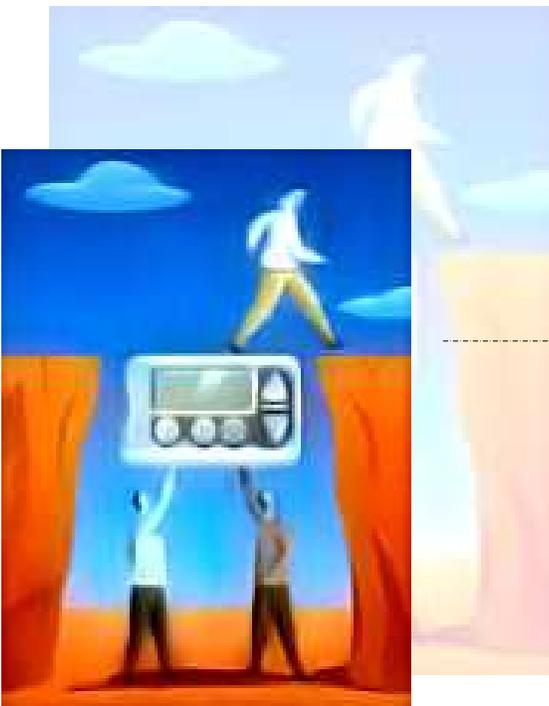


Pump Ergonomics Research
Phase 1 Final Report

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Ergonomic Problems In Diabetes Therapy with Insulin Pump

Abstract

In order to determine ergonomics related usage aspects Insulin Pumps Therapy (i.e. Continuous Subcutaneous insulin infusion, CSII) , 100 participants, all members of a Diabetic insulin pump therapy mailing list, were asked to fill in an online survey that investigated different domains related to the ergonomics of the product, from physical to cognitive including user psychology and experience. The survey consisted of quantitative as well as open ended qualitative questions. The quantitative part of the data is statistically analyzed in Matlab. The qualitative answers were separately analyzed and together some highly design relevant conclusions were drawn that might be useful for the design of future generations of pumps.

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Introduction

Problematic and Context

The Insulin pump therapy, also known as CSII (Continuous Subcutaneous Insulin Infusion), is considered in the medical world as the most effective way of controlling blood glucose in Diabetes Mellitus (Type 1 Diabetes) patients. The high effectivity, in turn, helps the patient reduce long-term complication risks of Diabetes and alleviates the costs of Social Health Insurance System related to long-term Diabetes Complications.

Properly used, Insulin pumps also help increase the flexibility and therefore quality of life for a diabetic person.

On the other hand, because the device has relatively recently been technically possible and commercially available and that the matter is of utmost medical importance, the ergonomics of the products available in the market today still need further refinement, an issue considered luxurious until recently. Nowadays the users continue to experience some problems related to the ergonomics and the use experience of the product. New efforts to improve the design are taken by manufacturers while the product gets more and more commonly used.

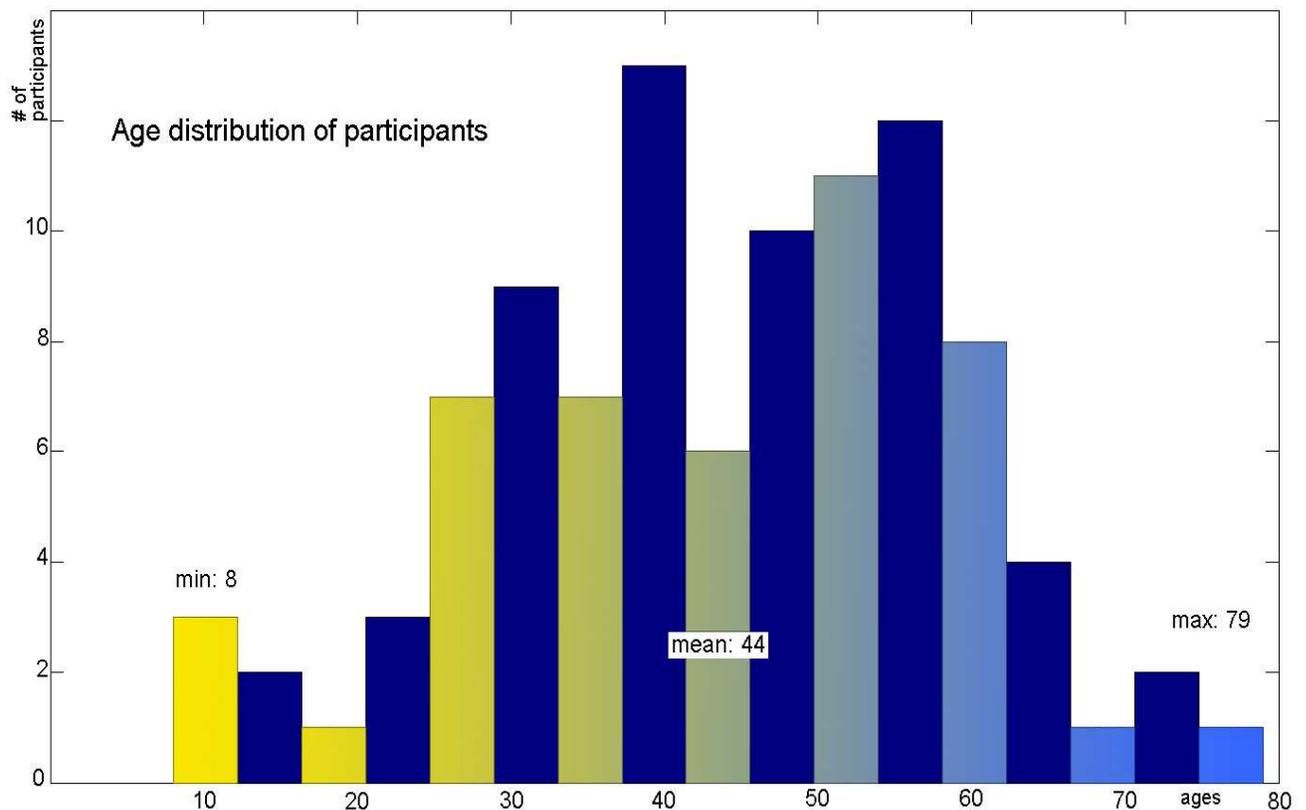
Today the device is not recommended for patients with low education because it demands complex interaction/care and the severity of the result due to a probable error is very high.

