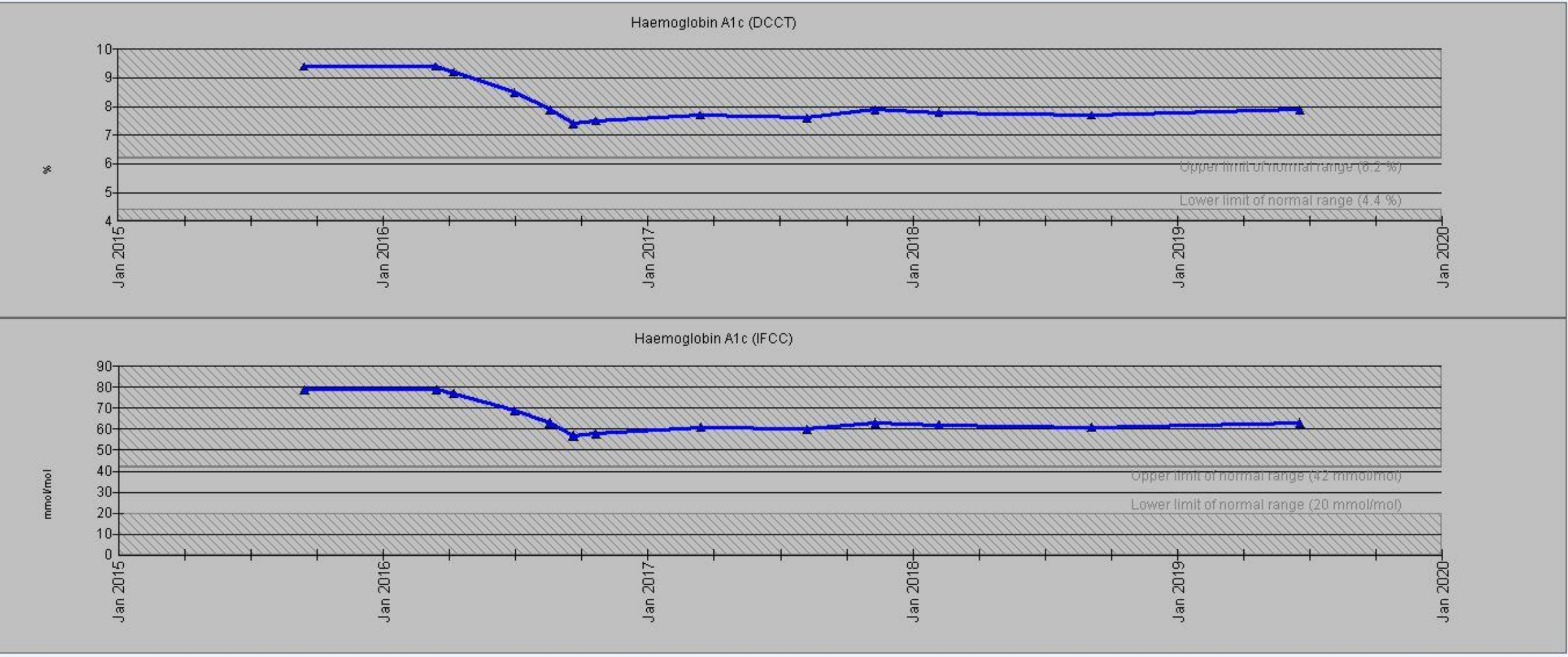
Place your hand over the pod and make a wide pinch around Your skin surrounding the viewing window. Then press the START button on the Personal Diabetes Manager. Let go when the Cannula inserts.

