Il diavolo veste…. la tecnologia: un delicato equilibrio tra visibilità e comfort

Tommaso Daffara
SCDU Endocrinologia, AOU Maggiore della Carità, Novara

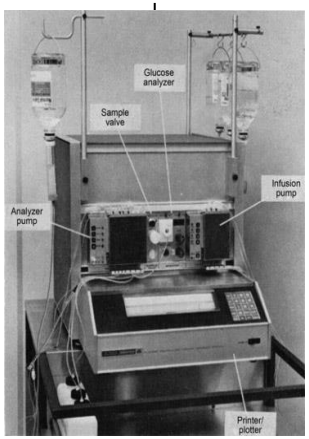
Torino, 10 Giugno 2023

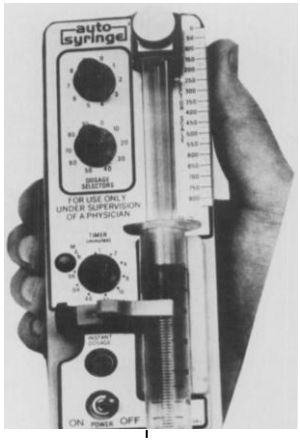
Agenda

- Cenni storici
- Generalità
- Tipologie di patch pump (PP)
- Il punto di vista degli interessati
- Vantaggi delle patch pump
- Svantaggi delle patch pump
- Conclusioni

1961
Arnold Kadish

1964
Biostator





1976
Autosyringe

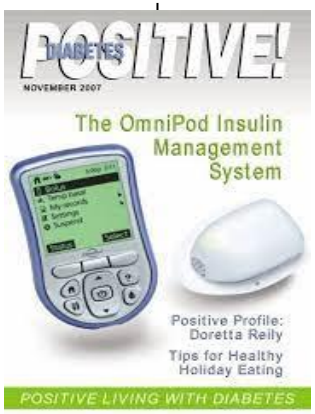
PRIMO TEMPO: COGITO ERGO SUM Diabete e tecnologia: la conosco?

SECONDO TEMPO: INTELLEGO ERGO SUM Diabete, cibo e tecnologia: come la utilizzo

2003

2000

2005



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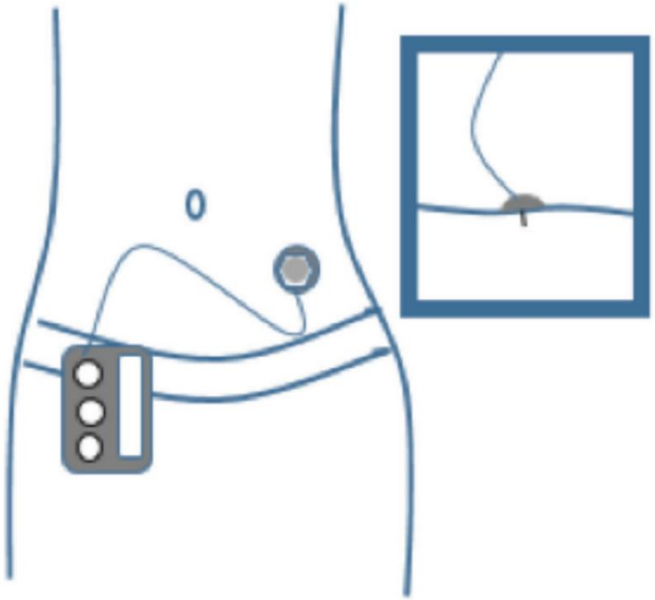
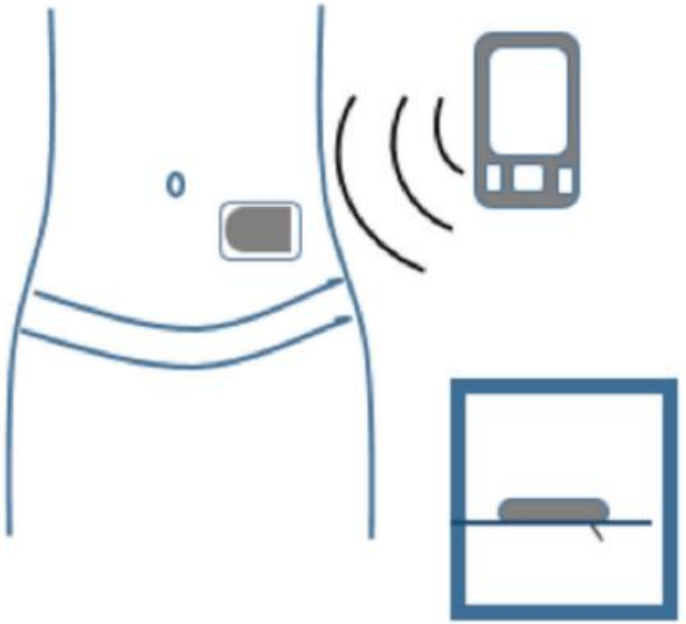




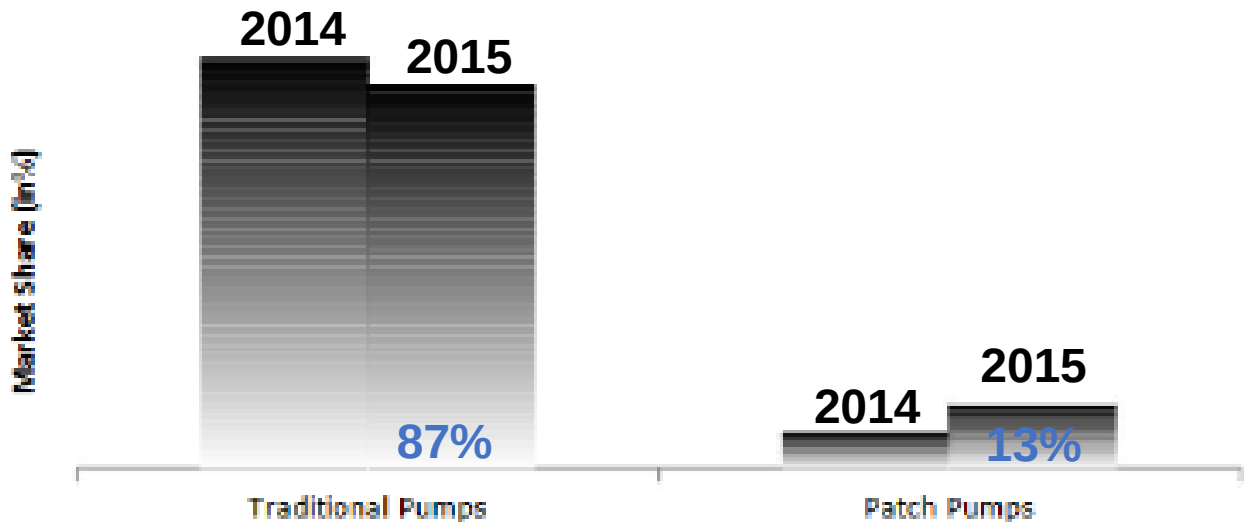
Berget, 2019

Cellnovo Stops Manufacturing and Commercial Operations

Administrators appointed at UK subsidiary have actioned a restructuring plan to focus on identifying strategic partners and investors

March 28, 2019 03:00 PM Eastern Daylight Time

Diffusione delle PP a livello mondiale



Jhon Pickup; Global Insulin Pump Market with Focus on Patch Pumps (2016-2020)

