ISSN: 2768-3699

Journal of Clinical Diabetes & Obesity

Review Article

Open Access

Automated Insulin Delivery in Type 1 Diabetes: Who Benefits Least and Why That Matters

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Received: 19 January 2026; Accepted: 18 May 2026; Published: 27 August 2026

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Abstract

Automated insulin delivery improves glycaemic outcomes in type 1 diabetes, and meta-analysis puts the gain in time in target range at roughly 8 to 12 percentage points. The average conceals a steep gradient. In a subgroup analysis of 168 trial participants with baseline HbA1c from 5.4 to 10.6 per cent, those starting below 6.5 per cent recorded a 4.4 percentage point reduction in time in range, while those above 8.5 per cent gained 21.9 points, rising to 30.4 points overnight. Benefit therefore scales with how poor control was to begin with. The awkward consequence is that early trials recruited people below a maximum HbA1c threshold, on established pump and sensor therapy, so the evidence was generated largely in the group that gains least. Where access was universal, a real-world cohort of 160 adults, 26.9 per cent non-White and 48.8 per cent in the two most deprived quintiles, showed no influence of ethnicity or deprivation on outcome.

Keywords: *Automated insulin delivery; Closed-loop; Time in range; Health inequity; Type 1 diabetes*

Introduction

Automated insulin delivery systems link a glucose sensor to an insulin pump through an algorithm that adjusts delivery, typically every five minutes [1,2]. They have moved from research to standard care for type 1 diabetes within about a decade [3,4,22]. Randomised trials have since extended to children and to very young children [20,21], and consensus recommendations for clinical use have been issued [4].

Meta-analyses of trial data in adults and children report improvements in time spent in target glucose range of approximately 8 to 12 percentage points, with reduced time in hyperglycaemia, lower mean glucose and either reduced or unchanged time in hypoglycaemia [5,6,7,23]. Time in range itself has been validated as a trial outcome and its interpretation standardised by international consensus [24,25].

Averages of that kind describe a population rather than a person. This review examines how the benefit is distributed, which groups gain least, and what follows for how these systems are offered.

Material and Methods

Search strategy: PubMed and the archives of the major diabetes, technology and paediatric journals were searched for studies of automated insulin delivery. Search terms combined closed-loop, hybrid closed-loop and automated insulin delivery with time in range, baseline HbA1c, subgroup, real-world and discontinuation. Reference lists of the principal trials [8,9] and implementation reports [10] were screened by hand for primary sources.

Eligibility: Studies were included if they reported glycaemic outcomes with these systems in defined populations, examined how outcomes varied between subgroups, or described real-world implementation. Trial inclusion criteria are reported where they bear on generalisability and are identified as such.

Data extraction and handling: Design, population, entry criteria, baseline glycaemic status and the reported outcome were

extracted as published. Entry criteria are stated alongside every trial estimate, because thresholds on HbA1c, insulin dose and prior technology use determine which patients the estimate describes and this bears directly on the argument. This review reports measured outcomes and does not constitute guidance on the selection or prescription of any device. No pooling or re-analysis was performed. Figures 1 to 6 and Tables 1 to 3 reproduce published values only. This is a narrative synthesis and was not registered as a systematic review.

Results

The pooled effect: Meta-analyses of trial data show these systems outperforming non-automated therapy, with improvements in time in target range of approximately 8 to 12 percentage points (Figure 6) [5,6,7]. A multicentre study in 86 children, adolescents and adults with suboptimal control despite pump therapy, with baseline HbA1c between 7.5 and 10.0 per cent, found time in range 10.8 percentage points higher over 12 weeks of free living [11]. An early system in auto mode raised time in range from 66.0 to 73.3 per cent and reduced time below 3.9 mmol/L from 2.7 to 2.1 per cent [12].

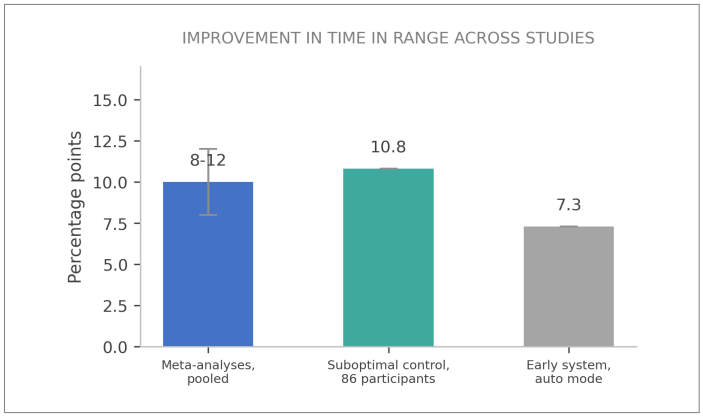

Figure 6: Improvement in time in range reported across studies [5,11,12]

