



Research article

Patient evaluations after local anesthesia with a computer-assisted method and a conventional syringe before and after reflection time: A prospective randomized controlled trial

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ABSTRACT

Objectives: This prospective randomized controlled trial aimed to evaluate and compare patient response to a conventional syringe and a computer-controlled local anesthetic delivery system (CCLAD) both immediately and after reflection time, including the impact of anesthesia duration.

Methods: Twenty adult patients (10 men and 10 women) with at least two tooth-neck defects each in different quadrants were treated with local buccal infiltration anesthesia. Using split-mouth design, one quadrant was anesthetized using a conventional syringe, the other with CCLAD. The time elapsed between time of injection and time of disappearance of numbness was recorded. Patients were asked to mark on a Visual Analog Scale their visual impression of the device regarding anxiety-inducement, their sensation of mucosal puncture, pain during administration, and pain perception during treatment for the two different methods as well as future preference immediately after treatment and after reflection time.

Results: The level of anxiety-inducement and pain during administration were ranked three times higher with the conventional syringe (35.95%–11.85%, $p < 0.001$ and 21.3%–7.7%, $p = 0.005$, respectively). There was no difference in mean sensation of mucosal puncture, nor a statistically significant correlation between duration of administration and time until disappearance of numbness. Once anesthesia was administered, no pain during treatment was detected using either method. Patients' preference of methods changed significantly with time in favor of CCLAD ($p = 0.01$).

Conclusions: The use of CCLAD increased patients' comfort visually and in terms of administration; patients' preference in favor of CCLAD increased with time.

Clinical significance: Patients' preference of CCLAD over against the conventional syringe, even more so after reflection time, can imply the preference of CCLAD for clinicians, too, in order to enhance patients' and clinicians' comfort.

1. Introduction

Dental treatment is often painful, and pain can lead to reduced patients' compliance or even absence from undergoing treatment [1]. Hence, pain control is one of the key factors to ensure unimpeded and successful dental treatment. The impact of anesthesia on the quality of treatment from the patients' view-point is well-documented in the "Burdens in Oral Surgery-Questionnaire (BiOS-Q)" [2]. That study

examined patients' discomfort regarding several aspects of oral surgery treatment, most of these referred to the perception of local anesthesia.

The computer-controlled local anesthetic delivery system (CCLAD) was developed to increase patients' comfort [3]. Its efficacy has been tested several times with respect to different aspects:

Studies from the late 1990s showed that patients' pain perception during administration of anesthesia was reduced by dentists' better speed control in administering the anesthetic agent [4, 5]. Likewise recent

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studies showed a preference for CCLAD over conventional syringe in terms of pain perception during administration and efficacy [6, 7]. On the other hand, there are studies that show no significant difference in pain perception when comparing CCLAD with a conventional syringe [8, 9]. In their systematic review and meta-analysis, Libonati et al. [10] demonstrated the difference between both methods of administering anesthesia. In 17 out of 20 studies pain perception was lower during administration when using CCLAD. However, these studies displayed a high level of methodological heterogeneity. Notably, in 8 of those 20 a dental treatment was performed after anesthesia; in the remaining 12 the anesthesia was applied with no consecutive treatment. Also, the interval between administering the anesthesia in individual patients varied between 1-2 min and 1 week. There was only one study included using split mouth design [11]; it compared the use of CCLAD and conventional syringe on 16 patients in very different injection sites.

Other studies comparing CCLAD with a conventional syringe followed up slightly different research questions: Children's preference for dental injectors was documented depending on their visual appearance by directly presenting them the devices [12]. There is no equivalent study with adults yet. Two further studies, also on children, assessed physiological parameters in relation to the administration of anesthesia. One of these measured blood pressure, heart rate and temperature before, during and immediately after administration of anesthesia on two separate appointments on consecutive days [13]. On the first appointment CCLAD was used, whereas on the second appointment a conventional syringe was used. As result, no statistically significant difference could be verified regarding the physiological parameters under survey. The other study measured blood pressure and heart rate before and during administration of anesthesia, also on two appointments, but this time with an interval of one week [14]. In some patients CCLAD was used at the first appointment and a conventional syringe at the second, in other patients the systems were used in reverse order. Here as result a significantly lower heart rate could be measured with CCLAD, irrespective of the order of the system used.

