

Reference Values for Cranial Morphology Based on Three-dimensional Scan Analysis in 1-month-old Healthy Infants in Japan

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Abstract

Currently, molded helmet therapy is used to treat infants with deformational plagiocephaly. However, the indices of normal cranial shape remain unclear, and thus, the prevalence of deformational plagiocephaly is unknown, particularly in Japan. We investigated the reference values for cranial morphological characteristics in 1-month-old Japanese infants using a three-dimensional scanner, to determine the prevalence of deformational plagiocephaly. One hundred fifty-three healthy infants who visited three hospitals (from April 2020 to March 2021) were enrolled. Cranial shape was measured using a three-dimensional scanner and was analyzed using image analysis software. Outcome measures were cranial volume, length, width, length-width ratio, circumference, asymmetry, and vault asymmetry index; cephalic index; and anterior, posterior, and overall symmetry ratios. The cranial vault asymmetry index $>3.5\%$ or $\geq 10\%$ were diagnosed as deformational or severe deformational plagiocephaly, respectively. The mean age at measurement was 35.7 days. The mean cranial volume was 559 mL; cranial length, 129 mm; cranial width, 110 mm; length-width ratio, 118%; cephalic index, 85.2%; cranial circumference, 377 mm; cranial asymmetry, 6.4 mm; cranial vault asymmetry index, 5.0%; and anterior, posterior, and overall asymmetry ratios, 93.1%, 91.3%, and 96.4%, respectively. The prevalence of deformational and severe deformational plagiocephaly was 64.7% and 6.6%, respectively. Sex-based differences were observed for cranial volume and width. The results obtained in this study can be considered standard values that can facilitate the differentiation of abnormal infant cranial morphological characteristics for Japanese medical practitioners.

Keywords: infant, deformational plagiocephaly, skull, three-dimensional imaging

Introduction

With recent advances in three-dimensional (3D) scanning analyzers (3D scanners), 3D assessment of various external body surfaces has become easier and safer, without the need for radiation exposure. Therefore, their application has gained widespread acceptance in various fields, such as orthopedics, neurosurgery, and dentistry. Such scanners are also used in the diagnosis and monitoring of the effects of treatment of infants with deformational plagiocephaly (DP).^{1,2)}

In the United States, the observed prevalence of DP has

increased since the *Back-to-Sleep* campaign.¹⁾ Thereafter, 3D scanners were recommended as necessary devices for DP evaluation.¹⁻⁴⁾ A noninvasive laser-based digitizer (STARScanner, Orthomerica, Orlando, Florida, USA) has been used to assess cranial shape and to evaluate and monitor treatment of DP since the 2000s.^{3,4)} Furthermore, this 3D scanner has received clearance as a medical device from the Food and Drug Administration (FDA).³⁾ For infants with severe DP, helmet therapy is initiated, and the FDA has approved many types of helmets for treating DP,¹⁻⁶⁾ such as the Michigan-style helmet (Michigan Cranial Reshaping Orthosis, Danmer Products, Michigan, USA).

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The University of Michigan reported that 84.3% of affected children who used Michigan-style helmets had an improvement over 3 years from 2009 to 2012.⁷⁾

In Japan, Aihara et al. introduced the use of a molded helmet as treatment for DP in 2007, with positive results⁵⁾. Its use has since become ubiquitous.^{6,8)} However, as of 2021, there are only a few therapeutic helmets registered by the Pharmaceuticals and Medical Devices Agency of Japan (PMDA) as medical devices: the Michigan-style helmet (medical device approval number: 23000BZX00094000) and Aihara's proposed helmet (Aimet, Japan Medical Company Inc., Tokyo, Japan; medical device approval number: 30100 BZX00022000) and so on. Although criteria for the severity of DP have been established to capture the pathological significance of the cranial shape,^{5,6)} there are still no reference values for healthy infants, including those with DP. Moreover, as handheld 3D scanners are not yet registered as medical devices by the PMDA, their use is limited.

This study analyzed the cranial shape of 1-month-old infants using a handheld 3D scanner. We obtained reference values for normal cranial morphology in infants, to determine the prevalence of DP at 1-month-old and to examine the reference values for helmet treatment of DP in Japan.

