Evaluating Cranial Growth in Japanese Infants Using a Three-dimensional Scanner: Relationship between Growth-related Parameters and Deformational Plagiocephaly

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Abstract

In this study, we aimed to evaluate the longitudinal changes in the cranial shape of healthy Japanese infants using a three-dimensional scanner and construct a normal values database for the growth process. Preterm infants (gestational age < 37 weeks), infants with neonatal asphyxia (5-minute Apgar score of <7), and patients who started helmet therapy for deformational plagiocephaly were excluded from this study. The first scan was performed at approximately 1 month of age, followed by two scans conducted at 3 and 6 months of age. The parameters considered were as follows: cranial length, width, height, circumference, volume, cranial vault asymmetry index, and cephalic index. A cranial vault asymmetry index >5% was defined as deformational plagiocephaly. Changes in each parameter were examined using repeated-measures analysis of variance classified by sex and deformational plagiocephaly status. The rate of increase in each parameter was also examined. In total, 88 infants (45 boys and 43 girls) were included in this study. All growth-related parameters were noted to increase linearly with time. Sex differences were observed in all parameters except cranial length. Deformational plagiocephaly was found to have no effect on growth-related parameters. Cranial volume increased by 60% from 1 to 6 months of age. The growth almost uniformly influenced the rate of increase in volume in each coordinate axis direction. Overall, the mean trends in three-dimensional parameters in infants up to 6 months of age were obtained using a three-dimensional scanner. These trends could be used as a guide by medical professionals involved in cranioplasty.

Keywords: infant, cranial shape, cephalic index, growth, 3D scanner

Introduction

The volume of the human brain dramatically has been determined to increase immediately after birth. In fact, a previous study, which used head computed tomography (CT) examination, reported that the intracranial volume doubles in the first 9 months of life.1 As the brain grows, the size of the skull also increases in all three dimensions (3D), and the newborn skull is soft and pliable with open sutures to accommodate this growth. Because skull growth is a 3D process, using 3D parameters to quantify skull morphology is deemed rational. However, traditional methods of assessment using tape measures are limited to two-dimensional (2D) assessments of the head circumference. Although techniques such as magnetic resonance imaging and CT can be used to create 3D data, these methods can have a major disadvantage because they require sedation and radiation exposure, respectively, when used in infants.
Attempts to use 3D scanners to evaluate the cranial shape and apply them to treat cranial deformities have been made in Europe and the United States since the 2000s. However, these approaches have not been widely used in Japan because there are no reference 3D scanner measurements of infant head shapes. Although databases for longitudinal 3D scanner measurements of infant head shapes have been established overseas, reports describing similar shape trends in normal Japanese infants are based on CT. We have previously reported changes in symmetry-related parameters such as cranial asymmetry (CA), the cranial vault asymmetry index (CVAI), anterior symmetry ratios, and posterior symmetry ratios using a 3D scanner from 1 to 6 months of age and found that the incidence of symmetry-related parameters and deformational plagiocephaly (DP) worsened up to 3 months of age and then improved over the next 3 months. In that study, we examined the trends in growth-related parameters and identified the need to clarify the relationship between DP and growth-related parameters. Therefore, in this study, we aimed to evaluate 3D data of the cranial shape of healthy Japanese infants, longitudinally evaluate growth in each of the three dimensions, and construct a database of normal values.

Materials and Methods

This study was conducted in collaboration with Nihon University Itabashi Hospital, Kasukabe Medical Center, and Hikawadai Noto Clinic. In this study, we aimed to examine different parameters, with data obtained at the same time points as those used in previous reports on symmetry-related parameters. The study protocol was approved by the Ethics Committee of each institution (Kasukabe Medical Center, Hikawadai Noto Clinic: approval no. 2019-032; Nihon University Itabashi Hospital: approval no. RK-200512-2) and conducted in accordance with the principles outlined in the Declaration of Helsinki and its revisions. Written informed consent was obtained from the parents and guardians of all participants when the mother was admitted to the hospital for delivery or at the 1-month checkup. Moreover, the procedures followed in experiments on human subjects were conducted in accordance with "Ethical Guidelines for Medical and Health Research Involving Human Subjects (Provisional Translation as of March 2015)" and its later amendments.

Targeted cases

This is a prospective follow-up study. Healthy infants who visited any of the three hospitals during the 13-month period from April 1, 2020, to April 30, 2021, were included in this analysis. Preterm infants (gestational age < 37 weeks) and infants with neonatal asphyxia (5-minute Apgar score < 7) were excluded. In addition, only Japanese infants were included, whereas infants of other races were excluded from this study.