How the benefit is distributed: A subgroup analysis of 168 participants aged 14 to 71 with type 1 diabetes for at least a year, and baseline HbA1c ranging from 5.4 to 10.6 per cent, examined outcomes by starting control. Those with an HbA1c below 6.5 per cent recorded a 4.4 percentage point reduction in time in range, while those above 8.5 per cent recorded a 21.9 percentage point improvement (Figure 1) [8,13].

Table 2: Reported outcomes by population studied

Table 3: How benefit and representation align across groups

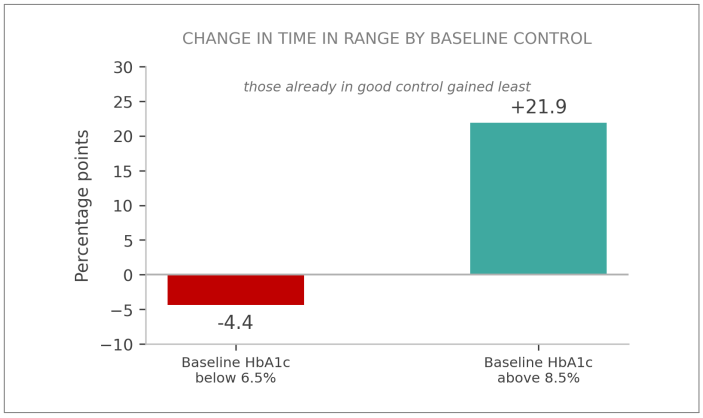

Figure 1: Change in time in range by baseline glycaemic control [8,13]

Day and night differ: The same analysis separated periods. Among those below 6.5 per cent the reduction was 3.6 points during the day and 6.8 points overnight; among those above 8.5 per cent the improvement was 19.2 points during the day and 30.4 points overnight (Figure 2) [8,13]. The investigators attributed the pattern to automated basal adjustment through the night and hourly automatic correction boluses compensating for missed meal boluses during the day [13].

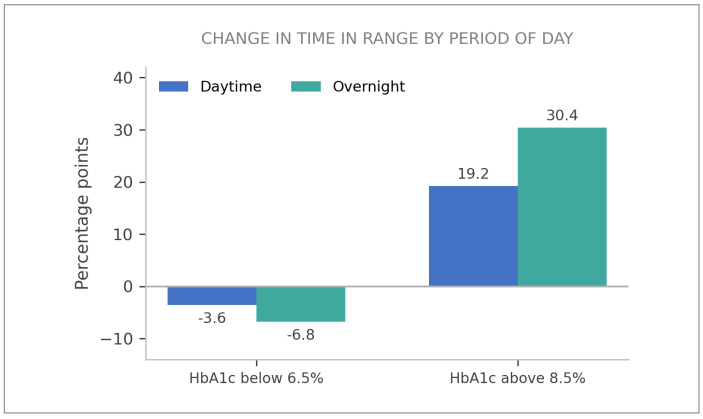

Figure 2: Change in time in range by period of day and baseline control [8,13]

Baseline HbA1c	Overall	Daytime	Overnight
Below 6.5%	-4.4	-3.6	-6.8
Above 8.5%	+21.9	+19.2	+30.4

Table 1: Change in time in range in percentage points, by baseline control and period of day [8,13]

Who the trials recruited: Clinical investigation of these systems has focused on adults and children aged six and above in low-risk groups defined by clinical ranges, including a maximum HbA1c threshold and a minimum total daily insulin dose (Figure 5) [1,14]. Many early studies demonstrated efficacy in individuals with good glycaemic control at recruitment, who may not represent the wider population with type 1 diabetes [12,15].