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Semplificati

- Funzionalità ridotte
- Semplici da utilizzare
- Non pensati per DM1

Kulzer, 2022

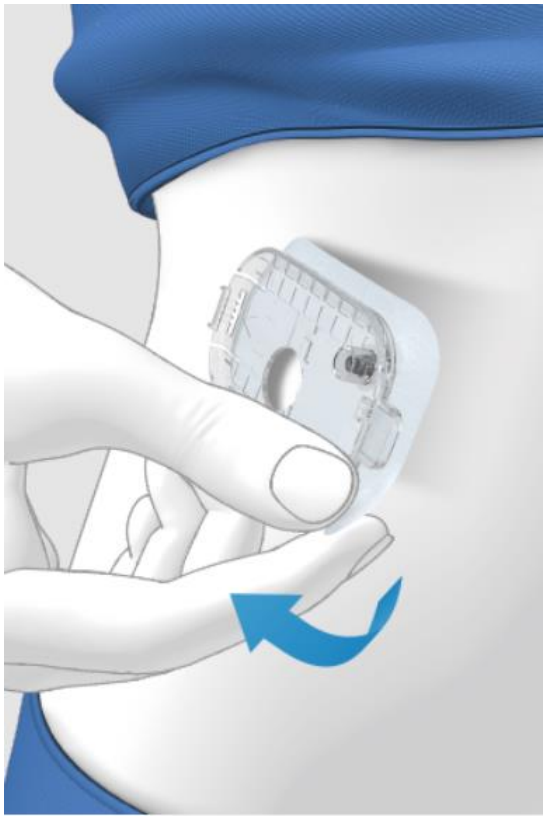
Completi

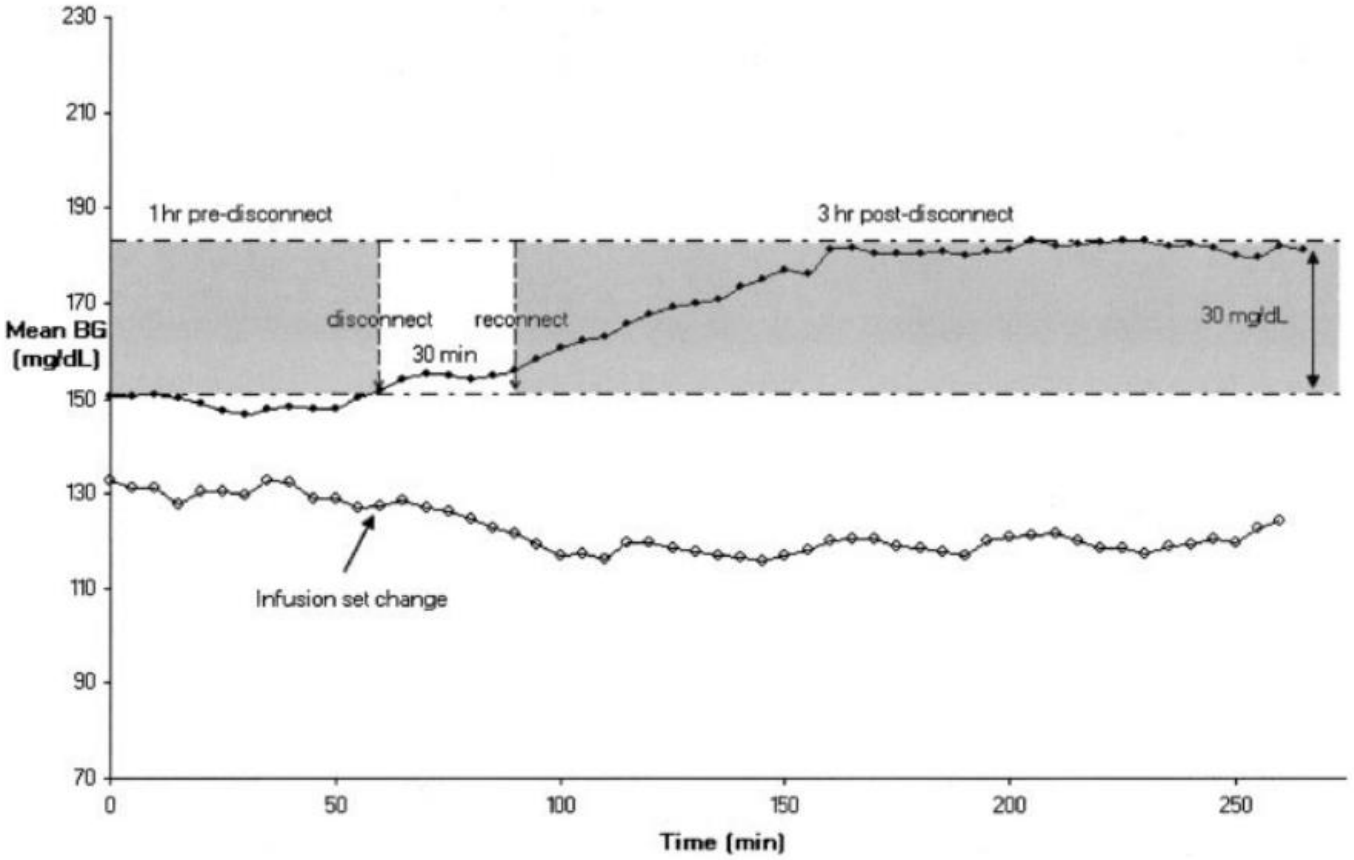
Stesse funzionalità di un microinfusore tradizionale

- Calcolatore di bolo
- Comandati da PDM/Smartphone
- Unità di infusione e impermeabilità

Kulzer, 2022

Unità di Infusione

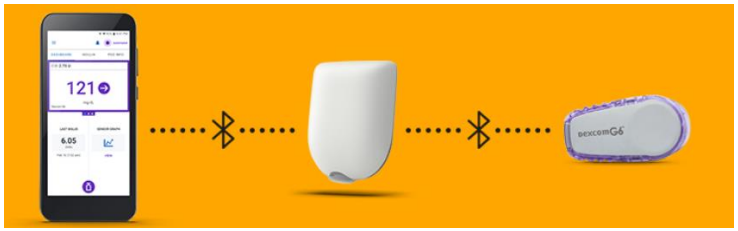



230
210
190
170
150
130
110
90
70
Mean BG (mg/dL)
1 hr pre-disconnect
3 hr post-disconnect
disconnect
reconnect
30 min
30 mg/dL
Infusion set change
0
50
100
150
200
250
Time (min)

Zisser, 2008

Avanzati

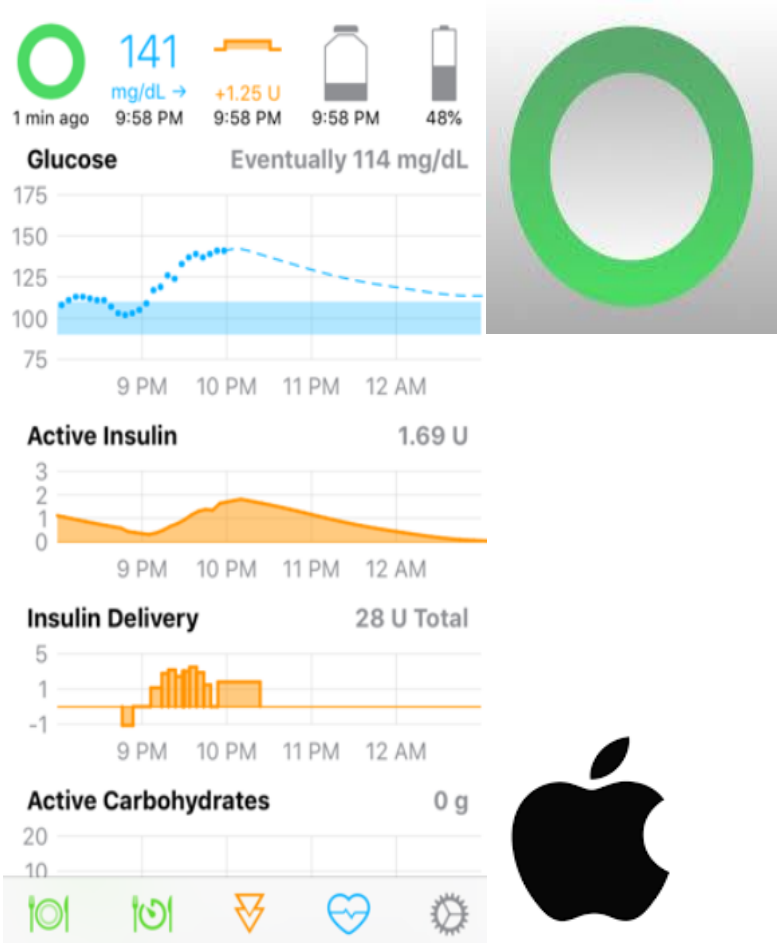
- PLGS
- AHCL
- DIY



Kulzer, 2022

PRIMO TEMPO: COGITO ERGO SUM Diabete e tecnologia: la conosco?

