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Enhancing Insulin Therapy Adherence Through Technology: Which Needles Do People with Diabetes Prefer?

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Abstract

Background: Despite major advances in insulin formulations and delivery systems since 1921, many people with diabetes (PwDs) still fail to achieve recommended glycemic targets. Common reasons include inadequate education, injection errors, and poor adherence due to factors such as needle phobia and pain. Recognition of these barriers has driven the development of improved injection systems, particularly thinner and shorter needles. An experimental study previously identified the Pic Insupen 34 G 3.5 mm needle as high performing. We therefore conducted an observational study to assess its acceptability directly among PwDs. Methods: This multicentre, open-label, real-world study enrolled 300 insulin-treated PwDs who compared their usual pen needle (30–33 G) with the new 34 G × 3.5 mm needle over two two-week periods. The primary outcome was perceived puncture pain. Results: Participants overwhelmingly preferred the 34 G needle, based on the following findings: Pain perception: 62% of 34 G users reported minimal or no pain, compared with only 8% using their previous needle. Conversely, 22% of participants reported the highest pain score with their old needle, compared with just 5% using the 34 G. Ease of use: 77% rated the 34 G needle at the highest level of ease of use, compared with 20% for their previous needle. Complications: The 34 G needle was linked to significantly fewer hypo-/hyperglycemic episodes and local skin complications such as bruising or irritation. Eighty per cent reported no glycemic fluctuations while using the 34 G needle. Robustness: Ninety-four per cent of PwDs never observed the 34 G needle bending during use, compared with 64% using their previous needle, confirming greater robustness despite its thinner profile. Conclusions: The Insupen® 34 G × 3.5 mm needle substantially reduces puncture pain and improves the overall manageability of insulin injections. Its innovative design—combining reduced thickness with optimised tip geometry—is associated with fewer complications and enhanced injection performance. Because reduced pain and ease of use are critical for improving adherence to insulin therapy, the features of the 34 G needle should inform future prescribing decisions.

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1. Introduction

According to the International Diabetes Federation (IDF), in 2024 some 537 million adults aged 20–79 had diabetes worldwide [1]. Despite ignoring how many patients are on insulin, we know that most of them have type 1 diabetes (T1D), with those with type 2 diabetes (T2D) requiring insulin during certain phases of the disease or when complications arise. In 2018, the estimated number of people requiring insulin worldwide was 150–200 million [2], with annual production of 100 IU vials increasing from 518.2 million to 633.7 million by 2020 [3] and rising further thereafter, given the ongoing rise in diabetes prevalence.

Technological progress over the past century has yielded increasingly advanced insulin formulations and delivery systems since 1921 [4]. Initially, insulin was administered using reusable glass and metal syringes with long, thick metal needles, which required sterilization by boiling at each injection (see Figure 1), frequently delivering insulin into the muscle rather than the subcutaneous tissue, leading to unpredictable absorption and variable glycemic control [5].

Figure 1. Old reusable glass and metal insulin injection needles. (Source: personal archive).

However, despite the progress in both insulin and injection devices, glycemic targets remain unmet for many persons with diabetes (PwDs) as reported by the Italian AMD Annals, based on one of the largest national diabetes databases. Indeed, among 758,820 PwDs, only 36.2% with T1D and 55.9% with T2D (36% of whom require insulin) achieve an HbA1c $\leq$ 7%, with 29.6% of those with T1D having an HbA1c > 8% [6].

This shortfall depends on multiple factors, like inadequate dosing, inappropriate diet, concurrent illness, incorrect injection technique (including injection into lipodystrophic areas or muscle), needle reuse, fear of hypoglycemia, and missed injections [7].

Extensive scientific literature addresses each of the previous points and the psychological barriers behind them. In clinical practice, several PwDs admit skipping injections for reasons including needle phobia, discomfort, low self-care motivation, and inadequate education about diabetes or injection devices.

Consultation with a diabetes patient chat triggers reflection on the just-mentioned humanistic aspects. Indeed, social media discussions among PwDs highlight the emotional and human aspects of injection therapy—issues often underestimated by healthcare professionals [8]. Platforms such as Instagram, Facebook, X, TikTok, and WhatsApp reveal that at least a quarter of PwDs express fear of needle pricks [9].

Awareness of these concerns has encouraged the development of increasingly refined injection technologies—specifically, thinner, shorter needles with improved tip geometry designed to penetrate the skin as painlessly as possible [10]. Indeed, laboratory inves-

tigations conducted under standardized conditions on pen needles of different gauges (i.e., 31, 32, 33, and 34), lengths (i.e., 3.5, 4, 5, and 8 mm), and bevels (i.e., 3 and 5) have demonstrated that thinner needles require less penetration force. (see Figure 2) [11].