Materials and Methods

This study protocol was approved by the ethics committee, and written informed consent was obtained from the parents and guardians of all participants when mothers were admitted for delivery or at their 1-month medical checkup. The ethics committee of each participating institution approved the study (Kasukabe Medical Center and Hikawadai Noto Clinic: approval number 2019-032, Nihon University Itabashi Hospital approval number RK-200512-2).

Subjects

Healthy 1-month-old infants who visited our hospitals between April 1, 2020, and March 31, 2021, were included in the study. Low-birth-weight infants (birth weight < 2,500 g), preterm infants (gestational age < 37 weeks), and infants with neonatal asphyxia (5-min Apgar score < 7) were excluded. Only Asians residing in Japan were included, and other races were excluded. Infants aged 28-55 days were considered 1-month old.

Data acquisition

A complete 360° scan of the head, including both ears, was performed using a specialized 3D scanner (Artec Eva, Artec, Inc., Luxembourg, Luxembourg) while the mother held the infant's head. The head was protected using an elastic wig cap to prevent tangling the hair. The 3D scanner scanned the cranium in a continuous mode, by emitting light at a maximum speed of 16 times per second. The scanner detects the light deflected from the object, re-

records the unevenness and color information of the object, and triangulates the pattern projected on the scanned object to create 3D data. The 3D resolution was 0.2 mm, and the accuracy was 0.1 mm. The entire 3D data were reconstructed by combining the overlapping regions in each successive scanned frame and converting them into STL files.

Three-dimensional data analysis

The obtained data were analyzed using image analysis software (Artec Studio, Artec, Inc., Luxembourg) to obtain 3D images and determine the shape of the head. Figure 1A shows the methods used to determine the reference plane, X-axis, and Y-axis. On the Artec Studio software platform, the plane connecting the sellion (SE; the lowest point of the nasal root) and the points of the left and right trignon (TR; the upper margin of the tragus) was used as the reference plane (level 0). The software identified the midpoint between the two TR landmarks. The Y-axis was defined as the line through the midpoint and SE. The X-axis was defined as the line perpendicular to the Y-axis at the midpoint in the level 0 plane. The software reconstructed 10 equal cross sections of the cranium superior to level 0 (Fig. 1B). The height of each cross section was determined by dividing the overall height of the infant's head above the level 0 plane into 10 equal levels.^{2,3,5)} The planar intersection between levels 2 and 8 was defined as the cranial volume (CrV).^{3,5)} The level 3 plane, which had the largest circumference,^{2,3)} was used as the measurement plane. The cranial length (CrL) and width (CrW) were measured as the Y-axis and X-axis lengths on the measurement plane, respectively. The cranial length-width ratio (LWR) was calculated as CrL/CrW (%). The cephalic index (CI) was calculated as CrW/CrL (%). Finally, the cranial circumference (CC) was measured as the circumference of the measurement plane.

Cranial asymmetry (CA) and cranial vault asymmetry index (CVAI) measure the differences between the longer and shorter diagonals at the level of the measurement plane at 30° to the Y-axis with respect to the length of the longer diagonal [CA = longer diagonal length - shorter diagonal length ; CVAI = (longer diagonal length - shorter diagonal length)/shorter diagonal length (%)]^{9,10)} (Fig. 1C). The CVAI describes the severity of the asymmetry.

Each cross section was subdivided into four quadrants along the X-axis and Y-axis planes above the skull base (Q1, anterior left; Q2, anterior right; Q3, posterior right; and Q4, posterior left) (Fig. 1D) using image analysis software. Quadrant volumes of Q1, Q2, Q3, and Q4 were the sum of the volumes from Levels 2 to 8. Quadrant volumes were used to define the symmetry quantitatively by specific ratios, such as the anterior symmetry ratio (ASR; Q1 volume: Q2 volume, or vice versa, whichever is <1), posterior symmetry ratio (PSR; Q3 volume:Q4 volume, or vice versa, whichever is <1), and overall symmetry ratio (OSR; Q1 + Q