SECONDO TEMPO: INTELLEGO ERGO SUM Diabete, cibo e tecnologia: come la utilizzo



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TOP RANKED NEW PUMP FEATURES

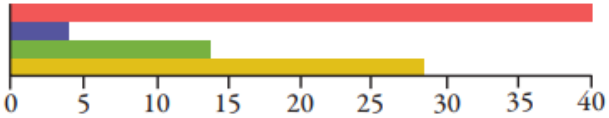
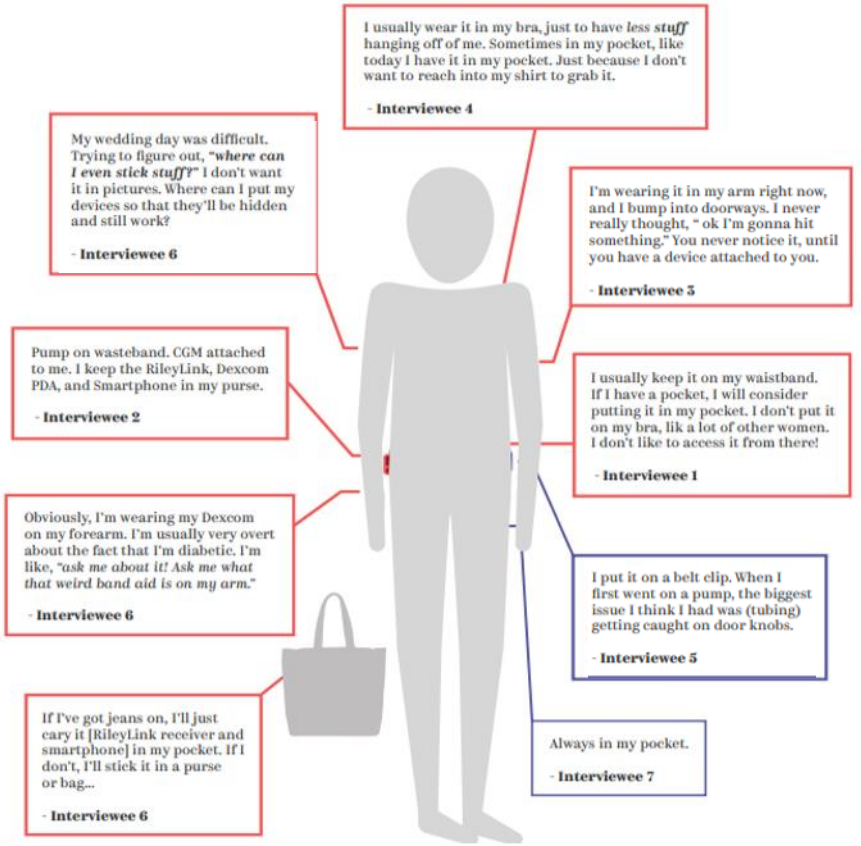


Figure 1: Ranked new features for a novel insulin pump design.

Key: Ranked New Features

- Small wireless controller
- Sends voice alerts to earbuds or hearing aids
- Better haptic/vibration feedback alerts
- Sends current detailed information to a family member

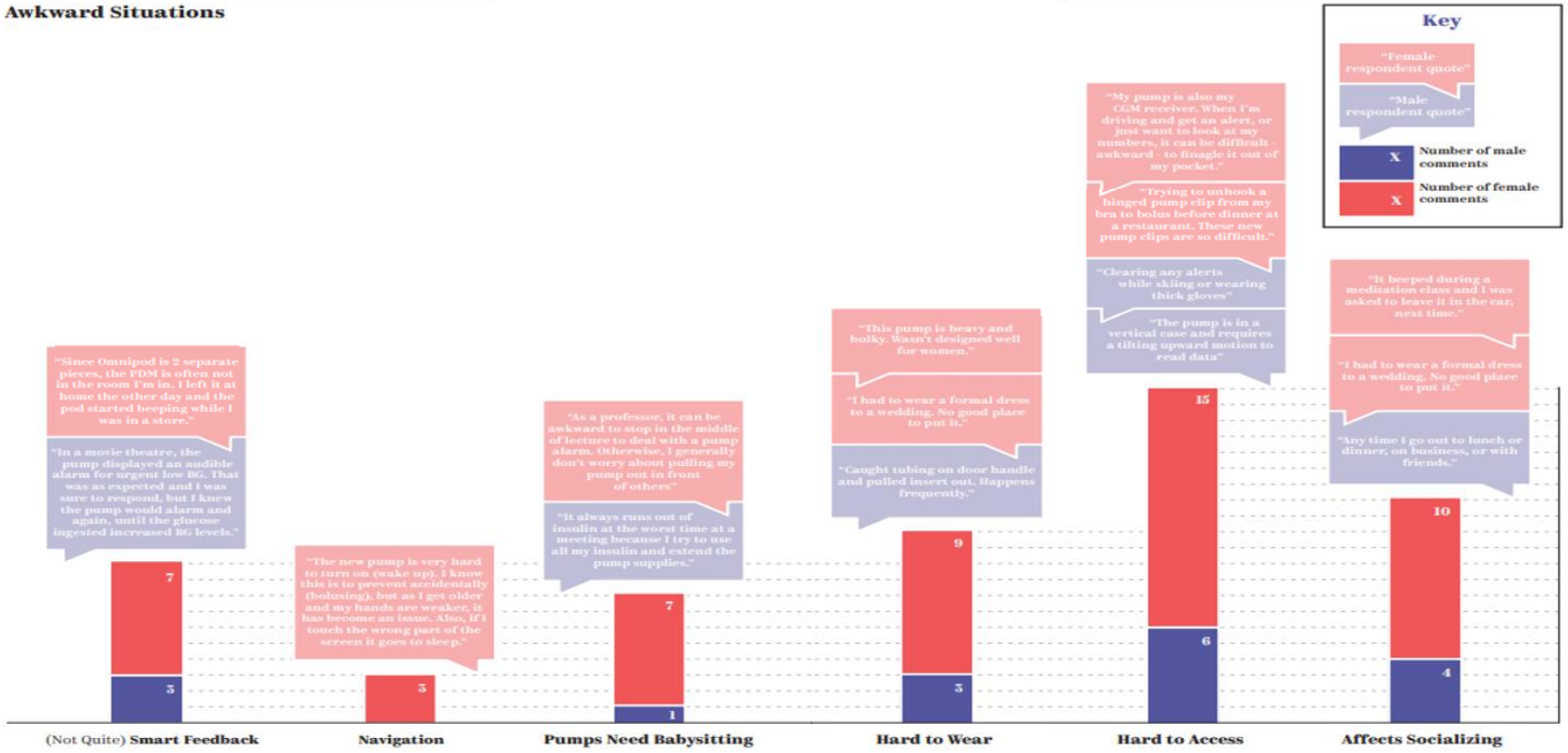
INTERVIEWEE'S PUMP WEARING LOCATIONS



Harper, 2021

PRIMO TEMPO: COGITO ERGO SUM Diabete e tecnologia: la conosco?