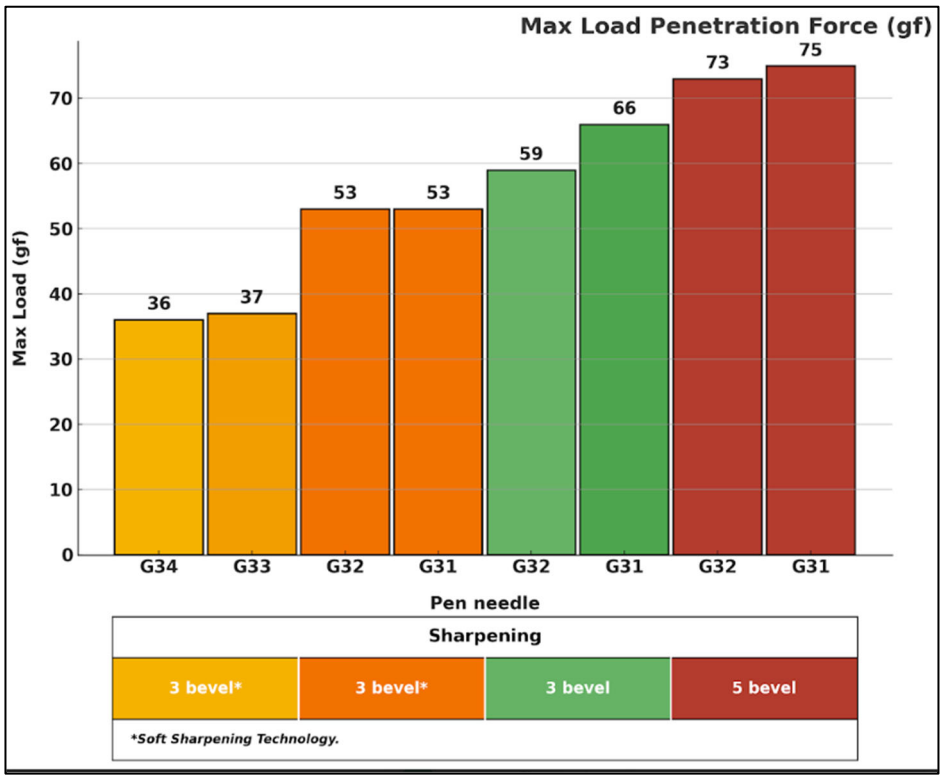

Figure 2. Relation between max load penetration force (gf) and Gauge of needles used in the Picasso Study (adapted from reference [11]. The bevel (i.e., the number of cuts on the tip) of each needle is indicated at the bottom of the panel.

However, until now, there has been limited real-life evidence on how PwDs perceive these needles. The present observational study was therefore designed to assess the acceptability and comfort of the new Pic Insupen 34 G × 3.5 mm needle compared with conventional pen needles, to determine which design best supports adherence to insulin therapy.

2. Methods

This was an observational, multicentre, open-label, real-life study conducted in accordance with the Declaration of Helsinki (1964, and subsequent amendments). All participants provided written informed consent after receiving full details of the study protocol and questionnaire. They agreed to record requested data sequentially while utilizing their usual needle and the new G34 test one (provided by the facility). The study was approved by the Nefrocenter Research Network Scientific Committee on 30 July 2025 (protocol NR/817).

Objective: To assess the perceptions of insulin-treated PwDs regarding the performance of the 34 G needle compared with their usual needle, focusing on pain, usability, and overall satisfaction.

Design: Participants used their usual pen needle for two weeks, then the 34 G test needle for a further two weeks. They recorded their perceptions and any hypoglycemic or hyperglycemic episodes throughout.

Inclusion criteria:

- one year of insulin pen use at least;

- two injections per day at least;
- use of any needle other than 34 G;
- ability to self-administer insulin and provide consent.

Exclusion criteria:

- cognitive or neurological impairment;
- motor neuropathy;
- pregnancy or lactation.

Participants were recruited consecutively by four diabetes specialists until the target number was reached. A validated bilingual questionnaire—including five dichotomous yes/no questions aimed at understanding how PwDs inject insulin, and five multiple-choice questions concerning assessed perceptions of injection pain, ease of use, robustness, and complications. In greater detail, the questionnaire was validated by translating it into English and then re-translating it back into the original language from English, comparing the two versions, and getting a 98% concordance among 20 independent assessors. It is available in Supplementary Materials.

The questions aimed to compare the old and the new G34 needle with respect to the following:

- pain caused by the puncture
- ease of screwing the needle onto the pen
- frequency of hypo/hyperglycemia with the two needles
- frequency of local skin complications at the injection site (redness, irritation, bruising)
- frequency of needle bending during the injection
- overall needle ease of use at the time of injection

The participants were required to complete it and to indicate their perception using a semi-quantitative visual scale of a 1 to 10 increasing intensity (see Figure 3) over the two experimental double-week periods. They also recorded any hypo- or hyper-glycemic events by consistently checking capillary glucose levels several times a day through their usual glucose meters.

Figure 3. Semi-quantitative visual scale of increasing intensity (SQVS-II) from 1 to 10, where 1 indicates the lowest intensity and 10 the highest.

Based on the ADA Standards of Care 2025 [12], we defined hypoglycemia as an episode with blood sugar $\leq$ 60 mg/d at SMBG or accompanied by typical symptoms (shakiness,

sweating, confusion, or a rapid heartbeat). We arbitrarily defined hyperglycemia as blood glucose levels $\geq$ 250 mg/dL at any time.

Statistical Analysis

Based on the mean and standard deviation of pain scores from the Picasso study [11], assuming an effect size of 50%, $\alpha = 0.05$, and power = 0.80, a minimum sample size of 250 was estimated, and we increased the total number of enrolled subjects up to 300 to improve the quality, reliability, and validity of the scientific results.