CASE STUDY 1

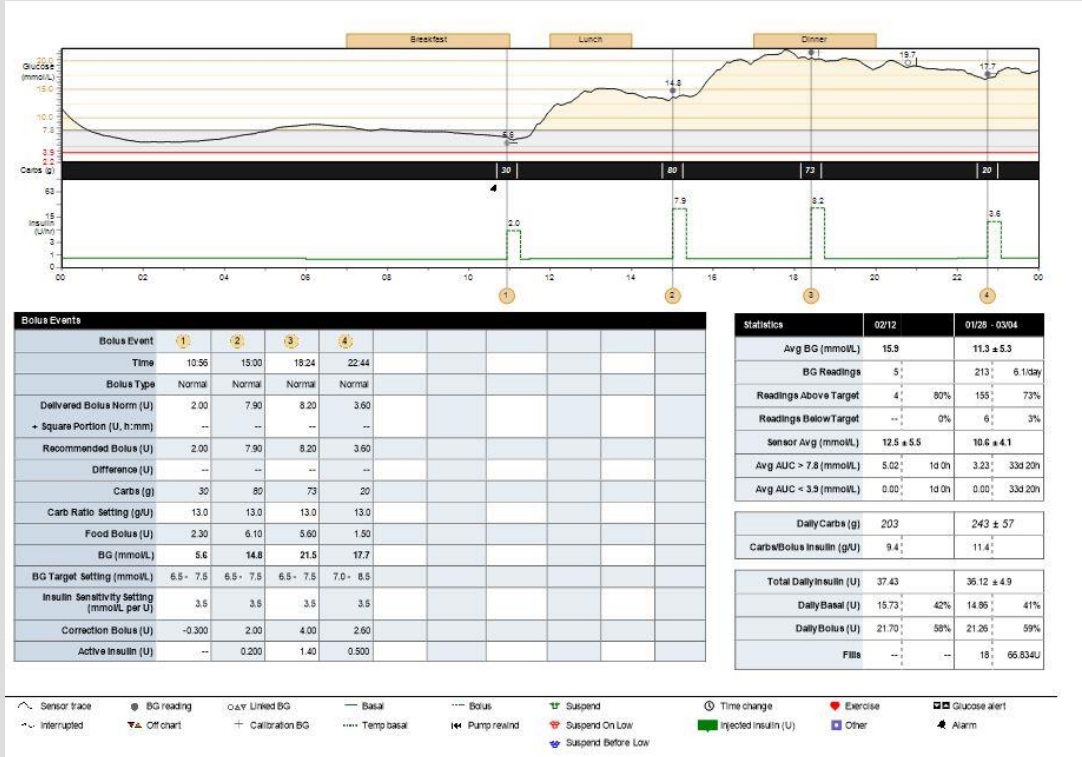
- 52yr old male T1DM 29 yrs
- Hypounaware for 2 years
- 5 severe hypoglycaemia with loss of consciousness in last 2 years
- Lost his job for medical reasons
- Has nystagmus an is severely visually impaired
- Testing blood glucose levels InsulinX meter
- Self injects – listens for clicks
- Attended a local structured Type1DM education programme

