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Comparison of molding helmet therapy versus natural course in twins with nonsynostotic head deformation

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ABSTRACT

This observational study aims to compare the effectiveness of helmet therapy versus natural course in twin siblings suffering from nonsynostotic head deformations.

A retrospective analysis of all twin couples treated with helmet therapy between March 2009 and May 2017 at an orthopedic hospital was conducted. Inclusion criteria were me if only one twin received helmet therapy. The other twin acted as control. A classification for different head shapes was used.

A total of 61 twin couples was included. Change in outcome parameters of helmet therapy and natural course differed significantly: cranial vault asymmetry (CVA) −0.66 cm vs. −0.04 cm, cranial vault asymmetry index (CVAI) −5.35% vs. −0.51% (both $p < 0.001$), cephalic index (CI) −3.10% vs. −1.91% ($p = 0.006$). Helmet therapy showed a success rate (CI < 90% and CVAI ≤7% or better) of 63.6% vs. 21.1% in children with natural course ($p = 0.002$).

Within the limitations of the study it seems that the results of this retrospective, single-center study confirm that helmet therapy to be a reliable treatment for mild to severe positional head deformation.

1. Introduction

The “back to sleep” campaign was introduced in 1992 in order to reduce the incidence of sudden infant death syndrome (SIDS). As a consequence, the occurrence of head deformities in infants has increased (Johnson et al., 1996). Extended time in a supine position may result in a symmetrical posterior flattening of the head (brachycephaly (B)). When a child prefers one side, the skull may flatten asymmetrically (plagiocephaly (P)). Since there are options to improve head shape (Moss, 1997; Carson et al., 2000; Loveday and de Chalain, 2001; Persing et al., 2003; van Vlimmeren et al., 2008; Wilbrand et al., 2013), it is of great importance to check all infants presenting with head deformation for the individual pathology and possible treatments. Late effects of cranial deformation such as malocclusion or neurodevelopmental disadvantages are being discussed (Collett et al., 2019; Speltz et al., 2010; Kluba et al., 2016).

While studies suggest helmet therapy to be a reliable method for the treatment of nonsynostotic skull deformities (Teichgraeber et al., 2004; Yoo et al., 2012; Couture et al., 2013; Çevik et al., 2020; Wen et al., 2020; Sestokas et al., 2012; Wen et al., 2020; Visse et al., 2020), few randomized controlled trials (RCT) are available, mostly due to ethical reasons. In many of the RCTs, patients with only mild deformation (control group) are compared to patients with severe deformation (intervention group). In an RCT with 84 patients, van Wijk et al. discouraged the use of helmet therapy. However, patients with a severe deformation were excluded from this study (van Wijk et al., 2014). In a matched-pair analysis, Wilbrand et al. found a clear improvement for children treated with an orthosis (Wilbrand et al., 2014). Besides this ongoing discussion about the necessity of helmet therapy, parameters for good outcome have been identified: young age at initiation

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Abbreviations and acronyms

CI	cephalic (cranioproportional) index
CVA	cranial vault asymmetry
CVAI	cranial vault asymmetry index
RCT	randomized controlled trials
SIDS	sudden infant death syndrome
3D	three-dimensional

of therapy and proper application of the orthosis (Çevik et al., 2020; Freudlsperger et al., 2016; Han et al., 2017; Mackel et al., 2017).

Twinning has been identified to be an individual risk factor for deformational plagiocephaly (Joganic et al., 2009; Pogliani et al., 2014), which can easily be explained by the intrauterine tightness. In order to elucidate the effectiveness of helmet therapy, a retrospective twin study was conducted that included twin couples where one sibling received molding helmet therapy while the other did not.

2. Methods

2.1. Study design & study population

A retrospective, non-randomized observational study was conducted to evaluate twin couples of which one twin was treated for skull deformation between March 2009 and May 2017. Indication for helmet therapy was clarified by the same physician for each patient via clinical and photogrammetric aspects. Inclusion criteria for this study required treatment with an orthosis for one twin and proper 3D-camera scans before and after treatment/observation for both twins. The ethics committee's approval for this study was given on July 7, 2014 (no. 2317-2014).