Given the statistically indistinguishable number of participants and the homogeneity of the answers, to compare Insupen 34 G with the others, we pooled all routinely used needles to avoid overly splitting cases, especially given that PWDs using the more recently available 33 G and 34 G needles were few (8% and 4%, respectively) and thus expected to have little influence on overall results.

We analyzed data using SAS OnDemand for Academics, 2021® University Edition (SAS Institute, Cary, NC, USA) with *t*-tests, χ^2, and non-parametric Wilcoxon or Spearman tests and applied multiple-comparison corrections as appropriate.; we expressed results as numbers, percentages, and means $\pm$ SD.

3. Results

Of 325 eligible participants, 300 completed the study and were included in the analysis. The general characteristics of the enrolled subjects are summarized in Table 1 and Figure 4.

Table 1. General characteristics of enrolled subjects.

General Characteristics of Subjects Enrolled N = 300	
Age ($M \pm SD$) (*range*)	45 ± 37 8–68
Gender (M/F) (%)	47/53
Diabetes type (%) 1 2	 42 58
Diabetes duration (years) $M \pm SD$ *range*	 25 ± 29 4–42
Years of Insulin use (%)	
<10 10–19 20–29 30–39 ≥40	23 28 19 19 11
Number of insulin injections/day ($M \pm SD$)	3.8 ± 0.8
Needle reuse (%)	28
Needle Gauge (%) G29 × 12 mm G30 × 6 mm G31 × 5 mm G32 × 8 mm G32 × 4 mm G33 × 5 mm G34 × 3.5 mm	 3 10 31 2 42 8 4

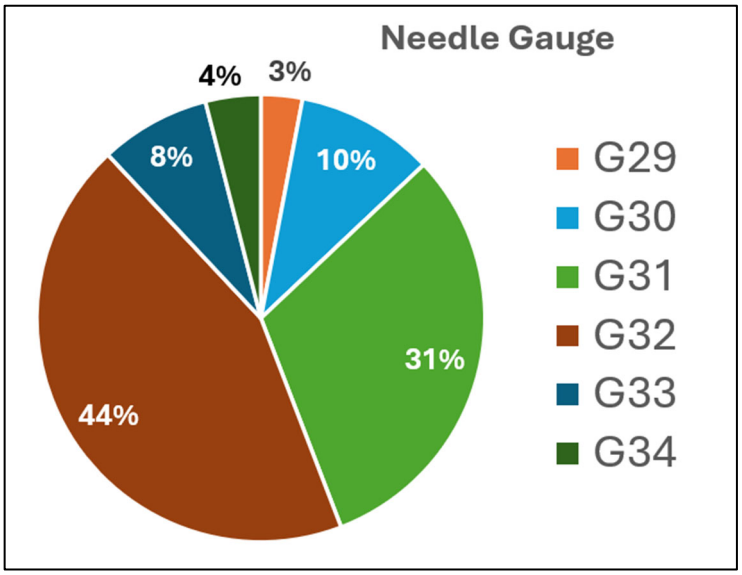

Figure 4. Percentage distribution of needles used by enrolled subjects.

When asked to identify the most important feature of a needle, 87.3% selected "painless", 10% "non-bending", and 2.7% "easy to screw onto the pen". Nearly all (95.3%) agreed that a painless needle would help them better follow treatment instructions. In greater detail, the age of the enrolled subjects is described in Table 2 and Figure 5. The subjects using insulin for over 40 years were 12%, while the distribution in the other decades was more homogeneous, ranging from 19% to 28%.

Table 2. Percentage distribution by age decades of enrolled subjects. ** = $p < 0.01$ vs. all other age classes.

Years	%
<10	23
≥10–19	28
20–29	19
30–39	19
40–49	8 **
50–59	4 **

Table 3 describes the number of daily insulin injections; 70% of the subjects self-injected insulin 3 to over 4 times per day. Based on daily injection rates, the table indicates the percentages of 30 to over 60 injections performed over the double-week observation periods of the study.

Table 3. Number of injections performed. * $p < 0.05$ vs. all other classes.

Number of Injections/Day	%	Number of Injections over 15 Days
>4	13	>60
4	70	60
3	13	45
2	4	30 *
1	0	0