SECONDO TEMPO: INTELLEGO ERGO SUM Diabete, cibo e tecnologia: come la utilizzo



Harper, 2021

Perceptions of Psychosocial Factors and the Insulin Pump

Women were more concerned than men about body image and social acceptance with pump use.

One woman described the pump as a "**fashion challenge**": Sometimes I think it's easier. A lot of times,I don't like it. I try and hide it. . . . I very rarely wear it outside of my clothing....I'm very self-conscious with it. **At times, I think that in that aspect shots were easier**. . .

When I go to a place and I am among people I don't know it raises your awareness that people may be looking at you more than usual. **And it makes you feel uncomfortable**, but **not to the point where it is something you would consider giving up**, **but it makes you feel a little more different than normal**

Ritholz, 2007

PRIMO TEMPO: COGITO ERGO SUM Diabete e tecnologia: la conosco?

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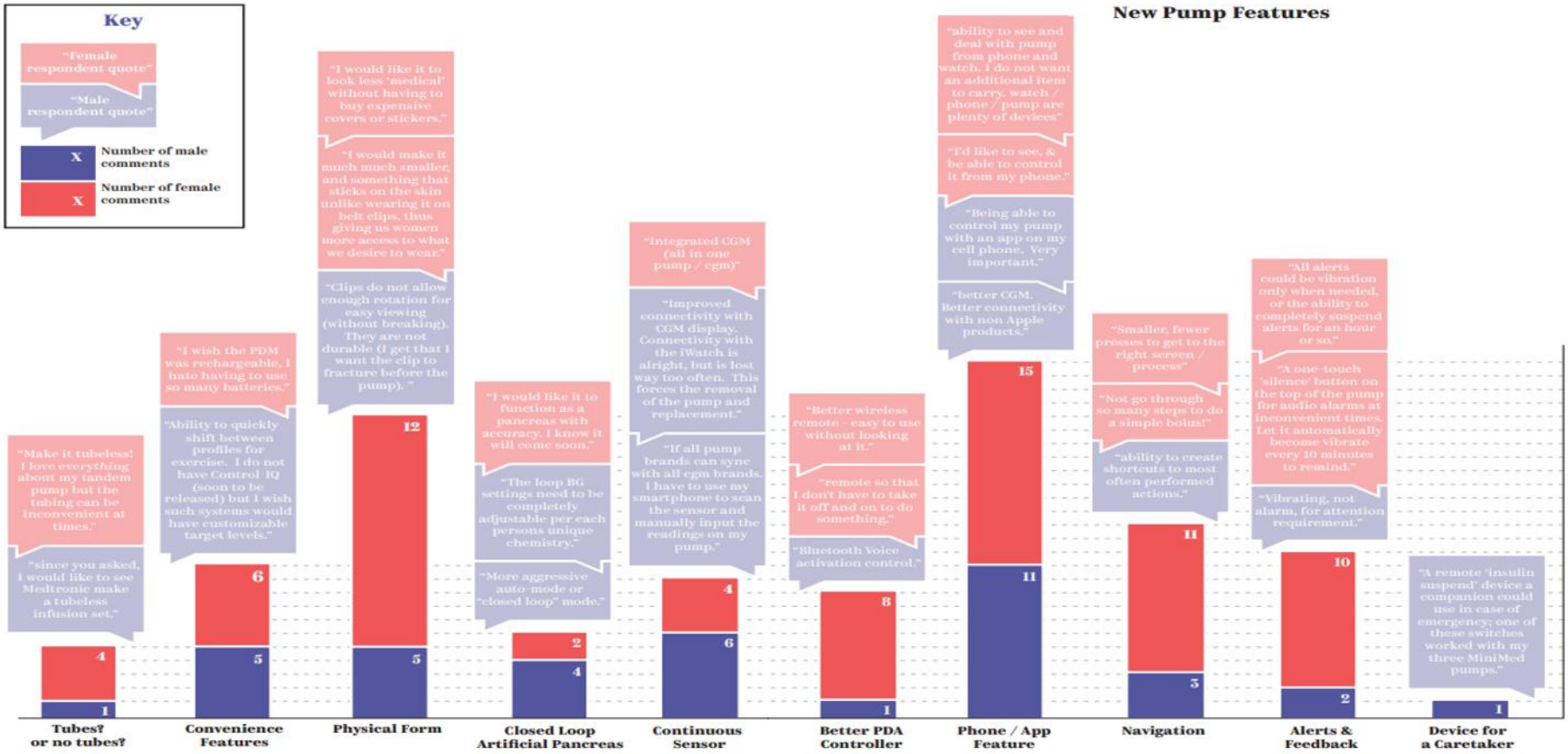
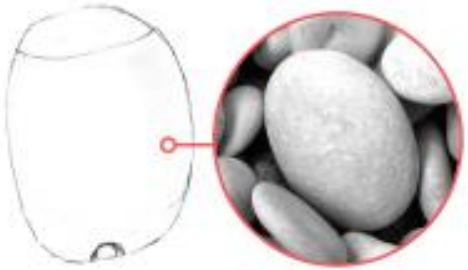


Harper, 2021

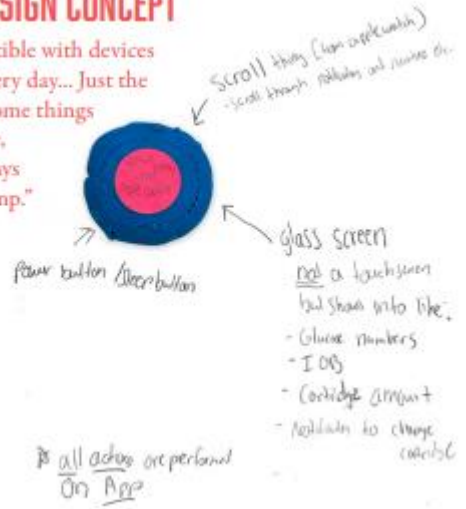
P1_WS DESIGN CONCEPT



"More circular, flat like a pebble. I think that just looks better on the body."

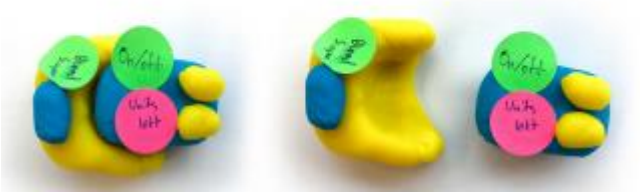
P2_WS DESIGN CONCEPT

"Being compatible with devices that we use every day... Just the ability to do some things on your phone, instead of always using your pump."



P3_WS DESIGN CONCEPT

"Why not have the pump also be a CGM? If I already have two. just



Harper, 2021

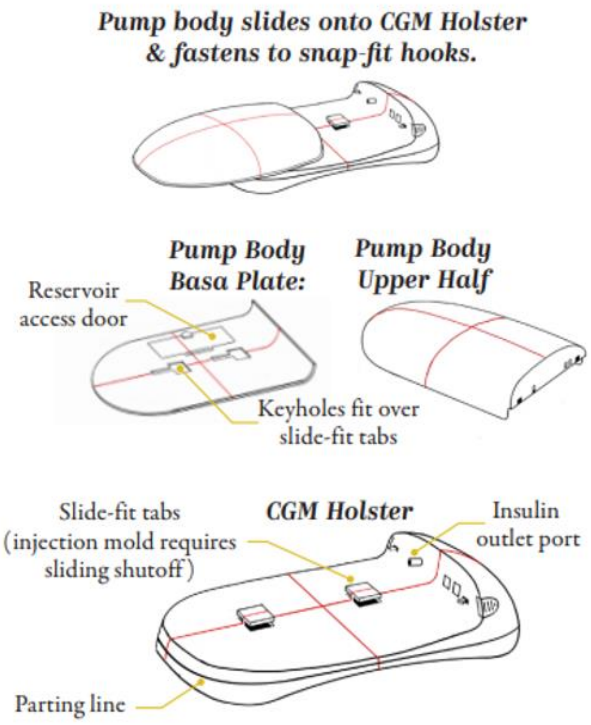


Figure 10: Illustration of Gemperle's humanistic form, juxtaposed with the pump's side-view, showing it's concave base.

