Three-Dimensional versus Two-Dimensional Evaluations of Cranial Asymmetry in Deformational Plagiocephaly Using a Three-Dimensional Scanner

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Three-Dimensional versus Two-Dimensional Evaluations of Cranial Asymmetry in Deformational Plagiocephaly Using a Three-Dimensional Scanner

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Abstract: This study aimed to assess the measurement precision of a three-dimensional (3D) scanner that detects the geometric shape as surface data and to investigate the differences between two-dimensional (2D) and 3D evaluations in infants with deformational plagiocephaly. Using the 3D scanner that can perform both 2D and 3D evaluations, we calculated cranial asymmetry (CA) for the 2D evaluation, and the anterior symmetry ratio (ASR) and posterior symmetry ratio (PSR) for the 3D evaluation. Intra- and inter-examiner precision analyses revealed that the coefficients of the variation measurements were extremely low (<1%) for all variables, except CA (5%). In 530 infants, the coincidence rate of CA severity by the 2D evaluation and the 3D evaluation was 83.4%. A disagreement on severity was found between 2D and 3D evaluations in 88 infants (16.6%): 68 infants (12.8%) were assessed as severe by 2D evaluation and mild by the 3D evaluation, while 20 infants (3.8%) were evaluated as mild by 2D and severe by 3D evaluation. Overall, the 2D evaluation identified more infants as severe than the 3D evaluation. The 3D evaluation proved more precise than the 2D evaluation. We found that approximately one in six infants differed in severity between 2D and 3D evaluations.

Keywords: anterior symmetry ratio; cranial asymmetry; head deformity; plagiocephaly; posterior symmetry ratio

1. Introduction

Head volume is obtained by computed tomography and magnetic resonance imaging, whereas the three-dimensional (3D) scanner detects the geometric shape of the object as surface data and calculates the ratio rather than the volume. There is currently no gold-standard measurement method for cranial asymmetry worldwide. A 3D evaluation method using a 3D scanning analyzer (3D scanner) was recently used to assess head deformity severity in infants because it is simple, safe, and convenient, and does not require the use of computed tomography or magnetic resonance imaging.

Two-dimensional (2D) evaluation is a method for assessing head deformities using diagonal length differences in a single plane [1]. The cross-section with the maximum head circumference is used for the measurement plane [2,3], such as the maximum posterior curved plane of the occiput [4], the plane passing through the contralateral lambda suture from the frontal junction point [5], and the plane at the inferior cranial level (superior orbital rim level) [6]. Some reports indicated that 2D evaluations have low measurement variability, but high interobserver variability [7,8]. Another report highlighted a potential

error in 2D plane selection [9]. In addition, the values calculated for different 2D cross-sections of the same infant differed [10]. Therefore, it is possible that 2D evaluations alone do not sufficiently assess the entire 3D cranial structure. In particular, the occiput, the main positional deformational plagiocephaly site, may be difficult to assess using 2D evaluations.

The 3D evaluation, which has been used previously [4,11], is expected to be able to evaluate cranial shape in a more detailed and multifaceted way. However, its measurement precision has not been yet analyzed on 3D images acquired with the 3D scanner device used in this present study. This study was the first to assess the measurement precision of the 2D and 3D evaluations using the 3D scanner that can perform both kinds of evaluations (Study 1).

In our previous study of infants (aged 4–8 months) with severe deformational plagiocephaly, 66% did not improve without cranial helmet therapy [12]. Therefore, treatment decisions at the appropriate time are important for infants with severe plagiocephaly. To enable more effective therapeutic interventions, it is necessary to clarify the correlations and differences between 2D and 3D evaluation methods. The 2D evaluation is currently popular for the classification of severe deformational plagiocephaly. Therefore, the second study aim was to investigate the differences between 2D and 3D evaluations using the 3D scanner and to clarify the diagnostic value of 2D evaluations (Study 2).

2. Materials and Methods

2.1. Study Design and Subjects

Two studies were conducted. In Study 1, to measure precision, we assessed the repeatability (intra- and inter-examiner precision analyses) of the Artec Eva 3D scanner that can perform the 2D and 3D evaluations (Artec, Inc., Luxembourg, Luxembourg). In Study 2, we examined the differences between 2D and 3D evaluations using the 3D scanner, and clarified the diagnostic value of the 2D evaluations.

Study 1: The randomly selected participant was a Japanese adult. To determine the repeatability of the values obtained using the 3D scanner, intra- and inter-examiner precision analyses were performed. The following variables were examined: cranial length, cranial width, head circumference, and cranial asymmetry (CA) in 2D evaluations, and anterior symmetry ratio (ASR) and posterior symmetry ratio (PSR) in 3D evaluations.

Study 2: This study included infants who visited three hospitals (Nihon University Itabashi Hospital, Kasukabe Medical Center, and Noto Children's Clinic) for medical checkups or head deformities between April 2020 and April 2021, and their cranial shapes were measured using a 3D scanner. The following variables were examined: CA in 2D evaluations and ASR and PSR in 3D evaluations.

A 360° scan of the cranial shape, including both ears, was performed using a 3D scanner. However, this has not yet been approved as a medical device by the Pharmaceuticals and Medical Devices Agency in Japan. Written informed consent was obtained from the parents or guardians of all participants. This study was approved by the ethics committees of the participating institutions (Kasukabe Medical Center and Noto Children's Clinic: approval number 2019-032; 12 March 2020; and Nihon University Itabashi Hospital: approval number RK-200512-2; 22 May 2020).