2.2. Helmet therapy

The severity of skull deformation was determined using a 3D-camera (Vectra M5, Canfield, Parsippany, USA) and corresponding software (Cranio Analytics 3.0) (Cranioform AG, Alpnach, Switzerland). Hereby the cranial vault asymmetry (CVA), cranial vault asymmetry index (CVAI) and cranial (cranioproportional) index (CI) were assessed. CVA is the difference between the longest and the shortest cranial diameter, both measured at a 30° angle from the anterior-posterior line, whereas the CVAI is the ratio of the CVA and the shortest cranial diameter multiplied by 100. Both CVA and CVAI represent plagiocephaly. For evaluation of brachycephaly CI was used, which is the ratio between width and length of a skull multiplied by 100 (Fig. 1) (Loveday and de Chalain, 2001).

Criteria for initiation of therapy was already published (Hinken et al., 2019) and started when clinical impression indicated the use of an orthosis, mostly if CVAI was greater than 7% or CI greater than 90%. Exclusion criteria were age greater 12 months, cranial synostosis or any other disease that prohibited the use of an orthosis. All orthoses were manufactured by one company (Cranioform AG, Alpnach, Switzerland). In order to gain a comfortable fit and reduce skin irritation, each individual orthosis was fitted at the department by the attending physician. The orthosis was applied for at least 23 h a day by the patient's caregivers, who were also advised to perform a daily cleaning. Every four to eight weeks, a 3D-camera scan was obtained for monitoring of therapy and progress. If necessary, the orthosis was then altered. Therapy was ended when parameters for plagiocephaly and brachycephaly came close to standard value or if the child did not tolerate the helmet any longer. Twins with natural course were observed likewise (Fig. 2). Duration of therapy was from initiation of therapy until end of therapy (last 3D-camera scan). Period of observation in controls was from first presentation until last 3D-camera scan.

2.3. Measurements and database

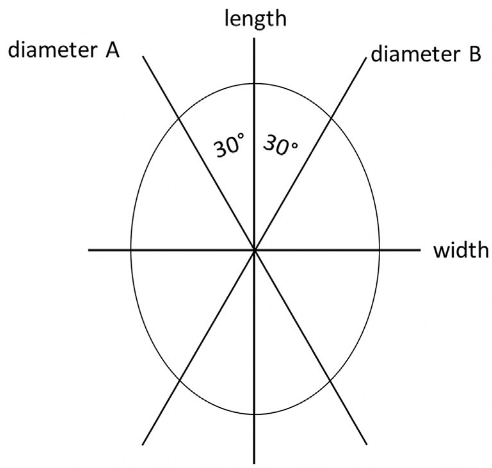
In line with a previous published study of the same author group, Cranio Analytics 3.0 was used to calculate the measurements before and after therapy/observation (Hinken et al., 2019). This software divides each 3D-model into twelve horizontal outlines and calculates the corresponding data. Data about the software's validity and reliability have not been published, but repeated caliper measurements by the study personnel have proven the software to be accurate. Baseline for this retrospective study was defined as the first presentation at our clinic and was identical for each pair of twins. Outcomes were compared at the time when helmet therapy was discontinued. To gather reproducible values, measurements were taken from the outline with the largest circumference. Further patient data (date of birth, duration of therapy/observation) was taken from the hospital information system “TurboMed” (CompuGroup Medical Deutschland AG, Molfsee, Germany). Before performing any biometrical analysis, the database was pseudonymized.

2.4. Classification

In order to differentiate between plagiocephaly, brachycephaly and skull deformations with a combination of both (asymmetrical brachycephaly), a classification was previously published based on a study group of 1050 patients (Hinken et al., 2019). However, for the presented study this graduation has been altered to use CVAI instead of CVA (Table 1). To date there is no consensus and often no clear definition of classification, so that different types of graduating exist (Çevik et al., 2020; Wen et al., 2020; Wilbrand et al., 2012; Schaaf et al., 2010; Doerhage et al., 2016). In this study, patients with CI equal or smaller than 90% and CVAI greater than 7% were categorized as plagiocephalic (P). Patients with CI more than 90% and CVAI equal to or less than 7% were categorized as brachycephalic (B). The combination of both (PB) was defined by CI higher than 90% and CVAI greater than 7%. The thresholds for a moderate deformation (CVAI >7%; CI > 90%) comply with literature (Yoo et al., 2012; Çevik et al., 2020; Freudlsperger et al., 2016; Han et al., 2017; Holowka et al., 2017; Hallac et al., 2019). Patients with CI equal to or less than 90% and CVAI equal to or less than 7% were defined to be healthy with a very mild to mild deformation (H) and no clear indication for helmet therapy. This group was used as the definition of successful therapy for the calculation of the success rate, since in these patients, helmet therapy was not necessary in the first place.

