

Reducing Infant Cranial Asymmetry with a Body-Positioning Sleep System

A single-arm pre–post clinical evaluation of the AiBrain infant body mattress: craniometric change, safety, and caregiver experience in positional cranial deformity

Product: **AiBrain** (아이브레인) infant body-positioning mattress · Manufacturer: **AiBrio Co., Ltd.** (아이브리오㈜)
Designed by a pediatric rehabilitation medicine specialist · Consumer product (not a medical device)

–47%

relative reduction in mean cranial asymmetry (CVAI 7.2% → 3.8%) over the use period

96%

of infants showed reduced asymmetry from baseline to final

43%

reached a normal head-shape range (CVAI < 3.5%)

0

serious device-related adverse events

Design: Single-arm, prospective pre–post evaluation • **Analyzed:** 23 infants with positional cranial deformity • **Setting:** University-affiliated hospital, Republic of Korea

Period: 2025–2026 • **Prepared:** July 2026 • **Classification:** Confidential — for professional use • Read together with the safety and limitations sections.

배경과 미충족 수요

자세성 사두변형은 영아에서 흔하다. 생후 7-12주 유병률이 최대 46.6%로 보고되며, 양와위 수면이 표준이 된 1990년대 이후 뚜렷이 증가했다. 대개 양성 경과를 밟지만, 일부에서 두개 비대칭이 지속되고 운동·인지 발달지연과의 연관이 보고되어 조기 관리의 근거가 된다. 중등도 이상에서 쓰이는 두개성형 헬멧은 무작위대조시험(HEADS)에서 자연경과 대비 이점이 확인되지 않았고 부작용이 흔했다. 반대로 자세선호를 교정하는 물리치료는 무작위시험에서 중증 사두를 6개월에 46%까지 낮췄다. 남은 공백은 분명하다. 헬멧 적용 연령 이전의 어린 시기에, 안전수면 원칙을 지키면서 부담 없이 쓸 수 있는 보조 수단이다.

제품과 작용 원리

아이브레인(AiBrain, 아이브리오㈜)은 소아재활의학과 전문가가 설계한 영유아 바디 매트리스다. 머리를 한자리에 고정하는 고정 베개가 아니다. 두 가지로 작동한다. 첫째, 후두부가 닿는 면을 오목하게 만들어 한 점에 몰리던 접촉 압력을 넓게 분산한다. 둘째, 몸통 아래에 완만한 경사(블록 1개 약 10°, 2개 약 20°)를 주어 몸통의 방향을 바꾼다. 어린 영아는 고개가 몸통 방향을 따라가므로, 늘 향하던 쪽의 반대로 고개가 돌아가도록 유도된다. 아기는 좋아하는 등 대고 자는 자세를 그대로 유지한다. 중요한 안전 원칙: 밤잠·긴 수면은 평평한 면에 등을 대고(양와위) 재우며, 경사 기능은 보호자가 곁에서 지켜보는 각성 시에만 쓴다. 이는 단단하고 비경사인 수면면을 권고한 미국소아과학회(AAP) 2022 지침과 부합한다.

방법과 결과

단일군 전향적 전후 관찰연구다. 등록 26명 중 기저·최종 두상 계측을 모두 보유한 23명을 분석했다. 두개비대칭지수(CVAI)와 두개지수(CI)를 캘리퍼로 산출하고, Wilcoxon 검정·효과크기(Cohen's d_z)·부트스트랩 신뢰구간·다중 민감도분석을 시행했다. 평균 2.7개월 사용 후 CVAI는 7.2%에서 3.8%로 감소했다($\Delta -3.41\%$, 상대 47%, $p < 0.001$, $d_z = -1.07$). 23명 중 22명(96%)이 개선, 17명(74%)이 중증도 1단계 이상 호전, 10명(43%)이 정상 범주에 들었다. 반면 두개지수는 유의하게 변하지 않았다($p = 0.14$). 이 선택적 결과는 우연이 아니다. 아이브레인은 좌우 비대칭을 만드는 방향성 압력에 작용할 뿐 양와위 전체 하중을 줄이지는 않으므로, 비대칭(CVAI)은 좋아지고 대칭적 후두 편평(CI)은 그대로일 것으로 사전에 예측되며, 관찰 결과가 이 예측과 일치한다. 효과는 모든 민감도분석에서 견고했다. 중대한 기기 관련 이상반응은 없었고 안전성·만족도는 양호했다.

결론

아이브레인은 자세성 사두(비대칭)의 보조적 관리 환경으로서, 사용 기간 중 두개 비대칭의 크고 일관된 개선과 양호한 안전성을 보였다. 무작위시험으로 효과가 입증된 '자세선호 교정'이라는 동일한 기전에 근거한다는 점이 논리적 강점이다. 다만 단일군 설계로 자연경과와 평균회귀를 배제할 수 없으므로, 대조군을 포함한 확증연구가 필요하다. 아이브레인은 질병을 치료·교정하는 의료기기가 아니며, 두상이 우려되면 전문의 상담을 병행해야 한다.

1 Background and Clinical Significance

Positional cranial deformity is common, largely benign, and — for a meaningful minority of infants — persistent enough to matter. Its management runs from watchful waiting through conservative repositioning to cranial orthoses, and each option carries a distinct evidence base and burden.

The condition became far more visible after the early 1990s. When supine sleep was adopted to reduce sudden infant death, referral centers reported a sharp rise in occipital flattening within just two years, and the timing tracked the change in sleep position almost exactly.^{1,2} Prevalence estimates have since settled at a high level: a Canadian cohort found positional plagiocephaly in 46.6% of infants at 7 to 12 weeks,³ a European cohort reported 37.8% at 8 to 12 weeks,⁴ and asymmetry is already detectable in a proportion of healthy newborns.⁵ Male sex, firstborn status, limited neck rotation, and a fixed head-turning preference are among the recognized risk factors.^{6,7,8}

Two shapes, measured two ways, need to be kept apart. Plagiocephaly is an oblique asymmetry, quantified by the Cranial Vault Asymmetry Index (CVAI), the percentage difference between the skull's two diagonals. Brachycephaly is a symmetric widening and posterior flattening, quantified by the Cranial Index (CI), the ratio of head width to length.⁹ The distinction is not academic. The two deformities have partly different mechanics, and — as this evaluation shows — they need not move together under the same intervention.