2.2. Data Acquisition Using the 3D Scanner

Head deformities were imaged using an Artec Eva 3D scanner. Before the scanning, the infant's head was protected using a stocking cap to avoid hair disturbance, and all hair was set inside the cap. With the caregivers holding the infants, 360-degree scans were performed. From a distance of 40 cm to 1 m from the infant's head, the 3D scanner continuously and intermittently shone lights at a maximum of 16 times per second. The scanner detected light deflected from the surface of the head and recorded information on unevenness and color. The frame rate per second constantly changed, depending on the computer environment during shining. The measurement time, including preparation, was approximately 5 min.

2.3. Data Analysis Method

The obtained data were analyzed using Artec Studio image analysis software (Artec, Inc., Luxembourg, Luxembourg) to obtain 3D images and determine cranial shape. The entire 3D dataset was constructed by combining the overlapping regions in successive scanned frames. We measured the following variables from the 3D scanned images: CA using the 2D evaluation method and ASR and PSR using the 3D evaluation method.

2.3.1. How to Calculate ASR and PSR

Figure 1 shows a 3D quantified global view. First, the sellion (SE: at the most concave point in the soft tissue at the nasofrontal angle between the forehead slope and proximal nasal bridge) [13–15] and the left and right tragions (TRs: at the upper margin of the tragus) were determined. Next, we determined the basic cross-section (XY plane) as the plane that passed through the SE and the left and right TRs. The midpoint of both TRs was defined as the origin. After setting these landmarks and the basic plane, the line passing through the SE and the origin was defined as the Y-axis. The X-axis was defined as the line perpendicular to the Y-axis that crosses the origin on the basic plane. The Z-axis was defined as the line perpendicular to the XY plane that crosses the origin [11,12,16]. From the XY plane (level 0), 10 equidistant, parallel cross-sections through the upper part of the skull (level 10) were constructed, and cross-sections from levels 2 to 8 were used to calculate the volume of the entire cranium, excluding the soft tissues of the ear and face [17] (Figure 1B).
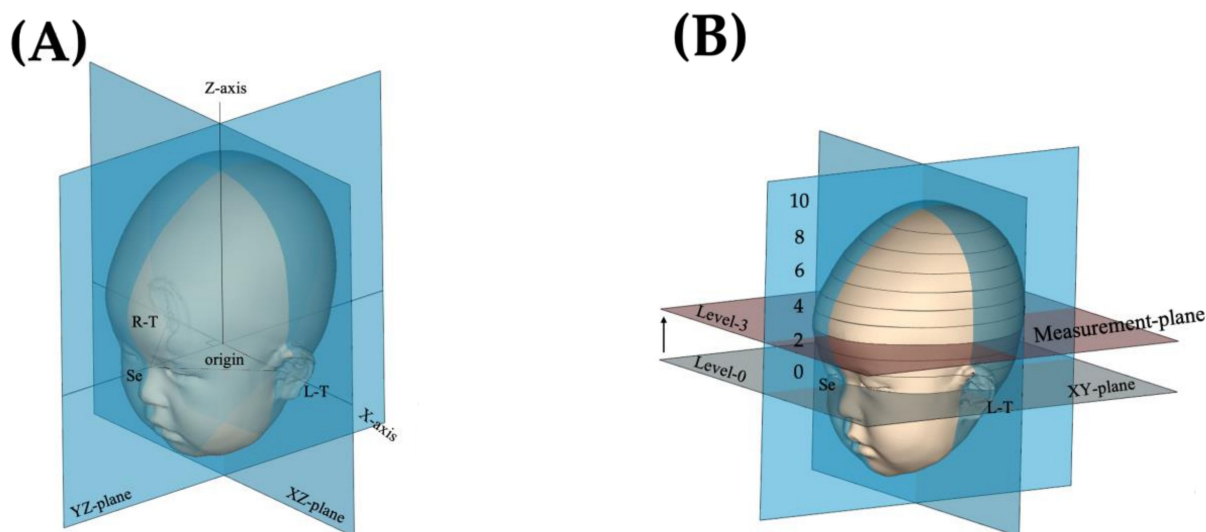
Figure 1. Three-dimensional images. (**A**) The methods by which the X-axis, Y-axis, and Z-axis were determined. (**B**) The base XY plane runs through the SE and the left and right TRs. Ten equidistant and parallel cross-sections are conducted to the cranium superior (level 10) from the base XY plane (level 0). The figures were cited from the figures by Noto et al. [12]. SE, at the most concave point in the soft tissue at the nasofrontal angle between the forehead slope and the proximal nasal bridge, TR, at the upper margin of the tragus.

The total volume was divided into four quadrants using planes passing through the X- and Y-axes and containing the Z-axis (XZ and YZ planes) (Q1, anterior left; Q2, anterior right; Q3, posterior right; Q4, posterior left). Finally, each quadrant volume was used to quantitatively define the bilateral symmetry ratio of ASR (Q1 volume/Q2 volume, or vice versa × 100 %) and PSR (Q3 volume/Q4 volume, or vice versa × 100%), a value where either the Q1 volume/Q2 volume, Q3 volume/Q4 volume, or vice versa, was <100% was chosen [11,16,18] (Figure 2).
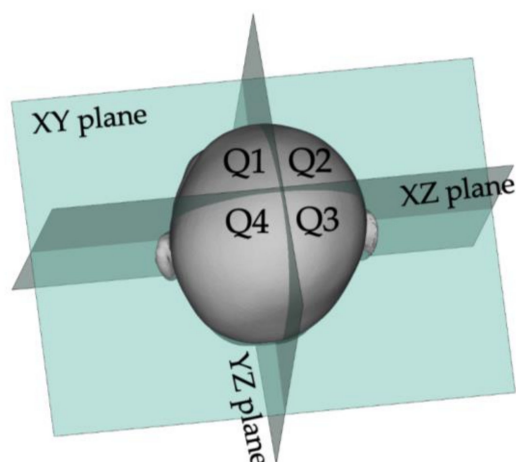
Figure 2. Four quadrant volumes. The total volume was divided into four quadrants along the XZ and YZ planes. Each quadrant volume was used to quantitatively define the bilateral symmetry ratio of ASR (Q1 volume/Q2 volume, or vice versa × 100, %) and PSR (Q3 volume/Q4 volume, or vice versa × 100, %); a value where either the Q1 volume/Q2 volume, Q3 volume/Q4 volume, or vice versa, is <100% was chosen. ASR, anterior symmetry ratio; PSR, posterior symmetry ratio.

