Overnight glucose control in people with type 1 diabetes

This paper presents an individualized model predictive control (MPC) algorithm for overnight blood glucose stabilization in people with type 1 diabetes (T1D). The MPC formulation uses an asymmetric objective function that penalizes low glucose levels more heavily. We compute the model parameters in the MPC in a systematic way based on a priori available patient information. The model used by the MPC algorithm for filtering and prediction is an autoregressive integrated moving average with exogenous input (ARIMAX) model implemented as a linear state space model in innovation form. The control algorithm uses frequent glucose measurements from a continuous glucose monitor (CGM) and its decisions are implemented by a continuous subcutaneous insulin infusion (CSII) pump. We provide guidelines for tuning the control algorithm and computing the Kalman gain in the linear state space model in innovation form. We test the controller on a cohort of 100 randomly generated virtual patients with a representative inter-subject variability. We use the same control algorithm for a feasibility overnight study using 5 real patients. In this study, we compare the performance of this control algorithm with the patient’s usual pump setting. We discuss the results of the numerical simulations and the in vivo clinical study from a control engineering perspective. The results demonstrate that the proposed control strategy increases the time spent in euglycemia.
Adaptive control in an artificial pancreas for people with type 1 diabetes

In this paper, we discuss overnight blood glucose stabilization in patients with type 1 diabetes using a Model Predictive Controller (MPC). We compute the model parameters in the MPC using a simple and systematic method based on a priori available patient information. We describe and compare 3 different model structures. The first model structure is an autoregressive integrated moving average with exogenous input (ARIMAX) structure. The second model structure is an autoregressive moving average with exogenous input (ARMAX) model, i.e., a model without an integrator. The third model structure is an adaptive ARMAX model in which we use a recursive extended least squares (RELS) method to estimate parameters of the stochastic part. In addition, we describe some safety layers in the control algorithm that improve the controller robustness and reduce the risk of hypoglycemia. We test and compare our control strategies using a virtual clinic of 100 randomly generated patients with a representative inter-subject variability. This virtual clinic is based on the Hovorka model. We consider the case where only half of the meal bolus is administered at mealtime, and the case where the insulin sensitivity increases during the night. The numerical results suggest that the use of an integrator leads to higher occurrence of hypoglycemia than for the controllers without the integrator. Compared to other control strategies, the adaptive MPC reduces both the time spent in hypoglycemia and the time spent in hyperglycemia.
Assessment of Model Predictive and Adaptive Glucose Control Strategies for People with Type 1 Diabetes

This paper addresses overnight blood glucose stabilization in people with type 1 diabetes using a Model Predictive Controller (MPC). We use a control strategy based on an adaptive ARMAX model in which we use a Recursive Extended Least Squares (RELS) method to estimate parameters of the stochastic part. We compare this model structure with an autoregressive integrated moving average with exogenous input (ARIMAX) structure, and with an autoregressive moving average with exogenous input (ARMAX) model, i.e. without an integrator. Additionally, safety layers improve the controller robustness and reduce the risk of hypoglycemia. We test our control strategies on a virtual clinic of 100 randomly generated patients with a representative inter-subject variability. This virtual clinic is based on the Hovorka model. We consider the case where only half of the meal bolus is administered at mealtime, and the case where the insulin sensitivity...
varies during the night. The simulation results demonstrate that the adaptive control strategy can reduce the risks of hypoglycemia and hyperglycemia during the night.

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**Predicting Plasma Glucose From Interstitial Glucose Observations Using Bayesian Methods**

One way of constructing a control algorithm for an artificial pancreas is to identify a model capable of predicting plasma glucose (PG) from interstitial glucose (IG) observations. Stochastic differential equations (SDEs) make it possible to account both for the unknown influence of the continuous glucose monitor (CGM) and for unknown physiological influences. Combined with prior knowledge about the measurement devices, this approach can be used to obtain a robust predictive model. A stochastic-differential-equation-based gray box (SDE-GB) model is formulated on the basis of an identifiable physiological model of the glucoregulatory system for type 1 diabetes mellitus (T1DM) patients. A Bayesian method is used to estimate robust parameters from clinical data. The models are then used to predict PG from IG observations from 2 separate study occasions on the same patient. First, all statistically significant diffusion terms of the model are identified using likelihood ratio tests, yielding inclusion of \( \sigma_{Isc} \), \( \sigma_{Gp} \), and \( \sigma_{Gsc} \). Second, estimates using maximum likelihood are obtained, but prediction capability is poor. Finally, a Bayesian method is implemented. Using this method the identified models are able to predict PG using only IG observations. These predictions are assessed visually. We are also able to validate these estimates on a separate data set from the same patient. This study shows that SDE-GBs and a Bayesian method can be used to identify a reliable model for prediction of PG using IG observations obtained with a CGM. The model could eventually be used in an artificial pancreas.