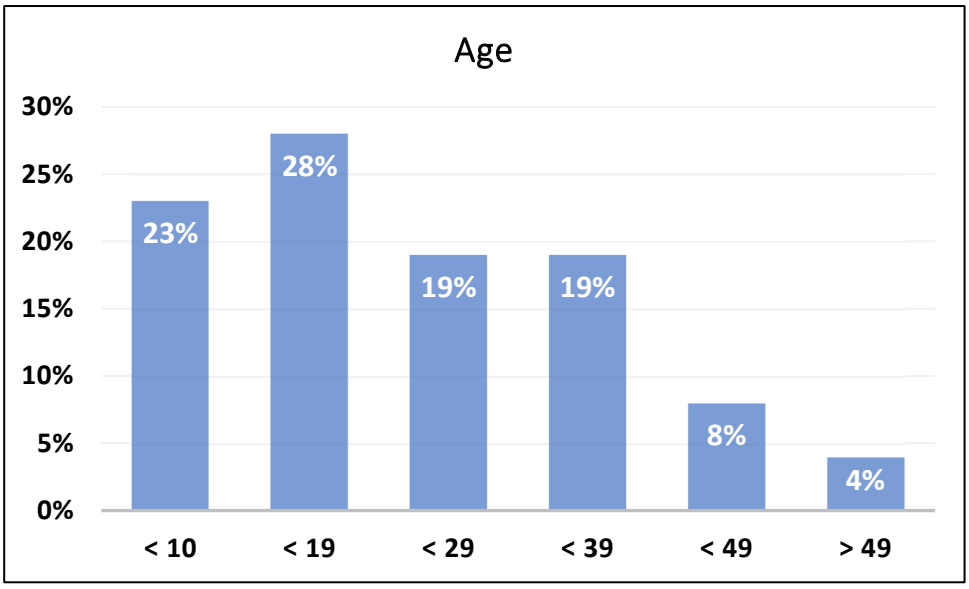

Figure 5. Percentage distribution of enrolled subjects by age decades.

As already stated in the Methods section, the data from G30-, G31-, G32- and G33-needle-user subgroups were cumulated into a single category.

When asked to indicate what the most important feature of a needle is, it was possible to choose between: (i) painless; (ii) that it does not bend; (iii) easy to screw on; iv) I don't know. All gave at least one answer out of four, and 17% of people gave 2 to 3 answers, but no one answered, "I don't know". 87.3% identified the main characteristic of a needle as "painless," 10% as "not bending" during injection, and 2.7% as "screwing on easily" to the pen.

To the subsequent question, "is a needle with a lower perceived degree of pain an important factor for complying with therapeutic instructions?" 95.3% of subjects answered "yes," 4.3% answered "no", while none were doubtful about the answer (Figure 6).

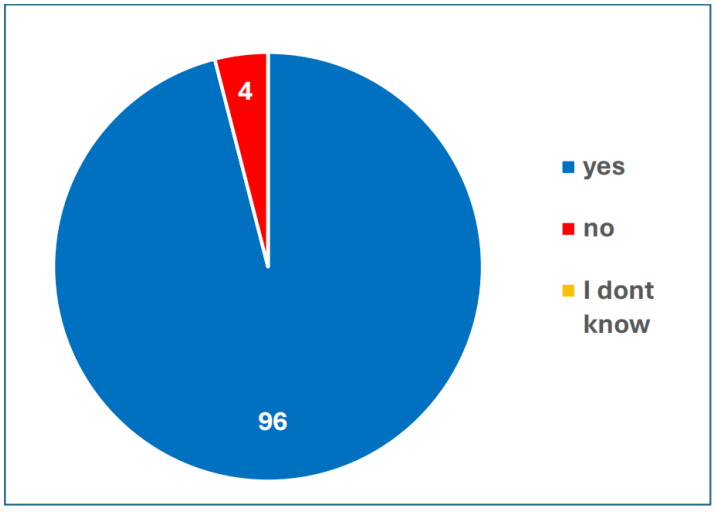

Figure 6. Answers to the question "Do you think a painless needle would allow you to better comply with therapeutic instructions?": 95.3% yes, 4.7% no, 0% I don't know ($p < 0.01$).

The perception of pain at the time of injection between the habitually used needle and the G34 test needle was evaluated using the semi-quantitative visual scale of increasing intensity (SQVS-II) administered after the two-week period of using the G34 needle. Figure 7 and Table 4 show the percentage of PwDs who indicate their perception for each score on

the scale. The lowest score, corresponding to a minimal or absent perception of pain, was indicated by 62% of G34 needle users versus 8% of old needle users ($p < 0.01$). Conversely, the highest score, indicative of the highest perception of pain, was indicated by 22% for the old needle versus 5% for the G34, respectively ($p < 0.01$).

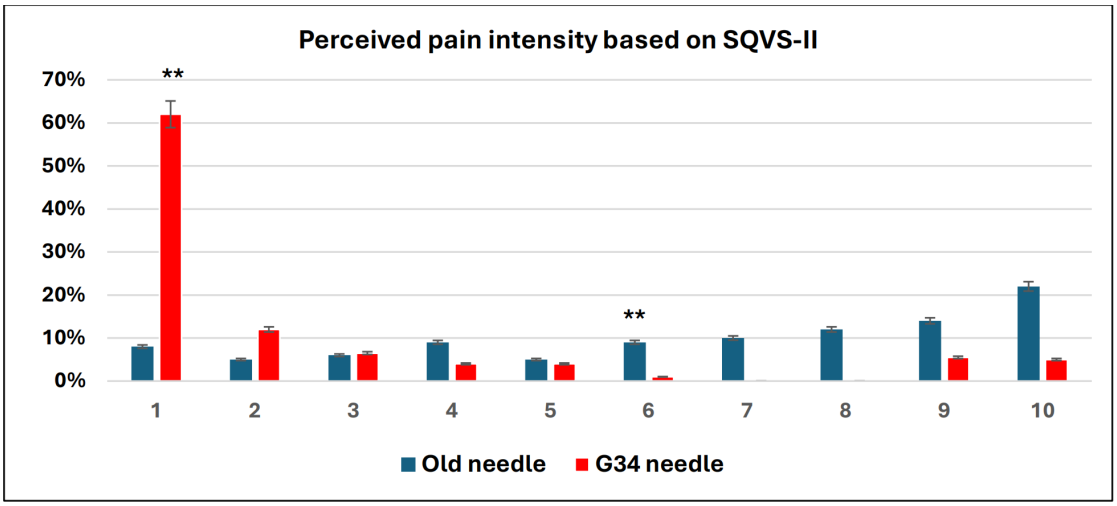

Figure 7. Comparative frequency of responses to the SQVS-II score ± SD for the pain intensity experienced with the habitually used needle (dark blue) and the new G34 (red). The significance of each score difference is indicated. ** $p \leq 0.01$ vs. comparator (semi-quantitative visual scale of increasing intensity from 1 to 10, where 1 indicates the lowest intensity and 10 the highest).