The hypothesis of the present study was that similar to the physiological changes in the course of time noted in the study mentioned last, overall patient preference for one or the other anesthetic system might change, too.

Hence, the aim of this study was to compare patients' response to anesthesia with CCLAD and with a conventional syringe under different parameters: first, to evaluate patients' response to CCLAD and the conventional syringe during appointment; second, to determine the impact of the systems' different flow rates on anesthesia duration; and third, to inquire if the patients' first preference changed after reflection time. This study was conducted on the basis of adult patients requiring a local buccal infiltration.

2. Material and methods

This study was approved by the Swiss Ethical Committee (EKNZ 2016-00690) and was registered in an International Clinical Trials Register (DRKS00014765). Informed consent was obtained from all patients prior to dental treatment.

2.1. Anesthetic device

The CCLAD used in the present study was the Wand/Single Tooth Anesthesia (STA) system (Milestone Scientific, Livingston, NJ, USA). This has two basic components: the pre-sterilized single-use handpiece and the drive unit. A needle was attached to the handpiece using a Luer-Lock mechanism.

The hand syringe was the Aesculap Aspira-Plus (B. Braun Medical AG, Sempach, Switzerland). It uses the same mechanism for needle attachment.

2.2. Inclusion criteria

The following patients were included: (1) Patients who provided written informed consent and had no contraindications for local anesthesia. (2) Contractually capable patients of minimum 20 years of age having no previous experience with CCLAD. (3) Patients with physical classification ASA I (a normal healthy patient) and with at least two tooth-neck defects in different quadrants requiring treatment.

2.3. Exclusion criteria

The following patients were excluded: (1) Patients with medically compromising conditions or with medicament-related altered pain perception. (2) Patients with positive aspirations of blood during administration of anesthesia. (3) Patients that did not meet the inclusion criteria.

2.4. Sample size

We expected that the average difference in terms of visual impression regarding anxiety-inducement, sensation of mucosal puncture, pain perception during administration, and pain perception during treatment between the two methods would be of the order of two-thirds of the standard deviation of individual differences. This corresponds roughly to the difference between the 75th and the 50th percentile of a normal distribution. Under this expectation and assuming no carry-over effects, we needed a total of 20 patients to obtain a statistically significant difference at the 5% level with a power of 90%.

2.5. Recruitment and study process

All patients were recruited and treated in a private dental clinic in Switzerland by the same clinician. The clinician was well-trained and experienced with both CCLAD and the conventional syringe. Six months prior to the beginning of the study the clinician anesthetized exclusively with CCLAD to make himself feel as comfortable with it as with the conventional syringe. The study was performed in a split-mouth design, and the patients served as their own controls. Both methods of anesthesia administration were performed during the same appointment and in a randomized computer-assisted order (random.org). In half of the patients the conventional syringe was used first followed by CCLAD, while in the remaining half the reverse order was used. Treatment was initiated exactly 15 min after mucosal puncture using both systems to allow a proper onset [15].

CCLAD was used in the regular modus (control flow), which corresponds to a speed of 0.005 mL/s. This resulted in an anesthesia delivery time of 4:50 min (including aspiration time). The average delivery time for the conventional syringe was half the time of CCLAD (including aspiration time). The needles used in both methods were 27 gauge, the length was 40 mm for CCLAD and 38 mm for the conventional syringe. A cartridge of 1.7 mL Ubistesin (3M, Rüschlikon, Switzerland) was used, which consists of 4% articaine as the anesthetic agent and 1:200,000 adrenaline as the vasoconstrictor. Due to the inherent characteristics of CCLAD, after the 1.7 mL anesthetic cartridge indicates empty, approximately 0.06 ml of anesthetic is left in the cartridge with an additional 0.13 ml in the tubing and the needle. In total, 0.19 mL \pm 10% of anesthetic is left in CCLAD. Therefore, approximately 1.5 mL of anesthetic was injected using CCLAD from a 1.7 mL cartridge. To inject the same amount of anesthetic using the conventional syringe, 0.2 mL of anesthetic was expelled from the cartridge of the conventional syringe into a sterile cylinder with an accuracy of \pm 10%. For both methods time was recorded at the point of mucosal puncture. No topical anesthesia was used. Mucosal puncture was performed with a pre-puncture technique by inserting the beveled part of the needle into the tissue with a continuous

positive pressure that delivered the anesthetic solution preceding the needle path to ensure atraumatic administration of local anesthesia [16] and maximum comfort with both systems. One aspiration was performed at the extent of half of the content of the cartridge in both systems.