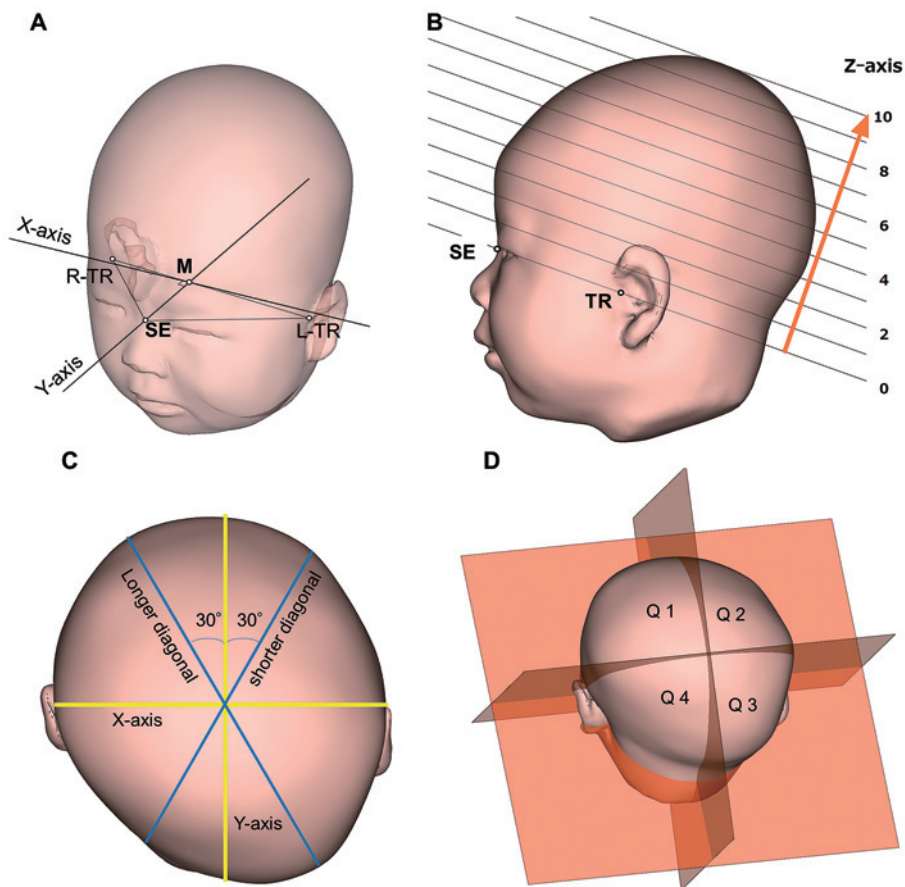


Fig. 1 Three-dimensional images.

This figure was modified from the figure created by the authors of reference 8.

A: Figure showing how the reference plane (level 0) and X,Y-axis are determined.

B: Figure showing how to determine the plane and Z-axis for levels 0-10.

C: Cross-sectional view of level 3 of the measurement plane.

X-axis, Y-axis, and 30° diagonals lines were used to quantify the cranial asymmetry and cranial vault asymmetry index.

D: Figure of the cranium divided into four sections by the X and Y axes, showing Q1-4.

M, midpoint between the tragions; L-TR, left tragon; R-TR, right tragon; SE, sellion; TR, tragon; Q, quadrant

4 volume:Q2 + Q3 volume, or vice versa, whichever is <1).^{2,5)}

Statistical analysis

The overall mean and sex differences were examined. A CVAI of >3.5% was considered to indicate DP.^{9,10)} DP severity was examined using the CVAI and the volume ratio for the Michigan-style and Japanese helmets, respectively.^{5,7)} A CVAI of <3.5% was defined as normal, 3.5%-6.9% as mild, 7%-9.9% as moderate, 10%-13.9% as severe, and ≥14% as very severe.^{6,9-11)} ASR and PSR values ≥90% were considered mild, 85%-89.9% as moderate, 80%-84.9% as severe, and <80% as very severe.^{5,12)} The severity of the volume ratio was determined using the lowest values of ASR and PSR.

The statistical software EZR (64-bit version 1.54)¹³⁾ was used for the appropriate statistical analyses. Each parameter was subjected to the Shapiro-Wilk normality test, where $p < 0.05$ indicated a nonparametric data distribution

and $p \geq 0.05$ indicated a normal distribution. Student's t -test and the Mann-Whitney U test were used to compare normal and nonparametric distributions, respectively. Fisher's exact test was used to determine the proportion between the groups. Statistical significance was set at a two-tailed p -value of <0.05. The correlations of age with CrV, CVAI, and PSR were analyzed using Spearman's rank correlation coefficient.