Method

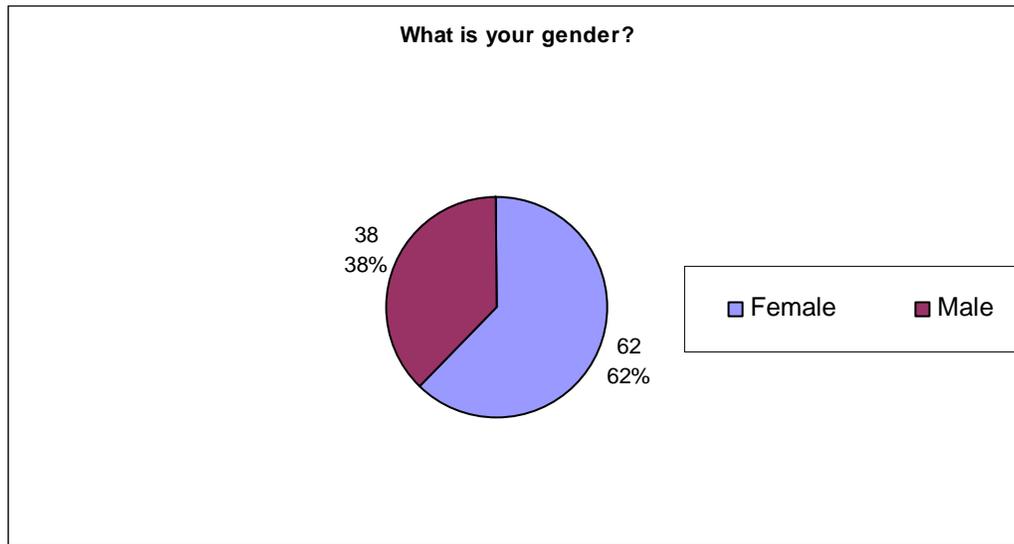
We have surveyed 100 pump users with prepared qualitative as well as quantitative questions that were published in a commercial online survey site. The participant group of the research consists of Diabetes Patients administering CSII Therapy. The volunteered participants were all members of an online insulin pumpers community, majority of which are USA nationals. The participant group is demographically very diverse, covering both sexes, a wide spectrum of ages and (although not spotted by the research, but probably) diverse income levels. The education level is from upper average to high.

The relatively large volume of data helped us draw conclusions based on statistics.