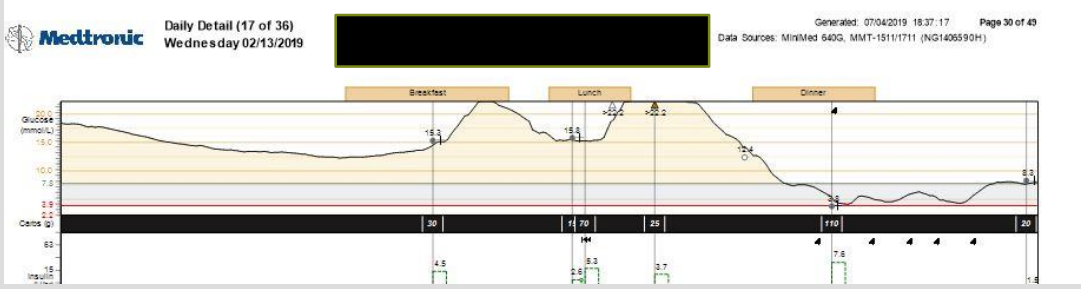
CASE STUDY 1

- 2015 referred to GSTT
- 2015 insulin pump pre assessment
- 2016 Risk of DKA highlighted and agreed his partner would change his IIS and ensure the insulin pump was working
- 2016 March 1:1 Medtronic 640G Saline pump start with (MIO 6mm 60cm)
- 2016 May 1:1 Insulin pump start
- 2016 June activity holiday – two failed cannulas CBGL > 30mmol/l
- 2016 July Requires partner to manage IIS - < 3 hypos per week, No severe hypoglycaemia
- 2016 End July Pump failure 'pump blocked' over night VRII – DKA dislodged cannula which occurred in the early hrs of the morning
- 2016 August 1:1 training with patient and partner changed to MIO 30
- 2016 September Frequency of hypoglycaemia had reduced dramatically and his confidence has improved
- 2016 October started socialising/going to the gym/reformed his band
- 2017 March recurring severe hypoglycaemia
- 2017 Sept A&E admission hyperglycaemia - no VRII
- 2017 Nov referred to study for hypoglycaemia unawareness
- 2018 Jab Pump failure – replacement pump
- 2018 Feb Severe hypoglycaemia requiring glucagon
- 2018 Sept started on augmented CGMS with 640G
- 2019 May DKA - Admitted
- 2019 June trial Sure T- 6mm longer tubing. Repeat education
- 2019 July Sure T not successful MiniMed Mio 30 110cm tubing, 13mm cannula/3M Tegaderm Film
- 2019 Nov 3M Tegaderm Absorbent Clear Acrylic Dressing 7.6cm x 9.5cm