Results

Subjects

During the study period, 179 1-month-old infants visited our hospital and underwent 3D scanning of the head. Twenty-five patients with a gestational age of <37 weeks and birth weight of <2,500 g were excluded. None of the patients had neonatal asphyxia. All participants belonged to the Mongoloid race: 151 and 2 infants were of Japanese

Table 1 Clinical characteristics and cranial shape in 1-month-old infants

	Overall	Sex		P value
		Male	Female	
		Mean ± SD	Mean ± SD	
N	153	84	69	
Gestational age (weeks)	39 ± 1	39 ± 1	39 ± 1	0.52*
Birth weight (g)	3,098 ± 333	3,039 ± 320	3,107 ± 350	0.93*
Age at measurement (day)	35.7 ± 6.3	35.8 ± 6.3	35.6 ± 6.5	0.72*
Weight at measurement (g)	4,352 ± 495	4,428 ± 502	4,261 ± 474	0.038**
Cranial volume (mL)	559 ± 55	574 ± 52	541 ± 55	<0.001**
Cranial length (mm)	129 ± 4.9	129 ± 4.6	128 ± 5.2	0.25*
Cranial width (mm)	110 ± 5.4	111 ± 5.1	108 ± 5.1	<0.001**
LWI (%)	118 ± 7.0	116 ± 6.6	119 ± 7.0	0.007*
Cephalic index (%)	85.2 ± 4.9	86.1 ± 4.8	84.0 ± 4.9	0.010**
Cranial circumference (mm)	377 ± 12	380 ± 11	373 ± 12	<0.001**
Cranial asymmetry (mm)	6.4 ± 3.8	6.9 ± 4.0	5.7 ± 3.5	0.070*
CVAI (%)	5.0 ± 2.9	5.4 ± 3.0	4.5 ± 2.7	0.087*
Prevalence of DP (%)	64.7	67.9	60.9	0.40***
Anterior symmetry ratio (%)	93.1 ± 4.8	92.8 ± 4.9	93.5 ± 4.7	0.27*
Posterior symmetry ratio (%)	91.3 ± 6.6	90.6 ± 6.6	92.1 ± 6.5	0.19*
Overall symmetry ratio (%)	95.6 ± 3.1	95.8 ± 3.1	95.3 ± 3.0	0.24*

Data are given as the mean value ± standard deviation or number (percentage).

*Mann-Whitney U test; **Student's t-test; *** Fisher's test.

CVAI, cranial vault asymmetry index; DP, deformational plagiocephaly; LWI, cranial length-width ratio; SD, standard deviation

and Chinese nationalities, respectively, but 1 African-American infant was excluded from the study. The final number of participants was 153 (84 boys and 69 girls). The mean gestational age was 39 ± 1 weeks, and the mean birth weight was 3,098 ± 333 g.

Maternal information

The average maternal age was 33.2 years. Seventy-three were primiparous mothers, and 78 were multiparous mothers. (Fifty-four women had one previous delivery, 22 had two previous deliveries, and 2 had three previous deliveries.) Overall, 79 (51.6%) and 59 (38.6%) participants were born via vaginal delivery and cesarean section, respectively. Of the infants, 143 (93.5%) had a cephalic presentation. Moreover, 24 mothers (15.7%) were current or former smokers, and gestational diabetes mellitus and hypertensive disorders of pregnancy were present in 19 (12.4%) and 12 (7.8%) mothers, respectively. None of the newborns had abnormalities at the 1-month checkup.

Reference values

3D scanning required approximately 5 min. Table 1 lists the results of the reference values. The mean value ± standard deviation was calculated for each parameter. The mean age at measurement was 35.7 ± 6.3 days, and the

mean weight was 4,352 ± 495 g. The mean values of each parameter were as follows: CrV, 559 ± 55 mL; CrL, 129 ± 4.9 mm; CrW, 110 ± 5.4 mm; LWR, 118% ± 7.0%; CI, 85.2% ± 4.9%; CC, 377 ± 12 mm; CA, 6.4 ± 3.8 mm; CVAI, 5.0% ± 2.9%; ASR, 93.1% ± 4.8%; PSR, 91.3% ± 6.6%; and OSR, 95.6% ± 3.1%. The overall prevalence of DP was 64.7%.