The first scan was performed at approximately 1 month of age (T1). Two measurements were subsequently taken at approximately 3 and 6 months of age (T2 and T3). Patients who started helmet therapy for cranial deformities were excluded from this study.

Data collection and analysis

The heads of infants were held by their mothers and scanned using an Artec Eva 3D scanner (Artec, Inc., Luxembourg, Luxembourg). The principles of 3D scanners have been explained in detail in our previous report. The infants’ heads were protected using an elastic wig cap to prevent hair tangling. The 3D data were reconstructed by combining the overlapping regions of each successively scanned frame and converting them into standard triangulated language files as the standard format for 3D images.

The obtained data were thereafter analyzed using Artec Studio image analysis software (Artec, Inc., Luxembourg, Luxembourg) and original analysis software from Japan Medical Company (Japan Medical Company, Inc. Tokyo, Japan). Fig. 1 shows the method used to determine the parameters based on a previous report, with some changes in the materials. The plane connecting the sellion (SE; the lowest point of the nasal root) and the points of the left and right tragi (TR; the upper edge of the tragus) were used as the reference plane (level 0). The software has the ability to identify the midpoint (M) of the two TRs; the line through SE and M was the Y-axis; the X-axis was the line perpendicular to the Y-axis at the midpoint on the plane of level 0 (Fig. 1A).

The software constructed ten equal cross sections of the cranium above level 0. The height of each cross-sectional level was determined by dividing the height from the top of the level 0 plane to the top of the head into 10 equal sections (Fig. 1B). The volume between levels 2 and 8 was defined as the cranial volume (CrV). The cranial height (CrH) was defined as the Z-axis length from level 0 to the top of the head.

Level 3, which has been reported to exhibit the largest circumference, was used as the measurement plane. Fig. 1C shows the cross-sectional view of the measurement plane. The cranial length (CrL) and cranial width (CrW) were measured as the length of the measurement plane in the y- and X-axis directions, respectively. The cephalic index (CI) was calculated as CrW/CrL (%). While CI is essentially an indicator of brachycephaly, it was included in this study because the calculation formula was established from CrL and CrW only. The difference between the longer and shorter diagonal lengths at 30° from the Y-axis of the measurement plane was defined as CA, whereas CA/shorter diagonal length (%) was defined as the CVAI. A CVAI > 5% was defined as DP in Japanese infants.
Study design and statistical analysis

Changes in mean values of growth-related parameters

Each parameter was tested for normality using the Shapiro-Wilk test. A repeated-measures analysis of variance (ANOVA) was used to examine the course of infants who underwent measurements three times during this study. A Bonferroni correction was applied for multiple comparisons. For the repeated-measures ANOVA, Mauchly's sphericity test was used to confirm sphericity, and the Huynh-Feldt (HF) correction was applied to the p-values when the values were rejected in the sphericity test. Statistically, significant differences are indicated by p-values < 0.05.

Effect of cranial deformation on each parameter

Comparison of the course of each measurement between the groups with and without DP at T3 was performed using repeated-measures ANOVA. The diagnosis of DP was based on a CVAI >5% at T3. The correlation coefficient between the CVAI and CrV at T3 was calculated using Pearson's product-moment correlation.

Contribution of each axial direction to the rate of increase in volume

The increase rate in each axial direction was defined as ΔX(CrW), ΔY(CrL), and ΔZ(CrH). The rate of increase for each parameter was calculated as (T3 − T1)/T1 (%). The rate of increase in the CC (ΔCC) and CrV (ΔV) was calculated using the same approach. Welch's ANOVA was used in comparing the three groups. Multiple regression analysis was used to examine the contribution of the rate of increase in each coordinate axis to the increase rate in cranial volume. Statistical calculations were performed using EZR statistical software (64-bit, version 1.54).\(^{30}\)

Results

During this study period, 184 neonates visited the research facility and underwent 3D scanning of their heads. Fig. 2 shows a flowchart of the infants enrolled in this study. In total, 16 infants with gestational age <37 weeks were excluded. Three non-Japanese infants (two Chinese and one American) were also excluded from this study. None of the infants developed neonatal asphyxia. Thus, 165 infants were found eligible for this study at T1, of whom 57 dropped out, and 108 underwent 3D measurements at T2. Five of the 108 infants were subsequently excluded because they began helmet therapy. Twelve more infants dropped out, and the remaining 91 underwent 3D measurements at T3. Three infants who started helmet therapy after T3 were excluded from this study. Therefore, 88 infants were included in this analysis.

