

Comment

Limitations of a Recent Study on Insulin Pen Needle Preferences in People with Diabetes. Comment on Gentile et al. Enhancing Insulin Therapy Adherence Through Technology: Which Needles Do People with Diabetes Prefer? *Diabetology* 2026, 7, 56

David C. Klonoff ^{1,*}, Mandy M. Shao ² and Agatha F. Scheideman ²

¹ Diabetes Research Institute, Mills-Peninsula Medical Center (Sutter Health), San Mateo, CA 94401, USA

² Diabetes Technology Society, Burlingame, CA 94014, USA

* Correspondence: dklonoff@diabetestechology.org

We read with interest a recent article in *Diabetology* titled “Enhancing Insulin Therapy Adherence Through Technology: Which Needles Do People with Diabetes Prefer?” [1]. Both qualitative and quantitative benefits accrued with a study product (a specific 34 G needle, the Pic Insupen 34 G 3.5 mm pen needle) compared to usual needle therapy, which was a mixture of 29, 30, 31, 32, 33, and 34 G needles. We noted specific limitations in the method that were not mentioned in the article, but which might have played a significant role in the favorable outcome reported for the specific study product, which was a specific needle. First, there is no mention of the study being randomized or whether random allocation of treatments was prespecified. Trials without adequate blinding tend to overestimate treatment effects, particularly when outcomes are subjective or behaviorally influenced [2]. Proper allocation of subjects in a randomized controlled trial requires that the person who generates the allocation sequence should not be the person who determines eligibility and entry of patients, and also the mechanism for treatment allocation should be determined by people not involved in the trial [3].

Two additional limitations with this study’s lack of dedicated matching between the intervention group and the usual care group included (1) a lack of control for the length of prior exposure to the subjects’ usual needles and (2) awareness of the unblinded intervention subjects that they were using a new device, which may result in the Hawthorne effect or novelty effect, which can lead to overestimation of treatment effectiveness [4]. This effect could have favorably influenced intervention subjects to report better qualitative outcomes, such as less injection site pain, which was the most important outcome of the study. The absence of a randomized crossover design further limits the internal validity of the findings. Despite these considerations, the manuscript offers minimal discussion of limitations, which may have decreased the impact of the study’s findings.

Finally, this study in *Diabetology* showed significantly fewer hypo-/hyperglycemic episodes with the interventional needle. However, the article’s Discussion Section did not mention that previous studies have shown that varying needle length within modern ranges (approximately 4–12.7 mm, 29–34 G) does not materially worsen glycemic control [5,6]. This omission might leave an impression that the benefit of improved glycemia noted in this study is typical of the literature, but this is not necessarily the case.

In conclusion, the results in the Gentile study demonstrated positive features of the Pic Insupen 34 G 3.5 mm needle compared to usual therapy. However, based on features of the



Academic Editor: Peter Clifton

Received: 5 May 2026

Accepted: 24 July 2026

Published: 26 August 2026

Copyright: © 2026 by the authors.

Licensee MDPI, Basel, Switzerland.

This article is an open access article distributed under the terms and

conditions of the [Creative Commons Attribution \(CC BY\)](https://creativecommons.org/licenses/by/4.0/) license.

study protocol and based on the discussion of the results, the relative advantages of this new product compared to more traditional needles might be less than what was implied in this article.

Data Availability Statement: No new data were created or analysed in this study. Data sharing is not applicable to this article.

Conflicts of Interest: D.C.K. is a consultant for Afon, Atropos Health, Embecta, Glooko, Glucotrack, Lifecare, Sanofi, SynchNeuro, and Thirdwayv. A.F.S. and M.M.S. have nothing to disclose. The authors declare no conflict of interest.

References

1. Gentile, S.; Fiorentino, R.; Lettieri, M.; Guarino, G.; Marino, G.; Tommasi, E.; Frison, V.; Satta, E.; Chiarello, M.; Caccavale, G.; et al. Enhancing Insulin Therapy Adherence Through Technology: Which Needles Do People with Diabetes Prefer? *Diabetology* **2026**, *7*, 56. [[CrossRef](#)]
2. Monaghan, T.F.; Agudelo, C.W.; Rahman, S.N.; Wein, A.J.; Lazar, J.M.; Everaert, K.; Dmochowski, R.R. Blinding in Clinical Trials: Seeing the Big Picture. *Medicina* **2021**, *57*, 647. [[CrossRef](#)]
3. Altman, D.G.; Schulz, K.F. Statistics notes: Concealing treatment allocation in randomised trials. *BMJ* **2001**, *323*, 446–447. [[CrossRef](#)]
4. Wolfe, F.; Michaud, K. The Hawthorne effect, sponsored trials, and the overestimation of treatment effectiveness. *J. Rheumatol.* **2010**, *37*, 2216–2220. [[CrossRef](#)]
5. De Berardis, G.; Scardapane, M.; Lucisano, G.; Abbruzzese, S.; Bossi, A.C.; Cipponeri, E.; D’Angelo, P.; Fontana, L.; Lancione, R.; Marelli, G.; et al. Efficacy, safety and acceptability of the new pen needle 34G×3.5 mm: A crossover randomized non-inferiority trial; AGO 02 study. *Curr. Med. Res. Opin.* **2018**, *34*, 1699–1704. [[CrossRef](#)]
6. Kreugel, G.; Keers, J.C.; Kerstens, M.N.; Wolffenbuttel, B.H.R. Randomized trial on the influence of the length of two insulin pen needles on glycemic control and patient preference in obese patients with diabetes. *Diabetes Technol. Ther.* **2011**, *13*, 737–741. [[CrossRef](#)]

Disclaimer/Publisher’s Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.