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Exercise effects in a virtual type 1 diabetes patient: Using stochastic differential equations for model extension

The use of virtual patients for in silico testing of control algorithms for an artificial pancreas is growing. It is an easy, fast and low-cost alternative to pre-clinical testing. To simulate the everyday life of a type 1 diabetes (T1D) patient a simulator must be able to take into account physical activity. Exercise constitutes a substantial challenge to closed-loop control of T1D. The effects are many and depend on intensity and duration and may be delayed by several hours. In this study, we use a model for the glucoregulatory system based on the minimal model and a previously published extension incorporating exercise effects on insulin and glucose dynamics. Our model is constructed as a stochastic state space model consisting of a set of stochastic differential equations (SDEs). In a stochastic state space model, the residual error is split into random measurement error and misspecification noise. The latter of the two can be used to pinpoint model deficiencies or unknown influential factors during the development of the model. The model is thus built on the basis of physiological knowledge of the system combined with information from observed data. Model parameters are estimated on clinical data from a study including exercise bouts of 20 minutes performed on 12 T1D patients treated with continuous subcutaneous insulin infusion. The predictive abilities of the model are investigated. In conclusion, this study illustrates the advantages of using SDEs in the development of an extended glucoregulatory model including effects of exercise suited for in silico testing.
Model-Based Closed-Loop Glucose Control in Type 1 Diabetes: The DiaCon Experience

Background:
To improve type 1 diabetes mellitus (T1DM) management, we developed a model predictive control (MPC) algorithm for closed-loop (CL) glucose control based on a linear second-order deterministic-stochastic model. The deterministic part of the model is specified by three patient-specific parameters: insulin sensitivity factor, insulin action time, and basal insulin infusion rate. The stochastic part is identical for all patients but identified from data from a single patient. Results of the first clinical feasibility test of the algorithm are presented.

Methods:
We conducted two randomized crossover studies. Study 1 compared CL with open-loop (OL) control. Study 2 compared glucose control after CL initiation in the euglycemic (CL-Eu) and hyperglycemic (CL-Hyper) ranges, respectively. Patients were studied from 22:00–07:00 on two separate nights.

Results:
Each study included six T1DM patients (hemoglobin A1c 7.2% ± 0.4%). In study 1, hypoglycemic events (plasma glucose < 54 mg/dl) occurred on two OL and one CL nights. Average glucose from 22:00–07:00 was 90 mg/dl [74–146 mg/dl; median (interquartile range)] during OL and 108 mg/dl (101–128 mg/dl) during CL (determined by continuous glucose monitoring). However, median time spent in the range 70–144 mg/dl was 67.9% (3.0–73.3%) during OL and 80.8% (70.5–89.7%) during CL. In study 2, there was one episode of hypoglycemia with plasma glucose <54 mg/dl in a CL-Eu night. Mean glucose from 22:00–07:00 and time spent in the range 70–144 mg/dl were 121 mg/dl (117–133 mg/dl) and 69.0% (30.7–77.9%) in CL-Eu and 149 mg/dl (140–193 mg/dl) and 48.2% (34.9–72.5%) in CL-Hyper, respectively.

Conclusions:
This study suggests that our novel MPC algorithm can safely and effectively control glucose overnight, also when CL control is initiated during hyperglycemia.
Model Identification Using Stochastic Differential Equation Grey-Box Models in Diabetes

BACKGROUND:
The acceptance of virtual preclinical testing of control algorithms is growing and thus also the need for robust and reliable models. Models based on ordinary differential equations (ODEs) can rarely be validated with standard statistical tools. Stochastic differential equations (SDEs) offer the possibility of building models that can be validated statistically and that are capable of predicting not only a realistic trajectory, but also the uncertainty of the prediction. In an SDE, the prediction error is split into two noise terms. This separation ensures that the errors are uncorrelated and provides the possibility to pinpoint model deficiencies.

