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ORIGINAL RESEARCH

Dialing Torque Preferences of People with Diabetes When Using Insulin Pens: A Pilot Study

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ABSTRACT

Introduction: Ergonomic dialing torque may enhance safety and comfort when setting doses with insulin pens. Limited data are available on the correlation of dialing torque and dialing comfort.

Methods: Three studies were performed with SoloSTAR® (SS; Sanofi), FlexPen® (FP; Novo Nordisk), KwikPen® (KP; Eli Lilly) and FlexTouch® (FT; Novo Nordisk) pens. Dialing behavior was examined with 20 pen-experienced people with diabetes. Participants dialed up to the maximum dose and back down to "zero" with each pen. Hand and pen movements were recorded by video camera and rotational speeds and angles calculated for each pen. In a laboratory study, dialing torque was measured discontinuously at a speed of 120°/s, reflecting typical patient behavior. Sixteen pen-experienced people with diabetes participated in a pilot preference study. Using a Likert scale, subjective dialing comfort rankings and ratings were obtained for each pen type and matched to their dialing torque. SS, FP, KP, and FT1 were investigated at 0–20 U each and at 60–80 U for FT2.

Results: SS was ranked most comfortable for up-dialing by 8 and down-dialing by 6 of the 16 participants, respectively; FP, 5 and 8; FT1, 2 and 1; and KP, 1 and 1. FT2 was ranked least comfortable by 12 and 10 participants. Comfort for up- and down-dialing was rated "very comfortable" for SS by 15 participants each, followed by FP (12 and 14), KP (10 each), and FT1 (9 and 7); FT2 was rated "less" or "not" comfortable by 10 and 11 people, respectively.

Conclusion: In this pilot study, subjective ratings of dialing comfort for different insulin pens by participants appear to concur with previous laboratory dialing torque study results. There appears to be a "torque comfort zone." Torques above 50 N mm reduced subjective handling comfort. Further, larger scale studies are needed to establish that

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dialing torque affects pen users' comfort.

Keywords: Diabetes; Dialing comfort; Dialing torque; FlexPen®; FlexTouch®; Insulin; Insulin pen; KwikPen®; SoloSTAR®; Torque comfort zone

INTRODUCTION

The use of injection devices has become more popular for patients with type 1 or type 2 diabetes mellitus who require insulin injections. The main advantages these devices have over traditional vial and syringes are their ease of use and convenience [1–4]. The growing popularity of insulin pen devices has led to a number of studies on their usage. Certain technical aspects of insulin pens—such as injection force [5–9] and dose accuracy [4, 5, 7, 8, 10–13]—are thoroughly studied, but there is a paucity of data on the dialing torque required for setting a dose.

Setting the dose is a vital step for people with diabetes who regularly self-inject insulin. All available insulin pen types require applying a torque for dialing a dose. Dialing comfort is influenced by dialing torque [14] and other factors, such as size and shape of the dose button. When turning dose buttons for selecting a dose, the torque level should not exceed a certain level from a human engineering point of view. The recommended torque for turning knobs with a diameter of 15–25 mm is 20–50 N mm [15]. For insulin pens, the torque useful for proper dose setting in clinical practice has been reported to be 10–30 N mm [16]; patient preferences and behavior, however, have not been studied until now.

Protocols used in recent laboratory torque studies using continuous dose dialing at dialing speeds of 1 U/s [16] are not based on real-life conditions and may not reflect user experience. With the aim to identify user preferences of dialing torques under conditions as close to real life as possible, three studies were performed: a field study to identify real-life dialing behavior of participants dialing a dose; a laboratory study of dialing torques using common dialing routines used by people with diabetes; and a pilot study to investigate the impact of different torque levels on perceived dialing comfort. All three studies compared four commonly used insulin pens: SoloSTAR® (SS; Sanofi), FlexPen® (FP; Novo Nordisk), KwikPen® (KP; Eli Lilly) and FlexTouch® (FT; Novo Nordisk).

METHODS

Compliance with Ethics Guidelines

All procedures followed were in accordance with the Helsinki Declaration, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

Test Pens

Four disposable insulin pen types were tested: SS, filled with insulin glulisine; FP and FT, filled with insulin aspart; and KP, filled with insulin lispro. The pens were fitted with needles according to the manufacturers' instructions.