2.3.2. Cross-Sectional Level for 2D Measurement

The largest head circumference should ideally be used as the basic 2D measurement plane [3,4,16]. In this study, however, to unify the level of the measurement plane, cross-Section 3 (Level 3) was selected as the standard measurement plane of the 2D evaluation [10,12,17] (see Figure 1B).

2.3.3. How to Calculate CA

According to Loveday et al. [19], two diagonals drawn 30° from the Y-axis were measured. The CA was calculated using these diagonals. The CA was calculated as diagonal A−diagonal B (mm) (Figure 3).
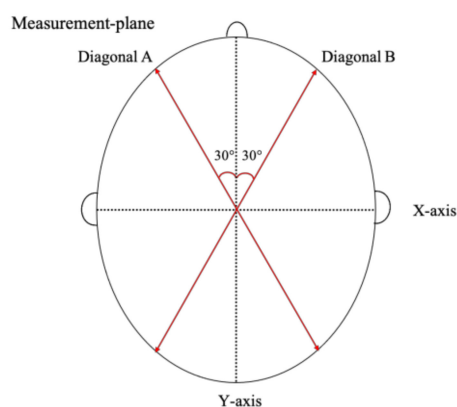
Figure 3. Measuring cranial asymmetry (CA). Two diagonals (A and B) are drawn 30° from the Y-axis on level 3. CA (mm) = Diagonal A–Diagonal B. This figure was cited from reference [12].

2.4. Severity Classifications

The severity of the 3D evaluation was defined as follows: mild if ASR $\geq$ 80.5%, or severe if ASR < 80.5%; mild if PSR $\geq$ 80.5%, or severe if PSR < 80.5%; and mild if both ASR and PSR were $\geq$80.5 %, or severe if ASR or PSR was <80.5% [11] (Supplementary Table S1). The severity of the CA-based 2D evaluation was defined as mild (CA = 0–12 mm), or severe (CA > 12 mm) [7,12,20,21].

2.5. Study Methods and Statistical Analyses

Study 1:

(1)   Age, height, weight, and head circumference at the measurement date were collected.
(2)   To determine the repeatability of the 3D scanner, six replicates of the scans were performed by one examiner (intra-examiner precision analysis). Six replicate scans were then performed by six different examiners (one scan per examiner; inter-examiner precision analysis). Mean, standard deviation (SD), and coefficient of variation (CV) were then calculated.

Study 2:

(1)   Perinatal and neonatal factors included sex, gestational weeks at birth, birth weight, age at the time of measurement, mode of delivery, and intrauterine position.
(2)   The values of head circumferences measured by the 3D scanner and by trained nurses were compared using bivariable normal ellipses, and regression analysis (correlation coefficient [r] was calculated).
(3)   Distribution maps of the ASRs, PSRs, and CAs are shown. Each infant was classified by severity (mild or severe) using CA for the 2D evaluation, and ASR alone, PSR alone, or ASR and PSR for the 3D evaluation. The coincidence rate was analyzed, and the indicative variable in the 3D evaluation that showed the maximum coincidence rate was determined.
(4)   Finally, infants whose severity assessed differently, especially the group identified as mild on the 2D evaluation and severe on the 3D evaluation, were selected. Using CA on planes other than level 3 at levels 2–8, we investigated whether there was a change in the coincidence rate.

Statistical calculations were performed using JMP (ver 14.0; SAS Institute Inc., Cary, NC, USA), when needed.

3. Results

3.1. Study 1

3.1.1. Subject

The randomly selected subject was a 28-year-old Japanese male with a height of 180.2 cm, weight of 74 kg, and head circumference of 582 mm.

3.1.2. Measurement Precision

The mean $\pm$ SD and CV for the intra- and inter-examiner precision analyses are shown in Table 1. The CV values were extremely low for all measurement variables, except CA.

Table 1. Intra- and inter-examiner precision analyses of the 3D scanner results.

	Intra-Examiner		Inter-Examiner	
	Mean $\pm$ SD $n = 6$	CV (%)	Mean $\pm$ SD $n = 6$	CV (%)
Cranial length, mm	202.3 $\pm$ 0.5	0.26	203.0 $\pm$ 0.8	0.39
Cranial width, mm	171.7 $\pm$ 0.2	0.13	171.8 $\pm$ 0.3	0.16
Head circumference, mm	582.9 $\pm$ 1.2	0.20	582.9 $\pm$ 0.7	0.12
CA, mm	10.0 $\pm$ 0.6	5.62	10.0 $\pm$ 0.5	5.33
ASR, %	98.7 $\pm$ 0.2	0.24	98.6 $\pm$ 0.2	0.15
PSR, %	83.4 $\pm$ 0.4	0.50	83.7 $\pm$ 0.3	0.38

ASR, anterior symmetry ratio; CA, cranial asymmetry; CV, coefficient of variation; PSR, posterior symmetry ratio; SD, standard deviation.