There were no significant differences based on the method of delivery or the background of the mother for any of the aforementioned parameters.

Sex differences

There were no significant differences in birth background data and age on the measurement day. The weight on the measurement day and CrV were significantly greater in boys (weight 4,428 g vs. 4,261 g, $p = 0.0375$; CrV 574 mL vs. 541 mL, $p < 0.001$). Significant differences between the sexes were noted in CrW, LWR, and CI, but not in CrL. No sex differences were observed in the index or volume ratio for evaluation of cranial deformation. No significant sex differences were observed in the prevalence of DP (Table 1).

Correlation between age and parameters

Figure 2 shows the correlation between age (days after birth) and CrV, CVAI, and PSR. A positive correlation was

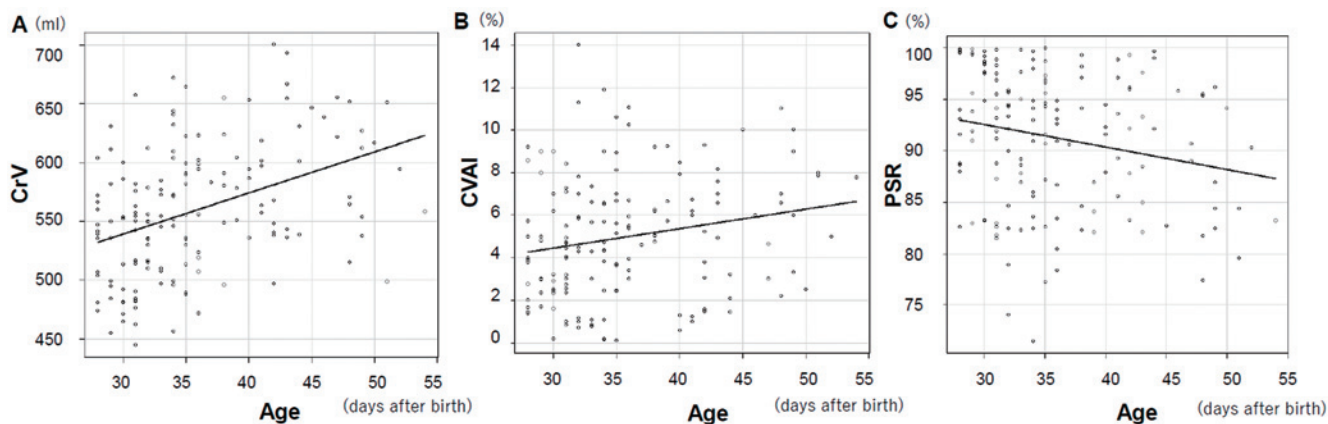


Fig. 2 Correlations between age and cranial vault asymmetry index, posterior symmetry ratio, and cranial volume.

A: age – CrV: correlation coefficient (r) = 0.416, $p < 0.01$

B: age – CVAI: $r = 0.231$, $p < 0.01$

C: age – PSR: $r = -0.241$, $p < 0.01$

CrV, cranial volume; CVAI, cranial vault asymmetry index; PSR, posterior symmetry ratio

Table 2 Deformational plagiocephaly severity criteria

A: Michigan-style helmet

CVAI (%)	Normal <3.5	Mild 3.5-6.9	Moderate 7.0-9.9	Severe 10-13.9	Very severe ≥14
N	54	58	31	9	1
(%)	35.3	37.9	20.3	5.9	0.7

B: Japanese helmet (Aimet)

ASR, PSR (%)	Mild ≥90	Moderate 85-89.9	Severe 80-84.9	Very Severe <80
N	69	39	37	8
(%)	45.1	25.5	24.2	5.2

Table 2A was partially modified from references 6, 7 and the Japanese package inside (reference 11).

Table 2B was partially modified from reference 5 and the Japanese package inside (reference 12).

ASR, anterior symmetry ratio; CVAI, cranial vault asymmetry index; PSR, posterior symmetry ratio

noted between age and CrV ($r = 0.416$, $p < 0.001$). Age and CVAI showed a weak positive correlation ($r = 0.231$, $p = 0.004$), whereas age and PSR showed a weak negative correlation ($r = -0.241$, $p = 0.003$).