Table 4. Percentage of subjects indicating a specific intensity of puncture pain with the habitually used needle compared to the new G34 according to a semi-quantitative increasing visual scale. The individual scores are indicated in the table; * $p \leq 0.05$ and ** $p \leq 0.01$ vs. comparator.

Score	1	2	3	4	5	6	7	8	9	10
Old needle	8.0 **	5.0 *	6.0	9.0 *	5.0	9.0 **	10.0 **	12.0 **	14.0 **	22.0 **
G34 needle	62.0	12.0	6.5	4.0	4.0	1.0	0.0	0.0	5.5	5.0

Figure 8 shows the frequency of responses to the question concerning which, between the habitually used needle (dark blue) and the new G34 (red), is overall easier to use. The G34 needle is indicated at the highest degree of ease by 77% of PwDs, against 20% observed for the old needle ($p < 0.01$). In particular, 98% of the responses related to the ease of use of the G34 needle are concentrated on scores from 1 to 3, while referring to the usual needle, all scores other than 1 (which has a low frequency itself) are distributed homogeneously. A significant difference ($p < 0.01$) between the two classes of needles was observed at all scores other than 2 and 3. Score 9 was not indicated by any subject for any type of needle.

Figure 9 compares the frequency of hypo/hyperglycemia episodes in the two double-week test periods. The differences between the two periods are significant for all four answers ($p < 0.01$). However, hypo/hyperglycemic episodes never occurred in 80% of G34 needle use versus only 4% of old needle use.

Figure 10 compares the frequency of bruising/erythema/inflammation at the injection site in the two double-week test periods. Differences between the two groups are evident for all four answers with a striking gap for "never" (8% with the usual needle vs. 90% with the G34 needle, respectively; $p < 0.01$).

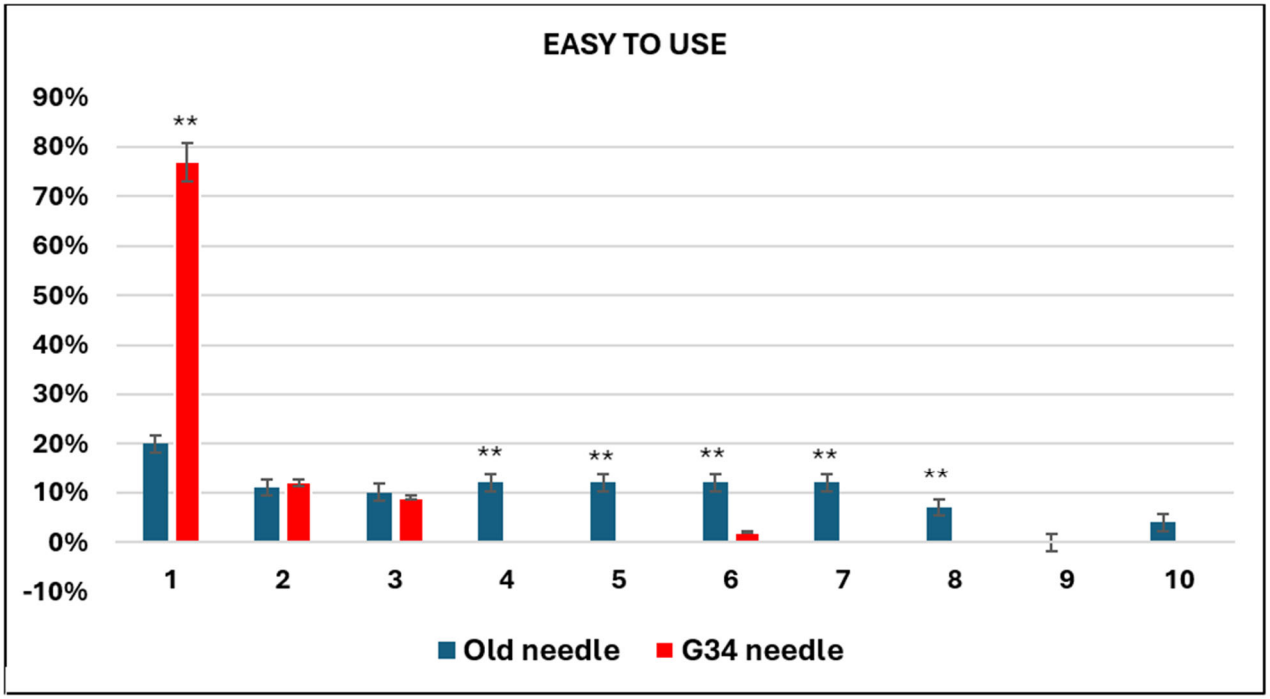

Figure 8. Perceived mean values ± SD of ease of use of the two needle groups. SQVS-II questionnaire; ** $p < 0.01$ versus comparator (semi-quantitative visual scale of increasing intensity from 1 to 10, where 1 indicates the lowest intensity and 10 the highest).