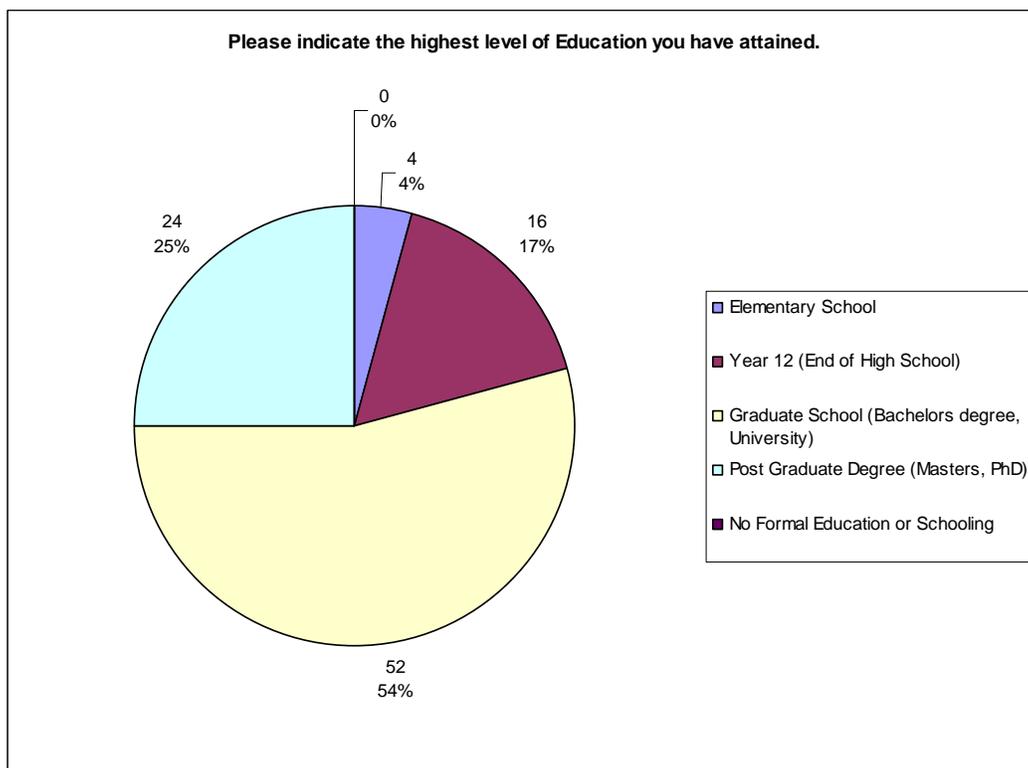
The age distribution of the 100 participants was as follows:



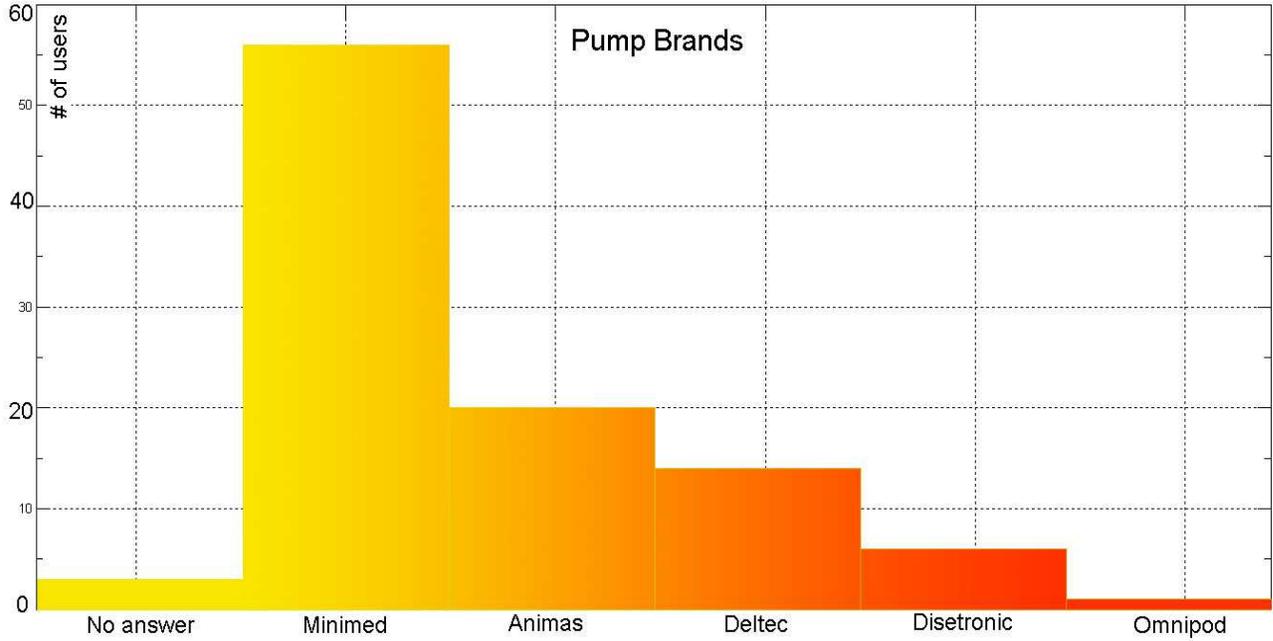
The gender distribution of the participants:



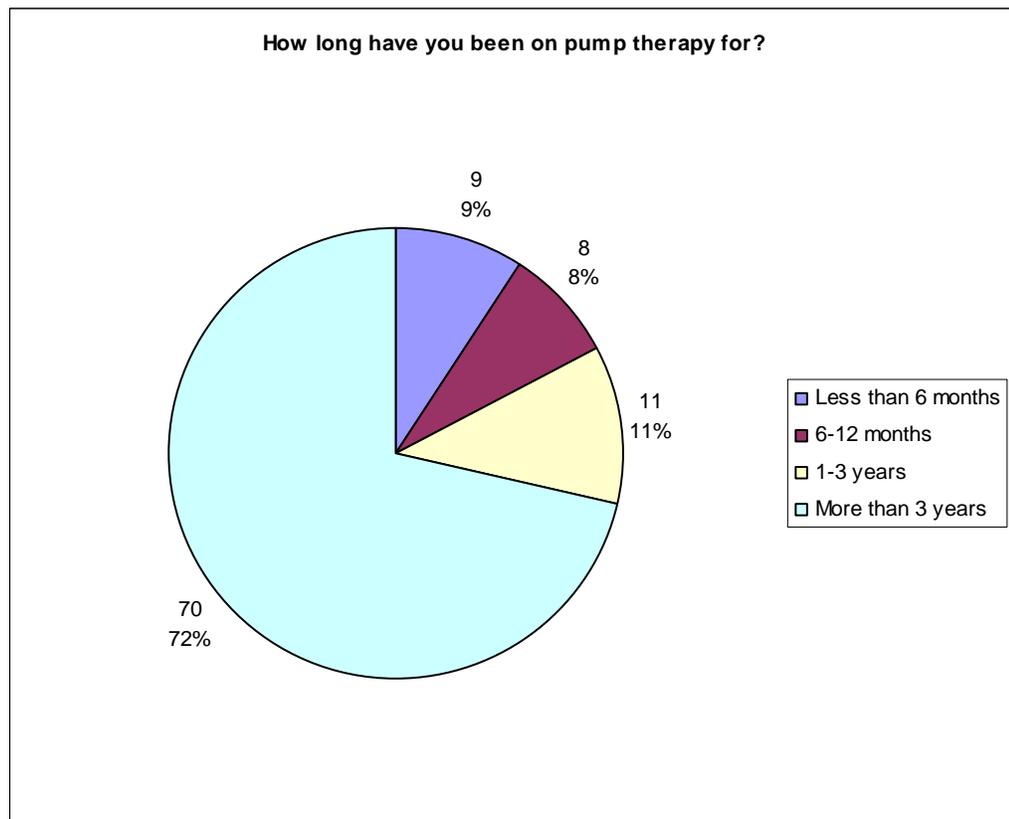
The education level:

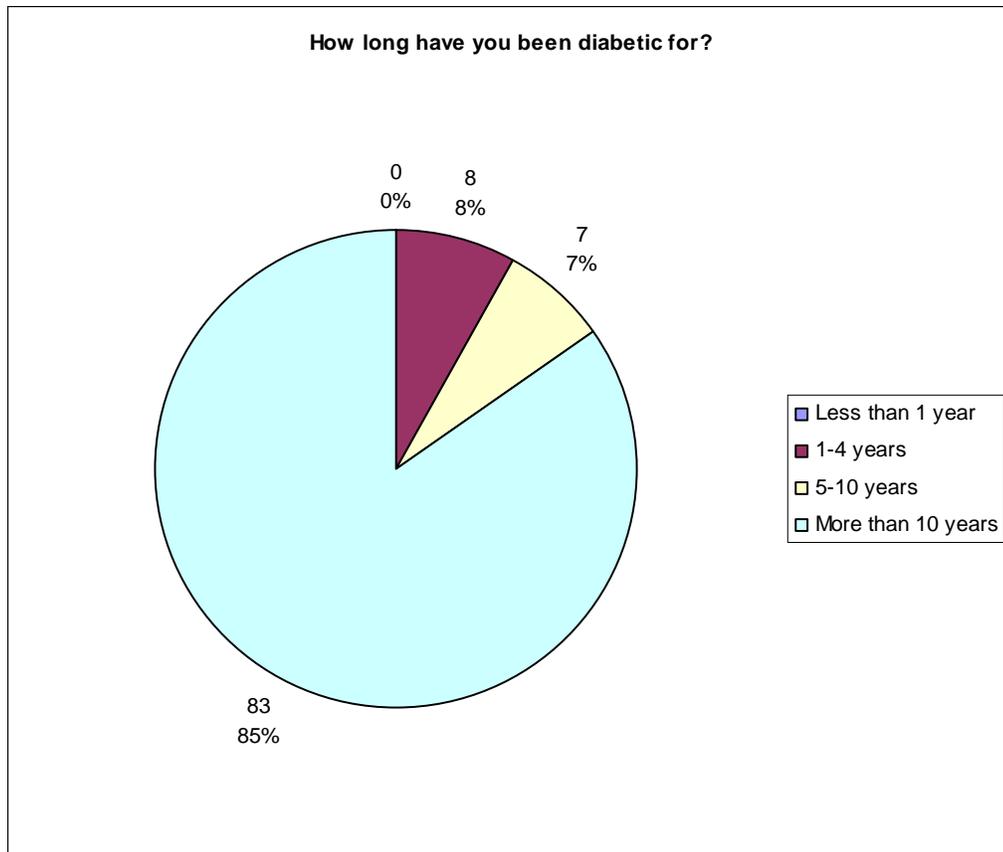


Pump brands:



Some other relevant data characterizing the participants are as follows:





The (quantitative part of) raw data can be found in the appendix.

For statistical analysis some modification was done over the raw data before analysis:

- The unanswered questions (empty matrix entries, see appendix) were filled up with “3= Neutral answers”.
- For the last question, the “0=no opinion” answers were replaced by “3=Neutral answers”.
- For better visualization, the absolute values of the correlation coefficients were plotted. Therefore the direction of correlations disappeared in the correlation graphs in appendix.

Analysis

Validity of survey:

The validity of the overall research can be checked by the correlations between the answers of some validation questions. We have seen, for instance, that the answers to the questions “Introducing the pump to other people” is highly correlated to the answer of the question “social reactions”. The answer to question “Need to learn pumping theory” is highly correlated to the answers of “Need to have extra trouble troubleshooting skills”. “Overall feeling of security” is also highly correlated to “overall feeling of everything being under your control”

Analysis of averages for the entire population:

Average scores for each question are shown in appendix.

These averages give a broad view about very general aspects of the pumps without taking into consideration any subgroup particularity.

The lowest ranking average scores, (indicating the aspects with lowest satisfaction) were in the following domains:

- Trying the cloths on while shopping
- On the sea side (swimming, sunbathing)
- Unexpected impacts on the infusion site
- Tube being caught by objects and pulled
- Loosening of adhesive due to sweating
- Worry about infections around the infusion site

The highest ranking average scores (indicating the aspects with highest satisfaction) were in the following domains:

- Introduce the pump to other people
- Ease of access to desired info/function
- Temporarily disconnecting the pump
- Ability to temporarily modify basal rates for different situations
- Knowledge and ability to use all functions of the pump
- Perception of increased wellbeing
- Overall feeling of security
- Overall feeling of everything being under user's control
- Improved HbA1C results
- Flexibility in food types & quantity
- Flexibility in scheduling meal & sleep times

A high level of disagreement was scored for the following two statements:

“I would readily want to convert back to my previous diabetes management method if my pump didn't improve my glucose levels”

“I feel more diabetic with my pump”

Analysis of averages of subgroups / deviation of subgroup averages from entire population averages :

To have a deeper insight into the scores, some subgroups that could possibly show some particularities were created. The complete list of subgroups can be found in appendix along with number of participants in each subgroup.

We have illustrated the average scores of particular groups as well as their deviation from the whole population. (See graph is appendix.)

Taking the two graphs as reference, the following relevant findings were obtained:

The change of averages through the following 4 subgroups were particularly crucial in that it demonstrates “the adaptation” of the user to his/her pump.

The subgroups focused are:

- Pump users since 6 months or less (n=9)
- Pump users since 6 to 12 months (n=7)
- Pump users since 1 to 3 years (n=15)
- Pump users since 3 years or more (n=69)

The agreement with the statement “I feel more diabetic with my pump” drops from 3 to 2.5 in the 2nd group and from the 3rd group on to 2.

The satisfaction from “flexibility in food types & quantity” (initially scoring 3.5) and “flexibility in scheduling meal & sleep times” (initially scoring 4) both mark a visible increase finally reaching 5.

We also notice a decrease in agreement with the statement “I am very worried about infections around the infusion site” first scoring 3,5 and finally scoring 2,5.

Another statement that receives less agreement as time goes by is “I would readily want to convert back to my old diabetes management method if my pump therapy did not change my glucose levels” scoring initially 2.5, very close to neutral, but finally 1.5, a strong disagreement.