Figure 11: Profile of the controller's curved trackpad.

Pump Design

Controller Design

Harper, 2021

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- Assenza di set infusionale e dei problemi connessi (occlusione, attorcigliamento)
- Libertà di movimento
- Applicabile in varie zone del corpo
- Meno visibile, più piccolo, leggero e discreto
- Ago non visibile, inserimento automatico e meno doloroso dell'ago
- Facilità di utilizzo
- Facilità del training
- Adatto ad alcune attività e situazioni particolari (doccia, nuoto, attività sessuale, sudorazione eccessiva)

Adattato da Kulzer, 2022

92 soggetti affetti da DM1 in terapia con microinfusore tradizionale per > 6 mesi

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]

Parameter	*Value*
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.

Pickup, 2014

Problem	%
Infusion set	
Kinking	64.1
Frequent kinking	12
Blockage	54.3
Frequent blockage	9.8
Leakage	16.3

Problem	%
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

Risk factor	*RR*	P *value*
>3 days set use with lispro	1.71 (1.03–2.85)	0.07
Insulin analog use, any duration		
Lispro	1.39 (0.95–2.10)	0.12
Aspart	0.76 (0.51–1.13)	0.27
Glulisine	0.62 (0.12–3.12)	0.60
Kinking	1.36 (0.89–2.10)	0.17
Teflon cannula use	0.76 (0.51–1.12)	0.28

Frequent kinking: regolarmente, frequentemente, molto spesso; ≥ 5 volte nell'ultimo anno; ≥ 10 volte

Frequent blockage: ≥ 5 volte nell'ultimo anno; ≥ 10 volte

Pickup, 2014

Malfunction	%
Any pump malfunction (% of patients)	48
Types (% of all malfunctions)	
Pump stop/no delivery	26
Keypad/button problem	12
Rewind malfunction	12
Battery compartment problem	11
Belt clip broken	6
Accidental damage by user	6
Display problem	5
Software problem	5
Other (e.g., no cartridge detected, continuous alarm, O-ring leak, unknown)	17

Problemi riscontrabili anche con PP

Pickup, 2014

Diabetes Care Volume 40, February 2017 181

Check for updates

Diabetes Device Use in Adults With Type 1 Diabetes: Barriers to Uptake and Potential Intervention Targets

Molly L. Tanenbaum,[1] Sarah J. Hanes,[1] Kellee M. Miller,[2] Diana Naranjo,[3] Rachel Bensen,[1] and Korey K. Hood[1]

Diabetes Care 2017;40:181–187 | DOI: 10.2337/dc16-1536

T1D Exchange (n 1503, 18-80 anni)

- Età: 35.3 ±14.8 anni
- Durata di malattia: 20.4 ± 12.5 anni
- F/M: 61/39%
- A1c (n 452): 7.5 ± 1.34%
- Terapia
  - ✓ CSII: 38%
  - ✓ CSII + CGM: 32%
  - ✓ MDIs: 25%
  - ✓ MDIs + CGM: 5%

Barrier	% Yes
Nonmodifiable	
Cost of supplies	61.3
Cost of device	57.4
Insurance coverage	57.3
Modifiable	
Hassle of wearing devices all of the time	47.3
Do not like having diabetes devices on my body	34.8
Do not like how diabetes devices look on my body	26
Nervous that the device might not work	20
Do not want to take more time from my day to manage diabetes	17.5
Nervous to rely on technology	17
Worries about what others will think of me	10.5
I do not like diabetes devices because people notice them and ask questions about them	10.4
Too busy to learn how to use a new technology or device	9.2
My diabetes care team has never talked with me about diabetes technology options	4.5
Do not understand what to do with the information or features of the devices	4.5
Not able to get my diabetes care team to write me a prescription	4.4
Not enough support from my family	3.7
Not enough support from my diabetes care team in using devices	2.9
Do not want to have more information about my diabetes	2
My family does not think diabetes devices are important for taking care of my diabetes	0.9

Tanenbaum, 2017

Reason for discontinuing	% Yes
CGM (*n* = 249)	
Cost of supplies	35.3
There were too many alarms	32.1
It was not accurate	30.1
Do not like diabetes devices on my body	29.7
Wearing a CGM took too much time and effort	28.9
It was uncomfortable or painful	28.1
Too hard to get it to work right	22.1
Cost of device	21.7
Made it hard for me to sleep	20.1
Did not trust it	18.1
Insulin pump (*n* = 72)	
Do not like diabetes devices on my body	45.8
It was uncomfortable or painful	44.4
Cost of supplies	20.8
Did not trust it	20.8
Too hard to get it to work right	16.7
Cost of device	13.9
Caused other people to ask too many questions about my diabetes	12.5

Tanenbaum, 2017

Table 3—Differences between CGM users and nonusers

	Users	Nonusers	*t*	*P* value	95% CI
Number of barriers reported	3.25 (2.3)	4.32 (2.56)	$t(1,301) = 8.33$	<0.001[a]	0.81, 1.32
Age	38.29 (14.64)	33.48 (14.55)	$t(1,501) = -6.21$	<0.001[a]	−6.34, −3.29
Diabetes duration	22.89 (13.09)	18.83 (11.91)	$t(1,045) = -5.8$	<0.001[a]	−5.4, −2.71
Technology attitudes					
General	26.0 (4.66)	24.84 (4.39)	$t(1,498) = -4.86$	<0.001[a]	−1.63, −0.69
Diabetes specific	22.61 (3.22)	21.44 (3.46)	$t(1,239) = -6.54$	<0.001[a]	−1.38, −0.62
Diabetes distress	1.99 (0.76)	2.06 (0.77)	$t(1,501) = 1.94$	0.052	−0.001, 0.16
HbA_{1c}					
%	7.3 (1.18)	7.67 (1.42)	$t(435) = 2.95$	0.003[a]	0.11, 0.61
mmol/mol	56 (13)	61 (15)			