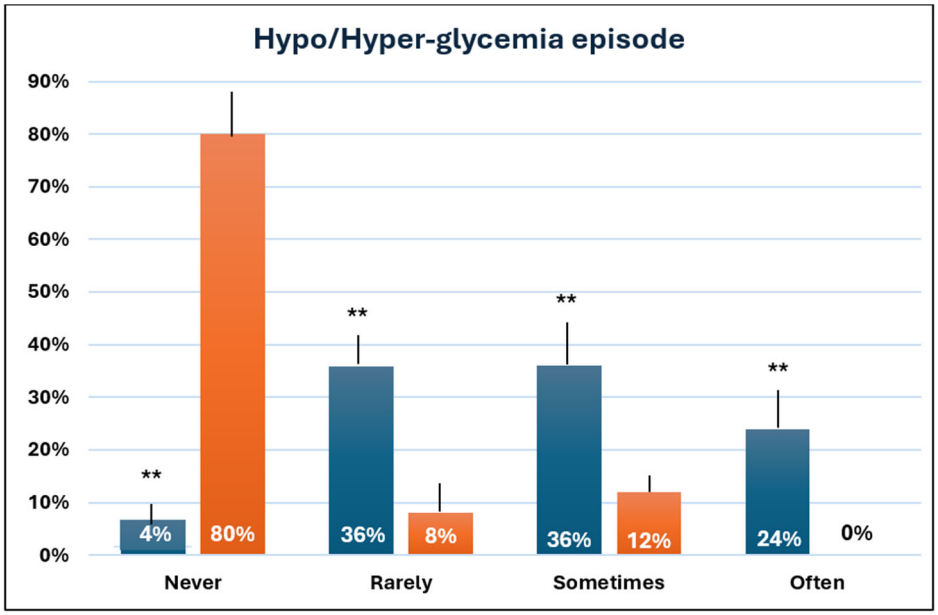

Figure 9. Compared mean frequency ± SD of hypo/hyperglycemia episodes experienced with the old needle (dark blue bars) and the G34 test needle (orange bars); ** = $p < 0.01$ versus comparator.

Figure 11 refers to the question about the frequency with which the two needle classes bent during use, 94% of PwDs "never" observed bending of the G34 needle compared to 64% of needles they had previously used ($p < 0.01$), and, respectively, while 4% vs. 34% ($p < 0.01$) observed it "rarely". The "sometimes" and "often" responses were comparably negligible for both needles.

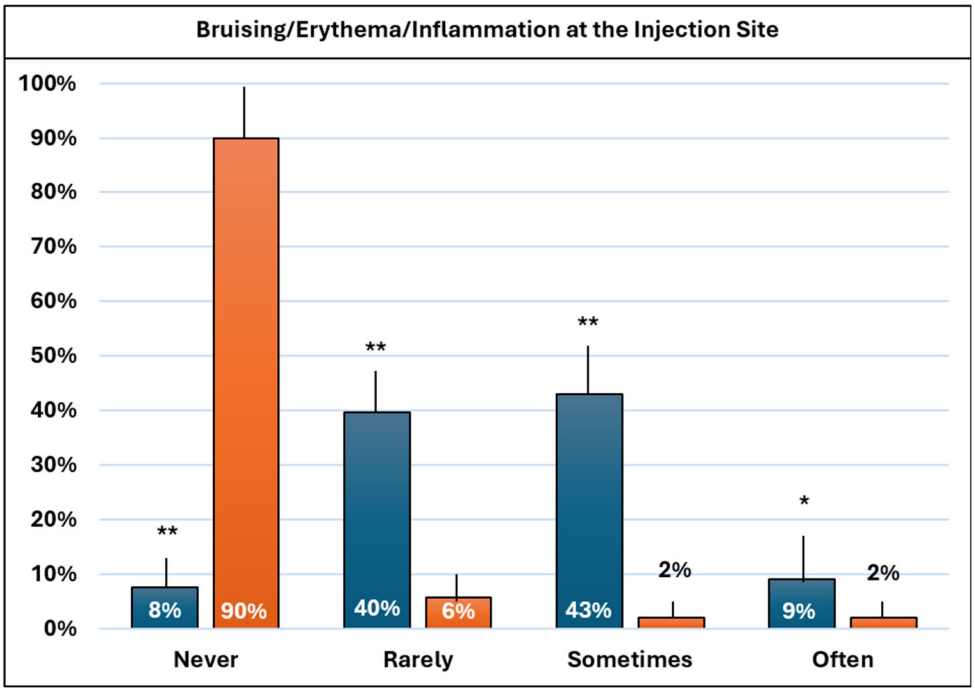

Figure 10. Compared mean frequency ± SD of bruising/erythema/inflammation at the injection site experienced with the old needle (dark blue bars) and the G34 test needle (orange bars). ** $p < 0.001$, * $p < 0.05$ versus comparator.