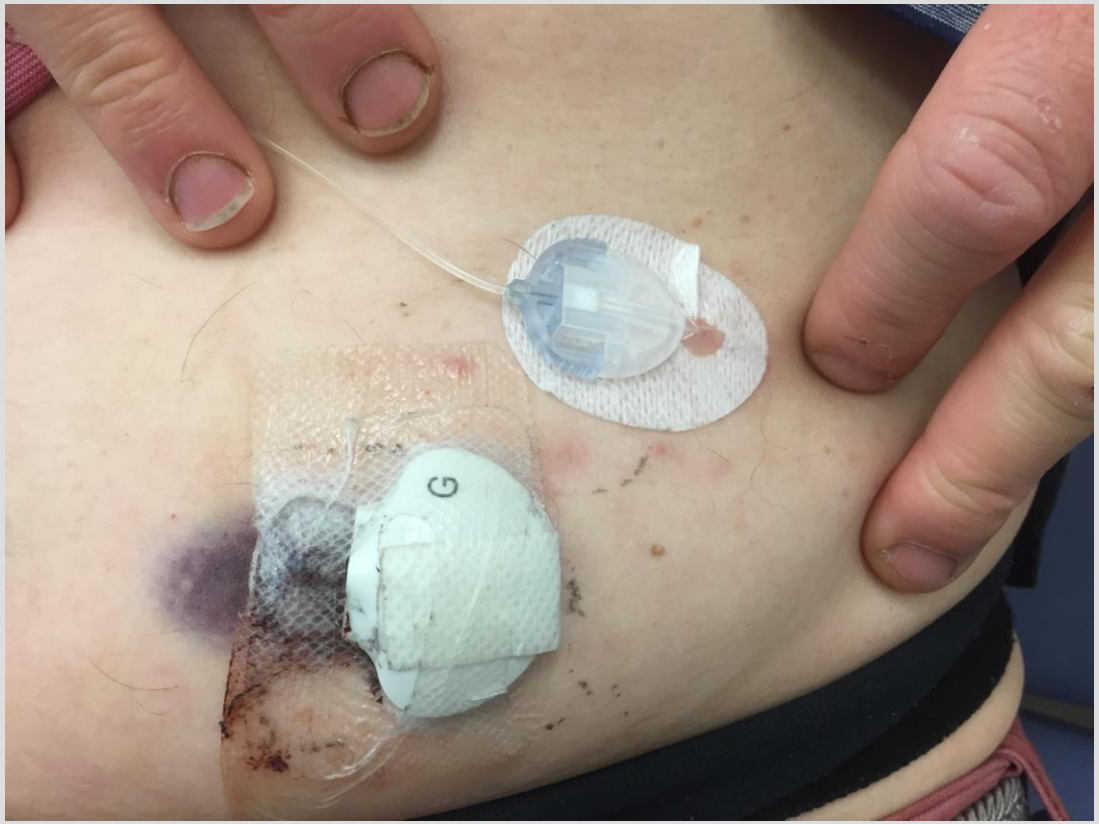

Haemoglobin A1c (DCCT)
%
10
9
8
7
6
5
4
Upper limit of normal range (6.2 %)
Lower limit of normal range (4.4 %)
Jan 2015
Jan 2016
Jan 2017
Jan 2018
Jan 2019
Jan 2020
Haemoglobin A1c (IFCC)
mmol/mol
90
80
70
60
50
40
30
20
10
0
Upper limit of normal range (42 mmol/mol)
Lower limit of normal range (20 mmol/mol)
Jan 2015
Jan 2016
Jan 2017
Jan 2018
Jan 2019
Jan 2020

CHALLENGES


Breakfast
Lunch
Dinner
Glucose (mmol/L)
Carbs (g)
Insulin (U/hr)
Bolus Events
Bolus Event
Time
Bolus Type
Delivered Bolus Norm (U)
+ Square Portion (U, h:mm)
Recommended Bolus (U)
Difference (U)
Carbs (g)
Carb Ratio Setting (g/U)
Food Bolus (U)
BG (mmol/L)
BG Target Setting (mmol/L)
Insulin Sensitivity Setting (mmol/L per U)
Correction Bolus (U)
Active Insulin (U)
Statistics
Avg BG (mmol/L)
BG Readings
Readings Above Target
Readings Below Target
Sensor Avg (mmol/L)
Avg AUC > 7.8 (mmol/L)
Avg AUC < 3.9 (mmol/L)
Daily Carbs (g)
Carbs/Bolus Insulin (g/U)
Total Daily Insulin (U)
Daily Basal (U)
Daily Bolus (U)
Fills
Sensor trace
BG reading
Linked BG
Basal
Bolus
Suspend
Time change
Exercise
Glucose alert
Interrupted
Off chart
Calibration BG
Temp basal
Pump rewind
Suspend On Low
Injected Insulin (U)
Other
Alarm
Suspend Before Low


Medtronic
Daily Detail (17 of 36)
Wednesday 02/13/2019
[redacted]
Generated: 07/04/2019 18:37:17
Page 30 of 49
Data Sources: MiniMed 640G, MMT-1511/1711 (NG1406590H)
Breakfast
Lunch
Dinner
Glucose (mmol/L)
Carbs (g)
Insulin (U/hr)

CHALLENGES



Next steps:

- If we exhaust IIS options - what next ?

- Explore Risks v benefits of returning to MDI
- + CGM

- RE: Severe hypoglycaemia
- RE: DKA risk

- Involve patient + Family + MDT

CASE STUDY 2

- 57yr old female T1DM 48 yrs
- MI 2012 , Carpel tunnel
- Nocturnal hypoglycaemia
- One severe hypoglycaemia requiring paramedic 2015
- Husband works nights, Fear of hypoglycaemia
- DAFNE 2010
- CBGM > 10 times per day