Most cases improve. That said, the improvement is neither universal nor guaranteed, and the stakes are not purely cosmetic. Follow-up cohorts have linked deformational plagiocephaly to measurable, if modest, differences in early motor and cognitive development, and to a higher use of developmental services at school age.^{10,11,12,13} Whether the head shape causes these differences or simply marks an underlying vulnerability remains unsettled; either way, the association is a reasonable argument for acting early rather than late, while the skull is still highly malleable.

The two active interventions sit at opposite ends of a burden spectrum. Cranial remolding helmets can reshape the skull, but the pivotal randomized trial (HEADS) found no significant advantage over the natural course at two years in moderate-to-severe cases, and every helmeted infant experienced side effects such as skin irritation, pressure, or heat.¹⁴ Large case series report benefit,¹⁵ yet the controlled comparison is what tempers enthusiasm. Conservative care is the other pole. A randomized trial of pediatric physical therapy targeting head-turning preference cut the risk of severe deformational plagiocephaly by 46% at six months and 57% at twelve, with no infant still showing a positional preference at follow-up.^{16,17} Conservative measures are safe and effective, but they lean heavily on caregiver consistency.

One constraint shapes everything in this space: safe sleep. The 2022 American Academy of Pediatrics recommendations are explicit that unsupervised infant sleep should be supine, on a firm and non-inclined surface, and that inclined or non-supine positioning is not a safe substitute.¹⁸ Any product touching the sleep environment has to be judged against that standard first, and its head-shape rationale has to survive within it. A practical gap follows from all of the above — a benign, low-burden aid that can be introduced early, works within supine sleep, and supports the same corrective lever that physical therapy uses. The remainder of this paper evaluates one such product against that gap.

2 The AiBrain System: Design and Proposed Mechanism

AiBrain is a consumer infant body mattress, not a medical device. Its design goal is narrow and specific: to make it easier for an infant to turn away from a flattened side while sleeping on the back, without caging the head and without abandoning supine sleep.

What the product is

The system pairs a memory-foam body mattress with a small set of adjustable accessories: a height-adjustable head pillow, two wedge blocks that create a gentle body incline (roughly 10° with one block, 20° with two), a soft securing blanket, straps that anchor the mattress inside a crib, and a carry bag. Skin-contact surfaces use OCS-certified organic cotton, unbleached and undyed; the core is a high-density memory foam that supports the body without letting it sink; an inner microfiber cover adds a water-repellent hygienic layer. The mattress was designed by a physician in pediatric rehabilitation medicine. It makes no claim to treat or correct disease.

The problem it targets: a self-reinforcing head-turn preference

Many affected infants do not distribute pressure evenly because they do not turn evenly. A directional preference — often accompanied by mild cervical asymmetry or torticollis — keeps the head resting on one side during supine sleep.^{7,8,19} Sustained loading flattens the occiput there, and the flattened surface then becomes the stable resting position, which deepens the preference. Parents notice this loop directly: turn the head to the other side, and before long it has rolled back. Manual repositioning alone rarely breaks the cycle, because it works against gravity and against the infant's settled posture.²⁰

Two design principles

1 · Redirect the trunk, not the head

A gentle incline tips the trunk toward the non-preferred side. In young infants the head follows the trunk, so the head is coaxed off the flattened side while the baby stays on its back. This differs from head-fixation pillows, which immobilize, and from side-lying or wedging, which conflict with both safe sleep and the infant's preferred posture.

2 · Spread the contact pressure

The concave occipital zone distributes contact over a wider area instead of concentrating it at a single flattened point, and the high-density foam conforms while still supporting. The aim is to lower and redistribute sustained load on the vulnerable region rather than to mold the skull mechanically.

Designed to live inside safe-sleep rules

The incline is not a sleep feature. For night sleep and any unsupervised sleep, the system is used flat and supine on a firm surface, in line with the AAP's firm, non-inclined standard.¹⁸ The incline is intended only for supervised, awake use — settled rest after a feed, or support during tummy time. During unsupervised sleep, then, the head-shape rationale rests entirely on the concave cradle and the directional pillow within supine positioning, not on inclined sleep. Section 6 returns to this point, because it governs how the product can be used responsibly.

THE FALSIFIABLE PREDICTION THAT SETS UP THE RESULTS

The mechanism acts on the **directional** component of loading. It redistributes and redirects where the head rests; it does not reduce the total supine load on the back of the head, and it adds no prone or upright time during sleep. A specific consequence follows. Improvement should concentrate in the **asymmetry** measure (CVAI) and should be small or absent in the symmetric posterior-flattening measure (cranial index). Section 4 tests this prediction directly, and Section 8 explains why the answer matters for causal interpretation.

3 Objective and Study Design

Objective

To measure the change in objective craniometric indices (CVAI and CI) from baseline to final follow-up in infants who used the AiBrain mattress, and to characterize the product's safety, tolerability, and caregiver-reported experience.

Design

This was a single-arm, prospective, pre–post evaluation conducted at a university-affiliated hospital in the Republic of Korea during 2025–2026. Each infant served as its own control. Cranial measurements were taken at enrollment and at final follow-up, with an interim measurement where scheduling allowed, and caregivers completed a structured questionnaire at the end of participation.

HOW FAR THIS DESIGN CAN CARRY AN INFERENCE

A single-arm study can establish what changed during use. It cannot, by itself, prove that the product caused the change, because positional asymmetry also improves with growth, with everyday repositioning, and through regression to the mean in infants enrolled precisely because they were asymmetric. The analysis below is built to test the finding from several angles and to state plainly where association ends and where a controlled trial would have to begin.

Participants and analysis population

Twenty-six infants with positional cranial deformity enrolled. The primary analysis set comprised the 23 infants with both a baseline and a final measurement separated by a valid interval; three infants had a baseline measurement only and could not contribute to paired analyses. Caregiver-reported outcomes were analyzed for the 19 respondents who returned the questionnaire.

Craniometric indices

Anteroposterior (AP) and mediolateral (ML) diameters and the two oblique cranial diagonals were measured with a craniometric caliper. From these, the cranial index ($CI = ML/AP \times 100$), the absolute diagonal difference (CVA, in mm), and the cranial vault asymmetry index ($CVAI = |\text{diagonal difference}| / \text{longer diagonal} \times 100$) were derived. CVAI severity followed the Children's Healthcare of Atlanta scale: normal below 3.5%, mild 3.5–6.25%, moderate 6.25–8.75%, severe 8.75–11%, and very severe above 11%; a CVAI of 3.5% or higher is the usual threshold for clinically relevant asymmetry.