METHODS:
An identifiable model of the glucoregulatory system in a type 1 diabetes mellitus (T1DM) patient is used as the basis for development of a stochastic-differential-equation-based grey-box model (SDE-GB). The parameters are estimated on clinical data from four T1DM patients. The optimal SDE-GB is determined from likelihood-ratio tests. Finally, parameter tracking is used to track the variation in the "time to peak of meal response" parameter.

RESULTS:
We found that the transformation of the ODE model into an SDE-GB resulted in a significant improvement in the prediction and uncorrelated errors. Tracking of the "peak time of meal absorption" parameter showed that the absorption rate varied according to meal type.

CONCLUSION:
This study shows the potential of using SDE-GBs in diabetes modeling. Improved model predictions were obtained due to the separation of the prediction error. SDE-GBs offer a solid framework for using statistical tools for model validation and model development.
Modelling the Effect of Exercise on Insulin Pharmacokinetics in "Continuous Subcutaneous Insulin Infusion" Treated Type 1 Diabetes Patients

Introduction: The artificial pancreas is believed to ease the burden of constant management of type 1 diabetes for the patients substantially. An important aspect of the artificial pancreas development is the mathematical models used for control, prediction or simulation. A major challenge to the realization of the artificial pancreas is the effect of exercise on the insulin and plasma glucose dynamics. In this report, we take the first step towards a population model of exercise effects in type 1 diabetes. We focus on the effect on the insulin pharmacokinetics in continuous subcutaneous insulin infusion (CSII) treated patients by modelling the absorption rate as a function of exercise.

Methods: Three models are estimated from 17 data sequences. All of them are based on a linear three-compartment base model. The models are based on stochastic differential equations to allow noise to enter the dynamics. In the first model, the insulin absorption rate parameter is replaced by a random walk. In the second model, the relationship between the absorption rate and exercise is modelled as a linear dependency, while in the third model this linear relationship depends on the intensity. A Lamperti transformation is used to ensure non-negative state values. A special focus is put on the structural identifiability of the base model, while the posterior identifiability is checked for all models from the conditional likelihood profiles.

Results: The first model is disregarded due to the small number of observations during the exercise bout. From likelihood-ratio tests and information criteria, the third model is appointed as the best model to model the relationship between exercise and the insulin absorption. The posterior identifiability check showed that it was not possible to identify the variance of the measurement variance.

Conclusion: A model to predict the insulin appearance in plasma during exercise in CSII treated patients is identified. Further clinical studies are needed to confirm the increase in insulin plasma concentration during exercise in type 1 diabetes patients. These studies should include dense sampling to allow for a fully data driven identification of an appropriate model.

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Stochastic Differential Equations in Artificial Pancreas Modelling

Type 1 diabetes accounts for approximately 5% of the total diabetes population. It is caused by the destruction of insulin producing β-cells in the pancreas. Various treatment strategies are available today, some of which include advanced technological devices such as an insulin pump and a continuous glucose monitor (CGM). Despite these technological advances in the treatment of type 1 diabetes, the disease still poses an enormous and constant challenge for the patients. To obtain tight glucose control the patients are required to assess how much they will eat prior to the meal. They have to assess the timing, intensity and duration of physical exercise in advance, to adjust the insulin dose accordingly. Additionally, several uncontrollable and unpredictable factors such as stress, hormonal cycles and sickness changing the metabolic state make this task even more difficult.

The development of the insulin pump and the CGM has paved the way for a fully automatic treatment regime, the artificial pancreas. The idea is to connect the CGM with the insulin pump via a control algorithm running on e.g. the patients smart phone. The CGM observations are sent to the smart phone and based on this information, the control algorithm computes the optimal dose adjustment and sends instructions to the insulin pump.

To develop control algorithms, mathematical models of the physiological dynamics are needed. They attempt to describe the significant dynamics of the system and hence they approximate the system behavior. However, uncertainty in the model occurs due to the nature of physiological systems and due to the presence of unknown disturbances. An attractive approach to deal with this uncertainty is to use stochastic differential equations (SDEs). In a model based on SDEs, the noise is separated into two terms: 1) a diffusion term occurring from model misspecifications, effects of unknown disturbances, or just true stochastic behavior of the system and 2) a measurement noise term representing the serially uncorrelated error occurring due to the imperfect analysing equipment. The diffusion term affects the evolution of the system directly.

The purpose of this PhD-project was to investigate the potential of SDEs in the artificial pancreas development. Especially, the emerging continuous monitoring of glucose levels makes SDEs highly applicable to this field. The current thesis aims at demonstrating and discussing the benefits and challenges by using SDEs compared to traditional methods on the basis of the results of the project.