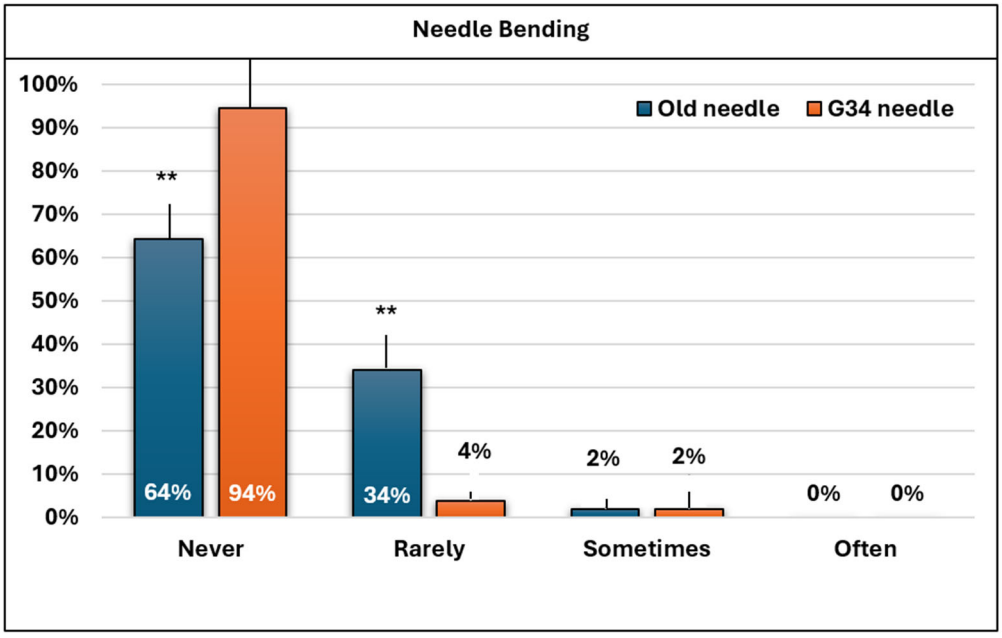

Figure 11. Compared mean frequency ± SD of bending at injection of the old needle (dark blue bars) and the G34 test needle (orange bars). ** = $p < 0.01$ vs. comparator.

4. Discussion

This real-life study complements laboratory findings from the Picasso study, which evaluated needle performance under controlled conditions using synthetic skin [11] by testing the new G34 needle against those habitually used for two weeks. PwDs confirmed that the Insupen 34 G × 3.5 mm needle is significantly less painful, easier to handle and, overall, more practical than thicker alternatives.

The reasons for such findings can be ascribed to different needle thickness (gauge), tip geometry, and angle of sharpness-ensuring cuts. As stated by the manufacturer (Pikdare Inc. Casnate con Bernate (CO), Italy), 34 G needles have improved technical characteristics compared to common types, including a lower primary bevel angle (7.5° versus 11°), resulting in a more gradual insertion into the skin due to a longer and more tapered needle tip.

In the Picasso study, the parameters characterizing the needle insertion into the synthetic skin were: (i) the maximum penetration force, defined as the maximum force required to insert the needle and expressed in grams; (ii) the sliding force, calculated as a percentage of the entire dragging force and defined as the average "friction" force measured using the sliding load up to 80% of the penetration depth (in grams). G34 × 3.5 mm needles performed significantly better for such parameters than all others. This data helps explain the broader preference for G34 needles among PwDs, driven by lower injection pain, fewer skin complications, and greater ease of use.

Of particular interest are G34 needle tip cuts, requiring less effort per se at the time of insertion. This, in turn, justifies better injection performance due to less damage to the skin. Moreover, the lower frequency of hypo- and hyperglycemia improves adherence to therapy. Our data further confirm that thinner needles are better accepted by PwDs and cause less pain than others. Previous studies have shown similar results: in the AGO 01 study (2015), a 33 G × 4 mm needle was preferred to a 32 G × 4 mm needle for reduced pain, confirming that thickness rather than length drives user preference [13]. The study also showed that, despite being 4 mm long, the thickness rather than the length of the needle drove preference among PwDs. So, although reducing needle length cannot eliminate pain perception and skin trauma, our data support the findings from previous studies concerning the ability of 34 G needles to penetrate and slide through the skin more easily, reducing pain perception [14], besides minimizing the risk of hypoglycemia related to unwilling intramuscular injection [15], thanks to reduced thickness and better tip geometry.

Furthermore, the 34 G's greater resistance to bending improves safety and confidence for daily users. Reduced puncture pain, fewer skin reactions, and higher structural robustness support better adherence to insulin therapy—a crucial goal in diabetes management, as highlighted by various authors [16–24].

These findings suggest that current guidelines on insulin injection technique and needle selection may need updating to reflect the superior performance, safety, and comfort of ultra-thin, short needles such as the Insupen 34 G × 3.5 mm.

The comparative evaluation of pen needles has been the subject of various investigations in recent years, often comparing needles with less advanced features, such as greater length (ranging from 4 to 6 or even 12.5 mm) or thicker gauges from 29 to 32, compared to those we tested [14,25–38].

In 2024, a consensus statement by the Italian Society of Metabolism, Diabetes, and Obesity (SIMDO) highlighted that the current gold standard is a 4 mm needle, 32 gauge. It noted that thinner and shorter needles are of interest but still require scientific evidence. Therefore, our research represents an advancement in scientific knowledge regarding more technologically advanced, shorter, and thinner needles [39].