Participant background characteristics

This study population included 45 boys and 43 girls. The mean gestational age was 38.6 ± 1.3 weeks, the mean birth weight was 3,019 ± 320 g, the mean birth height was 48.7 ± 1.7 cm, and the mean head circumference at birth was 337.0 ± 14.0 mm. In addition, the mean 5-min Apgar score was 9.0 ± 0.4, whereas the mean cord blood pH was 7.32 ± 0.07.

The mean maternal age was 34.0 ± 5.4 years old, and the mean maternal body mass index was 21.9 ± 3.6. In total, 42 (47.7%) mothers were primiparous, 4 were multiparous (two sets of twins), 44 (50%) delivered vaginally, 34 (38.6%) underwent cesarean delivery, 10 (11.4%) underwent suction or forceps delivery, and 82 (93.2%) underwent cephalic delivery. Twenty infants (22.7%) were breastfed exclusively. The delivery background and nutrition did not
affect any of the parameters at T3. Particularly, symmetry-related parameters at T1 did not differ significantly by delivery method.

**Changes in growth-related parameters**

Table 1 shows the changes in the growth-related cranial parameters. The Shapiro-Wilk normality test showed that all parameters were normally distributed. The mean infant ages at T1, T2, and T3 were 37.9 ± 6.4, 99.6 ± 8.6, and 189.3 ± 9.7 days, respectively. The mean values of each parameter were noted to increase significantly between each time point, and all parameters except CrL showed sex differences. The increase in each parameter during the period from T1 to T3 was 13.6% for CrL, 19.1% for CrW, 15.6% for CrH, 15.8% for CC, and 60.7% for CrV. No sex differences were observed in the percentage increments.

Fig. 3A shows the results of the repeated-measures ANOVA for each parameter. Because Mauchly tests for sphericity were rejected for all parameters, the HF correction was used to correct the p-values. For all parameters, the presence or absence of DP was not associated with growth-related parameters. At T3, the correlation coefficient ($r$) between CVAI and CrV was $-0.022$ (95% confidence interval: $-0.23$ to $0.19$; $p = 0.84$), which indicates no correlation.

**Rate of increase**

The rate of increase in each of the three directions of each coordinate axis was compared. The results of the Welch ANOVA are shown in Fig. 4. The overall $p$-value was $p < 0.01$, and multiple comparisons were able to yield $p < 0.01$ each. The rate of increase in each coordinate direction differed significantly, with the increase rate in the X-axis direction (CrW) being significantly greater than those in the others.

Multiple regression analysis was performed with the rate of increase in volume as the objective variable and the rate of increase in each coordinate axis as the explanatory variable. No correlations were observed between the explanatory variables, each with a value of $|r| < 0.4$. Variance inflation factors were 1.07, 1.06, and 1.07 for $\Delta X$, $\Delta Y$, and $\Delta Z$, respectively. The residuals were normally distributed ($p = 0.20$, Shapiro-Wilk test).

The multiple regression equation was

$$\Delta V = 3.116578 + 1.305734 \Delta X + 1.096480 \Delta Y + 1.200843 \Delta Z.$$  

The corrected $R^2$ value was 0.83. All parameters had $p$-
Table 1 Changes in growth-related cranial parameters of 88 infants

| Parameter                        | T1       | T2       | T3       | Increase rate (T3-T1)/T1 (%) |
|----------------------------------|----------|----------|----------|-------------------------------|
| Cranial length, mm               | 129.2 ± 4.7 | 138.1 ± 4.9 | 146.7 ± 5.4 | ∆Y, % 13.6 ± 3.7             |
| (male/female)                    | (130.0/128.4) | (138.9/137.1) | (147.5/145.9) | (13.6/13.7)                   |
| Cranial width, mm                | 109.4 ± 5.4 | 121.4 ± 6.0 | 130.2 ± 6.9 | ∆X, % 19.1 ± 5.0             |
| (male/female)                    | (111.1/107.8) | (123.8/118.9) | (133.2/127.1) | (20.1/18.0)                   |
| Cranial height, mm               | 98.6 ± 5.6  | 107.3 ± 3.8 | 113.8 ± 4.6 | ∆Z, % 15.6 ± 5.8             |
| (male/female)                    | (100.6/96.5)  | (108.6/106.0) | (115.2/112.3) | (14.8/16.6)                   |
| Cranial circumference, mm        | 376.7 ± 12.4 | 408.9 ± 11.3 | 436.0 ± 12.7 | ∆CC, % 15.8 ± 3.2            |
| (male/female)                    | (380.4/372.8) | (413.9/403.7) | (441.9/429.8) | (16.2/15.3)                   |
| Cranial volume, mL               | 559.6 ± 59.3 | 742.1 ± 63.5 | 901.0 ± 85.1 | ∆V, % 60.7 ± 13.1            |
| (male/female)                    | (578.0/540.4) | (767.6/715.4) | (937.8/862.4) | (63.1/60.2)                   |
| Cephalic index, %                | 84.7 ± 4.5  | 88.1 ± 5.6  | 89.0 ± 5.8  |                              |
| (male/female)                    | (85.4/84.0)  | (89.2/86.8) | (90.4/87.3) |                              |