First of all, we designed a clinical study to obtain high quality data from type 1 diabetes patients to identify the models from. The study included the main factors influencing the glucose level: insulin boluses, meals, and exercise. A modelling study showed that using SDEs in model development can be advantageous in several ways. We were able to pinpoint model deficiencies in a well-known model and to track parameter variation probably caused by a differences in meal type. This information could be added to the model to improve the fit. The study was limited by the lack of a software capable of handling SDE models of population effects instead of single-subject effects. A prototype of this type of software was developed parallel to the end of the project. Thus, we could finally identify a population model of the effect of exercise on the insulin absorption rate. The small amount of observations made it impossible to use SDEs to track parameter variation. Instead, we formulated a model structure with showed to be significantly better than the base model with a constant rate.

Two studies specifically related to the CGM observations were performed during the project. In the first study, we showed that SDEs could be used to tune a control algorithm for overnight glucose control on the basis of CGM observations. The tuned algorithm improved the controller performance in a subsequent clinical study. Further attempts to deal with the problems related to the CGM included a Bayesian estimation scheme. By incorporating prior knowledge about the uncertainty in the CGM observations into the estimation method, we succeeded in predicting the plasma glucose level with acceptable confidence from the CGM observations only.

Overall, the project confirms that SDEs have a large potential within this field. However, future modeling requires a robust software capable of handling the nonlinear population SDE models. When this is available, larger modeling studies can be initiated and the impact of SDEs would be expected to increase.

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Subdural to subgaleal EEG signal transmission: The role of distance, leakage and insulating affectors

Objective
To estimate the area of cortex affecting the extracranial EEG signal.

Methods
The coherence between intra- and extracranial EEG channels were evaluated on at least 10min of spontaneous, awake data from seven patients admitted for epilepsy surgery work up.

Results
Cortical electrodes showed significant extracranial coherent signals in an area of approximately 150cm² although the field of vision was probably only 31cm² based on spatial averaging of intracranial channels taking into account the influence of the craniotomy and the silastic membrane of intracranial grids. Selecting the best cortical channels, it was possible to increase the coherence values compared to the single intracranial channel with highest coherence. The coherence seemed to increase linearly with an accumulation area up to 31cm², where 50% of the maximal coherence was obtained accumulating from only 2cm² (corresponding to one channel), and 75% when accumulating from 16cm².

Conclusion
The skull is an all frequency spatial averager but dominantly high frequency signal attenuator.

Significance
An empirical assessment of the actual area of cerebral sources generating the extracranial EEG provides better opportunities for clinical electroencephalographers to determine the location of origin of particular patterns in the EEG.
Intra- and extracranial electroencephalography, Transfer function, Skull, Breach rhythm, Coherence

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Computational Methods for Model Predictive Control: New Opportunities for Computational Scientists
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Control of Blood Glucose for People with Type 1 Diabetes: an In Vivo Study

Since continuous glucose monitoring (CGM) technology and insulin pumps have improved recent years, a strong interest in a closed-loop artificial pancreas for people with type 1 diabetes has arisen. Presently, a fully automated controller of blood glucose must face many challenges, such as daily variations of patient's physiology and lack of accuracy of glucose sensors. In this paper we design and discuss an algorithm for overnight closed-loop control of blood glucose in people with type 1 diabetes. The algorithm is based on Model Predictive Control (MPC). We use an offset-free autoregressive model with exogenous input and moving average (ARMAX) to model the patient. Observer design and a time-varying glucose reference signal improve robustness of the algorithm. We test the algorithm in two clinical studies conducted at Hvidovre Hospital. The first study took place overnight, and the second one took place during daytime. These trials demonstrate the importance of observer design in ARMAX models and show the possibility of stabilizing blood glucose during the night.

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Effects of Everyday Life Events on Glucose, Insulin, and Glucagon Dynamics in Continuous Subcutaneous Insulin Infusion–Treated Type 1 Diabetes: Collection of Clinical Data for Glucose Modeling
Background: In the development of glucose control algorithms, mathematical models of glucose metabolism are useful for conducting simulation studies and making real-time predictions upon which control calculations can be based. To obtain type 1 diabetes (T1D) data for the modeling of glucose metabolism, we designed and conducted a clinical study.