Statistical analysis

Change in CVAI and change in CI were the two co-primary endpoints. The paired differences for CVAI were not normally distributed, so the Wilcoxon signed-rank test served as the primary test and the paired t -test is reported alongside it. Effect sizes are given as Cohen's d_z , and 95% confidence intervals for mean change come from a bootstrap with 10,000 resamples. Responder analyses report the share of infants who improved, who improved by at least one severity category, and who normalized. A two-stage longitudinal model estimated each infant's CVAI slope over time on the product. Robustness was probed with pre-specified sensitivity analyses — dropping a cranial-index outlier, dropping an infant who switched to a helmet, dropping an infant enrolled outside the usual age window, and restricting to per-protocol completers — plus a plagiocephaly-dominant subgroup. Analyses used Python (SciPy, scikit-learn).

Data-integrity handling. Three infants had conflicting birth dates across worksheets; the value consistent with a plausible age was used. One infant's final-visit date was corrected against the source record, restoring a valid interval. Indices were recomputed from raw measurements and matched the original worksheet formulas. The blue-diagonal fields were not recorded, so CVAI and CVA rely on the recorded diagonal pair; clinician diagnosis fields (plagiocephaly versus brachycephaly, torticollis, gestational age) were not recorded, so the morphology subgroup was derived from baseline anthropometry. Details appear in the Appendix.

5 Results

5.1 Participants at baseline

Twenty-three infants contributed paired measurements. Boys outnumbered girls (13 to 10), the mean age at enrollment was 3.4 months, and the average infant used the mattress for 2.7 months before the final measurement. As a group they started with moderate asymmetry (mean CVAI 7.2%) and a borderline cranial index (mean CI 90.0). Eight of the 26 enrolled infants (31%) discontinued; the reasons are covered in Section 6.

Baseline characteristic (n = 23)	Value	Range
Sex — male / female	13 (56.5%) / 10 (43.5%)	—
Age at baseline (months)	3.4 ± 2.1	0.8 – 12.1
Duration of use to final (months)	2.7 ± 1.1	1.5 – 5.0
Anteroposterior diameter, AP (mm)	130.0 ± 8.7	114 – 155
Mediolateral diameter, ML (mm)	116.8 ± 7.4	99 – 133
Cranial Index, CI	90.0 ± 5.1	82.6 – 100.8
Cranial Vault Asymmetry, CVA (mm)	9.1 ± 3.6	3.0 – 16.0
Cranial Vault Asymmetry Index, CVAI (%)	7.2 ± 2.8	2.3 – 12.5

Values are mean ± standard deviation unless noted.

5.2 Asymmetry fell sharply; the cranial index did not move

The primary result is a clean dissociation. Mean CVAI dropped from 7.2% to 3.8%, a fall of 3.41 percentage points and a relative reduction near 47% (Wilcoxon $p < 0.001$; paired t -test $p < 0.001$; $d_z = -1.07$, a large effect). The absolute diagonal difference tracked it down, from 9.1 to 5.1 mm. The cranial index, by contrast, showed no meaningful change (90.0 to 91.9; $p = 0.14$). Exactly as Section 2 predicted, the intervention moved the asymmetry measure and left the brachycephaly measure alone.

Endpoint	Baseline	Final	Change Δ (95% CI)	p (Wilcoxon)	d_z
CVAI (%) — asymmetry	7.20 ± 2.82	3.80 ± 2.99	-3.41 (-4.62, -2.10)	< 0.001	-1.07
CVA (mm)	9.13 ± 3.65	5.13 ± 4.10	-4.00 (-5.70, -2.13)	< 0.001	-0.91
CI — brachycephaly	90.01 ± 5.07	91.89 ± 6.18	+1.88 (-0.21, +4.06)	0.14 (n.s.)	+0.35

n = 23. Δ = final – baseline; a negative CVAI/CVA change is an improvement. Confidence intervals are bootstrap. n.s. = not significant.

Change in cranial shape after body-mattress use (baseline → final)

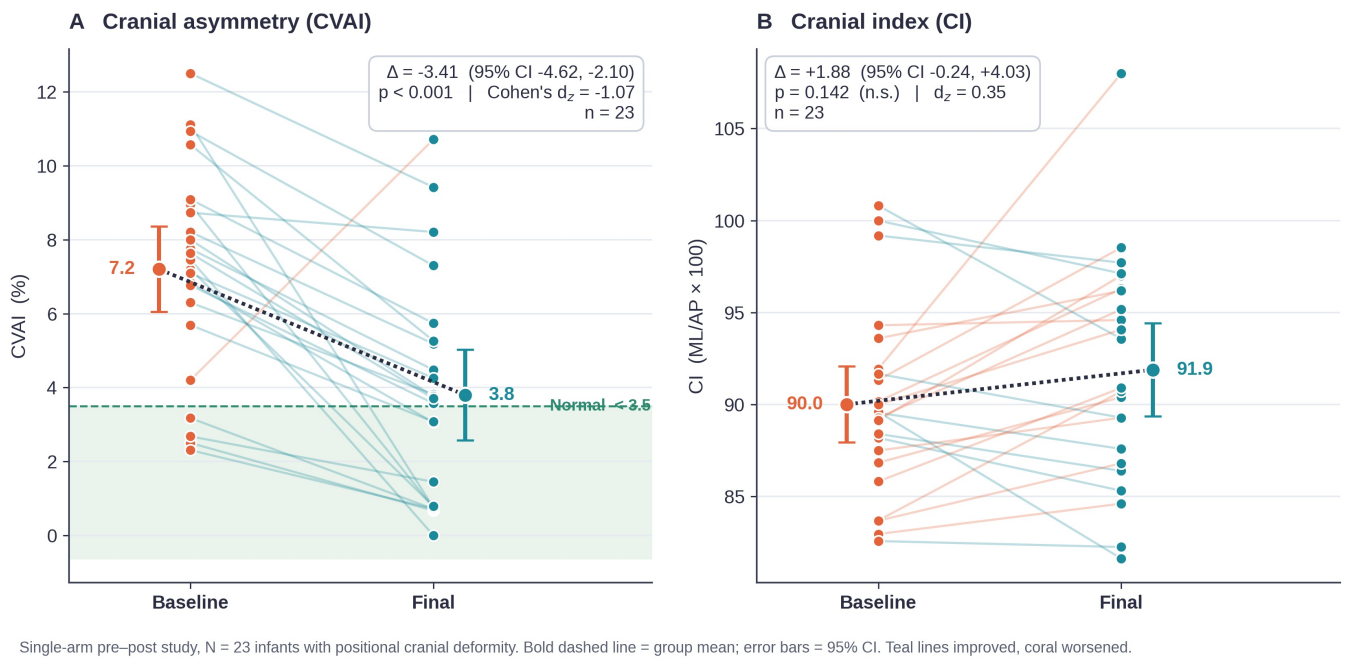


Figure 1. Change from baseline to final. **(A)** CVAI converges downward toward the normal range (shaded, < 3.5%). **(B)** The cranial index shows no consistent direction. The split points to a benefit specific to asymmetry rather than to posterior flattening.