CASE STUDY 2

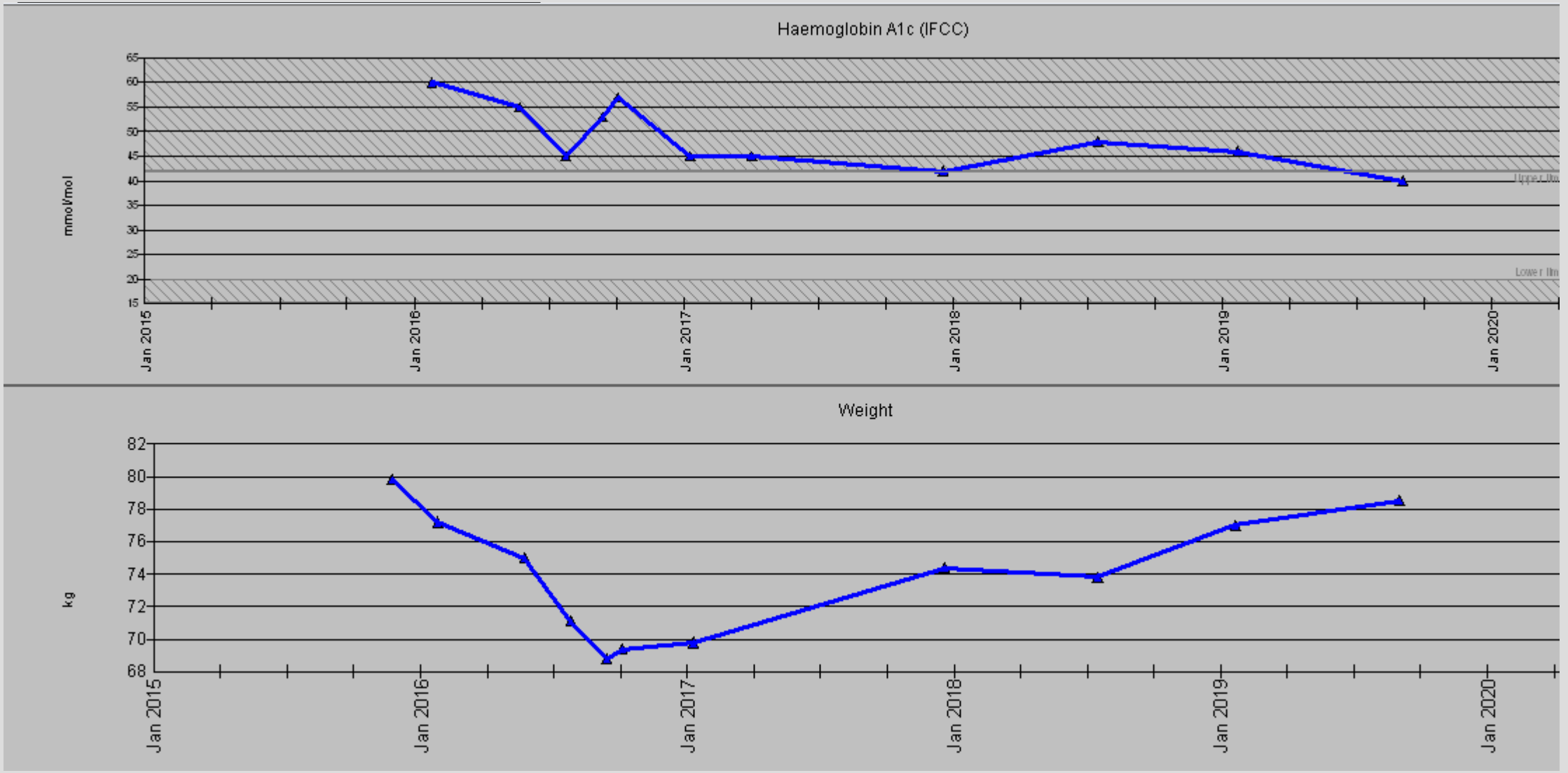
- 2015 Nov referred to GSTT severe hypoglycaemia
- 2016 Jan insulin pump pre assessment – Appropriate MDI
- 2016 Feb DSN/Dietician/Psychiatrist
- 2016 March 1:1 Medtronic 640G 1:1 pump start with (Quick set 6mm, 60cm tubing) TDD 20% reduction
- 2016 March 1st week successful
- 2016 March reverted back to MDI – lost confidence IIS failures
- 2016 April restarted CSII in the hospital