The following four parameters were analyzed: (1) visual impression of the anesthetic system regarding anxiety-inducement, (2) sensation of mucosal puncture, (3) pain perception during administration, (4) and pain perception during treatment. The scorings were requested separately for each method of anesthesia. To begin with, and still before treatment, the visual impression of the first anesthetic system was requested; this was to be assessed between “inspiring confidence” and “scaring”. The scoring of sensation of mucosal puncture and pain perception during administration was requested directly after administration of anesthesia, while pain perception during treatment was requested directly after treatment; all three questions were to be assessed between “no pain perceived” to “unbearable pain”. All four assessments were marked on the Visual Analog Scale (VAS). Then, the same procedure was repeated for the second anesthetic system. After this was completed, too, patients were asked for preference of either method of anesthesia; here patients had to choose between CCLAD, or the conventional syringe, or indifference. Finally, patients were also asked to score their general anxiety of dental treatments on the VAS, ranging from “no anxiety” to “unbearable anxiety”. At the end of the entire appointment all patients were given a questionnaire to determine the time of disappearance of numbness in the cheeks and/or lips, to note down any potential discomfort in the puncture area, and to indicate again their preferred method of anesthesia delivery in the future on the basis of this experience. This questionnaire was to be filled in after anesthesia recovery. This time lapse since treatment was defined as “reflection time”. After completing the questionnaire, patients were asked to return it to the dental office. The response rate was 100%.

2.6. Statistical methods

For each patient, the difference between the second and the first measurement of each “outcome” variable was regressed against the “method” variable, which was defined as 1 if the “standard” method (the syringe) was used first followed by CCLAD, and as -1 otherwise. The regression coefficient of this variable provides the average score difference between CCLAD and the “standard” method. Moreover, the intercept of the regression model provided an estimate of the period effect. Additionally, interactions of the variable “method” were considered with the factors “gender” and “age group” (<65 years, vs. ≥ 65 years), and with the covariate “anxiety category” (anxiety score >11 vs. ≤ 11). The thresholds for age and anxiety score were chosen close to the respective median values (64 years and 11.5, respectively). These models also included the main effects of gender, age group, and anxiety category. Statistical significance was defined as a two-tailed p-value < 0.05. All analyses were conducted using the Stata software version 14.0 (Stata Corp LLC, Texas, USA).

3. Results

20 adult patients (10 men and 10 women) participated in the present study. The age of patients ranged between 42 and 76 years, with a mean age of 64 years (Table 1). No additional anesthetics were required for any

Table 1. Age and anxiety score distribution.

	Age (yrs) *	Anxiety score (0–100) *
Overall (n = 20)	64 (42–76)	11.5 (0–60)
Women (n = 10)	67.5 (50–76)	8.0 (0–60)
Men (n = 10)	63 (42–74)	12.5 (0–44)

* median (range).

treatment using either method of anesthesia. All aspirations performed using the two systems were negative. In total, 46 tooth-neck defects were treated. Seventeen patients showed two tooth-neck defects each and three patients showed four (two adjacent each) tooth-neck defects each. The mean administration time with CCLAD was 4 min 50 s, which was almost exactly twice the mean administration time with the conventional syringe (2 min 20 s). This longer duration of anesthesia administration with CCLAD was ranked unfavorably by 14 patients (70%; 95%-confidence interval (CI): 45.7–88.1%). No significant correlation between administration time and disappearance of numbness could be detected. There was also no significant difference between the two anesthesia methods in terms of sensation of mucosal puncture ($p = 0.66$) and pain perception during treatment ($p = 0.06$). However, there was a significant difference between the two systems in visual impression regarding anxiety-inducement ($p = 0.0002$) and pain during administration ($p = 0.005$), with the values for CCLAD being three times that of the conventional syringe (Figure 1). No significant correlation between anesthesia delivery method and anesthesia duration was detected (Table 2).