5.3 Nearly every infant improved

The group means are not carried by a few responders. Twenty-two of 23 infants (96%) reduced their asymmetry, 17 (74%) improved by at least one severity category, and 10 (43%) reached the normal range. Of the 19 infants who were abnormal at baseline, six crossed into normal. Only one infant worsened.

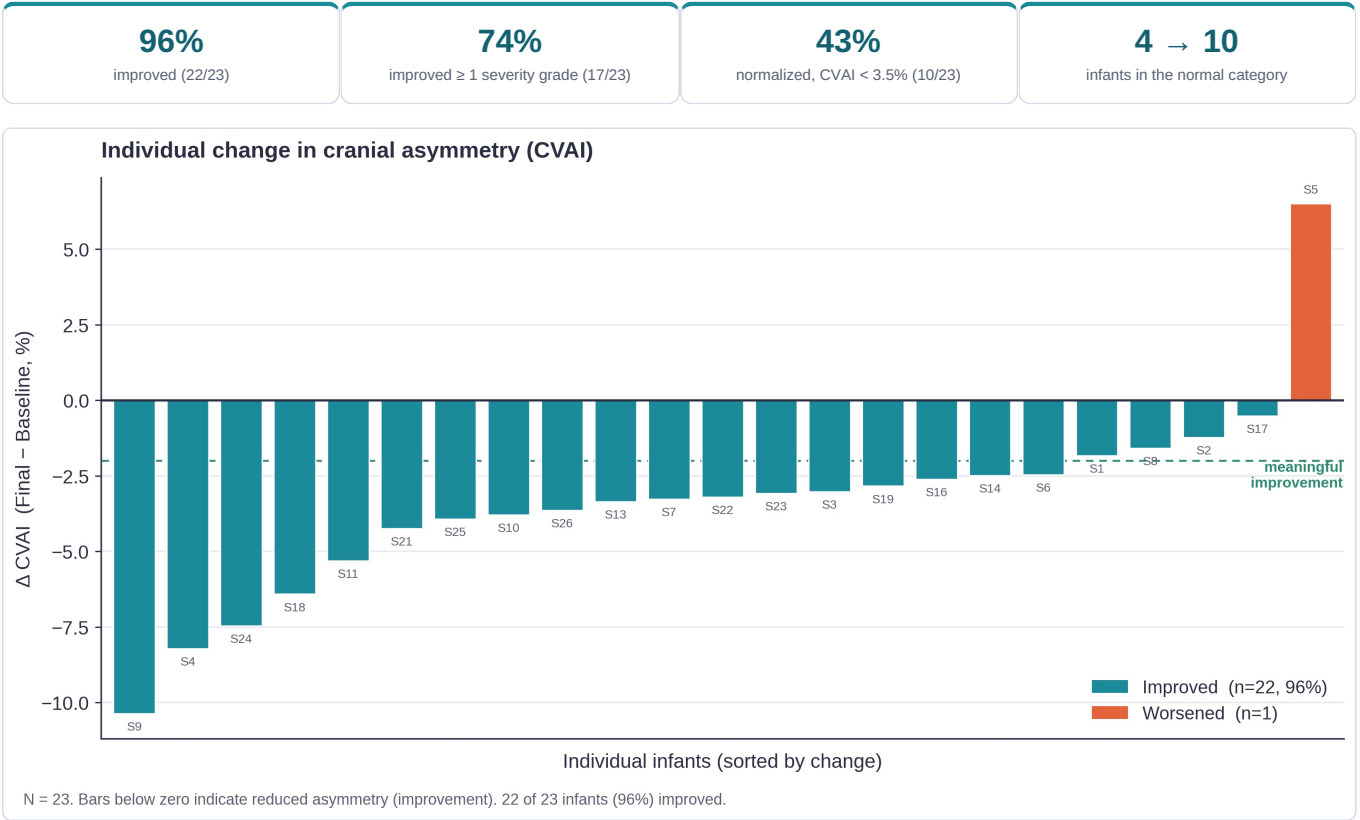


Figure 2. Individual CVAI change, sorted. Bars below zero mark reduced asymmetry. The improvement is broad, not concentrated in a handful of infants.