Study Designs

The field study for the investigation of dialing behavior was performed with 20 pen-experienced people with diabetes [12 female, 8 male; mean (SD) age 55 ± 14 years; 5 with type

1 diabetes, 15 with type 2; all without motor impairment]. Participants dialed up to the maximum dose and down from the maximum dose to "zero" with each pen. Hand and pen movements were recorded by a video camera at 25 frames per second. Rotational speeds and angles were calculated from video data for each pen.

The laboratory study evaluated dialing torques of the four pens when dialing up to the maximum dose and dialing down from the maximum dose to "zero" [17]. Dialing torque was measured discontinuously at a speed of 120°/s, reflecting typical patient behavior as determined by the field study; in addition, torque was measured continuously at 1 U/s in order to compare the results with published data. Torque was measured with a Mecmesin torque machine (Mecmesin Ltd, West Sussex, UK) using an ITC Sensor with 1.5 N mm sensitivity. The machine and torque sensor were calibrated by the manufacturer prior to the measurements. Dial torque was measured for 20 pens of each pen type, with two repetitions per pen.

The pilot preference study included 16 pen-experienced people with type 2 diabetes (8 female, 8 male; mean (SD) age 60 ± 10 years; no chronic motor impairments). Subjective dialing comfort rankings and ratings were obtained for each pen type and matched to the same pen type tested in the laboratory torque procedure. FT was used in two setups (FT1: 0–20 U and FT2: 60–80 U) because of the difference in dialing torque levels found in the laboratory study [17]. The pens were randomly presented and participants asked to up-dial from 0 to 20 U and from 60 to 80 U for FT1 and FT2, respectively. Then the up-dialing comfort of all pens was ranked by participants. The procedure was repeated for down-dialing. Comfort ratings were obtained after the ranking for up- followed by down-dialing. Participants answered the question "For me, the up-dialing/the down-dialing of the pen is very comfortable" using a Likert scale where 1 = I absolutely agree; 2 = I agree; 3 = I rather agree; 4 = I rather disagree; 5 = I disagree; and 6 = I absolutely disagree.

Statistical Analysis

Descriptive statistics (mean, SD) were calculated for rotational speeds and angles. No inferential statistics were conducted due to the small study group. Differences between torque data were calculated using the paired two-sample Student's t test. Differences between comfort rankings were calculated with a Wilcoxon rank sum test. The level of significance for all tests was set to 5% ($P = 0.05$).

RESULTS

Dose Dialing Under Field Conditions

In contrast to laboratory procedures, people dialed doses discontinuously with a pause of 0.3 ± 0.1 s between dialing intervals. The measured angles were equivalent to approximately 10 U per rotation and to rotational speeds >13 U/s (Table 1). Mean rotational angle for up- and down-dialing was $171 \pm 44°$ and $190 \pm 37°$, respectively; mean rotational speed was $238 \pm 87°$/s and $259 \pm 99°$/s, respectively. Rotational angle and rotational speed differed considerably for both people and pen types.

Laboratory Determination of Dialing Torque

The up-dialing torque was significantly greater than the down-dialing torque for all pen types

Table 1 Rotational angle and speed for up- and down-dialing with four disposable pens by pen-experienced people with diabetes

Pen	Up-dialing				Down-dialing			
	Rotational angle (°)	Units per rotation	Rotational speed (°/s)	U/s	Rotational angle (°)	Units per rotation	Rotational speed (°/s)	U/s
SoloStar	179 (47)	9.9 (2.6)	249 (89)	13.83 (4.96)	197 (43)	10.9 (2.4)	267 (96)	15.39 (5.36)
FlexPen	177 (47)	9.8 (2.6)	249 (107)	13.83 (5.93)	240 (38)	13.3(2.1)	303 (125)	16.83 (6.92)
FlexTouch	154 (42)	10.3 (2.8)	197 (71)	13.13 (4.70)	180 (33)	12.0 (2.2)	198 (79)	13.20 (5.30)
KwikPen	174 (41)	9.7 (2.3)	259 (81)	14.39 (4.51)	179 (35)	9.9 (1.9)	256 (76)	14.22 (4.21)

Values are mean (SD)