In 2025, a review was published titled "Needle characteristics and the insulin injection experience in patients with diabetes", extensively examining the available literature. It reported comparisons between needles with different characteristics, including the recent 34 G/3.5 mm one, concluding that "pen needle geometry affects the insulin injection experience of diabetic patients. Increased needle gauge, shorter length, improved tip design, and mechanical characteristics are all associated with a perceived reduction of pain during insulin injection and an overall improved patient experience." This review

also emphasized users' perceptions of the various needles tested, based on personal and repeated use in real-life insulin injection [40].

Our study results align with the review's conclusions, although previous data (quoted in the review) had been published considering second-generation 32 G/4 mm, 5-bevel needles with the primary endpoint of non-inferiority versus 33–34 G/3.5–4 mm concerning injection pain, thumb force for injection, and leakage [41]. In this study, 209 subjects with T1D and T2D compared pain, thumb force, and leakage after injecting saline using 6 pairs of pen needles, including the new generation 32 G/4 mm (12 pairs) as the investigational needle, compared with four other needles as comparators: (i) Insupen Extr3me 33 G 4 mm (two pairs); (ii) Comfort EZ 33 G 4 mm (two pairs); (iii) Insupen Extr3me 34 G 3.5 mm (two pairs); and Terumo Nanopass 34 G 4 mm (six pairs), concluding non-inferiority of the investigational needle.

Differences with our study are evident not only in the cohort size, divided into two subgroups, with the first using the investigational needle versus the first three comparators in a 6:2 ratio (n = 154 subjects) and the second testing in a 1:1 ratio against the fourth comparator. These ratios indicate a significant difference from our study, as the number of injections was small, the new generation 32 G/4 mm needle was used much more frequently than the comparators, potentially influencing patient judgment. Furthermore, the authors did not evaluate ease of use, needle resistance to bending during injection, nor did they provide a quantitative measure of injection force, aspects assessed in our study. These elements cast doubt on the patients' ability to provide a sufficiently tested evaluation and bolster the statistical power of our data, based on a larger cohort and, importantly, on the prolonged use of the needles under real-life conditions, injecting insulin rather than saline.

Therefore, our data contribute to expanding the understanding of insulin needle use, based on the perceptions of a large patient cohort.

5. Conclusions

Among 300 insulin-treated PwDs, the Insupen 34 G × 3.5 mm needle demonstrated clear advantages over traditional needles (see Figure 12): markedly reduced pain, improved handling, fewer local reactions, and greater robustness. The innovative manufacturing process achieves exceptional thinness and precision without compromising strength, resulting in superior injection performance and more stable glycemic control.

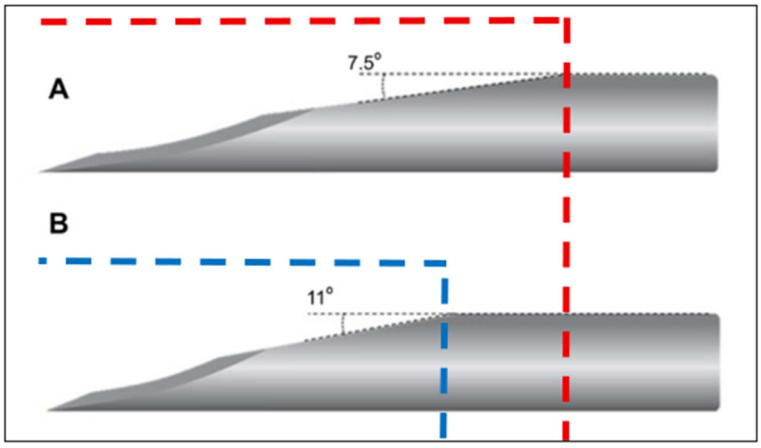

Figure 12. (**A**), Pikdare three-bevel needle, with a lower primary bevel angle (7.5°) and a more streamlined shape; (**B**), traditional three-bevel needle, with a higher primary bevel (11°). From Picasso study, modified [11].

Our data support the improved injection performance of the G34 needle compared to previously available needles, with lower risks of hypoglycemia and hyperglycemia, and fewer local complications, including bruising, irritation, and skin redness. At the same time, the needle proved to provide the required structural robustness, as it was the least susceptible to bending with use.

Because reduced pain and improved usability enhance patient acceptance and adherence [21–24], the Insupen 34 G × 3.5 mm needle should be considered by prescribers and educators as a reference standard for modern insulin delivery. These results should also be considered in public tenders for device supply and inform procurement decisions within national health systems to improve both therapeutic outcomes and quality of life for people with diabetes.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/diabetology7030056/s1, File S1: Questionnaire.

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Informed Consent Statement: This study was conducted in conformance with good clinical practice standards. The study was led in accordance with the original Declaration of Helsinki and subsequent amendments. Written informed consent was obtained from the person whose story we reported in an anonymized way.

Data Availability Statement: The data reported in the current study is available from the corresponding author on reasonable request.

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Conflicts of Interest: Sandro Gentile S, Raffaella Fiorentino, Elisabetta Tommasi, Giuseppina Guarino, Ersilia Satta, Maddalena Lettieri, Giampiero Marino, Vera Frison, Maria Chiarello, Giuseppe Caccavale, Emilia Masuccio and Felice Strollo have no financial interests to declare in relation to the present manuscript.

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