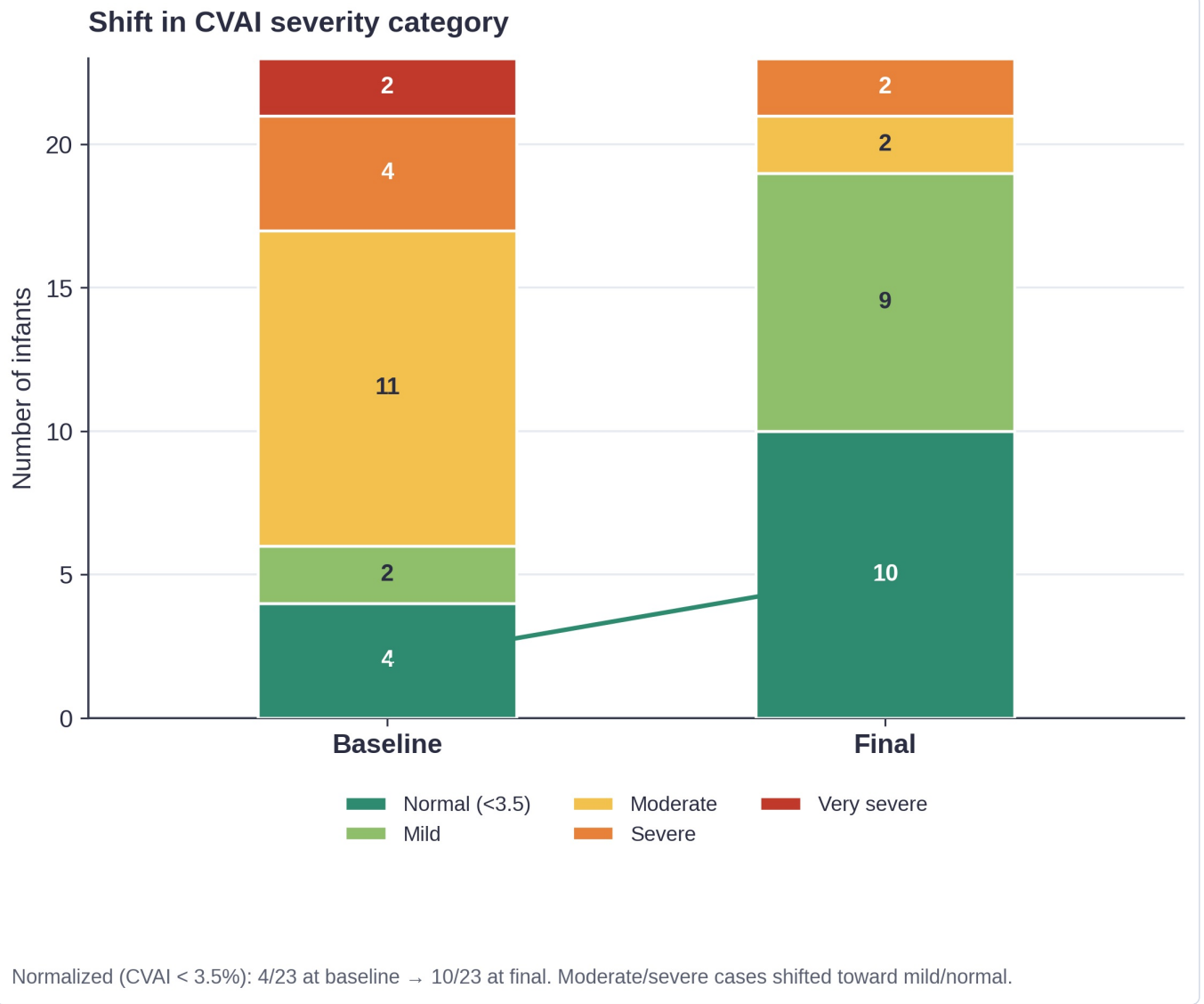


Figure 3. Severity categories at baseline versus final. Moderate and severe cases move toward mild and normal, and the normal category grows from 4 to 10 infants.

5.4 Improvement accrued over time and held up under scrutiny

Change did not appear all at once. Across visits, each infant's asymmetry fell by about 1.4 CVAI points per month of use (two-stage slope, $p < 0.001$), a gradient more consistent with cumulative repositioning than with a one-off measurement shift (Figure 4).

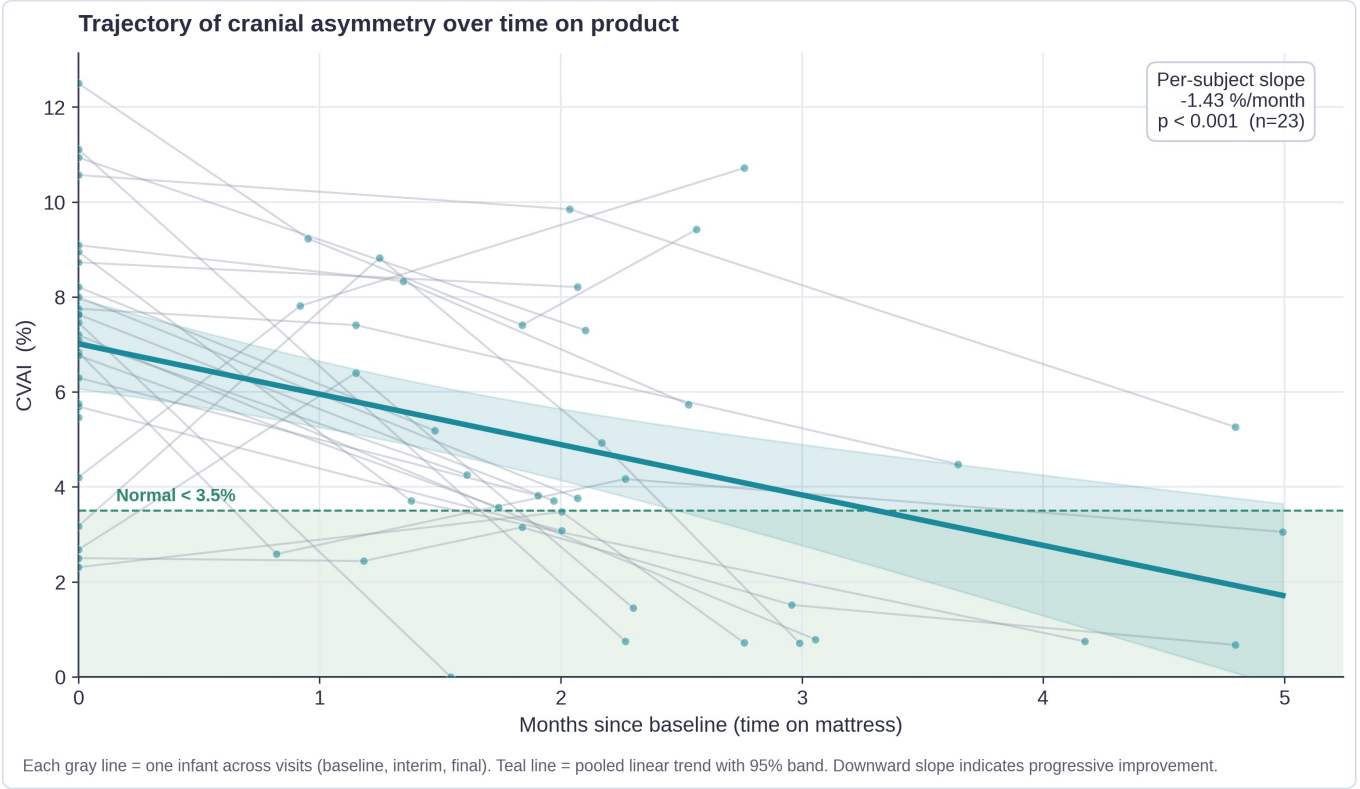


Figure 4. CVAI against time on the product. Gray lines are individual infants; the teal line is the pooled trend with a 95% band. The slope runs downward across the observation window.