Table 2 Torque for discontinuous and continuous up- and down-dialing at rotational speeds of 1 U/s and 120°/s with four disposable pens

Pen	Discontinuous dialing			Continuous dialing		
	Up-dialing	Down-dialing	*P* value	Up-dialing	Down-dialing	*P* value
At 1 U/s						
SoloStar	17.37 (2.08)	14.78 (1.54)	<0.001	15.91 (2.33)	15.17 (3.70)	0.287
FlexTouch	75.70 (9.35)	59.45 (10.73)	<0.001	81.46 (14.74)	57.21 (9.70)	<0.001
FlexPen	12.47 (1.81)	5.18 (0.67)	<0.001	11.96 (3.51)	3.38 (3.25)	<0.001
KwikPen	27.18 (6.47)	10.36 (6.88)	<0.001	24.79 (4.97)	12.38 (4.69)	<0.001
At 120°/s						
SoloStar	16.98 (2.33)	15.18 (1.66)	<0.001	18.45 (5.43)	14.79 (6.03)	0.005
FlexTouch	81.80 (11.49)	60.66 (11.79)	<0.001	86.43 (12.58)	72.90 (15.13)	<0.001
FlexPen	14.23 (2.74)	6.41 (0.94)	<0.001	14.60 (4.00)	4.03 (3.69)	<0.001
KwikPen	23.34 (5.46)	12.60 (5.52)	<0.001	22.64 (3.87)	12.35 (4.04)	<0.001

Values are mean (SD) in N mm

using discontinuous or continuous dialing at 1 U/s or 120°/s, except for continuous dialing at 1 U/s with SS (Table 2). The difference in torque between up-dialing and down-dialing was greater for KP and FP than for SS and FT. Also, torques differed when comparing continuous versus discontinuous dialing, though not all differences reached significance. The maximum dialing torque depended strongly on the chosen speed setting.

Regardless of the chosen speed, different pen types required different dialing torques to dial a maximum dose (Fig. 1). FP had the lowest dialing torques, followed by SS, with consistently lower dial-up torques than KP. FT required up to seven times higher dial-up torques than FP, due to its spring-loaded mechanism. Maximum dial-up torques for discontinuous dialing exceeded 80 N mm with FT at 120°/s (8 U/s).

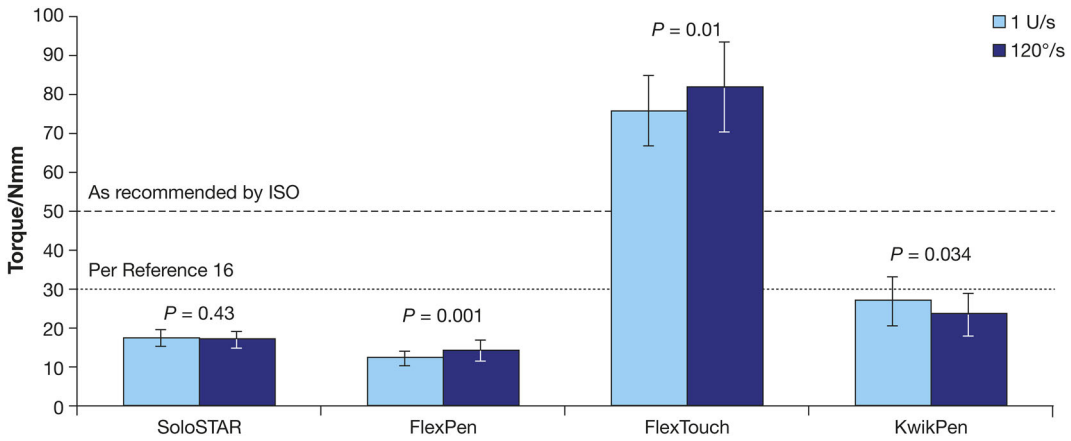

Fig. 1 Comparison of maximum torque for discontinuous up-dialing at 1 U/s and 120°/s in relation to dialing torque recommendations by ISO [15] and Asakura [16]. *P* values were calculated with a paired two-sample *t* test