2.5. Data analysis

Data was collected using Excel (Microsoft Corporation, Redmond, USA) and analyzed with SPSS 26 (IBM, Armonk, USA) for further analysis. Our classification was applied to all patients with helmet therapy (the controls were grouped accordingly). Summary statistics for the parameters CVA, CVAI and CI were assessed for the entire study population and each group and visualized in boxplots.



$$\text{Cranial Vault Asymmetry (CVA)} = \text{longest diameter} - \text{shortest diameter}$$

$$\text{Cranial Vault Asymmetry Index (CVAI)} = \frac{\text{CVA}}{\text{shortest diameter}} \times 100$$

$$\text{Cranial (cranioproportional) Index (CI)} = \frac{\text{width}}{\text{length}} \times 100$$

Fig. 1. Calculation of CVA, CVAI and CI
Reprinted from Hinken et al. (2019) with permission from Elsevier.

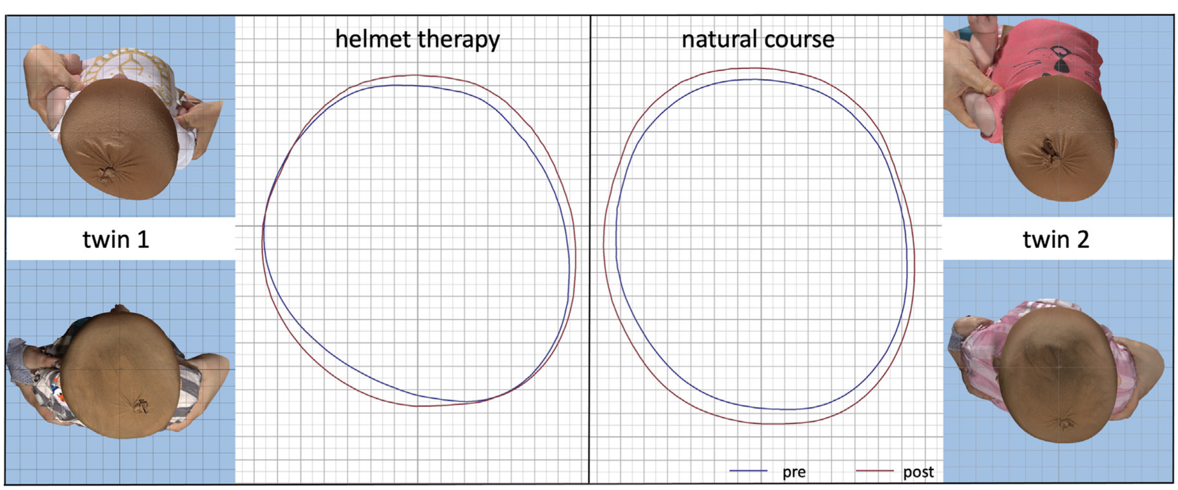


Fig. 2. Visual comparison of helmet therapy vs. natural course
With helmet therapy, growth of the head is guided into a symmetrical shape (left, blue line = before, red line = after), while in natural course, head shape stays almost the same.

Table 1
Definition of groups.

P	PB	B
CI ≤ 90%; CVAI >7%	CI > 90%; CVAI >7%	CI > 90%; CVAI ≤7%
H		
CI < 90%; CVAI ≤7%		

Each group is defined by a combination of cranial index (CI) and cranial vault asymmetry index (CVAI). P = plagiocephaly, B = brachycephaly, PB = combination of plagiocephaly and brachycephaly, H = healthy.

Change from baseline (post-treatment − pre-treatment) in outcomes was compared by means of Student's paired *t*-test (using twins as pairs). Success rates were compared among those initially classified as not healthy by means of Fisher's exact test. Success of therapy was assumed if patients changed from group P, PB or B to H (no success when there was no change or if patients changed from H to another group). Nominal statistical significance at the two-sided level $\alpha = 0.05$ was considered an indicator for an association between helmet therapy and outcomes. There was no multiplicity control, as this is an exploratory study.