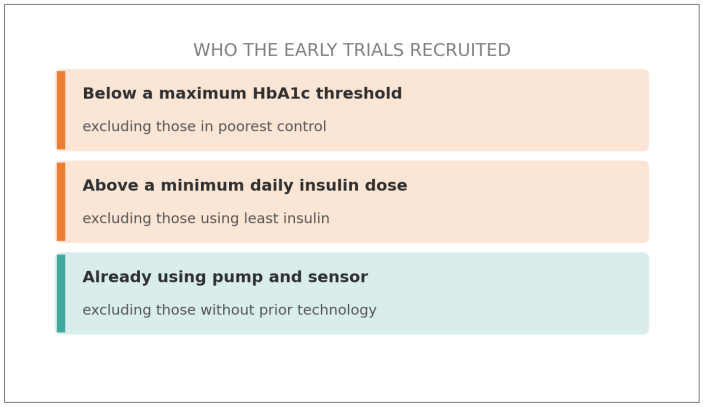

Figure 5: Entry criteria applied in early trials of these systems [1,12,14]

National implementation: A pilot evaluating real-world implementation included 251 children and 570 adults. Among 226 children and young people with complete data at six months, HbA1c fell by 0.7 percentage points and time in target range rose from 49 to 63 per cent. Among 520 adults continuing at six months, HbA1c fell by 1.7 percentage points and time in range rose from 34 to 62 per cent, with a significant reduction in time in hypoglycaemia in both groups (Figure 3) [10,16].

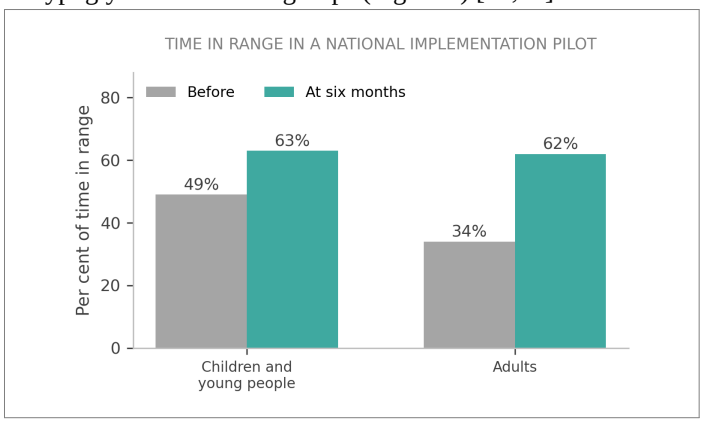

Figure 3: Time in range in a national implementation pilot [10,16]

Ethnicity and deprivation: A retrospective study of 160 adults starting a tubeless system at a publicly funded multi-site service examined social determinants. Of the cohort, 26.9 per cent were non-White and 48.8 per cent lived in the two most deprived quintiles. Mean time in range improved from 52.7 plus or minus 16 per cent to 67.9 plus or minus 12.7 per cent at twelve weeks ($p < 0.001$), and neither ethnicity nor socioeconomic status influenced the glycaemic outcome (Figure 4) [17].

Study	Population	Reported outcome
Subgroup analysis [8,13]	168, HbA1c 5.4 to 10.6%	-4.4 to +21.9 points
Suboptimal control [11]	86, HbA1c 7.5 to 10.0%	+10.8 points
National pilot, adults [10]	520 continuing at 6 months	34% to 62%
National pilot, children [10]	226 with complete data	49% to 63%
Real-world cohort [17]	160 adults, diverse	52.7% to 67.9%

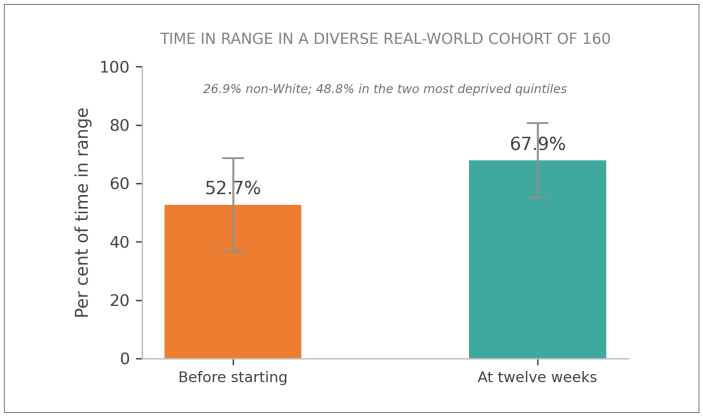

Figure 4: Time in range in a diverse real-world cohort of 160 adults [17]

Discontinuation: A real-world observational study of 93 children and young adults using an early system in auto mode for a mean of eight months demonstrated high rates of discontinuation [12,18]. Reviews of these systems note that user characteristics influencing clinical impact include baseline glucose management, with the greatest improvements observed in those with poorest starting control [1,19]. Long-term follow-up of a national programme reports glycaemic outcomes and quality of life beyond the first year [34].