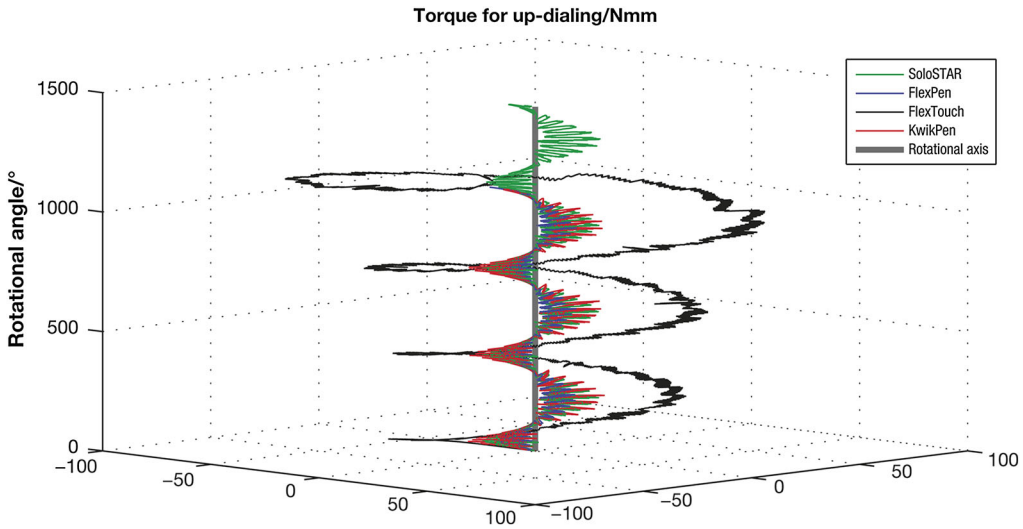

Fig. 2 Illustration of torque for discontinuous up-dialing at 120°/s. Sample data of one test pen for each pen model

Additionally, torque variation patterns were different for each pen type. The torque pattern of FT for up-dialing was different from that of all the other pens (Fig. 2). When dialing up or down, maximum and mean torques were constant for SS, FP, and KP during the dialing process (cylinder shape). For FT, however, torque for up-dialing increased significantly ($P < 0.001$) when dialing from zero to 80 U ("tornado" shape).

Assessment of Dialing Torque Comfort: A Pilot Study

In a ranking that combined evaluation of the comfort during up- and down-dialing, SS was ranked best, being preferred by 8 participants for up-dialing and by 6 participants for down-dialing, followed by FP (5 for up, 8 for down-dialing; Fig. 3a). FT1 was preferred by only 2 participants for up and 1 for down, while KP