3.2. Study 2

3.2.1. Clinical Characteristics

This study included 530 infants ($n = 257$ at Nihon University Itabashi Hospital, $n = 69$ at Kasukabe Medical Center, and $n = 204$ at Noto Children's Clinic). The median age at the

time of measurement was three months. Detailed clinical characteristics of the infants are shown in Table 2.

Table 2. Infants' clinical characteristics (*n* = 530).

Male, %		315 (59.4)
Gestational age at birth, weeks		39 (37–42)
Birth weight, grams		3024 (1639–4144)
Age at measurement, months		3 (0–47)
Mode of delivery		
	Vaginal	313 (59.0)
	Caesarean	161 (30.3)
	Vacuum	45 (8.4)
	Forceps	11 (2.0)
Intrauterine position		
	Cephalic	494 (93.2)
	Breech	31 (5.8)
	Transverse	5 (0.9)

Data for gestational age at birth, birth weight, and age at measurement are shown as median (min–max). Others are shown as number (percentage).

3.2.2. Correlation of Measurement Values

To determine the correlation between the head circumference values measured by trained nurses and the 3D scanner, the measurements of 321 infants were compared. A strong correlation was found between the two values (r = 0.963, *p* < 0.001; Figure 4).
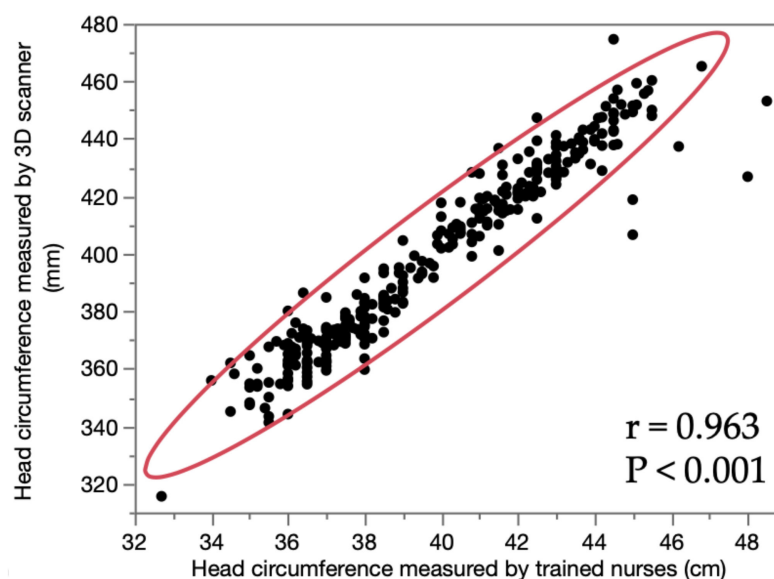
Figure 4. Correlation of the measurement values. Correlation of head circumference values measured by trained nurses versus the 3D scanner.

3.2.3. Severity Classifications

The severity coincidence rates between the 2D evaluation by CA and the 3D evaluation by ASR or PSR were evaluated using the different selected thresholds, such as 75.0%, 80.5%, 82.5%, and 85.0%. The severity coincidence rates were 77.9%, 83.4%, 83.8%, and 80.8%, respectively (Supplementary Table S1), indicating that the thresholds of 80.5% and 82.5% had approximately the same coincidence rate. Therefore, the threshold of 80.5% was selected for Study 2. Figure 5 shows the distribution maps of ASRs, PSRs, and CAs.
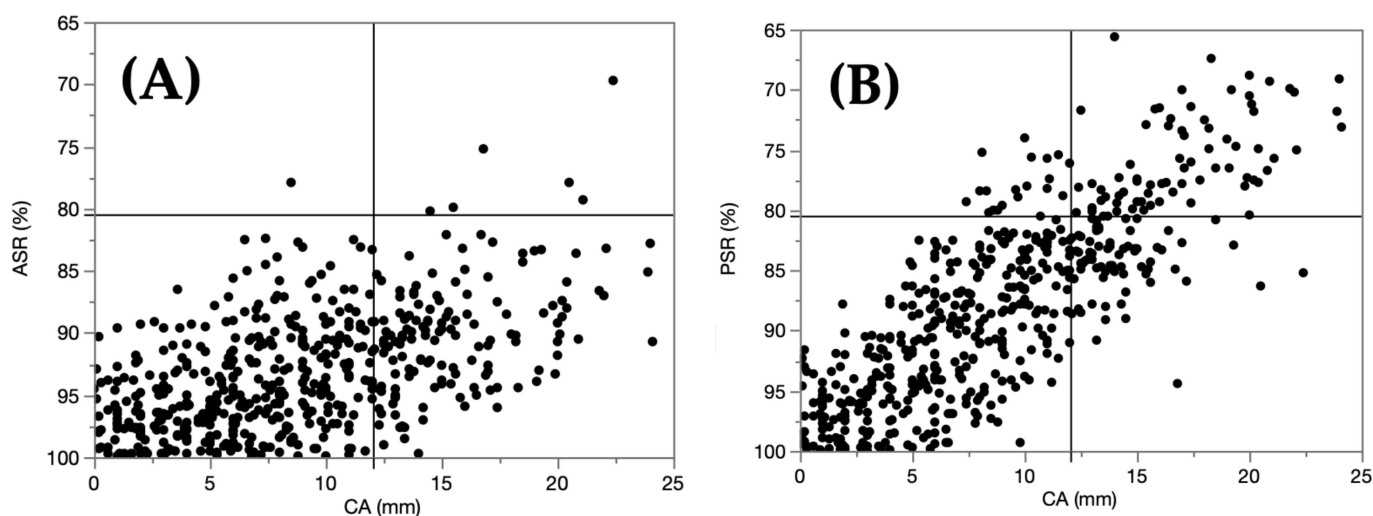
Figure 5. The distribution map of ASRs and CAs **(A)** and PSRs and CAs **(B)**. ASR, anterior symmetry ratio; CA, cranial asymmetry; PSR, posterior symmetry ratio.