Methods: Patients with insulin pump–treated T1D were recruited to perform everyday life events on two separate days. During the study, patients wore their insulin pumps and, in addition, a continuous glucose monitor and an activity monitor to estimate energy expenditure. The sequence of everyday life events was predetermined and included carbohydrate intake, insulin boluses, and bouts of exercise; the events were introduced, temporally separated, in different orders and in different quantities. Throughout the study day, 10-min plasma glucose measurements were taken, and samples for plasma insulin and glucagon analyses were obtained every 10 min after an event and subsequently every 30 min.

Results: We included 12 patients with T1D (75% female, 34.3±9.1 years old [mean±SD], hemoglobin A1C 6.7±0.4%). During the 24 study days we collected information-rich, high-quality data during fast and slow changes in plasma glucose following carbohydrate intake, exercise, and insulin boluses.

Conclusions: This study has generated T1D data suitable for glucose modeling, which will be used in the development of glucose control strategies. Furthermore, the study has given new physiologic insight into the metabolic effects of carbohydrate intake, insulin boluses, and exercise in continuous subcutaneous insulin infusion–treated patients with T1D.
Overnight Control of Blood Glucose in People with Type 1 Diabetes

In this paper, we develop and test a Model Predictive Controller (MPC) for overnight stabilization of blood glucose in people with type 1 diabetes. The controller uses glucose measurements from a continuous glucose monitor (CGM) and its decisions are implemented by a continuous subcutaneous insulin infusion (CSII) pump. Based on a priori patient information, we propose a systematic method for computation of the model parameters in the MPC. Safety layers improve the controller robustness and reduce the risk of hypoglycemia. The controller is evaluated in silico on a cohort of 100 randomly generated patients with a representative intersubject variability. This cohort is simulated overnight with realistic variations in the insulin sensitivities and needs. Finally, we provide results for the first tests of this controller in a real clinic.

Tuning of Controller for Type 1 Diabetes Treatment with Stochastic Differential Equations

People with type 1 diabetes need several insulin injections every day to keep their blood glucose level in the normal range and thereby avoiding the acute and long term complications of diabetes. One of the recent treatments consists of a pump injecting insulin into the subcutaneous layer combined with a continuous glucose monitor (CGM) frequently observing the glucose level. Automatic control of the insulin pump based on CGM observations would ease the burden of constant diabetes treatment and management. We have developed a controller designed to keep the blood glucose level in the normal range by adjusting the size of insulin infusions from the pump based on model predictive control (MPC). A clinical pilot study to test the performance of the MPC controller overnight was performed. The conclusion was that the controller relied too much on the local trend of the blood glucose level which is a problem due to the noise corrupted observations from the CGM. In this paper we present a method to estimate the optimal Kalman gain in the controller based on stochastic differential equation modeling. With this model type we could estimate the process noise and observation noise...
separately based on data from the first clinical pilot study. In doing so we obtained a more robust control algorithm which is less sensitive to fluctuations in the CGM observations and rely more on the global physiological trend of the blood glucose level. Finally, we present the promising results from the second pilot study testing the improved controller.

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Clinical evaluation of 3D/3D MRI-CBCT automatching on brain tumors for online patient setup verification - A step towards MRI-based treatment planning
Background. Magnetic Resonance Imaging (MRI) is often used in modern day radiotherapy (RT) due to superior soft tissue contrast. However, treatment planning based solely on MRI is restricted due to e. g. the limitations of conducting online patient setup verification using MRI as reference. In this study 3D/3D MRI-Cone Beam CT (CBCT) automatching for online patient setup verification was investigated. Material and methods. Initially, a multi-modality phantom was constructed and used for a quantitative comparison of CT-CBCT and MRI-CBCT automatching. Following the phantom experiment three patients undergoing postoperative radiotherapy for malignant brain tumors received a weekly CBCT. In total 18 scans was matched with both CT and MRI as reference. The CBCT scans were acquired using a Clinac iX 2300 linear accelerator (Varian Medical Systems) with an On-Board Imager (OBI). Results. For the phantom experiment CT-CBCT and MRI-CBCT automatching resulted in similar results. A significant difference was observed only in the longitudinal direction where MRI-CBCT resulted in the best match (mean and standard deviations of -0.05 +/- 2.55 mm for CT and -0.05 +/- 2.55 mm for MRI). For the clinical experiment the absolute difference in couch shift coordinates acquired from MRI-CBCT and CT-CBCT automatching, were

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DiasCon: an interdisciplinary approach to diabetes control

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**Stokastisk dynamisk modellering til kort-tidsregulering af glukose/insulin-metabolismen**

Department of Informatics and Mathematical Modeling
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