3. Results

3.1. Collective, age and sex

During the observation period (March 27, 2009–May 9, 2017) 61 twin couples were included in the study (57.4% male vs. 42.6% female). Out of these children, 61 twins received helmet therapy and the corresponding twins acted as control (68.9% male vs. 31.1% female). 60.7% of the couples were same sex (62.2% male vs. 37.8% female). Out of the mixed sex couples, in 79.2% of the cases a male received helmet therapy. There was no meaningful difference between duration of helmet therapy and observation period (natural course) (mean difference 0.29 months) or age at the beginning of the study (mean difference 0.11 months). Growth of the head as measured as increase in circumference did not differ significantly between twins (2.59 cm vs. 2.44 cm, $p = 0.38$).

3.2. Baseline values and treatment

Baseline values are shown in Table 2. Patients' mean age at initiation of therapy was 8.16 months (8.05 months in observation group) and therapy lasted 5.91 months on average (vs. 5.61 months of observation). For twins with helmet therapy mean CVAI was 10.01% (CVA 1.35 cm) and CI was 89.41%. In the group without therapy (control) mean CVAI was 4.84% (CVA 0.68 cm) and CI was 84.25%.

3.3. Classification

The classification was applied to the treated twin (patients) and the twin without therapy (observation) was grouped accordingly. Of 61 treated twins, 27 showed a plagiocephalic deformation (P) (44.3%), 8 had an isolated brachycephalic deformation (B) (13.1%) and 21 a combination of both (PB) (34.4%). 5 twins received helmet therapy with only very mild to mild head deformation (H) (8.2%).

3.4. Change of parameters

Overall, during helmet therapy [results for natural course in brackets] mean CVAI changed by −5.35% [−0.51%] and mean CVA by −0.66 cm [−0.04 cm] ($p < 0.001$). CI changed by −3.19% [−1.91%] ($p = 0.013$).

For patients with plagiocephalic deformation (P) mean CVAI changed by −6.28% [−0.37%] and CVA by −0.67 cm [−0.01 cm] ($p < 0.001$). Infants with a combination of plagiocephaly and brachycephaly (PB) showed the following changes: CVAI -5.43% [−0.6%], CVA -0.62 cm [−0.05 cm] (both $p < 0.001$) and CI -2.97% [−2.41%] ($p = 0.479$). For the children with isolated brachycephalic deformation (B) change in CI was −3.4% [−1.81%] ($p = 0.199$). These patients showed a change in CVAI by −3.3% [−0,45%] and CVA by −0.74 cm [−0.04 cm] ($p = 0.15$ and $p = 0.002$).

Tables 3 and 4 demonstrate the mean change of the parameters CVAI, CVA and CI for twins with helmet therapy and controls as well as for each subgroup. Fig. 3 compares the change of the parameters CVA, CVAI and CI in the relevant groups for helmet therapy and natural course in boxplots.

Table 2
Baseline values.

	helmet therapy (n = 61)		natural course (n = 61)	
	mean	SD	mean	SD
duration (months)	5.91	2.80	5.61	3.48
age (months)	8.16	2.08	8.05	2.89
CVAI (%) pre	10.01	3.90	4.84	2.81
CVA (cm) pre	1.35	0.49	0.68	0.37
CI (%) pre	89.41	7.26	84.25	6.79
CVAI (%) post	4.66	2.6	4.32	2.52
CVA (cm) post	0.69	0.38	0.64	0.36
CI (%) post	86.22	5.78	82.35	6.62

3.5. Success rate

Success was assumed if twins switched classification from P, PB or B to H (healthy) after therapy/observation ($n = 39$). No success was assumed if there was no change in groups or if twins with very mild to mild deformation (H) switched to another group ($n = 35$). 48 patients were excluded since they were grouped as healthy (very mild to mild deformation) at the beginning and did not change. The success rate for helmet therapy was 63.6% vs. 21.1% in twins with natural course ($p = 0.002$). Table 5 shows the contingency table for helmet therapy versus natural course and success.

4. Discussion

In the presented study the outcome of helmet therapy was compared to the natural course of growth.