Table 3 shows the severity classifications using the 2D evaluation by CA and 3D evaluation by ASR alone, PSR alone, and ASR/PSR. A total of 389 infants (73.4%) had the same severity classifications for CA and ASR in the 3D evaluation (Table 3A). A total of 438 infants (82.6%) had the same severity of CA and PSR in the 3D evaluation (Table 3B). As shown in Table 3C, the severity by CA in the 2D evaluation and that by ASR or PSR in the 3D evaluation agreed with each other for 442 infants (83.4%). More infants were determined as severe using the 2D versus the 3D evaluation (27.5% and 18.5%, respectively).

Table 3. Severity classification using 2D evaluation by CA and 3D evaluation by ASR or PSR.

(A)		CA		
		Mild	**Severe**	**Total**
ASR ≥ 80.5%	Mild	383 (72.3%)	140 (26.4%)	523 (98.7%)
ASR < 80.5%	Severe	1 (0.2%)	6 (1.1%)	7 (1.3%)
	Total	384 (72.5 %)	146 (27.5 %)	530

The severity coincidence rate was 73.4% (389/530).

(B)		**Mild**	**Severe**	**Total**
PSR ≥ 80.5%	Mild	365 (68.9%)	73 (13.8%)	438 (82.6%)
PSR < 80.5%	Severe	19 (3.6%)	73 (13.8%)	92 (17.4%)
	Total	384 (72.5%)	146 (27.5%)	530

The severity coincidence rate was 82.6% (438/530).

(C)		**Mild**	**Severe**	**Total**
ASR and PSR ≥ 80.5%	Mild	364 (68.7%)	68 (12.8%)	432 (81.5%)
ASR or PSR < 80.5%	Severe	20 (3.8%)	78 (14.7%)	98 (18.5%)
	Total	384 (72.5%)	146 (27.5%)	530

The severity coincidence rate was 83.4% (442/530).

ASR, anterior symmetry ratio; CA, cranial asymmetry; PSR, posterior symmetry ratio.

As shown in Table 3C, there were 68 infants (12.8%) in the group with severe 2D and mild 3D evaluation findings and 20 infants (3.8%) in the group with mild 2D and severe 3D evaluation findings, showing more severe results for the 2D evaluation by CA.

3.2.4. CAs of Other Levels

Twenty infants, who showed more severe results in the 3D evaluation than the 2D evaluation, were selected for the further study. We investigated the CA on the planes at levels 2–8, other than level 3, in 20 infants. Eight (40%) of the 20 infants had severe classifications when other levels were evaluated (the yellow highlights show CA > 12 mm in Table 4), indicating consistency with the severity in the 3D evaluation.

Table 4. CA values at levels 2–8 in the group with mild 2D and severe 3D evaluation findings (*n* = 20 in Table 3C).

No.	CA (mm)						
	Level 2	Level 3 (Standard)	Level 4	Level 5	Level 6	Level 7	Level 8
1	8	9.0	8.3	8.9	9.4	8.2	5.5
2	10.9	11.5	13.9	15.9	15.7	13.7	10.9
3	9.4	9.6	9.8	10.9	10.7	9.4	7.7
4	7	8.8	8.2	8.6	9.4	10.0	8.6
5	8.3	8.4	9.4	11.5	11.8	10.3	7.4
6	8.9	10.1	11.5	12.5	12.2	11.3	8.8
7	9.7	11.1	11.1	11.2	10.9	9.5	7.9
8	10.7	11.7	12.3	12.6	11.8	10.1	8.4
9	12.2	10.3	14.2	15.7	15.6	13.4	8.8
10	6.2	10.0	12.2	14.7	13.6	11.7	9.1
11	5.5	7.4	6.3	8.0	9.4	9.1	7.4
12	7.3	8.3	9.1	9.4	9.6	7.8	6.4
13	8.5	8.5	10.1	9.6	8.6	7.2	5.6
14	7.1	9.7	7.8	10.3	12.2	11.9	10.7
15	8.8	12.0	16.9	18.7	17.7	15.3	11.7
16	10.2	11.0	11.1	11.3	11.1	10.3	8.5
17	8.5	11.0	10.7	12.4	12.1	10.5	9
18	6.5	8.0	9.8	10.8	10.8	10.7	9.8
19	6.6	8.6	8.0	9.4	10.0	9.6	8.5
20	7.8	8.1	9.6	10.6	10.8	9.5	8.3

Yellow highlights represent severe classifications by 2D evaluation (CA > 12 mm). 2D, two-dimensional; 3D, three-dimensional; CA, cranial asymmetry.