Tanenbaum, 2017

Original Article

Journal of Diabetes Science and Technology
2016, Vol. 10(5) 1130–1135
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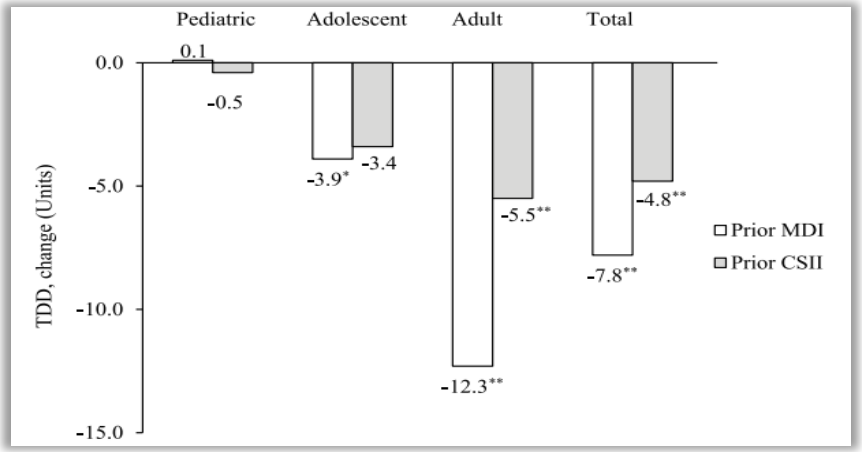
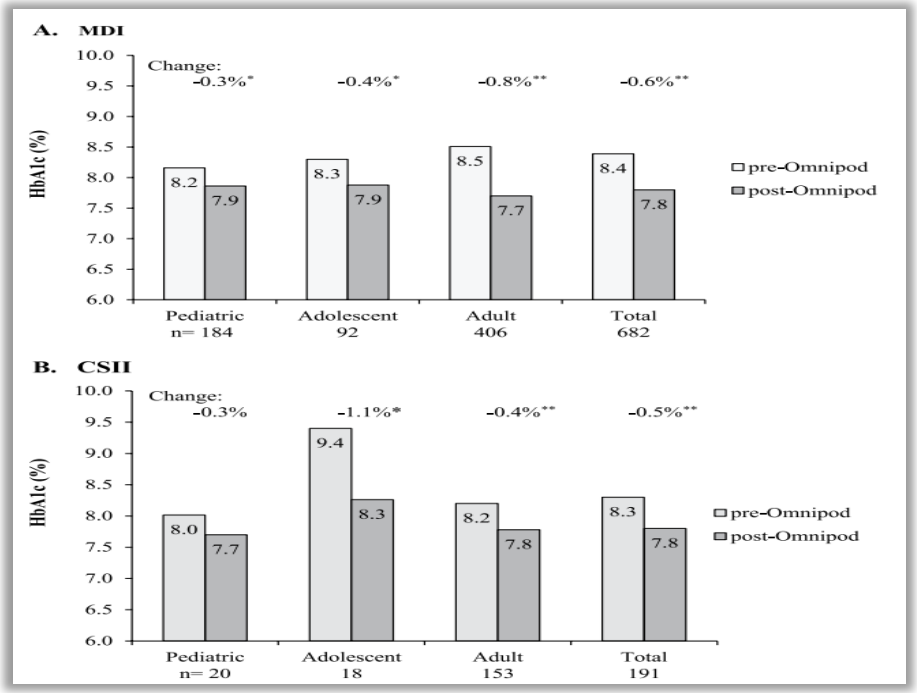
DOI: 10.1177/1932296816638674
dst.sagepub.com
SAGE

Efficacy of the Omnipod Insulin Management System on Glycemic Control in Patients With Type 1 Diabetes Previously Treated With Multiple Daily Injections or Continuous Subcutaneous Insulin Infusion

Jennifer E. Layne, PhD[1], Christopher G. Parkin, MS[2], and Howard Zisser, MD[1]



- Studio retrospettivo in 471 centri in USA
- 873 pazienti in terapia MDIs (78.1%) e CSII tradizionale (21.9%) di tutte le età
- Riduzione A1c in ogni fascia di età e riduzione TDD

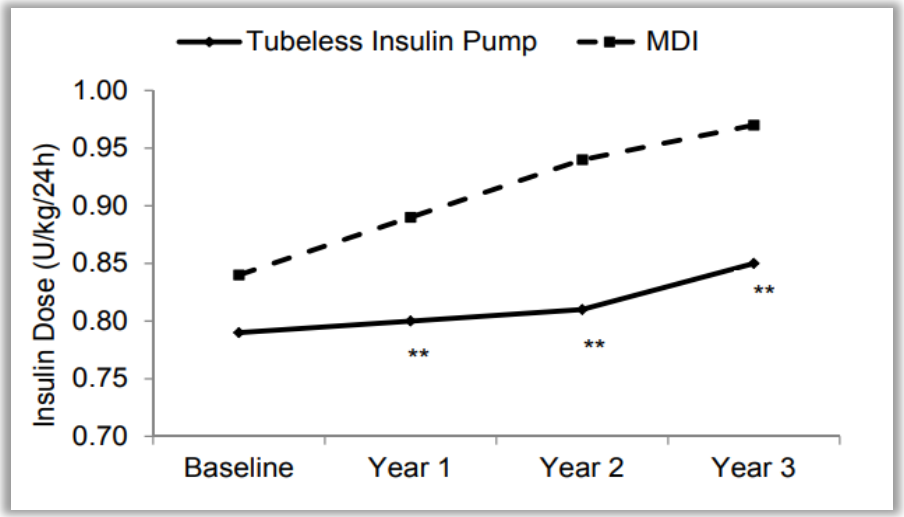


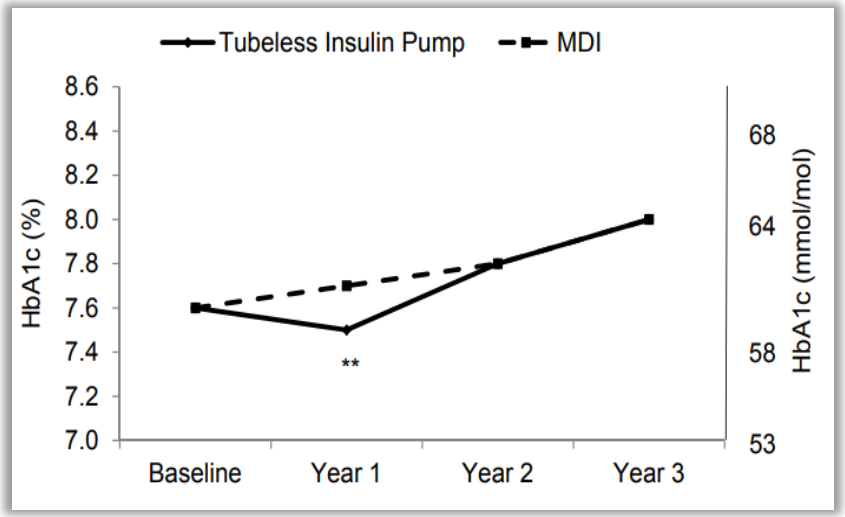
Layne, 2016

Long-term Study of Tubeless Insulin Pump Therapy Compared to Multiple Daily Injections in Youth with Type 1 Diabetes: Data from the German/Austrian DPV-Registry

Thomas Danne[1], Anke Schwandt[2,9], Torben Biester[1], Bettina Heidtmann[3], Birgit Rami-Merhar[4], Holger Haberland[5], Silvia Müther[6] , Semik Khodaverdi[7], Thomas Haak[8] and Reinhard W. Holl[2,9] for the DPV Initiative[10]

- Studio retrospettivo (registro DPV)
- 2529 soggetti con DM1 e età < 20 anni
- Switch da MDI a patch pump (MDI=1869, PP=660)





Danne, 2018

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 23, Number 8, 2021
Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2020.0675

DTT

ORIGINAL ARTICLE

Declining Frequency of Acute Complications Associated with Tubeless Insulin Pump Use: Data from 2,911 Patients in the German/Austrian Diabetes Patienten Verlaufsdokumentation Registry

Torben Biester, MD,[1] Anke Schwandt, MSc,[2,3] Bettina Heidtmann, MD,[4] Birgit Rami-Merhar, MD, MBA,[5] Thomas Haak, MD,[6] Andreas Festa, MD,[7] Susanne Kostow, MD,[8] Antonia Müller, MD,[9] Kirsten Mönkemöller, MD,[10] and Thomas Danne, MD;[1] for the DPV Initiative*