There is a slight amelioration (each 0.5 in average) in the following aspects as well:

- Perception of increased well being
- Sense of being connected to a machine
- Overall perception of increased freedom with pump
- Overall opinion about your pump

The scores of satisfaction about “Sleeping at night” increases from 2.5 to a final of 3.5 marking another aspect of adaptation of pump users to initially confronted problems.

There is no significantly deteriorating satisfaction score in these subgroups marking the passage of time and gain of experience with insulin pump.

Analysis of correlations between question scores:

The correlation of answers to each other (pair-wise) is shown in the table (see appendix). For the sake of a more comprehensible graph, the direction of correlation is discarded by taking the absolute value of the resulting coefficient. Weak correlations, (i.e. below 0.3) are discarded as well.

Some very high correlations, almost equaling 1, are grabbing the attention at the first sight. These high correlations (that are generally relatively closer to the diagonal line) are the correlations between similar questions. The high correlation coefficients are a good mark of validity of the results, as discussed previously in the validation part.

Ignoring those validating ones, some other high correlations become apparent.

The age is moderately (and inversely) correlated to the scores of agreements for the following statements “I would enjoy a more playful, customizable pump with a better style and fun add-ons” and “I would prefer an mp3 player / mobile phone like pump”

To put it in another way, this finding makes it clear, not surprisingly, that younger pump users prefer their pump to be more “fun” and less “medical”, incorporating other functions than solely medical ones.

Another weaker, nevertheless relevant correlation is between the gender and the score of comfort manifested in question “Loosening of adhesive due to sweating”. Also visible from

subgroup averages, we can say that male users are suffering more because of their sweat loosening the adhesive of the infusion set than female pump users.

A very important chain of correlations is visible in the row of “Wearing the pump”. Among many others the most important ones are the correlations with “Perception of increased well being”, “Sense of being connected to a machine”, “Overall feeling of security“, “Overall feeling of everything being under your control”, “Overall perception of increased freedom with pump” and “Overall opinion about your pump” .

Supporting this fact is the moderately high negative correlation with agreement for the statement “I would readily want to convert back to my old diabetes management method if my pump therapy did not change my glucose levels”

These findings makes it clear that wearability of the pump is one of the key stones for building an improved quality of life.

Another interesting finding is the correlation between “Overall opinion about your pump” and “Hyperglycemia occurrence” which is significantly higher than the one with “Hypoglycemia occurrence”

Analysis of qualitative questions & comments by participants

The following 3 open-ended and qualitative questions were asked to the participants consecutively in order to get their comments:

- The ultimate goal in insulin pump research& development is to achieve an “*artificial pancreas*” capable of delivering insulin automatically according to the blood glucose values, without the intervention of the patient. Today’s pumps are not “*smart*”.

Please answer the following two questions a. and b.

Please feel free to offer an answer even though you think it is technically unachievable.

- a. Regardless of technical impossibilities, and in exception of making your pump smart, if you were given the chance of eliminating one negative aspect, what aspect would you choose to eliminate in the pump of your dreams? Please give brief details.
 - b. Regardless of technical impossibilities, and in exception of making your pump smart, if you were given the chance of adding one positive aspect, what aspect would you choose to add in the pump of your dreams? Please give brief details.
- Please feel free to add your comments about any pump therapy aspect that was not covered in this survey.

The answers were revealing more particularities at the expense of quantifiability.

Some of the answers below are “one offs” proposed by only one participant but having substantial design relevant content. Some other answers are just representatives for many similar ones proposed very frequently by participants.

Frequently proposed:



- The warning alerts system is not very loud and isn't adjustable - WHY?(my hearing is perfect, but often my pump is tucked away in my clothes)
- customizable food database incorporated in the pump
- 'Make it "wireless" - for example, I like the idea of the Omnipod (which has no tubing), but the part attached to the body is too large to consider seriously using.'
- 'A lot of factory settings can't be easily customized by the user (duration of time to screen-saver, programming certain aspects of boluses and temp rates, etc.) Easily customizable settings either from attached software through desktop computer or through pump menus would be great.'
- 'screen. Glossy screen and not enough contrast between lettering and background make it difficult to read the screen in some situations.'
- 'I hate having to fill the reservoir with insulin. Insulin pens have been on the market for years - why can't the pump have a pre-filled reservoir''
- 'bigger reservoir and longer battery life'
- 'The 3 day limit for infusion sites.'
- 'Entirely WATERPROOF'
- 'no physical insertion of catheters/sensors'



“One offs” :