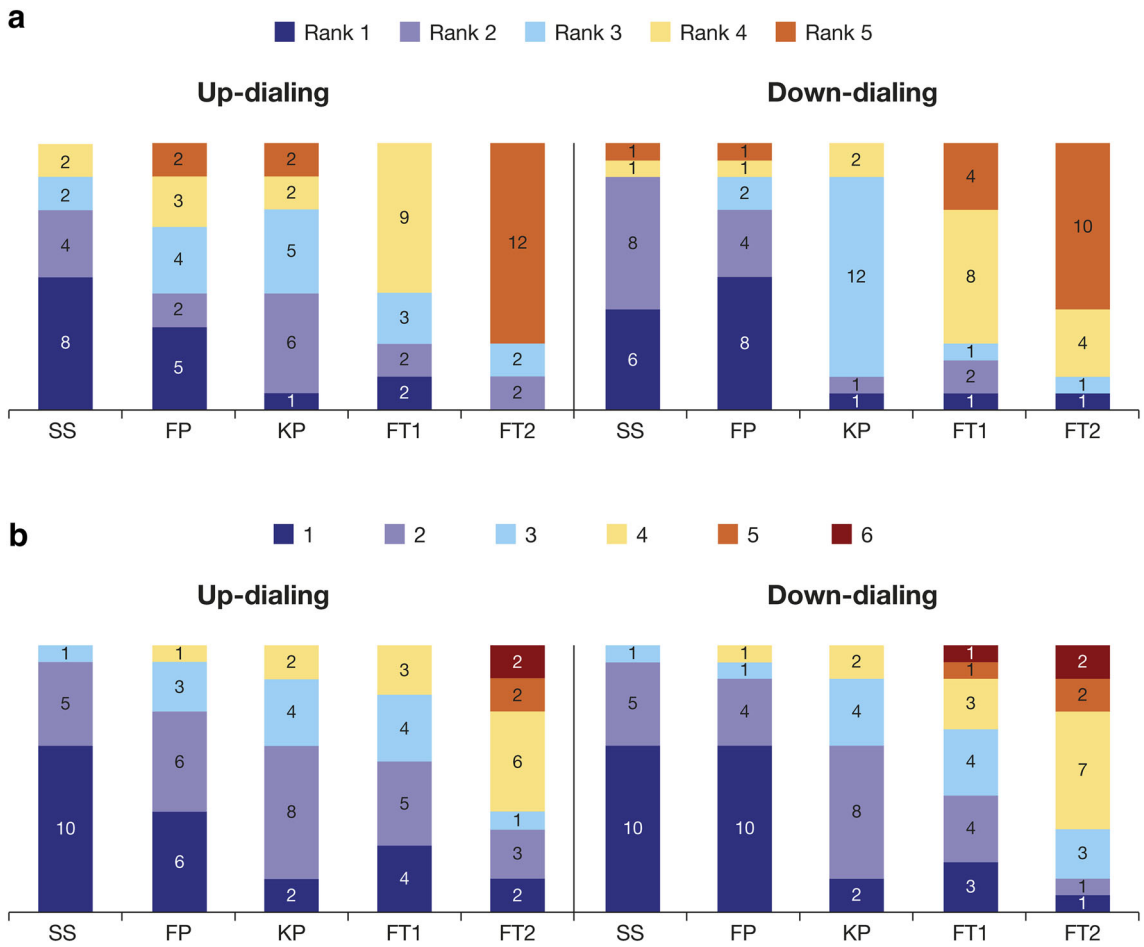

Fig. 3 Distribution of rankings (**a**) and ratings (**b**) for up- and down-dialing with four disposable pens: a pilot study. *FP* FlexPen, *FT1* FlexTouch (dialing from 0 to 20 U), *FT2* FlexTouch (dialing from 60 to 80 U), *KP* KwikPen, *SS* SoloSTAR

was preferred by only 1 for up and 1 for down. FT2 (dialing from 60 to 80 U and back) was not rated best by any participant. The majority of participants (12/16 for up-dialing and 10/16 for down-dialing) rated FT2 the worst of all the pens (Fig. 3b).

This sequence was confirmed by the results using the Likert scale, where SS stood out with 15 participants rating it very comfortable for up- as well as for down-dialing compared with 12 and 14, respectively, for FP; KP (10 for each) and FT1 (9 and 7, respectively). FT2 was rated "less" or "not" comfortable by the majority of participants (10 and 11, respectively).

DISCUSSION

This pilot study suggests a new basis for the evaluation of dialing torque in commonly available insulin injection pens by taking into consideration the behavior of patients under real-life conditions. With knowledge of how people handle pens during a field study, laboratory evaluation of dialing torque can be performed with protocols that more closely mimic real-life use. Comparison of these dialing torque values with user rankings and ratings from a preference study then can allow for conclusions to be drawn about the clinical

relevance of dialing torque and about appropriate torque values for future devices.

The results of this study suggest that common laboratory procedures for dialing insulin doses differ markedly from how they are dialed by pen-experienced people with diabetes. People dial doses discontinuously at dialing speeds >13 U/s and at rotational angles >10 U per rotation, with pauses of 0.3 ± 0.1 s between dialing intervals, whereas laboratory procedures employ continuous dose dialing at slower dialing speeds.

Dialing speed had an impact on the measured dialing torque for all tested pens, but the effect differed between pens. For example, up-dialing torque increased significantly for FP and FT at the higher speed of 120°/s compared with 1 U/s (dialing discontinuously), while for SS and KP it decreased at the higher speed. Significant differences between pens were also found for dialing torque with discontinuous dose button rotation. This was true using real-life dialing behavior of pen-experienced people with diabetes as well as other measurement protocols [14]. Interestingly, torque for down-dialing was found to be lower than for up-dialing for all pen types. This is unusual in the design of the torque course of small turning knobs, but may increase comfort for patients with visual or motor impairments. Further studies would be beneficial to confirm the effects of varying torques for up- and down-dialing. These results show that people using insulin pens encounter varying torque when setting a dose. Thus, it is reasonable to use dialing speeds and angles close to the real-life dialing behavior of pen-experienced people with diabetes for future studies on dialing torques.