- Urgent review due to issues with IIS
- Reviewing technique and insertion of cannula. Excellent and correct approach utilising Medtronic handbook.
- **Issues:**
- Limited dexterity pressing down the Quick set inserter
- Areas below unbilicus lipohypertophy and loose skin as had lost 30kg over recent years.
- The cannula entering the dermal layer rather than subcutaneous tissue
- Insert the cannula above her waistband.
- For dexterity moved to the MIO 6mm with 60cm tubing

CASE STUDY 2

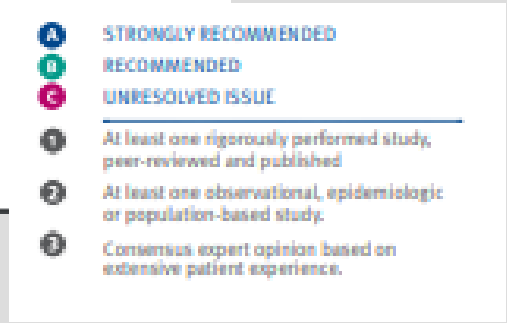
- 2016 June Reports hypoawareness
- 2016 July weight loss caused reduced insertion sites
- 2016 August Local referral for excess skin apron flap surgical removal
- 2016 Sept Using Cavilon Barrier
- 2017 Jan On waiting list, IIS discomfort, IIS changes delayed
- 2017 Dec On waiting list for surgery
- 2018 July CSII 3 years, optimal biomedical outcomes
- 2019 Jan 2019 Sept successful outcome following Abdominoplasty surgery allowed her to use more of her abdomen for insulin infusion sites for the pump