The finding also refused to disappear when pressed. Removing a cranial-index outlier, removing the infant who moved on to a helmet, removing an infant enrolled outside the usual age window, restricting to per-protocol completers, and narrowing to the plagiocephaly-dominant subgroup each returned a mean change between -3.3 and -3.8 points, a large effect, and $p < 0.002$. Every interval sits well to the left of zero (Figure 5).

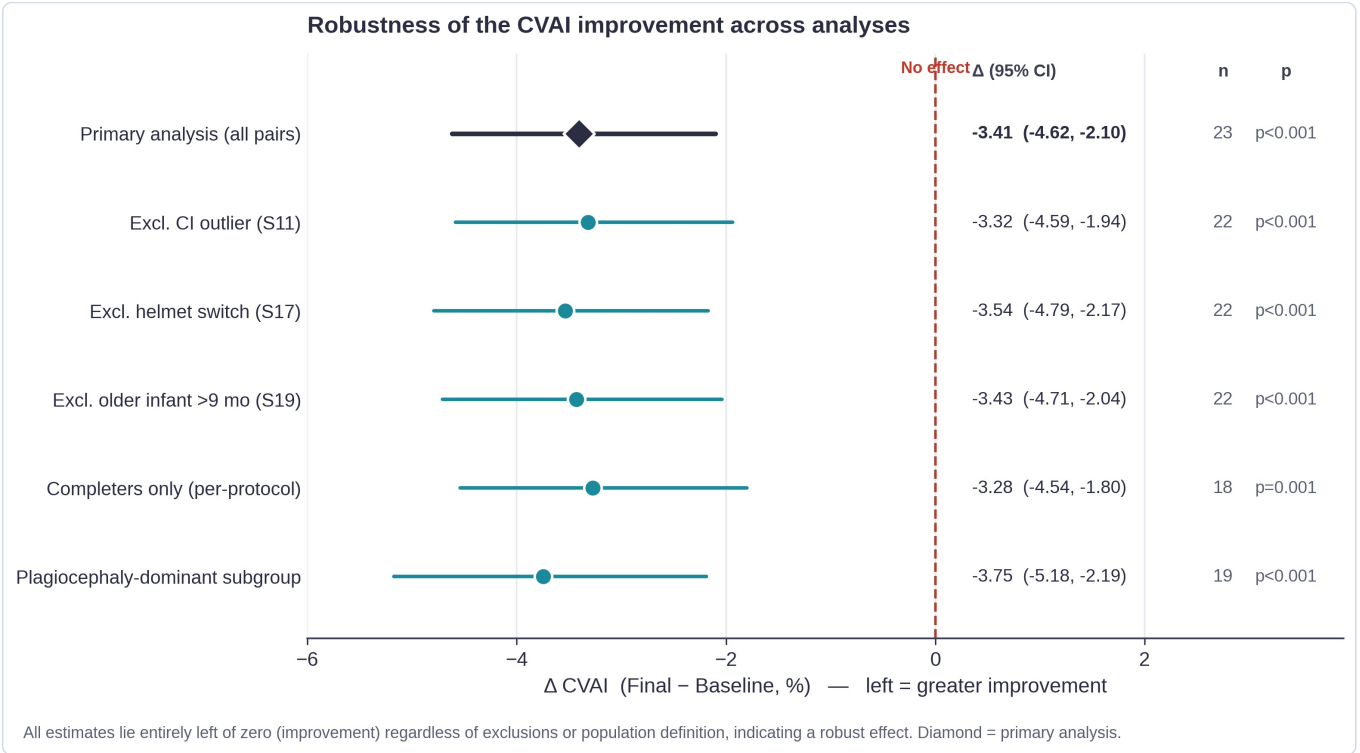


Figure 5. The CVAI change across analysis definitions. All estimates and confidence intervals lie entirely on the improvement side of zero. The diamond marks the primary analysis.

5.5 More severe heads improved more

Response scaled with severity. Infants who began in the moderate-or-worse range improved by 4.4 CVAI points on average, against 0.5 points for those who began mild, and baseline CVAI correlated with the size of the change ($r = -0.51$, $p = 0.014$). A larger correctable deficit is one reading of this pattern; regression to the mean is another, and Section 8 keeps both on the table. Age at enrollment and duration of use were not independent predictors in this sample.

6 Safety, Tolerability, and Safe-Sleep Alignment

No serious device-related adverse event occurred, and skin or pressure findings were rare. The one meaningful safety signal, and the feasibility pattern of who stopped using the product, both point to the same conclusion: the product is safe when used within its intended window and its supervised-incline rule.

Adverse events

Among 19 respondents, one reported prominent skin redness or heat rash and none reported prominent contact-site pressure marks. Caregivers rated safe sleep on the mattress favorably. One caregiver described an incident in which soft bedding covered the infant's face during sleep — a potential airway obstruction. No harm resulted, and the event traces to accessory bedding rather than the mattress structure, but it is exactly the hazard that the product's supervised-use rule exists to prevent, and it should be treated as a design and instruction priority: secure the blanket clear of the airway, anchor the mattress, and keep the nose and mouth visible.

Why the safe-sleep frame is not optional

The AAP is unambiguous. Unsupervised infant sleep belongs on a firm, non-inclined, supine surface; inclined and non-supine positioning is not endorsed as a sleep intervention, and infants placed on a meaningful incline can slide into a position that compromises breathing.¹⁸ AiBrain is compatible with this standard only when used as intended — flat and supine for night and unsupervised sleep, with the incline reserved for supervised, awake time. Presented that way, the product supports head positioning without asking families to trade away safe sleep. Presented any other way, it would not be defensible. This paper takes the first position without reservation.

USE GUIDANCE IMPLIED BY THE DATA

Roughly a third of caregivers noted some discomfort or risk situation, most often as the infant began to roll or when accessories shifted. Read together with the discontinuations below, the message is consistent: supervised use, within an age window that closes at the onset of independent rolling, with airway checks whenever the incline is used.

Feasibility and discontinuation

Eight of 26 infants (31%) stopped before completing the protocol. The reasons map onto a sensible use window rather than onto safety failures.