Severity of deformational plagiocephaly

Table 2A shows the severity criteria based on the CVAI for the Michigan-style helmet and the prevalence of DP in our cohort.^{6,7,9-11} Table 2B shows the severity criteria of the volume ratio for the Japanese helmet and the prevalence of DP in the infants enrolled in our study.^{5,12} In Japan, 6.6% of infants were eligible for helmet treatment when severe disease was indicated by the CVAI using the Michigan

method. Or the infants, 5.2% had severe DP indicated for Japanese helmet treatment according to the volume ratio criteria.

Discussion

The conventional index for cranial shape, the CC, is a planar parameter, which makes it difficult to evaluate shape deformations. However, we calculated used a 3D scanner to measure various cranial 3D parameters and established reference values in 1-month-old Japanese infants. We found no differences in cranial shape according to maternal background or delivery method. Moreover, we demonstrated that DP prevalence was 64.7% in the Japanese infants in our study. This report is the first evaluation of cranial shape in healthy newborns using a 3D scanner in Japan.

Three-dimensional cranial scanner

In Japan, no handheld 3D scanners have been registered to date by the PMDA as a medical device. Even the Artec Eva used in this study is not a PMDA-registered medical device; therefore, this scanner was used clinically after approval from the ethics committee of each facility, with written informed consent from the infants' guardians and parents. According to the technical data provided by the Artec Group, the scanner is small ($261.5 \times 158.2 \times 63.7$ mm) and lightweight (800 g). Koban et al. reported that it has accuracy comparable with that of nonportable 3D scanners.¹⁴ Verhulst et al. compared the facial reproducibility of three 3D scanners and reported that the Artec Eva had lower reproducibility than other devices but that its accuracy was still sufficient for clinical use.¹⁵

The confounding effect of the subject's movement was avoided by combining the overlapping regions of succes-

sive scan frames. It is currently used to evaluate the indication for helmet therapy in infants, and it has been considered useful for cranial shape evaluations.¹⁶⁾ It is a handheld, noncontact scanner that can be used for simple, rapid measurements.

Cranial volume

The mean CrV in the neonatal period was 330 ± 78.3 mL in a previous study that used computed tomography (CT).¹⁷⁾ Additionally, CrV values were reported to be 376 mL in boys and 308 mL in girls, in an estimate based on CC and other factors.¹⁸⁾ Additionally, in a 3D scanner-based study on preterm infants with a modified age of 35 weeks, the median CrV was reported as 332.5 (208-630) mL.³⁾ Dean et al. examined the brain volumes of 149 1-month-old infants with magnetic resonance imaging (MRI) and reported a total brain volume of 611.48 ± 47.5 mL in boys and 562.7 ± 50.6 mL in girls.¹⁹⁾ In this cohort, the mean CrV of 559 ± 55 mL was reasonable for 1-month-old infants. Burkhardt et al. reported that brain volumes on MRI can be approximated by CrV determined using a 3D scanner.²⁰⁾ The CrV values obtained in this study showed a trend similar to that of MRI-based brain volumes. Moreover, using a 3D scanner has the advantage that it does not require sedation, is not time-consuming, and can be used for understanding the external skull surface and shape, as well as for approximating brain volumes. There was a positive correlation between age and CrV: the CrV doubles by 9 months of age²¹⁾ and the growth in CrV was particularly rapid in the early postnatal period.²²⁾ In this cohort of healthy infants, the CrV showed significantly increasing trend with age, even though the infants' age range was narrow (28-55 days).

Sex differences

Although sex-based anthropometric differences in infants are already known, in this study, sex-based differences were observed in weight, CC, CrV, and CrW. Because LWR and CI included CrW in their formulas, the difference in CrW was considered to underlie their significant differences. Sex-based differences in CrV have been reported previously.^{18,19)} This study revealed no such differences in CrL, but there was a difference in CrW. Because CC and CrV contain elements of CrL and CrW,¹⁸⁾ sex differences in CC and CrV were likely caused by a sex difference in CrW.

A systematic review of DP reported a higher risk in boys,^{23,24)} but in this Japanese study, no sex differences were observed in the prevalence and deformity indices of DP. Whether these sex differences are specific to the Japanese population requires further evaluation.