IIS insertion

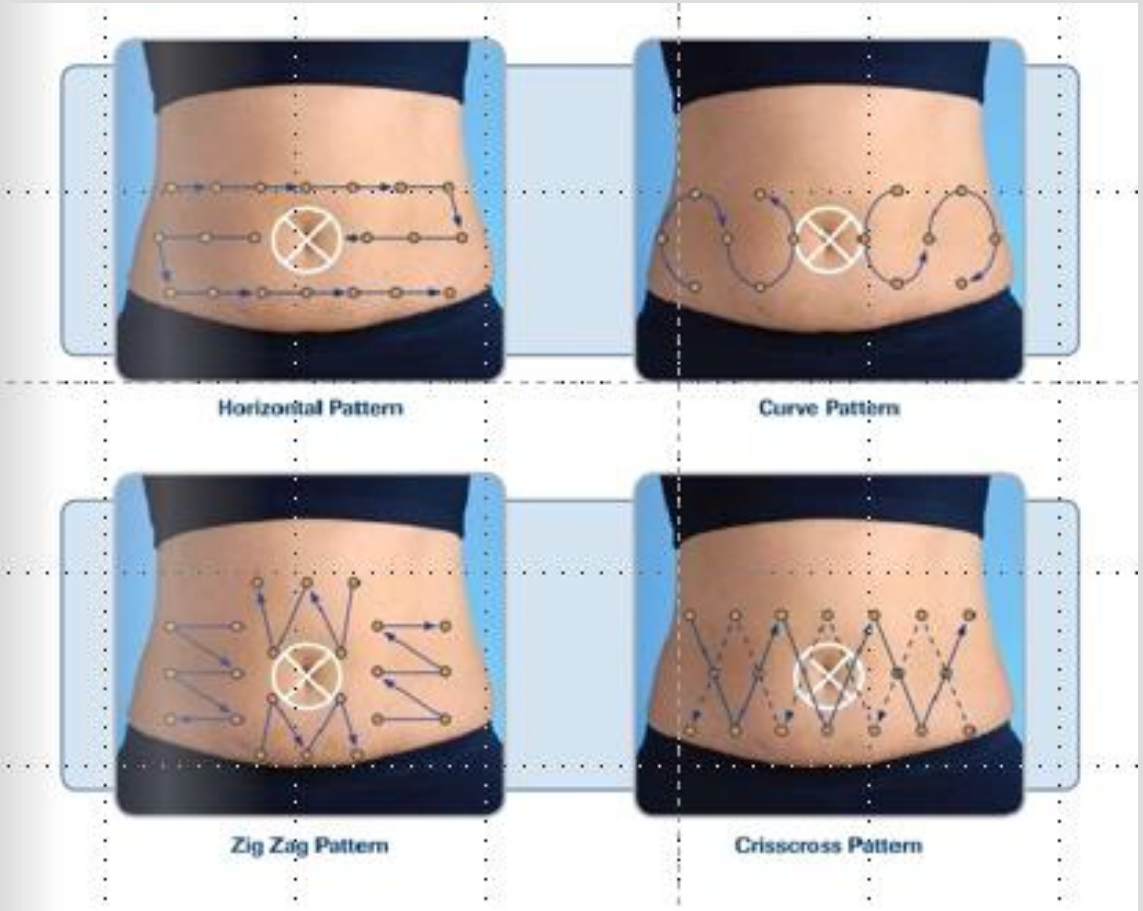

Haemoglobin A1c (IFCC)
mmol/mol
65
60
55
50
45
40
35
30
25
20
15
Upper lim
Lower lim
Jan 2015
Jan 2016
Jan 2017
Jan 2018
Jan 2019
Jan 2020
Weight
kg
82
80
78
76
74
72
70
68
Jan 2015
Jan 2016
Jan 2017
Jan 2018
Jan 2019
Jan 2020

FIT UK FORUM FOR INJECTION TECHNIQUE UK: 4TH EDITION

1. Change IIS every 48- 72hrs
2. Teach patients how to rotate IIS
3. Site check unexplained glucose variability
4. Annual check for Lipohypertrophy
5. Lipohypertrophy suspected change IIS site
6. Suspect silent occlusion or interruption of insulin flow with unexplained glucose variability/or hyperglycaemia consider alternate IIS



SITE ROTATION



- Using a pattern can help site rotation
- Choose a new site at least 5cm from the recent site
- Avoid the area within 5cm of the belly button
- Avoid waistbands
- Teach how to self-inspect signs lipohypertrophy
- Remain using same area if possible to reduce variability
- Check cannulae twice a day
- Set up insulin infusion set change alerts on the pump

STANDARD RECOMMENDATIONS TO IMPROVE IIS OUTCOMES

Asking the right questions following a IIS failure

Table 5 Causes of unexplained hyperglycaemia

Possible causes of unexplained hyperglycaemia		
Infusion Set	**Insulin Pump**	**Insulin**
• Is the tubing primed or filled with insulin? • Is there air in the tubing? • Did you remember to fill the cannula with insulin after inserting new set? • Is the tubing connected to the cartridge? • Is the set connected to your body? • Are there any leaks? • Is the cannula dislodged or kinked? • Has the infusion set been in longer than 2-3 days? • Is there redness or discomfort at the site? • Is there blood on/at the site?	• Did you forget your last bolus? • Have you received any recent alarms? • Is your cartridge empty? • Is the date and time correct? • Are your basal rates programmed correctly?	• Is your insulin expired/inactive? • Has your insulin been exposed to extreme temperatures? • How long has the insulin been in the cartridge and tubing?