Patients’ preference for a particular system was altered significantly with time. Immediately after treatment 9 out of 20 patients preferred CCLAD to the conventional syringe, while 4 patients preferred the conventional syringe; 7 patients were indifferent. After reflection time 2 patients changed their preference from the conventional syringe to CCLAD, and one patient from indifferent to CCLAD. In total, 12 patients preferred CCLAD, 6 patients were still indifferent, while only 2 patients preferred the conventional syringe after reflection time. Consequently, directly after treatment the preference for CCLAD was statistically not significant ($p = 0.27$), but it became highly significant after reflection time ($p = 0.013$) (Table 3).

The mean anxiety score was 11.5 on the VAS. The difference in mean visual impression score between the conventional syringe and CCLAD was significant in men ($p = 0.0001$), but not in women. Likewise, the difference in mean visual impression score was significant in patients with an anxiety score >11 ($p = 0.0001$), but not in patients with an anxiety score ≤ 11. By contrast, the difference in mean visual impression score was significant in both age groups, ≤ 65 years ($p = 0.001$) and >65 years ($p = 0.01$). Therefore, a significant positive association was detected between mean visual impression score and gender ($p = 0.02$) as well as anxiety score ($p = 0.005$), but not age. Regarding pain perception during administration, even though the score was also significant in favor of CCLAD in men ($p = 0.047$), but not in women ($p = 0.08$), there was no significant positive association between pain perception during administration and gender. Likewise, no significant positive association was detected with regard to the relation of pain perception during administration and age. By contrast, a significant borderline positive association was observed between pain during administration and anxiety score ($p = 0.053$): While the difference in mean pain perception score between the conventional syringe and CCLAD was not significant in patients with an anxiety score ≤ 11, it was highly significant in patients with an anxiety score >11 ($p = 0.004$) (Table 4).

Associations of gender, age and anxiety score with the two remaining parameters sensation of mucosal puncture and pain perception during treatment were also assessed, but no positive associations were detected.

4. Discussion

In the present study, two methods for buccal infiltration of local anesthetics were compared (conventional syringe and CCLAD). It was found that CCLAD enhanced patients’ comfort visually regarding anxiety-inducement and during anesthesia administration. Overall patients’ preference for CCLAD increased after reflection time.

No topical anesthesia was used. Even though topical anesthesia may reduce the anticipatory anxiety associated with an impending dental injection, it has been shown that this has no influence on the actual pain sensation during mucosal puncture [17]. In fact, placebo topical anesthesia could reduce pain perception with subsequent anesthesia