- 3657 soggetti (DM1=3582, DM2=25, LADA/altro=50) in terapia con patch pump

	Age category, year							
	0 to <5	*5 to <10*	*10 to <15*	*15 to <20*	*20 to <30*	*30 to <40*	*>40*	*Overall*
n (%)	77 (2.2)	532 (15.4)	1505 (39.8)	909 (25.2)	182 (4.6)	161 (4.5)	291 (8.4)	3657
Age, year	3.9 (3.2, 4.3)	7.8 (6.8, 8.9)	12.3 (11.0, 13.4)	16.4 (15.5, 17.5)	24.7 (22.1, 27.2)	34.2 (31.9, 37.1)	50.9 (46.3, 57.9)	13.7 (10.8, 17.3)
HbA1c, %[a]	7.2 (6.9, 8.2)	7.2 (6.7, 7.7)	7.5 (6.7, 7.7)	7.7 (7.0, 8.6)	7.6 (6.8, 8.5)	7.5 (6.8, 8.4)	7.6 (7.1, 8.3)	7.5 (6.9, 8.2)
Insulin dose, U/(kg·day)[a]	0.65 (0.47, 0.78)	0.66 (0.54, 0.77)	0.76 (0.61, 0.95)	0.80 (0.64, 1.0)	0.60 (0.42, 0.77)	0.47 (0.36, 0.60)	0.47 (0.37, 0.50)	0.71 (0.55, 0.90)
BMI-SDS[a]	0.96 (0.07, 1.53)	0.45 (−0.04, 0.92)	0.36 (−0.25, 1.07)	0.57 (−0.09, 1.20)	0.80 (0.24, 1.68)	0.79 (0.18, 1.69)	1.22 (0.48, 2.01)	0.55 (−0.09, 1.22)
DKA, %[b]	1.3	4.5	3.6	3.6	3.8	3.7	2.7	3.9
SH (coma), %[b]	2.6	0.7	1.6	1.8	0	1.8	2.0	1.5
SH (Level 3), %[b]	9.0	5.4	5.8	4.7	1.9	1.0	5.5	5.4
SMBG/day[a]	7 (5, 9)	6.5 (5, 8)	5 (4, 7)	5 (3.5, 6)	5 (3.5, 6)	4 (2, 6)	4 (4, 6)	5 (4, 7)
CGM (%)[a]	33.8	38.6	37.6	31.4	18.6	17.4	13.7	32.7
Previous therapy (tethered pump/MDI%)[a]	58/42	35/65	23/76	27/73	66/33	81/17	77/18	38/59
Retention rate (%)	100	96.4	94.8	83.3	94.0	95.7	96.6	92.4

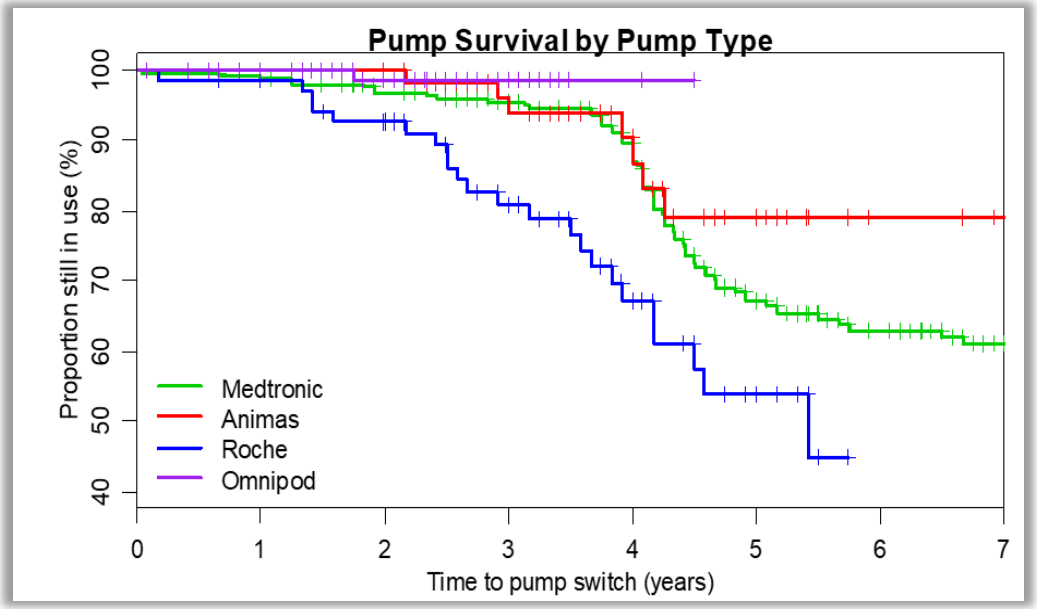
Biester, 2021

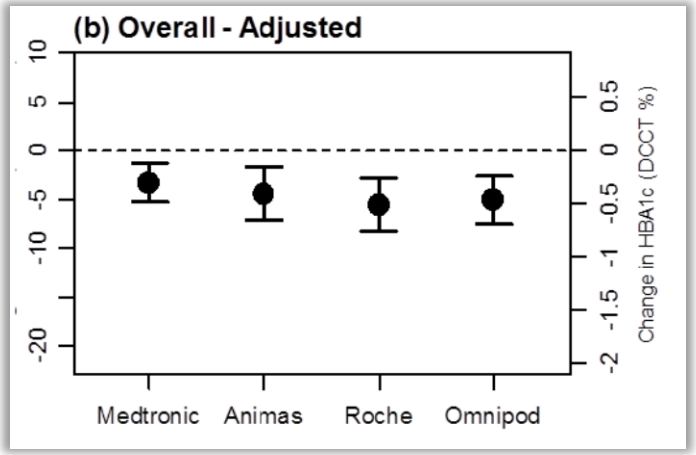
Comparison of different insulin pump makes under routine care conditions in adults with Type 1 diabetes

Short title: Comparison of different insulin pumps

L. Leelarathna[1,2], S. A. Roberts[3], A. Hindle[2], K. Markakis[1], T. Alam[2], A. Chapman[1], J. Morris[1], A. Urwin[1], P. Jinadev[1] and M. K. Rutter[1,2]

- Studio retrospettivo su 508 soggetti (94% con DM1)
- In terapia con CSII:
  - ✓ Medtronic (50%)
  - ✓ Animas (12%)
  - ✓ Roche (14%)
  - ✓ Omnipod (24%)





Leelarathna, 2017

Agenda

- Cenni storici
- Generalità
- Tipologie di patch pump (PP)
- Il punto di vista degli interessati
- Vantaggi delle patch pump
- Svantaggi delle patch pump
- Conclusioni

- Minor accuratezza dell'erogazione
- Sito di infusione non accessibile (infezioni misconosciute)
- Possibile spreco di insulina (sostituzione patch con serbatoio parzialmente pieno)
- Consumo eccessivo di materiale
- Serbatoio di dimensioni limitate (200 UI=66.6 UI/die)
- Necessità (quasi sempre) di un dispositivo di controllo esterno

