

## Pilot Studies of Transdermal Continuous Glucose Measurement in Outpatient Diabetic Patients and in Patients during and after Cardiac Surgery

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### Abstract

#### Background:

We tested the hypothesis that glucose can be measured continuously and reliably in patients in diverse settings using a transdermal biosensor coupled to a permeated skin site. In addition, we compared a novel, abrasion-based skin permeation method to an ultrasound-based method for transdermal continuous glucose monitoring.

#### Method:

Transdermal continuous glucose monitors were applied to patients with diabetes (study I), patients undergoing cardiac surgery (study II), and healthy volunteers (study III). Reference blood glucose measurements were performed with glucometers or standard blood glucose analyzers. At the conclusion of the 24-hour study, data were postprocessed for comparison with the reference blood glucose values collected during the study period.

#### Results:

Data were validated for 10 subjects for 12 hours in study I, 8 subjects for 24 hours in study II, and 6 subjects in study III. The transdermal continuous glucose monitors usually required 1 hour of warm up. Depending on the study setting, single or multiple calibrations were applied to the datasets. Comparing predicted glucose versus reference blood glucose values, we found that study I yielded 89.6% in zone A and 9.0% in zone B in the Clarke error grid (222 data points), study II yielded 86.4% in zone A and 13.6% in zone B (147 data points), and study III yielded 89.9% in zone A and 10.1% in zone B (378 data points).

#### Conclusions:

Continuous transdermal glucose monitoring was demonstrated successfully in diverse clinical settings. The performance of abrasion was equivalent to ultrasound skin permeation methodology for transdermal glucose monitoring.

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**Abbreviations:** (BG) blood glucose, (CTU) cardiothoracic intensive care unit, (CEG) Clarke error grid, (IRB) institutional review board, (ICU) intensive care unit, (intra-op) intraoperation, (MARD) mean absolute relative difference, (PEGDA) polyethylene glycol diacrylate, (post-op) postoperation, (tCGM) transdermal continuous glucose monitor

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