RECOMMENDATIONS

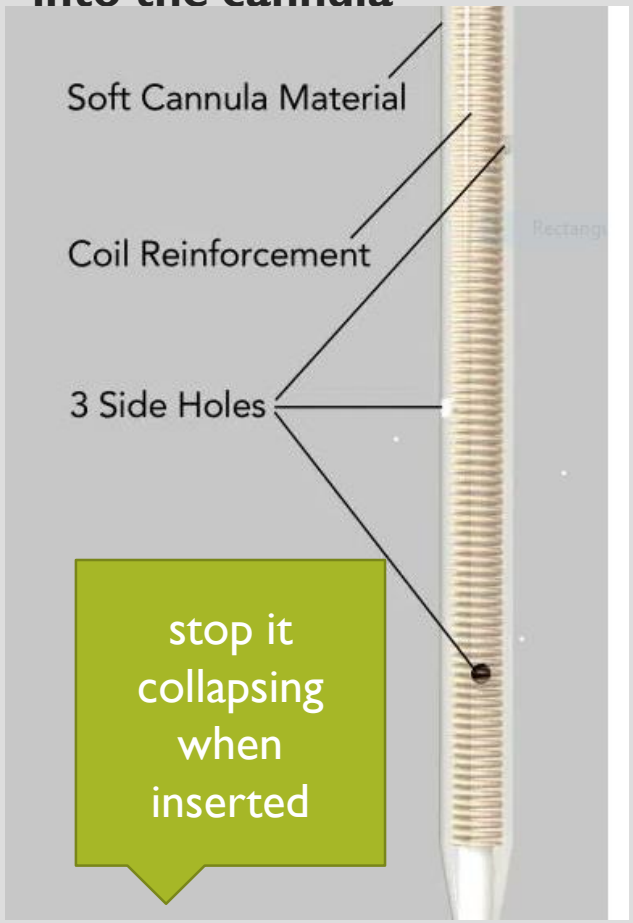
- Robust standardised education packages people with T1DM at new start and annually
- Increased emphasis on site rotation, skin care, and distinguishing between what is healthy and unhealthy tissue
- Using downloads to detect/troubleshoot unexplained hyperglycaemia/flow interruptions
- Not relying on the CSII inbuilt alarms
- Robust audits – reasons for pump failures, DKA, tissue infection events

CONCLUSIONS

- Insulin set remains the weak point of pump use & largely under appreciated
- Wear-time considerably varies between patients and the choice of catheter material
- IIS recommendations are based on personal preferences and clinician experience rather than scientific facts
- The rate of local and glycaemic infusion set complications in long-term pump users is high, regardless of education status or site choice
- IIS can contribute to potentially life-threatening problems of unexplained hyperglycaemia

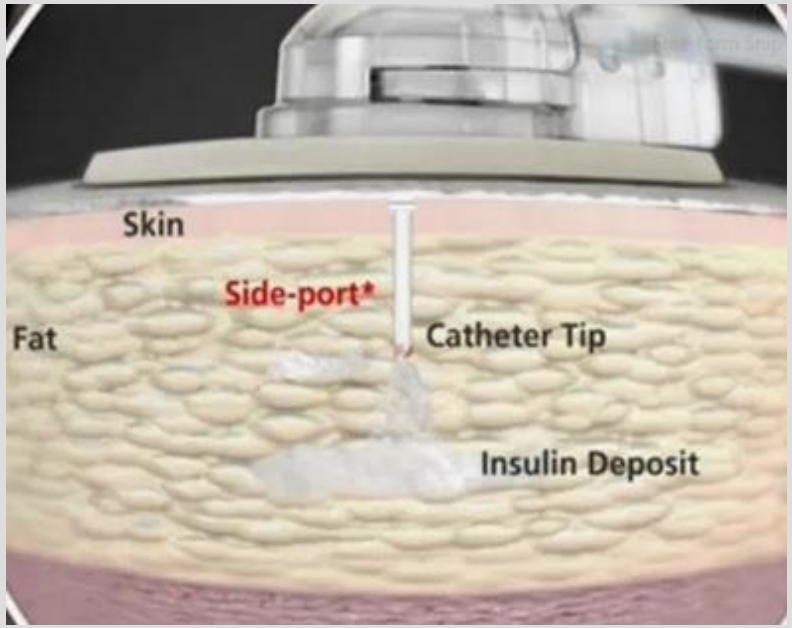
CURRENT AREAS OF RESEARCH

A coil reinforcement into the cannula



stop it collapsing when inserted

FlowSmart and Steadiflow and helps reduce unplanned insulin flow interruptions



side opening, spread out double surface area facilitates flow even if the cannula tip is blocked

Lantern infusion set

Intended to allow for long insertion periods

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