Two thirds of the patients treated with an orthosis were male. This is in line with literature, where boys are more likely to develop positional cranial deformation (Çevik et al., 2020; Wen et al., 2020; Hinken et al., 2019). Otherwise, there was no significant difference between groups according to age, observation period or growth in circumference. Small differences in mean age and observation period between therapy group and control is due to different dates for collection of 3D-images and initiation of therapy. Mean age at the initiation of therapy was 8.16 months, which is greater than the recommended age of six months for good results of helmet therapy (Çevik et al., 2020; Freudlsperger et al., 2016; Han et al., 2017).

The majority of patients were treated due to plagiocephalic deformation (44.3%) or combination of plagiocephaly and brachycephaly (34.4%). Isolated brachycephaly (13.1%) is a rare finding in this collective as well as in literature (Teichgraeber et al., 2004). Five children were treated without clear indication for helmet therapy according to our classification (group H). Clinical impression may have led to therapy even though parameters for head deformation were low.

As a main result of this study and when analyzing the entire study population, treated children showed a greater change in all outcome parameters (CVAI, CVA and CI) in comparison to the untreated twins. When comparing each individual group, the greatest reduction in CVAI can be seen in group P and PB (−6.28% and −5.43%), while CI decreases by 2.97% and 3.4% in groups PB and B. Regarding CI, there is no significant difference between helmet therapy and natural course besides the plagiocephalic group. This might be explained by a physiological increase in head length and thus a decrease of cephalic index over time (Likus et al., 2014; Pindrik et al., 2016).

Furthermore, a success rate of 63.6% was calculated for twins treated with helmet orthosis according to our classification (success if CI < 90% and CVAI ≤7%). This is almost threefold that in the observation group (63.6% vs. natural course 21.1%; $p = 0.003$). Han et al. calculated a mean success rate of 43.0% when using a cutoff value of CVAI ≤3.5% and in older infants (mean age 27.2 months) Kim et al. still report a success rate of 22.0% (Han et al., 2017; Kim et al., 2014). This suggests that success rates depend on the chosen definition of success, which was the same for treated and untreated twins in this study. Even though the initial deformation was less severe in twins with natural course, due to insufficient

Table 3
Change in outcome parameters of therapy vs. natural course.

	helmet therapy			natural course			difference helmet vs. natural course		
	mean	SD	95% CI	mean	SD	95% CI	paired mean difference	95% CI	p-value
CVAI (%)	−5.35	2.96	−6.11, −4.59	−0.51	1.23	−0.83, −0.2	−4.83	−5.63, −4.03	<0.001
CVA (cm)	−0.66	0.36	−0.75, −0.56	−0.04	0.16	−0.8, −0.01	−0.62	−0.72, −0.52	<0.001
CI (%)	−3.19	3.16	−4.0, −2.38	−1.91	2.40	−2.52, −1.29	−1.29	−2.28, −2.57	0.013

Table 4
Change in outcome parameters of therapy vs. natural course for each head deformation.

		helmet therapy			natural course			difference helmet vs. natural course		
		mean	SD	95% CI	mean	SD	95% CI	paired mean difference	95% CI	p-value
P	CVAI (%)	−6.28	3.38	−7.61, −4.94	−0.37	1.47	−0.96, 0.21	−5.9	−7.24, −4.56	<0.001
	CVA (cm)	−0.67	0.37	−0.82, −0.53	−0.01	0.18	−0.08, 0.07	−0.67	−0.83, −0.5	<0.001
	CI (%)	−3.27	3.69	−4.74, −1.81	−1.40	2.80	−2.51, −0.29	−1.87	−0.06, −2.12	0.044
PB	CVAI (%)	−5.43	2.35	−6.5, −4.36	−0.60	1.12	−1.11, −0.09	−4.83	−6.02, −3.64	<0.001
	CVA (cm)	−0.62	0.36	−0.78, −0.45	−0.05	0.15	−0.12, 0.02	−0.57	−0.76, −0.38	<0.001
	CI (%)	−2.97	2.96	−4.32, −1.62	−2.41	1.94	−3.29, −1.53	−0.56	−2.17, 1,06	0.479
B	CVAI (%)	−3.30	2.24	−5.18, −1.42	−0.45	0.65	−1.0, 0.1	−2.85	−4.96, −0.74	0.15
	CVA (cm)	−0.74	0.42	−1.1, −0.39	−0.04	0.11	−0.13, 0.05	−0.7	−1.04, −0.36	0.002
	CI (%)	−3.4	2.46	−5.45, −1.35	−1.81	2.52	−3.92, 0.3	−1.59	−4.23, 1.06	0.199