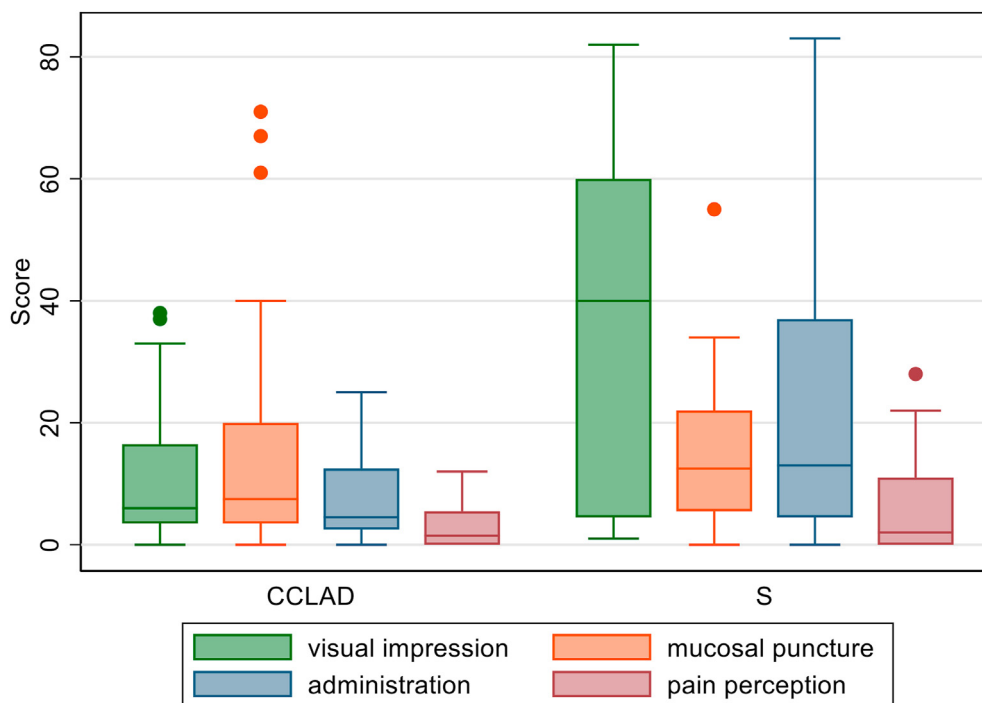


Figure 1. Boxplot comparison between the conventional syringe (S) and CCLAD for the four parameters (visual impression of the device, sensation of mucosal puncture, pain during administration and pain perception during treatment).

Table 2. Estimated device and period effects.

	N	Mean S	SD S	Mean CCLAD	SD CCLAD	Difference CCLAD – S*	Period effect	p-value*
Visual impression	20	36.0	28.7	11.9	12.1	-24.1 (-35.1, -13.1)	11.6 (0.6, 22.6)	0.0002
Sensation of mucosal puncture	20	15.6	13.8	17.8	23.0	2.2 (-7.9, 12.2)	20.2 (10.1, 30.2)	0.66
Pain during administration	20	21.3	21.7	7.7	7.3	-13.6 (-22.6, -4.6)	13.5 (4.5, 22.5)	0.005
Pain perception during treatment	20	5.8	8.11	2.75	3.48	-3.05 (-6.21, 0.11)	4.05 (0.89, 7.21)	0.06
Time until the disappearance of numbness	20	3.26	1.1	2.83	1.06	-0.42 (-1.01, 0.17)	0.13 (-0.46, 0.72)	0.15

S = Standard (conventional syringe), CCLAD = Computer-Controlled Local Anesthetic Delivery System, SD = Standard deviation.

* of the mean difference in individual perceptions of the respective outcome under C and S.

significantly in patients with low pain expectancy [18]. To exclude any interference in the present study, no topical anesthesia was used. Other psychological aspects need to be taken into account in issues of patients' pain expectancy, too, as shown in a study on the influence of dental-related images on patients' pain expectancy [19]. Indeed, anxious patients tend to assess CCLAD more beneficially when compared to the conventional syringe [20]. The present study confirmed this tendency only in patients with an anxiety score > 11 (Table 4). Present patients, however, had an overall low average anxiety score (median 11.5) (Table 1).

Table 3. Patients' preference before and after the reflection time.

Assessment	After treatment	After reflection time
No preference	7 (35%)	6 (30%)
CCLAD preferred to S	9 (45%)	12 (60%)
S preferred to CCLAD	4 (20%)	2 (10%)

S = Standard (conventional syringe), CCLAD = Computer-Controlled Local Anesthetic Delivery System.

Preference for CCLAD was higher than preference for S both after treatment (p = 0.27) and after reflection time (p = 0.01).

As for the anesthetic volume lost in CCLAD due to technical reasons, several studies have shown the effect of the amount of anesthetic agent on the onset, pain control, and duration of anesthesia [21, 22]. Hence, in the present study the volume of anesthetics was adjusted to ensure the same anesthetic volume in both devices.

Furthermore, some practical advantages and disadvantages of CCLAD relevant to the clinician's handling ought to be mentioned. One of the advantages of this system is the comfortable tactile sensation because of the lightweight handpiece and the ability to rotate the needle as it is introduced into the tissues, producing a coring penetration that minimizes needle deflection. Although all aspiration tests were negative in the present study, detection of a positive aspiration in CCLAD might be challenging due to the small diameter of the plastic tube, where a slight discoloration of the anesthetic liquid might be overlooked. In such cases, the clinician is the determining factor. Additionally, the aspiration cycle is longer for CCLAD than that for the conventional syringe, so the clinician must remain in the same position with the needle for a longer time. Finally, the beep of CCLAD that allows the clinician to determine the speed of anesthesia administration might disturb the patient.

The spilt-mouth design was chosen for the present study to take into account individual patients' differences in terms of pain expectancy and perception as well as circadian changes in local anesthesia duration [23, 24]. In another split-mouth study on this subject, which investigated the

Table 4. Visual impression and pain perception during administration using the two anesthetic devices in interaction with gender, age, and anxiety score.