For each parameter, the mean ± standard deviation is presented. †: p < 0.05; T1: first measurement at 1 month; T2: second measurement at 3 months; T3: third measurement at 6 months.

values < 0.01. With regard to the factors affecting the increase in volume, each direction was found to have contributed virtually identically to the increase in CrV.

**Discussion**

In this study, the natural history of cranial shape in 88 healthy infants between 1 and 6 months of age was examined using a 3D scanner, which can easily obtain 3D data of the cranial shape without radiation exposure. The growth-related parameters showed a linear increase, indicating that the presence or absence of DP did not affect cranial growth. An increase in each 3D direction was found to have an almost identical effect on volume. To the best of our knowledge, this is the first Japanese study to longitudinally measure the course of cranial developmental parameters in young Japanese infants using a 3D scanner.

**Growth-related cranial parameters**

Growth-related parameters exhibited a significant increase in all three axes. Previous reports on somatic growth of the head collected data after the first year of life using a cross-sectional study design. However, longitudinal data on the 3D growth of the head in infants during the first year of life remain to be relatively scarce. According to previous reports, CrV increased by 18.8% between 6 and 12 months. However, in this present study, the young infants showed a significant increase in volume. Tomita et al. performed a cross-sectional study of intracranial volume using CT in healthy Japanese children and calculated the approximate equations for each age group by sex. According to their results, the predicted values for males/females at T1, T2, and T3 were 631/550 mL, 839/756 mL, and 970/886 mL, respectively, which were similar to the measurements obtained in the present study. The other parameters (CrL, CrW, CrH) also showed similar trends to those in Tomita’s report, confirming that the measurements of the 3D scanner were almost as good as those of CT.

Only the CrL showed no sex differences at any time point. The other parameters showed sex differences at each time point, but the time-sex interaction was only observed for CrW and CrV. Thus, the sex differences in cranial shape development may depend on CrW.

**Brachycephaly**

Cl is commonly used when analyzing the shape of a deformed head and is particularly used to classify brachycephaly. In this study, the CI was calculated from CrL and CrW and was found to increase over time. According to international classifications, mesocephaly, brachycephaly, and hyperbrachycephaly are categorized by CIs of 76.0%-80.9%, 81.0%-85.4%, and ≥85.5%, respectively. According to these criteria, most infants in Japanese studies, including this present study, were considered hyperbrachycephalic. Koizumi et al. suggested the following standards for classifying CI in Japanese infants: mesocephaly, 79.2%-93.8%; brachycephaly, 93.9%-101.1%; and hyperbrachycephaly, 101.2% or more. Based on these standards for Japanese infants, the infants in this study met the standards for mesocephaly. Thus, further discussions on cra-
Fig. 3 Results of the repeated-measures ANOVA.
A: Time-sex repeated-measures ANOVA
CrL: sex p = 0.09, time p < 0.01, sex-time p = 0.90
CrW: sex p < 0.01, time p < 0.01, sex-time p < 0.01
CrH: sex p < 0.01, time p < 0.01, sex-time p = 0.18
CrV: sex p < 0.01, time p < 0.01, sex-time p = 0.07
CC: sex p < 0.01, time p < 0.01, sex-time p < 0.01
CI: sex p = 0.03, time p < 0.01, sex-time p = 0.06

B: Time-DP repeated-measures ANOVA
CrL: DP p = 0.58, time p < 0.01, DP-Time p = 0.40
CrW: DP p = 0.88, time p < 0.01, DP-Time p = 0.61
CrH: DP p = 0.92, time p < 0.01, DP-Time p = 0.66
CC: DP p = 0.76, time p < 0.01, DP-Time p=0.41
CrV: DP p = 0.23, time p < 0.01, DP-Time p = 0.99
CI: DP p = 0.91, time p < 0.01, DP-Time p = 0.92

ANOVA: analysis of variance; CC: cranial circumference; CI: cephalic index; CrH: cranial height; CrL: cranial length; CrV: cranial volume; CrW: cranial width; DP: deformational plagiocephaly
T1: first measurement at 1 month; T2: second measurement at 3 months; T3: third measurement at 6 months.
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Fig. 4 Increase rate in each coordinate axis. †: p < 0.05.