4. Discussion

This study had several novel findings. First, it demonstrated the intra- and inter-examiner precision of the Artec Eva 3D scanner. Second, the severity assessments differed slightly between the 2D and 3D evaluations of head deformity; 16.6% were assessed differently (88/530 infants). In particular, 3.8% were evaluated as mild on the 2D evaluation and severe on the 3D evaluation (20/530 infants). Third, the coincidence rate of the severity increased at a higher level (levels 4–7) from the standard measurement plane (level 3), showing that the level that usually reflects the largest head circumference does not necessarily represent the maximum deformity.

The measurement precision using intra- and inter-examiner precision analyses with the Artec Eva 3D scanner showed extremely high repeatability. Compared with the other variables, the CV of CA was high. This may have been due to hair disturbances. To avoid this effect, the hair was placed inside the cap as much as possible. In addition, a significant strong and positive correlation was noted between the measurements of head circumference by trained nurses and the 3D scanner.

A 2D evaluation is used to classify severe deformational plagiocephaly. Our study found that 83.4% of infants had the same severity on the 2D and 3D evaluations of head deformities. In the 3D evaluation, if PSR was used, more infants were identified as severe than with the 2D evaluation. Many positional head deformities are caused by sleep positioning [22]. Our results are consistent with those of a previous report by Argenta et al. in that

the occipital region usually shows CA [23]. Although 16.6% of the infants were assessed differently in the current study, 2D evaluations can generally substitute for 3D evaluations.

Of the 88 infants assessed differently, 20 infants (23%) were evaluated as mild by 2D and severe by 3D evaluation. Thus, the infants subjected to the 2D evaluation may miss the appropriate timing for cranial helmet therapy. Therefore, we focused on the group with mild 2D and severe 3D evaluation results (*n* = 20) and performed further studies. We found that when the 2D evaluation was used at a higher level (levels 4–7), the severity consistency increased (40%). A previous report suggested that very severe occipital asymmetry could occur in the absence of frontal asymmetry associated with occipital plagiocephaly [24]. In this case, the CA value should be low because the CA value includes the frontal and occipital regions of the cranium. Therefore, in some infants, even when 2D evaluation classifies the condition as mild, a head deformity may be present at higher levels from the measurement level. Because the 3D evaluation can evaluate the asymmetry of the head shape from multiple aspects, if possible, it would be suitable to use both 2D and 3D evaluations to evaluate the exact severity. We believe that referring to the CA values at levels other than the maximal cranial circumference can lead to a multifaceted evaluation of cranial asymmetry. If it is difficult to measure on multiple 2D measurement planes, other parameters of 2D evaluation, such as the cranial vault asymmetry index and oblique cranial length ratio, may be useful [20,24].

To conduct the current study, we searched the literature for a definition of severity used in 3D evaluations, but those we found were inconsistent [7,11,12,20,21]. Although there was no firm professional consensus for the severity threshold in 3D evaluations, a certain criterion was needed to analyze the difference between the 2D and 3D evaluation methods in the current study. We analyzed the severity coincidence rates between 2D evaluation by CA, and 3D evaluation by ASR or PSR using the different selected thresholds, such as 75.0%, 80.5%, 82.5%, and 85.0%. The thresholds of 80.5% and 82.5% showed approximately the same coincidence rates (Supplementary Table S1).

Many institutions in Japan face hurdles in using 3D techniques for diagnostics because 3D scanners are expensive. Compared to a scanner that can take measurements within a few milliseconds from several spatial directions and create a stereophotogrammetric dataset, the Artec Eva 3D scanner used in the current study has the advantage of being mobile, although it takes a little longer to take images, and artifacts occur due to infant movements [25]. As shown in our measurement precision analyses, the 3D scanner used in our current study was useful for considering human errors between measurers in 2D evaluations [7,8]. Normal reference values of the measurement variables obtained by the 3D scanner in 1-month-old healthy Japanese male or female infants were shown in our recently published report [26].

Our study has some limitations. First, because 2D and 3D evaluations have different aspects, it was not possible to directly examine a correlation. Second, in the current study, we compared the CA values as representative 2D and 3D evaluation variables. Future studies are needed to evaluate the relationship between the cranial vault asymmetry index, which can appropriately express 3D shapes, and 3D evaluation results.

5. Conclusions

The Artec Eva 3D scanner provides high measurement precision. Using this scanner, this study found that the severity of five of six infants was the same between the 2D and 3D evaluations of head deformity, indicating that the former can generally be used as a substitute for the latter. Meanwhile, one of six infants were assessed differently. Therefore, if possible, it would be ideal to use both methods to evaluate head deformity severity.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/children9060788/s1: Table S1. Severity classification of two-dimensional evaluation by cranial asymmetry versus three-dimensional evaluation by anterior symmetry ratio or posterior symmetry ratio using different selected thresholds.

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博士の専攻分野の名称：博士（医学）

論文題名： Three-Dimensional versus Two-Dimensional Evaluations of Cranial Asymmetry in Deformational Plagiocephaly Using a Three-Dimensional Scanner（3D スキャナーを用いた変形性斜頭症の評価　3 次元評価と Cranial Asymmetry を用いた 2 次元評価の比較）

【背景と目的】

　米国小児科学会は 1992 年、乳幼児突然死症候群の発症を減少させるため、仰向け寝運動を推奨した。その結果、その目的は達成し成功を収めたが、変形性斜頭症の乳幼児が急激に増加してしまうという別の問題を引き起こしてしまった[1-4]。