	Visual impression						Pain perception during administration					
	Gender		Age		Anxiety score		Gender		Age		Anxiety score	
	Men	Women	≤ 65 yrs	>65 yrs	≤ 11	>11	Men	Women	≤ 65 yrs	>65 yrs	≤ 11	>11
Mean S	50.2	21.7	39.4	31.8	14.5	57.4	20.9	21.7	19.4	23.7	9.1	33.5
SD S	28.8	21.4	31.7	25.8	22.1	15.0	14.6	28.0	15.1	28.7	8.9	24.2
Mean CCLAD	16.9	6.8	15.3	7.7	7.7	16	9.1	6.3	10.1	4.8	8.2	7.2
SD CCLAD	14.2	6.9	14.8	6.1	7.3	14.7	7.4	7.3	8.1	5.2	7.1	7.9
p-value CCLAD - S*	0.0001	0.10	0.001	0.01	0.28	0.0001	0.047	0.08	0.06	0.07	0.71	0.004
p-value interaction**	0.02		0.55		0.005		0.84		0.88		0.053	

S = Standard (conventional syringe), CCLAD = Computer-Controlled Local Anesthetic Delivery System, SD = Standard deviation.

* p-value of the mean difference in individual visual impression resp. pain during administration under CCLAD and S.

** p-value of interaction between visual impression resp. pain perception during administration and respective personal characteristic.

difference in pain perception during mucosal puncture and administration, significantly higher patient comfort was detected with CCLAD in both parameters [11]. The present study confirmed those results in terms of administration only. In contrast, the identical low pain perception during puncture in the present study independently from the anesthetic system could be seen as a result of the handling of both devices. In contrast to the split mouth design of the present study, Aggarwal et al. [25] obtained patients' feedback after treatment at two different appointments for each anesthetic system; this procedure led to a preference for CCLAD. In the present study, patients' feedback was recorded again after reflection time. While the first enquiry already showed a preference for CCLAD, it was not until the second that this preference became statistically significant. This finding suggested that reflection time influenced patients' preference. Possibly the higher preference for CCLAD after reflection time was due to the shorter, albeit statistically not significant, mean duration of numbness.

Administration of the anesthetic was assessed three times more favorable when CCLAD was used. This stands in accordance with other recent studies, where CCLAD showed a significantly lower pain level during administration [6, 25]. Administration speed with CCLAD was kept constantly at 0.005 mL/s for every patient. The slower administration speed with CCLAD in contrast to the conventional syringe entails a longer administration time, but the pressure applied to the soft tissues was relatively low compared to the conventional syringe. As it is not possible to administer anesthesia as evenly with a conventional syringe, a significant difference in the disappearance of lip/cheek numbness between the two methods was expected. In fact, Saoji et al. [15] showed a significantly faster recovery time for CCLAD. However, in the present study the difference of numbness duration in both injection systems was not statistically significant. In fact, the longer administration time with CCLAD was even assessed inconvenient by some patients. The reason for the incongruous results of these two studies can be seen in the fact that in the present study patients reported the time of disappearance of numbness according to their own perception, whereas Saoji et al. tested tooth sensitivity themselves with an electric pulp tester. Hence, a limitation of the present study can be seen in the relative inaccuracy of patients' evaluation of time span as opposed to an electric pulp tester. Another limitation of this study was the fact that patients were not blinded. Thus, as CCLAD was assessed less frightening visually, this might have reduced pain expectancy prior to actual anesthesia [20]. However, the visual impression of the devices was part of this study.

5. Conclusion

CCLAD increases patient comfort when used for buccal infiltration, and patients' feedback changes significantly after reflection time in favor of CCLAD. The different flow rate of both systems has no impact on anesthesia time.

Declarations

Author contribution statement

S. Flisfisch: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

J. Woelber: Analyzed and interpreted the data; Wrote the paper.

W. Walther: Conceived and designed the experiments; Wrote the paper.

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Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

The clinical trial described in this paper was registered at the German Clinical Trials Register under the registration number DRKS00014765. The study was conducted in accordance with the CONSORT 2010 Checklist-1.

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