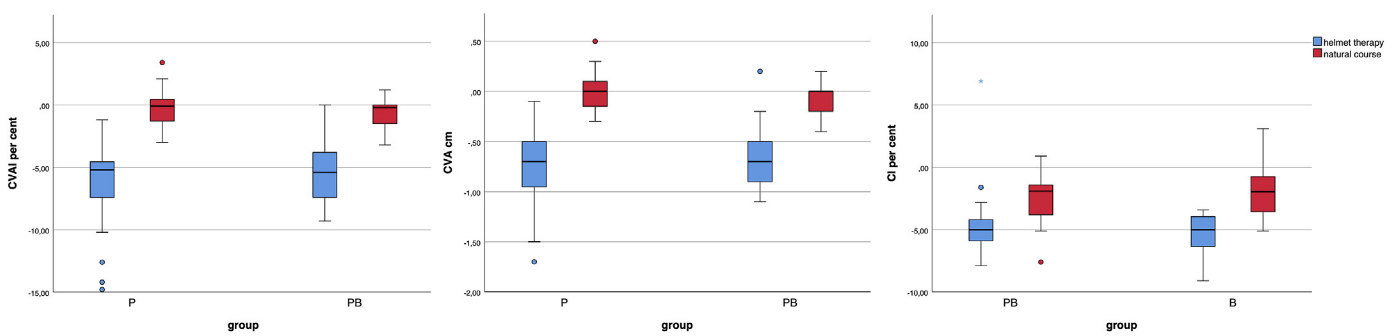


Fig. 3. Boxplot of CVAI, CVA and CI
Comparison of reduction of CVAI, CVA and CI for helmet therapy (blue) and natural course (red) (in percent for CVAI and CI, in centimeters for CVA).

Table 5
Contingency table for success rate.

	success		total
	yes	no	
helmet therapy	35	20	55
	63.6%	36.4%	100%
natural course	4	15	19
	21.1%	78.9%	100%
total	39	35	74
	52.7%	47.3%	100%

p-value = 0.003 (Fisher's exact test).

spontaneous recovery the success rate was almost three times higher in children treated with molding orthosis. It also becomes obvious that 15 children of the control group did not receive helmet therapy, although it was indicated according to our classification. In these cases, the authors consider that the respective twin with worse deformation must have been in the focus of caregivers and physicians.

To our knowledge this is the first twin study analyzing the outcome of helmet therapy. The results of this study suggest the effectiveness of helmet therapy in comparison to natural course. In children with moderate to severe head deformation, helmet therapy should be preferred to the natural development of head shape. However, due to missing randomization, causality cannot be proven. As second results, the distribution of head deformation among twins seems to be similar to the standard population. In order to further examine the effectiveness of helmet therapy, randomized studies will be required. The authors are of the opinion that such randomized controlled studies require a very careful design in order to avoid the issue that severely affected children would be untreated.

4.1. Limitations

The authors are aware of the limitations of this study. First, the results are based on retrospective data without any randomization. There are apparent differences in head shape between twins treated or not treated with helmet therapy which are considered to affect the possibility of improvement in head shape. There were slight differences in timing of baseline and follow-up within pairs of twins which may have a minor impact on observed changes in outcomes. The set of measured patient characteristics is limited and may not fully capture prognosis of head shape (e.g. comorbidities were not included in the data). When comparing success rates, due to exclusion of subjects classified as healthy, a simplified analysis omitting the correlation between twins was chosen. Second, sample sizes are limited, in particular in the subgroup of control patients with head deformation. Third, the data come from a single center. Therefore, the author group could only give an insight into their own indication for treatment in nonsynostotic head deformation in children because of the lack of uniform criteria.

5. Conclusion

Within the limitations of the study it seems that the results of this retrospective, single-center study confirm that helmet therapy to be a reliable treatment for mild to severe positional head deformation.

Declaration of competing interest

No internal or external support was received for this study.

The authors declare no conflicts of interest.

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