　そのため急速に頭蓋形状を評価する方法が必要となり、様々な評価方法が考えられた。

　例えば、頭蓋の変形度合いや耳介の位置の違いを視覚的に捉えて評価する方法(Argenta 分類)や、ノギスやメジャーを用いて頭蓋の単一平面上における対角線の長さの差を比較する 2 次元評価法などが考案されている。しかし頭蓋変形を評価する標準的な方法は、世界的に未だ確立していない。

　適切な時期に治療法を決定することは重症斜頭症の乳児にとって重要である。より効果的な治療介入を可能とするためには、単一平面上の評価(2 次元評価法)と立体的な評価(3 次元評価法)の違いを明らかにする必要がある。

　また、最近は 3D スキャナーの進歩により、放射線被ばくを伴わずに様々な体外表面の 3D 評価が容易に、かつ安全に行えるようになった。しかし、今回使用する Artec Eva 3D スキャナーの測定精度は未だ解析されていない。

　よって本研究では、まず Artec Eva 3D スキャナーの測定精度を評価すること、次に 3D スキャナーを用いた 2 次元評価法と 3 次元評価法の差異を検討することを目的とした。

【頭蓋形状計測方法】

① 被検者の頭部にストッキングをかぶせる。できる限り髪はストッキングの中に入れる。

② 頭部から 40 cm～1 m 離れたところから、3D スキャナーの光を当て、撮影する。

③ 頭部の表面から反射してきた凹凸や色情報をとらえて記録する。得たデータを重ね合わせることにより、3D 画像を構築する。

【頭蓋変形評価項目の算出方法】

① 3D 画像における軸、断面の決定方法

　軸や測定平面の決定は、先行報告されている方法を用いた[5-8]。

　まず Tragion（耳珠）の両上縁の中点を Origin（原点）と設定し、Sellion（鼻の付け根）から原点を通る線を Y 軸と設定する。そして Y 軸から直角の線を X 軸に設定した。この X 軸、Y 軸を通る平面を XY 断面とした。Origin を通り、XY 断面に垂直な線を Z 軸に設定した。X 軸、Z 軸を通る平面を XZ 断面、Y 軸、Z 軸を通る平面を YZ 断面とした(図 A)。

② 2 次元評価法の測定断面、2 次元評価法における Cranial Asymmetry(CA)について

　XY 断面を Level 0 とし、これに並行で頭頂部を通る断面を Level 10 とする。Level 0 から Level 10 までを 10 分割した際の下から 3 番目の断面が 3D 画像の Level3 となる。この Level3 を 2D 評価

法の計測断面として用いた。

　　CA(㎜)は、Y軸から30°の対角線の長さの差で求めた。

③　3次元評価法：前頭部左右対称比率(ASR)・後頭部左右対称比率(PSR)について

　　Level 2〜8を全頭部体積として定義し、XZ断面、YZ断面で4分割する。さらに前頭部、後頭部に分けて考え、大きい方の体積を100％とした際の小さい方の体積比率(Q1：Q2、Q3：Q4)を求めた。

【対象と方法】

研究1：

　　日本人男性1人を無作為に選び、頭蓋形状を測定した。検査者内、検査者間での3Dスキャナーにより得られた値の変動係数(CV)を求めた。頭蓋前後径・横幅・頭囲を計測した。また、頭蓋の非対称性はCAを用いた2次元評価法、・ASR・PSRを用いた3次元評価法を計測した。

研究2：

　　2020年4月から2021年4月までに3病院を受診した乳児530名に対し3Dスキャナーを用いて頭蓋形状を測定した。研究に参加する前に保護者に対しインフォームドコンセントを得た。研究のプロトコルは日本大学医学部附属板橋病院の臨床研究審査委員会で承認を得て実施した。頭蓋の非対称性はCAを用いた2次元評価法、ASR、PSRを用いた3次元評価法を用いて、それぞれの重症度による分類を行った。CA>12mmを重症斜頭症と定義し、ASRまたはPSRが80.5％未満を重症斜頭症と定義した。それらの重症度の一致率を分析した。

【結果】

研究1：変動係数は、CAを除く全ての計測値において極めて低く、またCAも低値であった。(表1)

研究2：2次元評価法を用いた重症度と3次元評価法を用いた重症度の一致率は83.4％だった。2次元評価法では27.5％、3次元評価法では18.5％が重症と判断された。(表2)

【考察】

研究1：

　　一般的なCV値は5％前後、正確であるとされるCV値の最大値はおよそ10％とされている。よってCAも含めた全ての計測値から、Artec Eva 3Dスキャナーの測定精度は高いことが分かった。CAのみCV値が他の計測値より高いことに関しては、対象となった成人男性は比較的毛髪量が多く、撮影の度に、また帽子に毛髪を入れ込む度に、頭髪の位置が変わってしまうことの影響が考えられた。まれに毛髪量が多い乳児も存在するため、毛髪量の差に注意しておく必要がある。

　　本研究で用いたArtec Eva 3Dスキャナーは、放射線被ばくを伴わず、診察室にてデータを取得することが可能である。出生後早期の新生児、乳児に対し、わずかな侵襲で、かつ正確な評価を可能とする機器であると考える。

研究2：

　　6人中5人の乳児の頭蓋変形の重症度が、2次元評価法と3次元評価法で一致する結果となった。このことから、2次元評価法は3次元評価法の代わりに一般的に使用することが可能であると考えられた。今後、より臨床的な環境に合わせて、ノギス計測による2次元評価法と3Dスキャナーによる2次元評価法を比較検討していく必要がある。