Results of the pilot comfort study suggest that people may have a preference regarding dialing torque (Fig. 4). The comfort of pens with high dialing torque was ranked and rated very low, suggesting that a torque exceeding 30 N mm [16] decreased perceived dialing comfort while torque levels of ≥50 N mm [15] appeared to induce dialing discomfort. Surprisingly, the pen with the lowest dialing torque (FP) was not rated or ranked best during the study. This suggests that either there is a comfort zone of dialing torques for people or that other factors influence

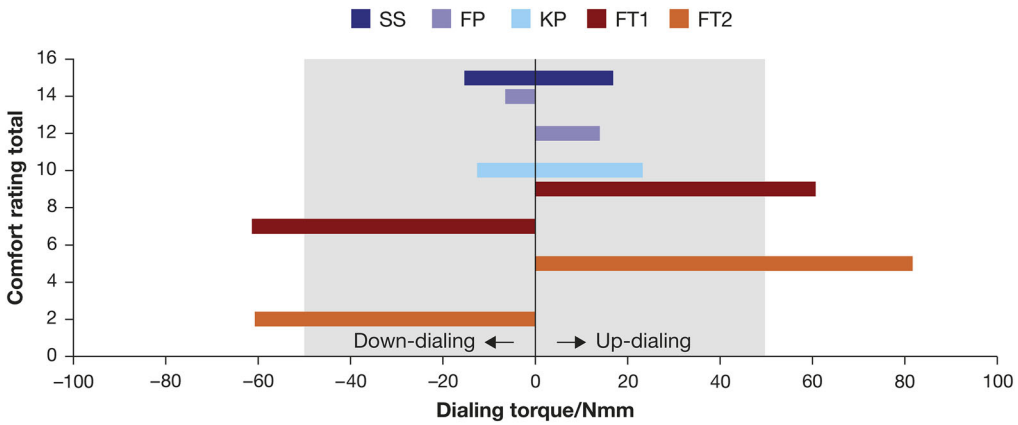

Fig. 4 Relation of dialing torque and dialing comfort for four disposable pens. Comfort rating was the total of best and second best ratings in the pilot study. The *gray zone* indicates the range up to 50 N mm as recommended by ISO 894–3:201015; $n = 16$ patients. *FP* FlexPen, *FT1* FlexTouch (dialing from 0 to 20 U), *FT2* FlexTouch (dialing from 60 to 80 U), *KP* KwikPen, *SS* SoloSTAR

their choice. It also suggests that an appropriate dialing torque might be a key feature of pen handling: discomfort might lead to deficient adherence to the therapy and consequently to problems in glycemic control, especially given the impaired manual dexterity of many people with diabetes mellitus.

There are limitations to our studies. Since the user studies performed were small in size and all three studies were limited to the most common pens, they might be biased and not fully mirror peoples' behavior. We also did not measure dialing torque and evaluate user comfort simultaneously, which might result in some deviation of both parameters from the present results. In addition, the study was not aimed at differentiating between differences in up- and down-dialing. Further, larger scale comfort studies that are sufficiently powered will be required to definitively provide proof of concept that dial torque affects user comfort. Nevertheless, the preferences shown in our pilot study appear to emphasize the relevance of dialing torque measurement for user comfort—as well as the importance of considering all tasks performed with pens, not just the act of injection alone [8].

CONCLUSION

In this pilot study, subjective ratings of dialing comfort for different insulin pens by participants appear to agree with previous laboratory dialing torque study results. There appears to be a "torque comfort zone". Lowest dialing torques did not imply best comfort, while torques above 50 N mm reduced subjective handling comfort. Further, larger scale studies will be needed to establish that dialing torque affects pen users' comfort and adherence to therapy.

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Conflict of interest. A. Friedrichs is an employee of LWS Risk Management Consult GmbH. S. Adler is an employee of LWS Risk Management Consult GmbH. LWS Risk Management Consult GmbH is a paid consultant to Sanofi. S. Kamlot is an employee of Sanofi. M. Schmitz is an employee of Sanofi.

Compliance with ethics guidelines. All procedures followed were in accordance with the Helsinki Declaration, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

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