Group	Position in the evidence
Poorest baseline control	Gains most; least represented in early trials [8,13]
Best baseline control	Gains least; most represented in early trials [12,15]
Deprived or minority groups	Same benefit where access is universal [17]
Early system users	High discontinuation reported [12,18]

Discussion

The central finding inverts the usual worry about new technology. Automated insulin delivery helped most the people whose control was worst, with a 21.9 percentage point gain in time in range above an HbA1c of 8.5 per cent, and it did not help those already below 6.5 per cent, who recorded a 4.4 point reduction [8,13]. The gradient is steep and it runs in the clinically favourable direction.

The problem is who was studied. Early trials applied a maximum HbA1c threshold, a minimum insulin dose and in many cases prior pump and sensor use as entry criteria [1,12,14,15]. Those criteria select for engagement, existing technology familiarity and reasonable control, which is to say they select for the group the subgroup analysis identifies as gaining least. The evidence base was therefore built where the effect is smallest, which if anything understates what these systems achieve in the population that most needs them.

That has a practical corollary about how devices are allocated. Where eligibility criteria in services mirror trial entry criteria, requiring prior pump use, demonstrated engagement or an HbA1c below some ceiling, they systematically exclude the group in whom the benefit is largest. The reasoning behind such

criteria is usually that these systems demand competence and that poor control predicts poor adherence, but the subgroup data are the direct test of that reasoning and they do not support it [8,13].

The equity finding is the cleanest in this literature and deserves emphasis. In a service with universal access, a cohort in which nearly half lived in the two most deprived quintiles and more than a quarter were not White achieved a fifteen point improvement in time in range, with no influence of ethnicity or deprivation on outcome [17]. Whatever produces disparity in diabetes technology, it is not that these groups respond differently to the device. The disparity is upstream, in who is offered one. Inequity in access to diabetes technology by ethnicity and insurance is documented across a decade and across countries [26,27,28].

A caution belongs against reading all of this too optimistically. High discontinuation was reported in real-world use of an early system in children and young adults [12,18], and the national pilot reports outcomes among those continuing at six months, which excludes anyone who stopped [10]. Continuation is itself an outcome, and a system that works well for those who persist may still fail a substantial minority. The published denominators do not always make that visible. Qualitative work with users, families and clinicians describes the training and support these systems require, which bears directly on whether people continue [31,32], alongside benefits that glycaemic metrics do not capture, such as sleep and reduced fear of hypoglycaemia [33].

Study limitations

The limitations belong to the underlying literature. The central subgroup finding comes from a post hoc analysis of 168 participants and was not the randomised comparison the trial was designed to make, so the gradient is an association within a trial population rather than an estimate of differential treatment effect [8,13]. Entry criteria differ between studies, which is the point of the argument but also limits pooling [11,14]. The national pilot reports those continuing at six months and does not describe those who stopped [10]. The equity analysis is retrospective, single-service and involves 160 adults over twelve weeks, so it cannot exclude differences emerging over longer periods [17]. Time in range is a surrogate, and no study reviewed here reports complications or mortality [5,6]. Devices and algorithms differ substantially and results from one system do not transfer directly to another [1,19,29]. Comparative trials against conventional treatment and against threshold-suspend systems report differing magnitudes [23,30]. And the technology has changed throughout the period these studies span, so the discontinuation data describe systems that have since been superseded [12,18].

Conclusion

Automated insulin delivery raises time in target range by roughly 8 to 12 percentage points on average, and that average hides a steep gradient: a 21.9 point gain in those starting above an HbA1c of 8.5 per cent and a 4.4 point loss in those starting below 6.5. The people who benefit least are those already doing well, and they are precisely the people early trials recruited, because entry criteria capped HbA1c and required prior technology use. Where service eligibility rules reproduce those criteria they exclude the group with most to gain, and the subgroup data are a direct argument against them. Where access was universal, ethnicity and deprivation made no difference to the result, which places the inequity in who is offered the device rather than in who can use it.

Acknowledgements

The authors thank the investigators who published subgroup analyses by baseline control, which is the analysis that makes the distribution of benefit visible, and the services that reported real-world outcomes including those of people who discontinued.

Funding

No dedicated funding from public, commercial or charitable sources supported the preparation of this review.

Conflict of Interest

The authors declare no competing interests.

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Ethics Statement

This article reviews previously published studies only. No new patient data were collected and no participants were recruited, so ethical approval was not required.

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Citation: Baumgartner A, Ellingsen H, Benesova L. "Automated Insulin Delivery in Type 1 Diabetes: Who Benefits Least and Why That Matters". DOI: 10.5281/zenodo.22261606