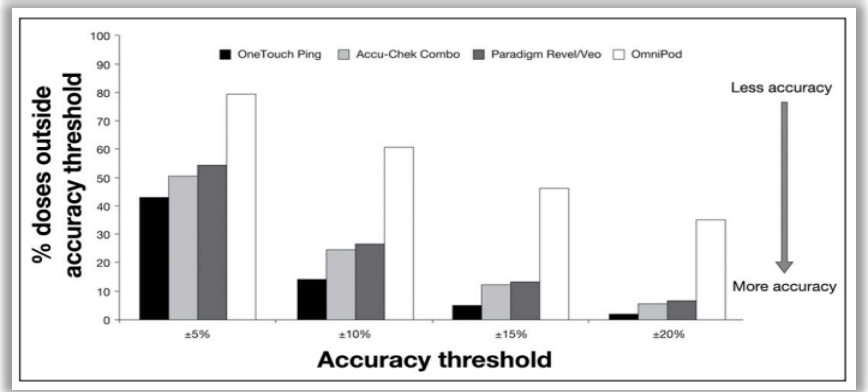
Adattato da Kulzer, 2022

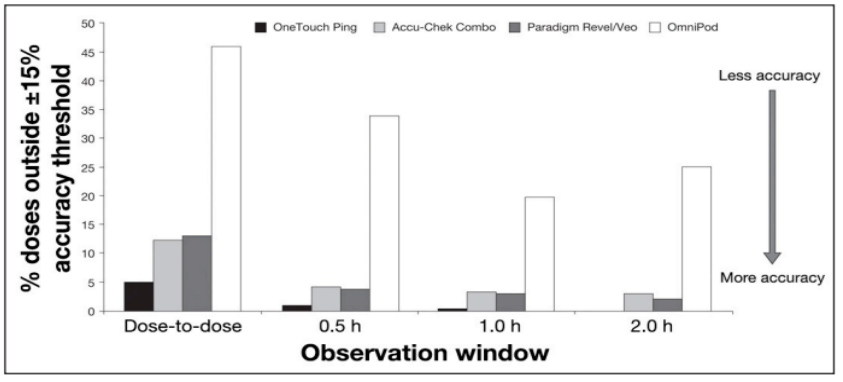
Journal of Diabetes Science and Technology
Volume 7, Issue 4, July 2013

TECHNOLOGY REPORT

Comparative Dose Accuracy of Durable and Patch Insulin Infusion Pumps

Luis G. Jahn, Ph.D., Jorge J. Capurro, M.Sc., and Brian L. Levy, M.D.





DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 4, 2019

DOI: 10.1089/dia.2018.0376

DTT

ORIGINAL ARTICLE

Accuracy of Bolus and Basal Rate Delivery of Different Insulin Pump Systems

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

Insulin pump
Accu-Chek® Insight
Accu-Chek Insight
Accu-Chek® Spirit Combo
Accu-Chek Spirit Combo
Animas® Vibe®
MiniMed® 640G
mylife™ OmniPod®
Paradigm® VEO™
Paradigm VEO
Paradigm VEO

Conclusions: In general, all compared insulin pump systems showed a similar level of accuracy. Differences, especially between durable pumps and the patch pump, were observed when considering each hour of basal rate delivery separately.

Jahn, 2013

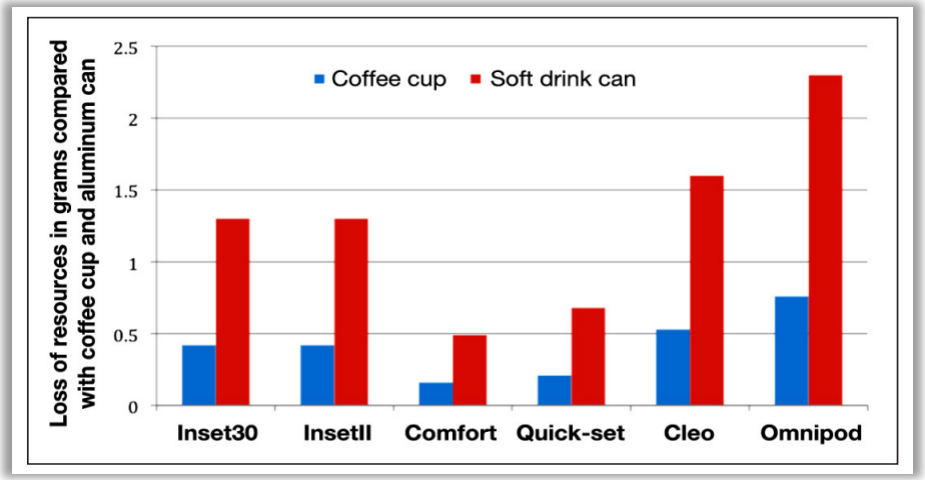
Freckmann, 2019

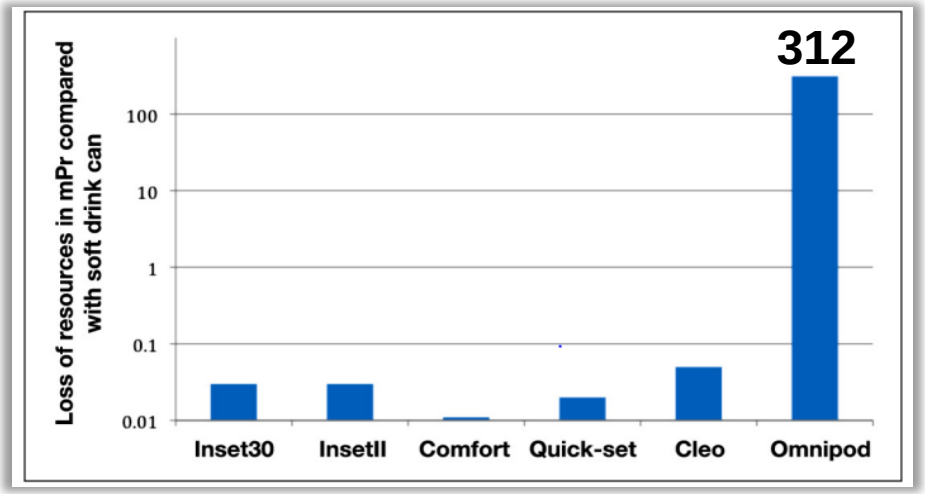
Journal of Diabetes Science and Technology
Volume 5, Issue 4, July 2011

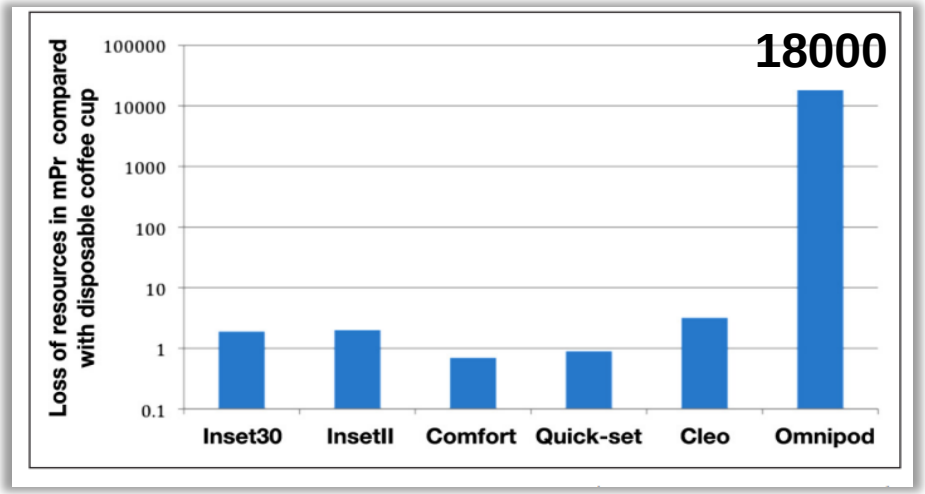
SYMPOSIUM

Analysis of the Environmental Impact of Insulin Infusion Sets Based on Loss of Resources with Waste

Andreas Pfützner, M.D., Ph.D.,[1] Petra B. Musholt, M.D.,[1] Bjoern Malmgren-Hansen, M.Sc.,[2] Nils H. Nilsson, M.Sc.,[2] and Thomas Forst, M.D.[1]







Pfutzner, 2011

Agenda

- Cenni storici
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- Svantaggi delle patch pump
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L’indossabilità riveste un ruolo importante nella scelta del microinfusore

L’uso di un microinfusore tradizionale, più visibile e ingombrante, può portare alla scelta di proseguire con una terapia multi-iniettiva

Le patch pump sono una possibile alternativa…

…seppur con possibili limitazioni

Minor accuratezza?

Problema ambientale

Mancanza di sistemi AHCL approvati in ITA

Grazie per l'attenzione

La Tecnologia