- 'Insertion sites need to be able to be purchased separately - as sites and as tubing.'
- 'My daughter would like it to have "cool games". Would be nice if it was slimmer with rounded edges.'
- 'Tubing coil up when not needed.'
- 'infusion sets should have retractable tubing.'
- 'Smaller insertion set without a bulky attachment to the tubing.'
- 'Making my pump Mac compatible - I know it is possible to do lots of downloads and data management, but all software is for PC users.'
- 'Create an automatic insertion device for infusion sets that go in at an angle'
- 'Pumps are becoming TOO over-featured. Things like alarm clocks are cute, but NOT necessary for insulin pumps, and just add a potential for things to go wrong -- on something as critical as an insulin pump, "Keep It simple'
- 'colored tubing. :-)'
- 'I would find it useful to have a cannula alert that reminded me to change the insertion set - I forget when I put it in and tend to only change it when it gets itchy or I pull it out by mistake - I'm sure that a lot of users would find this useful.'
- 'I feel more secure with the addition of the "Bolus Wizard" which lessens my anxiety about hypoglycemia events. And I like the Auto Off feature, too.'
- 'risk the battery running out and having to change it. This is particularly true if I'm in public or in class. I'd rather just sneak myself a shot under the table than risk my pump beeping and having to dig in my purse for the batteries.'
- 'I hate all the extra baggage I need to carry around with me – separate BG meter, strip, backup meter and strips, backup syringe and vial of insulin, backup infusion set and reservoir, spare batteries for all devices. The more all of this that can fit into one device that I wear the more happy I would be.'
- I would make it easier to download into a computer - or increase the memory for stored events so that I could check back more easily – this 'is probably more relevant to women as hormonal changes during menstruation make a monthly adjustment necessary and it would be useful to see what the pattern is rather than relying on memory.
- 'as I aged and my bosom went South I lost accessible infusion sites at the waist. Finding good sites after 53 years of diabetes is a major problem, as is decreased ability to twist and turn to insert.'
- stretchable tubing, so the length is adjustable



A read through the comments above gives very important design hints for amelioration of the pumps. Some among others are:

The ergonomic aspects related to legibility of the screen and audibility of the alerts are aspects that are most complained about.

The tubing is perceived frequently as one of the most annoying parts of the pumps. The tubeless pump, Omnipod, is not widely accepted mainly because of the bulkiness of the apparatus situated on the infusion site. Some users suggest making the tube retractable which might be a good design solution for the tubing problem.

The reservoirs are very frequently complained about because of the fact that they generally don't come pre-filled. The complaints are ranging from general inconvenience of additional effort for filling them to difficulty experienced when removing air bubbles trapped inside the reservoir.

A preference towards devices that could possibly be totally waterproof is manifested.

Conclusions, Discussion & Recommendations

This was a research about ergonomic aspects of insulin pumps. The research was administered online to 100 volunteering participants. It involved open-ended qualitative and quantitative questions enabling a combined use of qualitative techniques that provided more insight into aspects as well as statistical techniques that helped to come up with findings on numerical basis. Some very important, highly design related issues have been discovered and discussed in the related sections.

A general conclusion would be that the physical ergonomics of the products available in the market require substantial improvement. Some improvements are technically feasible today whereas some other might come true only with improvements in the technology from short to long-term. Some other ergonomic problems are inherent to pump therapy and are very unlikely to be solved.

The cognitive ergonomics aspects related to the pumps seemed not to be a major issue in the research. But this should be interpreted with caution since the research population is highly educated. On the other hand the fact that pumping therapy requires high intellectual and cognitive skills is a cognitive ergonomics problem by itself.

There has been some weak points in the research.

- The correlations that are analyzed are pair-wise and any multiple dimensional correlations (involving the relation between more than 2 variables) are not studied in this research.
- Some possible correlations might have not manifested themselves because of some highly invariable participant characteristics, such as, high education level, long diabetes history and such. Those characteristics, being more or less constant

throughout the research population are, as one would expect, weakly correlated to other variable if at all. A better down sampling of the entire participant population to artificially create variance in those aspects might be considered at the expense of downsizing the population and reducing the significance of any statistical conclusion that will be drawn.

- 5 unknown matrix entries in the raw data matrix (5 out of 600) are unintentionally modified and the original information as well as the location is lost irrecoverably. But the conservative approach during analysis helped reducing the risk of any false finding.

Almost all participants agreed to be contacted once more and added their contact details in the database. This gives the possibility of more detailed analysis on certain aspects that require further attention.