DP and growth-related parameters

The incidence of DP at T3 was 43.2%, and the ANOVA showed no significant difference in terms of growth-related parameters between children with and without DP. This study has also demonstrated that DP did not affect the growth of the entire cranium. However, because we excluded children with severe DP who were indicated for helmet therapy, future studies should include children with severe DP. In this study, we included six patients (6.8%) with severe DP with CVAI > 8.75% at 6 months. Peterson et al. compared DP infants with and without helmet therapy and reported no significant differences in final CrV. The lack of significant differences in CrV with and without DP and with and without helmet therapy could guide decision-making regarding the suitability of helmet therapy for children with DP. Previous report shows that DP exacerbates until 3 months of age before spontaneously improving throughout the first 6 months of life. We have also reported that helmet therapy could improve CA three times better than spontaneous recovery. These facts could be important determinants in the decision-making process for the indications for helmet therapy for DP.

Although a reduction in cranial volume has been a concern in some craniosynostosis, as it may cause cranial deformation similar to DP, no effect on cranial volume was observed in DP. This could imply that the presence or absence of bony suture closure had a significant effect on cranial development.

Volume and the rate of increase in each coordinate axis direction

The increase in cranial volume is a 3D process, and in this present study, we have showed that the volume in each dimension increased independently. The increase in each axial direction was also found to contribute almost equally to the overall increase. This finding is expected to be helpful for the surgical treatment of craniosynostosis. Our findings suggest that the multidirectional cranial distraction osteogenesis method (a method targeting equal correction in each 3D direction) is more physiological than single-direction bone extension in cases of multiple-suture craniosynostosis. Furthermore, this study’s new 3D growth-related parameters are expected to be an important index, such as early detection when considering whether suturectomy should be performed for sagittal synostosis before 6 months of age.

Whether helmet orthodontic therapy can be effective in correcting the parameters in the absence of findings of premature skull fusion requires future validation based on the results of this study.

3D scanner

A 3D scanner has been known to be an effective tool for evaluating morphology without the need for sedation and the risk of radiation exposure. Notwithstanding their benefits, 3D scanners are unfortunately not as widespread in Japan as in other countries; one reason may be that handheld 3D scanners are not registered as medical devices by the Pharmaceuticals and Medical Devices Agency of Japan. In our study, 3D scanners specifically improved subject measurement time to 5 minutes or less and were considered less burdensome for infants. It may also be useful in detecting craniosynostosis, DP, and other craniofacial shape abnormalities.

In our previous report, we found that the incidence of DP is high among Japanese infants, with approximately 5% of healthy infants requiring helmet therapy. Concerns that the number of infants requiring cranial correction will increase in the future and that the limited availability of 3D scanners will delay accurate diagnosis have already been raised. Early registration of handheld 3D scanners as medical devices is therefore desirable.

Limitations

The accuracy of 3D scanner measurements was the primary limiting factor in this study. Artec Eva has been reported to be comparable to other scanners for head scanning and is ready for clinical use. It has also been used clinically to evaluate cranial deformities in infants. Artec Eva intra- and inter-examiner precision analyses results for our facility have been previously reported to be good. However, we could not compare measurement accuracy for
different measurements obtained for the same participant. Although the experienced personnel, future studies should focus on the generalization of the technique, including skills training.

Conclusion
A 3D scanner was used to examine the natural history of cranial shapes among healthy infants aged between 1 and 6 months. The growth-related parameters showed a linear increase, and CrV increased by 60% during this period. These results provide an important reference for future studies on cranial development. In addition, a future shift toward the use of 3D scanners to assess the shape of an infant’s cranium is expected.

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List of Abbreviations
2D: two-dimensional, 3D: three-dimensional, ANOVA: analysis of variance, CA: cranial asymmetry, CC: cranial circumference, CI: cephalic index, CrH: cranial height, CrL: cranial length, CrV: cranial volume, CrW: cranial width, CT: computed tomography, CVAI: cranial vault asymmetry index, DP: deformational plagiocephaly, HF: Huynh-Feldt, M: midpoint of the right and left tragi ons, SE: sellion, T1: first measurement at 1 month, T2: second measurement at 3 months, T3: third measurement at 6 months, TR: tragion

Conflicts of Interest Disclosure
The authors declare no conflict of interest.

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