Cephalic index

The CI is a well-established indicator of cranial shape. Defined by the Swedish anatomist Anders Retzius in the 19th century, it is expressed as the ratio of the skull width

to the greatest skull length and has been used in natural anthropology.²⁵⁾ In this study, the CI was measured on the basis of CrL and CrW, determined using a 3D scanner. The overall mean value was $85.2\% \pm 4.9\%$, corresponding to the brachycephaly type in the international classification system.^{26,27)} The CI for Japanese children, based on a head CT study, was $86.5\% \pm 7.3\%$, and the mean CI for 0- to 3-month-old infants was $86.7\% \pm 7.9\%$.²⁸⁾ The results for infants in this study were similar to those previously reported for Japanese children. Koizumi et al. clarified the racial differences in cranial shape and reported that the reference values of Japanese cranial shape need to be established.²⁸⁾ Our results indicate that there are racial differences in the CI and other parameters.

Characteristics of deformational plagiocephaly

The prevalence of DP is 46.6% in Canada²⁹⁾ and 48% in the United States.³⁰⁾ A German study on extremely preterm infants at full-term equivalent age reported 38% DP prevalence.³¹⁾ According to the classification of Loveday et al.,^{9,10)} infants with CVAI of $>3.5\%$ were diagnosed with DP, and this study revealed that the prevalence of DP in Japan is 64.7%. As predicted by Takamatsu et al.,⁶⁾ DP was more prevalent in the Japanese population than in previous reports.²⁹⁻³¹⁾ If the diagnostic criterion for DP was set at the international criterion, most Japanese infants fell into the DP category. Clearly, Japanese-specific diagnostic criteria are necessary. Concerning racial differences in cranial shape, this study found a mean Japanese CVAI of 5.0%. If we assume that the criterion for DP in Japanese is $\geq 5.0\%$, the prevalence of DP was 47.7%, which corresponds to the figures created in the previous reports.²⁹⁻³¹⁾ Therefore, future large-scale studies should examine whether the existing diagnostic criteria apply to Japanese patients. Additionally, the normal range of CA and CVAI in the Japanese population and transition during growth require future research.

The indications for treatment of DP in Japan include the severity of CVAI for the Michigan-style helmet^{6,7)} and the volume ratio of the Japanese helmets.⁵⁾ Compared with these results, the number of patients with severe DP requiring treatment with either of these helmets was approximately 6.6% and 5.2%, respectively.

Helmet therapy is recommended to be started at approximately 4-6 months of age for infants with DP.^{5,6,32,33)} These reference values for 1-month-old infants did not affect the assessment of DP but were considered necessary for evaluating morphological changes after a few months. CVAI and PSR correlated weakly with age and DP disease progression. Hence, further follow-up studies should determine if this trend is specific only to the first month. The significance of the CVAI value at 1 month will be reported in the follow-up study. Whether craniomaxillofacial parameters at the age of 1 month can be used as treatment indication criteria requires additional studies, including evaluation of follow-up variations.

Limitations

This study had some limitations. First, the measurement accuracy of the 3D scanner was not verified. The measurement was performed only once for one subject. Errors and biases due to variations in facilities and measurers cannot be eliminated. The second limitation is the size of the sample; measurements were taken at several hospitals in a small area of the Kanto region in Japan. Therefore, a nationwide study is necessary to calculate the mean parameters of infants in all regions of Japan. The sample size was too small to assess racial differences. Moreover, it was impossible to examine other racial groups in this study. We did not compare the results with those of other devices capable of producing 3D images (head CT and MRI) and thus could not determine whether the examination was performed faster, more accurately, or more safely using the 3D scanner. In the future, it will be necessary to further examine racial differences and clarify these differences with respect to other devices.

Conclusions

The reference values for the cranial shape of 1-month-old healthy infants in Japan were established by measuring the morphological characteristics of the head of infants using a 3D scanner. Moreover, we determined the prevalence of DP in Japanese infants to be 64.7%. We also showed that a handheld 3D scanner is useful for measuring the CrV and shape of infant heads, which could help to differentiate between normal and abnormal cranial morphology in Japanese infants.

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Conflicts of Interest Disclosure

I.M. received lecture fees from AbbVie Inc.

The other authors (H.M., N.N., R.K., T.N., S.H., and K.S.) had no conflicts of interest.

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