Quantitative Questions (in order) & Scoring:

- What is your age?
- What is your gender?
0.Female 1.Male
- Please indicate the highest level of Education you have attained:
1.Elementary School
2.Year 12 (End of High School)
3.Graduate School (Bachelors degree, University)
4.Post Graduate Degree (Masters, PhD)
5.No Formal Education or Schooling
- How long have you been on pump therapy for?
1.Less than 6 months
2.6-12 months
3.1-3 years
4.More than 3 years
- How long have you been diabetic for?
1.Less than 1 year
2.1-4 years
3.5-10 years
4.More than 10 years

How confident are you with using various functions of a:

- Personal Computer
- Mobile Phone
1.Not confident at all
2.Not confident
3.Neutral
4.Confident
5.Very Confident

Below are some potentially positive and negative "Daily Experiences" related to the use of the insulin pump. Please rate the emotion/impression caused by each of them on a scale from 1 to 5:

- 1.Very annoying, very disappointing, or very uncomfortable*
- 2.Annoying, disappointed, or uncomfortable to some extent*
- 3.Neutral, never thought of it, or no opinion*
- 4.Enjoyable, satisfying, or comfortable to some extent*
- 5.Very enjoyable, very satisfying or very comfortable*
- Eating out
- Exercising

- Wearing the pump
- Things to do before leaving house (daily)
- Traveling
- Trying the cloths on while shopping
- On the sea side (swimming, sunbathing)
- In the shower
- Sleeping at night
- Introduce the pump to other people
- During sexual intercourse
- Unexpected impacts on the infusion site (hitting the door etc.)
- Tube being caught by objects and pulled
- Loosening of adhesive due to sweating
- Entering secure areas, passing through police control and magnetic detectors
- Adhesive of the set epilating the infusion site while taking the set off
- Obtrusiveness of alerts, in exams, meetings, presentations, cinema, driving
- Social reactions

Below are some potentially positive and negative aspects related to your "Interaction" with the insulin pump. (Please rate the emotion/impression caused by each of them on a scale from 1 to 5)

- 1. Very annoying, very disappointing, or very uncomfortable*
- 2. Annoying, disappointing, or uncomfortable to some extent*
- 3. Neutral, never thought of it, or no opinion*
- 4. Enjoyable, satisfying, or comfortable to some extent*
- 5. Very enjoyable, very satisfying or very comfortable*

- Inserting the set
- Pain in the infusion site
- Filling the reservoir
- Readability of the screen
- Ease of access to desired info / function
- Audibility of alerts
- Temporary disconnecting the pump
- Ability to temporarily modify basal rates for different situations
- Accidental pressing of buttons
- Need to learn pumping theory
- Need to have extra trouble-shooting skills
- Remote control
- Knowledge & Ability to use all functions of the pump

Below are some potentially positive and negative aspects related to the "Emotional Result" of using an insulin pump. (Please rate the emotion/impression caused by each of them on a scale from 1 to 5)

1. *Very annoying, very disappointing, or very uncomfortable*
2. *Annoying, disappointing, or uncomfortable to some extent*
3. *Neutral, never thought of it, or no opinion*
4. *Enjoyable, satisfying, or comfortable to some extent*
5. *Very enjoyable, very satisfying or very comfortable*

- Perception of increased well being
- Sense of being connected to a machine
- Pump colours, ability to personalize
- Overall feeling of security
- Overall feeling of everything being under your control
- Overall perception of increased freedom with pump
- Overall opinion about your pump

Below are some potentially negative aspects related to the use of insulin pump. (Please rate the adequacy of statements below on a scale from 1 to 5)

1. *Strongly disagree*
2. *Disagree to some extent*
3. *I am neutral, I have no opinion*
4. *Agree to some extent*
5. *Strongly agree*

- I am very concerned about the cost of therapy
- I am very worried about infections around the infusion site
- I am very concerned about unexpected / sudden pump problems

Below are some potentially positive and negative aspects related to the "Performance" of your insulin pump. Please rate the change after you started using your insulin pump

1. *Clearly worse*
2. *Worse to some extent*
3. *Neutral, never thought of it, or no opinion*
4. *Better to some extent*
5. *Clearly better*

- Improved HbA1C results
- Hyperglycemia occurrence
- Hypoglycemia occurrence
- Ketoacidosis occurrence
- Flexibility in food types & quantity
- Flexibility in scheduling meal & sleep times

Below are some statements related to the pump therapy. (Please rate the adequacy of the statements on a scale of 1 to 6)

1.Strongly disagree

2.Disagree to some extent

3.Neutral

4.Agree to some extent

5.Strongly Agree

0.No opinion

- I would readily want to convert back to my old diabetes management method if my pump therapy did not change my glucose levels
- I would enjoy a more playful, customizable pump with a better style and fun add-ons
- I would prefer an mp3 player / mobile phone like pump
- I think some inconveniences of my pump are related to bad design & can be improved easily with enough user feedback
- There are times I use my pump in a way that was not suggested by the pump company but invented by me or other pump users
- I feel more diabetic with my pump