Reason for discontinuation	n	What it implies
Began rolling independently	2	Marks the upper age/motor limit for use
Refusal or poor adaptation	2	An early tolerability barrier; introduce gradually
Moved to helmet therapy	2	More severe cases may still escalate to standard care
Older or larger infant, size mismatch	1	Fit is bounded by age and size
Lost to follow-up	1	—

7 Caregiver-Reported Outcomes

The questionnaire (19 respondents; 27 items across six domains, with reverse-scored safety items) leaned positive. On a five-point scale, caregivers rated safety at 4.2, overall usability and satisfaction at 3.8, firmness and cover at 3.7, perceived head-shape change at 3.2, and adaptation and sleep at 3.0. Willingness to recommend was solid: 68% (13 of 19) gave a top rating of 4 or 5, and no one rated below the midpoint.

Questionnaire domain (n = 19)	Mean $\pm$ SD (1–5)	Reading
Safety (reverse-scored items applied)	4.2 $\pm$ 0.5	Strong; few adverse experiences
Usability and overall satisfaction	3.8 $\pm$ 0.6	Positive
Firmness and cover	3.7 $\pm$ 0.6	Generally satisfactory
Perceived head-shape change	3.2 $\pm$ 0.8	Modest; asymmetry above flattening
Adaptation and sleep	3.0 $\pm$ 0.7	Neutral

Two details deserve emphasis because they cut against easy over-reading. Caregivers saw more benefit for left–right symmetry (item mean 3.4) than for posterior flattening (2.8), which is the subjective echo of the objective dissociation between CVAI and CI. And parents' overall impression of change did not correlate with the measured CVAI change (Spearman $\rho \approx 0.1$, not significant). Perception and millimeters captured different things here, and the craniometric outcome is the more reliable of the two. Free-text comments frequently mentioned easier head-turning and, where relevant, improvement in torticollis, alongside limited change in posterior flattening — again consistent with the mechanism and the measurements.

SIGNALS FOR THE NEXT PRODUCT ITERATION

Recurring caregiver requests were practical and low-risk: a cooler and more breathable cover, a waterproof option, compatibility with common crib sizes, more secure accessory fixation, and clearer instructions including video. None require a change to the core mechanism.

Infants who used AiBrain showed a large, consistent, and robust reduction in cranial asymmetry over roughly two and a half months. CVAI fell by about 47%, nearly every infant improved, and close to half reached a normal head-shape range. The effect survived every sensitivity analysis and accrued gradually over time. Those facts are not in dispute. The question worth spending words on is what they license us to conclude.

The strongest internal argument comes from the shape of the effect, not its size. Section 2 committed in advance to a specific prediction: because the product acts on directional loading rather than on total supine load, it should move CVAI and leave the cranial index largely untouched. That is precisely what happened. A driver unrelated to the mechanism — general maturation, a secular tendency for heads to round out, or simply more attentive parenting during a study — has no particular reason to produce a clean directional dissociation aligned to the device's specific action. It might improve both indices, or neither. The selectivity of the result is therefore harder to explain away than the magnitude alone, and it is the single most useful piece of evidence in a design that lacks a control group.

External evidence points the same way. The lever AiBrain pulls — correcting a head-turning preference — is the same one tested in a randomized trial of pediatric physical therapy, where it reduced severe deformational plagiocephaly by roughly half.¹⁶ The mechanism, in other words, is not speculative; a controlled study has already shown that acting on positional preference changes the trajectory of the deformity. AiBrain attempts to deliver that same corrective influence passively, during sleep the infant already prefers, and without the adherence demands of a therapy program. Set against the other active option, the contrast is instructive: helmets carry cost, wearing-time burden, and universal side effects for a benefit that the pivotal trial could not separate from natural history.¹⁴ A benign positioning aid that works early and within safe sleep occupies the space those two options leave open.

Honesty requires the counter-arguments in the same breath. Natural history alone improves many of these infants, and it can improve asymmetry faster than it improves the cranial index, which blunts the force of the dissociation argument. Regression to the mean is expected in a cohort enrolled for asymmetry, and the fact that the most affected infants improved most is consistent with it. The observation window was short and uneven. None of this erases the finding; it bounds it. The result is fully consistent with a genuine, mechanism-specific benefit, and it is also consistent with a smaller device effect layered on top of favorable natural history. A single-arm study cannot adjudicate between those two, and this paper does not pretend otherwise.

9 Limitations

The limitations below are the reason the conclusions are phrased as association rather than proof, and they double as the specification for a confirmatory study.

- **No concurrent control.** Without a comparison arm, the device effect cannot be separated cleanly from growth, everyday repositioning, and regression to the mean. This is the central limitation, and the mechanism-specificity argument mitigates it only partially.
- **Regression to the mean.** Enrollment required existing asymmetry, and larger baseline deficits improved more — a pattern expected in part regardless of any intervention.
- **Short, heterogeneous follow-up.** The average observation period was 2.7 months (range 1.5–5.0), shorter than a standard six-month endpoint, so durability is unknown.
- **Small, exploratory sample.** With 23 paired infants, the subgroup and predictor findings generate hypotheses rather than confirm them.
- **Perception did not track measurement.** Caregiver impressions did not correlate with measured change, which argues against leaning on satisfaction data as evidence of efficacy.
- **Measurement scope.** Indices came from caliper anthropometry using a single recorded diagonal pair rather than 3D scanning, and clinician diagnosis fields (plagiocephaly versus brachycephaly, torticollis, gestational age) were not recorded, so morphology was derived. A few source discrepancies were reconciled conservatively.
- **Attrition.** Thirty-one percent discontinued, so reported experience reflects infants who tolerated the product and completers may differ from non-completers.
- **Not a medical-device evaluation.** AiBrain is a consumer product and was assessed as one. Nothing here should be read as a claim of medical treatment or correction.

THE STUDY THAT WOULD SETTLE IT

A prospective controlled trial — randomized or matched against a repositioning-only arm — with 3D-scan craniometry, a standardized six-month endpoint, pre-specified plagiocephaly and brachycephaly strata, and complete clinical covariates would convert this signal into confirmatory evidence and quantify the device's contribution over natural history.

In infants with positional cranial deformity, use of the AiBrain body-positioning mattress was accompanied by a large and internally consistent reduction in cranial asymmetry, with 96% of infants improving and 43% reaching a normal head-shape range, and with no serious device-related adverse events. The benefit was specific to asymmetry; the cranial index did not change. That specificity, together with the fact that the product's mechanism — correcting a head-turning preference — is the same one a randomized trial has shown to alter the course of the deformity, is what makes the result more than a bare before-and-after.