　　一方、2次元評価法で重度、3次元評価法で軽度となる群(偽陽性群)に関して、頭蓋変形と病的な意

義(斜視、歯の噛み合わせ、運動発達遅延、自閉症スペクトラム症等)が絶対的に結び付けられていない現状では、ヘルメット治療が不必要な治療となる可能性がある。しかし、美容的な観点からはヘルメット治療が不必要となる可能性は低い側面もあるため、患児への負担や、治療の大部分を保護者が行う負担等、保護者への説明、同意は充分に行い、治療可否の判断を行っていく必要があると考える。

　また、2 次元評価法で軽度、3 次元評価法で重度となる群(偽陰性群)は、臨床の場において、必要な治療が受けられない可能性がある。3D 計測に頼るだけでなく、観察者による頭蓋の変形度合いや耳介の位置の違いを視覚的に捉えて評価する（Argenta 分類)ことや、2D での計測断面を頭囲実測定部位だけでなく、頭囲測定部位より高位の断面での計測を追加するというような対策が必要と考えられた。

【結論】

　本研究で使用した Artec Eva 3D スキャナーは精度が高く、またこのスキャナーを使用した本研究において、6 人中 5 人の乳児の頭蓋変形の重症度が、2 次元評価法と 3 次元評価法で一致する結果となった。2 次元評価法は 3 次元評価法の代わりに一般的に使用することができる。

【限界】

　2 次元での評価法と 3 次元での評価法は、それぞれ違った側面を持つため、相関性を検討することは難しいと考える。よって今回は重症度の一致率を検討した。

　また今回の検討では、2 次元評価法の評価項目として CA を用いた。表 2 において、偽陽性群(2 次元評価法による重症、3 次元評価法による軽症)は、重症度が一致する群より、計測月齢が高いことが明らかになった(Kruskal-Wallis 検定　p=0.024, Steel-Dwass 検定　p=0.028)。CA 値は、頭蓋の対角線の長さの差により求めた絶対値である。月齢が進むほど頭蓋も大きく成長しているため、単に値が大きいからといって、斜頭症が強いと判断しないよう注意する必要がある。

　今後は、2 次元評価法として、頭蓋を相対的に評価できる指標、Cranial Vault Asymmetry Index(=CA/短い方の対角線の長さ)、との検討も必要と考える。


【臨床への応用】

　生後 1 か月から生後 6 か月までの頭蓋形状の変化としては、生後 3 か月頃に頭のゆがみのピークを向かえるが、生後 6 か月頃には、生後 1 か月頃と同程度まで改善することが明らかとなっている [9]。このため、乳児期早期からの頭蓋変形予防策が必要であると考えている。
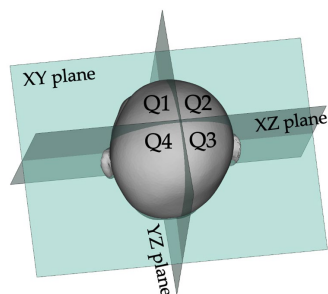
　Artec Eva 3D スキャナーは、放射線被ばくを伴わず、かつ高い測定精度で頭蓋形状の評価を行うことが可能であることが明らかとなった。しかし、日本において 3D スキャナーはコストが高く、未だありふれた機器ではない。

　2 次元評価法を一般的に使用することができるのであれば [10]、ノギス等の計測器を用いることで医療機関を限定することなく、新生児・乳児への負担を減らしたまま、乳児期早期からの適切な診断、治療方針の決定ができる可能性がある。

(図 A および B)
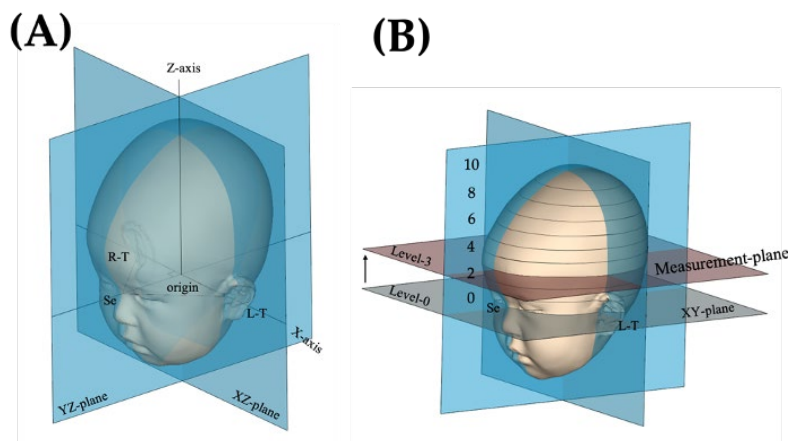
(図 C)

(表 1)

	検査者内		検査者間	
	Mean ± SD n = 6	CV (%)	Mean ± SD n = 6	CV (%)
Cranial length, mm	202.3 ± 0.5	0.26	203.0 ± 0.8	0.39
Cranial width, mm	171.7 ± 0.2	0.13	171.8 ± 0.3	0.16
Head circumference, mm	582.9 ± 1.2	0.20	582.9 ± 0.7	0.12
CA, mm	10.0 ± 0.6	5.62	10.0 ± 0.5	5.33
ASR, %	98.7 ± 0.2	0.24	98.6 ± 0.2	0.15
PSR, %	83.4 ± 0.4	0.50	83.7 ± 0.3	0.38

(表 2)

		CA		
		軽症	重症	計
ASR and PSR ≥ 80.5%	軽症	364 (68.7%)	68 (12.8%)	432 (81.5%)
ASR or PSR < 80.5%	重症	20 (3.8%)	78 (14.7%)	98 (18.5%)
	計	384 (72.5%)	146 (27.5%)	530

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