The appropriate reading is measured. AiBrain is best understood as a benign, low-burden positioning aid for the asymmetric component of positional deformity, suited to young infants below the usual helmet window, usable within safe-sleep rules when the incline is reserved for supervised waking time, and paired with specialist advice whenever head shape is a clinical concern. It is not a brachycephaly treatment, not a replacement for orthotic therapy in severe cases, and not a medical device. On present evidence it earns a place as an adjunct — and it earns a controlled trial to establish how much of the observed change it can claim as its own.

References

- Argenta LC, David LR, Wilson JA, Bell WO. An increase in infant cranial deformity with supine sleeping position. *J Craniofac Surg*. 1996;7(1):5–11.
- Kane AA, Mitchell LE, Craven KP, Marsh JL. Observations on a recent increase in plagiocephaly without synostosis. *Pediatrics*. 1996;97(6 Pt 1):877–885.
- Mawji A, Vollman AR, Hatfield J, McNeil DA, Sauv   R. The incidence of positional plagiocephaly: a cohort study. *Pediatrics*. 2013;132(2):298–304.
- Ballardini E, Sisti M, Basaglia N, et al. Prevalence and characteristics of positional plagiocephaly in healthy full-term infants at 8–12 weeks of life. *Eur J Pediatr*. 2018;177(10):1547–1554.
- Peitsch WK, Keefer CH, LaBrie RA, Mulliken JB. Incidence of cranial asymmetry in healthy newborns. *Pediatrics*. 2002;110(6):e72.
- de Bock F, Braun V, Renz-Polster H. Deformational plagiocephaly in normal infants: a systematic review of causes and hypotheses. *Arch Dis Child*. 2017;102(6):535–542.
- van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, L'Hoir MP, Helden PJ, Engelbert RH. Risk factors for deformational plagiocephaly at birth and at 7 weeks of age: a prospective cohort study. *Pediatrics*. 2007;119(2):e408–e418.
- Boere-Boonekamp MM, van der Linden-Kuiper LT. Positional preference: prevalence in infants and follow-up after two years. *Pediatrics*. 2001;107(2):339–343.
- Rogers GF. Deformational plagiocephaly, brachycephaly, and scaphocephaly. Part I: terminology, diagnosis, and etiopathogenesis. *J Craniofac Surg*. 2011;22(1):9–16.
- Miller RI, Clarren SK. Long-term developmental outcomes in patients with deformational plagiocephaly. *Pediatrics*. 2000;105(2):e26.
- Speltz ML, Collett BR, Stott-Miller M, et al. Case-control study of neurodevelopment in deformational plagiocephaly. *Pediatrics*. 2010;125(3):e537–e542.
- Collett BR, Gray KE, Starr JR, Heike CL, Cunningham ML, Speltz ML. Development at age 36 months in children with deformational plagiocephaly. *Pediatrics*. 2013;131(1):e109–e115.
- Hutchison BL, Stewart AW, Mitchell EA. Deformational plagiocephaly: a follow-up of head shape, parental concern and neurodevelopment at ages 3 and 4 years. *Arch Dis Child*. 2011;96(1):85–90.
- van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CGM, van der Ploeg CPB, IJzerman MJ, Boere-Boonekamp MM. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ*. 2014;348:g2741.
- Couture DE, Crantford JC, Somasundaram A, Sanger C, Argenta AE, David LR. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. *Neurosurg Focus*. 2013;35(4):E4.
- van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, L'Hoir MP, Helden PJ, Engelbert RH. Effect of pediatric physical therapy on deformational plagiocephaly in children with positional preference: a randomized controlled trial. *Arch Pediatr Adolesc Med*. 2008;162(8):712–718.
- Flannery AB, Looman WS, Kemper K. Evidence-based care of the child with deformational plagiocephaly, Part II: management. *J Pediatr Health Care*. 2012;26(5):320–331.
- Moon RY, Carlin RF, Hand I; AAP Task Force on Sudden Infant Death Syndrome and the Committee on Fetus and Newborn. Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment. *Pediatrics*. 2022;150(1):e2022057990.
- Stellwagen L, Hubbard E, Chambers C, Jones KL. Torticollis, facial asymmetry and plagiocephaly in normal newborns. *Arch Dis Child*. 2008;93(10):827–831.
- Bialocerkowski AE, Vladusic SL, Howell SM. Conservative interventions for positional plagiocephaly: a systematic review. *Dev Med Child Neurol*. 2005;47(8):563–570.
- Kaplan SL, Coulter C, Sargent B. Physical therapy management of congenital muscular torticollis: a 2018 evidence-based clinical practice guideline. *Pediatr Phys Ther*. 2018;30(4):240–290.
- Oh AK, Hoy EA, Rogers GF. Predictors of severity in deformational plagiocephaly. *J Craniofac Surg*. 2009;20(Suppl 1):685–689.
- Hutchison BL, Hutchison LA, Thompson JM, Mitchell EA. Plagiocephaly and brachycephaly in the first two years of life: a prospective cohort study. *Pediatrics*. 2004;114(4):970–980.
- Loveday BP, de Chalign TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? *J Craniofac Surg*. 2001;12(4):308–313.
- American Academy of Pediatrics, Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. Prevention and management of positional skull deformities in infants. *Pediatrics*. 2011;128(6):1236–1241.

Appendix — data-integrity notes. (i) Birth-date conflicts across worksheets in three infants were resolved to the physiologically consistent value. (ii) One final-visit date was corrected against the source record, restoring a valid interval. (iii) CI, CVA, and CVAI were recomputed from raw AP/ML and diagonal measurements and matched the worksheet formulas. (iv) Five records showed CI ≥ 100 ; one final value (CI 108) is a possible AP/ML transposition, retained but flagged, with the primary result unchanged on its exclusion. (v) Blue-diagonal and clinician-diagnosis fields were unrecorded; CVAI used the recorded diagonal pair and morphology grouping was derived from baseline anthropometry. Analytic code and the reconciled dataset are available on request.

Disclaimer. This document reports an internal, single-arm evaluation for professional information only. AiBrain (AiBrio Co., Ltd.) is a consumer product and is not a medical device; it does not diagnose, treat, or correct any disease. Nothing here is a substitute for professional medical advice, and the findings should be read together with the limitations in Section 9. Caregivers with concerns about an infant's head shape should consult a qualified clinician.