

Normal Fetal Growth Profile at 10–41 Weeks of Gestation – An Update Based on 10225 Normal Singleton Pregnancies and Measurement of the Fetal Parameters Using 3D Ultrasound

Das normale fetale Wachstumsprofil zwischen 11 und 41 Schwangerschaftswochen – ein Update anhand von 10225 normalen Einzelschwangerschaften und Messung der fetalen Parameter mittels 3D-Ultraschall

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ABSTRACT

Objective To construct new growth charts and tables for the following fetal growth parameters: biparietal diameter (BPD), occipitofrontal diameter (OFD), head circumference (HC), abdominal transverse diameter (ATD), abdominal sagittal diameter (ASD), abdominal circumference (AC), femur length (Fe), tibia length (Ti), fibula length (Fi), humerus length (Hu), radius length (Ra), and ulna length (Ul).

Patients and Methods This prospective study was conducted at a level III ultrasound center as a population-based cross-sectional study on 10225 normal singleton pregnancies with a gestational age between 10 and 41 completed weeks. Gestational age was confirmed in all cases by an ultrasound examination with crown-rump measurement before 10 weeks of gestation. All examinations were performed with 3 D probes. BPD, OFD, ATD, and ASD were measured as outer-to-outer measurements (skin-to-skin) after identifying the exact biometric planes by 3 D multiplanar display. HC was computed using the formula $HC = 2.34 \times \sqrt{(BPD^2 + OFD^2)}$. For AC the approximate elliptical formula $AC = (ATD + ASD) / 2 \times 3.142$ was used. Measurements of the limb bones included the entire ossified shaft.

Results Based on a nonlinear regression model for the age-specific mean values, distribution-free reference ranges were calculated for the parameters BPD, OFD, HC, ATD, ASD, AC, Fe, Ti, Fi, Hu, Ra and Ul. The new reference ranges were compared with our reference ranges published in 1996 as well as with different reference charts published by other authors.

Conclusion 3 D ultrasound allows a controlled demonstration of all fetal planes required for exact biometric measurements. The fetal growth profile including the 12 biometric parameters gives a precise overview of normal or abnormal fetal growth.

ZUSAMMENFASSUNG

Ziel Konstruktion neuer Wachstumskurven und -tabellen für die fetalen Wachstumsparameter biparietaler Kopfdurchmesser (BPD), frontookzipitaler Kopfdurchmesser (FOD), Kopfumfang (KU), abdominaler Transversaldurchmesser (ATD), abdominaler Sagittaldurchmesser (ASD), Abdomenumfang

(AU), Femurlänge (Fe), Tibiallänge (Ti), Fibulalänge (Fi), Humeruslänge (Hu), Radiuslänge (Ra) und Ulnalänge (Ul).

Patienten und Methoden Diese prospektive Studie wurde in einem Level-III-Zentrum als populationsbasierte Querschnittsstudie an 10 225 normalen Einlingsschwangerschaften mit einem Schwangerschaftsalter zwischen 10 und 41 kompletten Schwangerschaftswochen (SSW) durchgeführt. Bei allen Schwangeren war das Gestationsalter mittels sonografischer Messung der Scheitel-Steiß-Länge vor 10 SSW gesichert worden. Alle Untersuchungen erfolgten mit 3D-Ultraschallsonden. BPD, FOD, ATD und ASD wurden in Form einer Außen-Außen-Messung (von Haut zu Haut) erfasst, nachdem die Biometrieebenen im 3D-Multiplanarmodus exakt identifiziert waren. Der KU wurde mit Hilfe der Formel $KU = 2,34 \times \sqrt{(BPD^2 + FOD^2)}$, der Abdomenumfang mittels der adaptierten Ellipsenformel $AU = (ATD + ASD) / 2 \times 3,142$ berechnet. Bei den Extremitätenknochen wurde der gesamte ossifizierte Knochenschaft gemessen.

Ergebnisse Basierend auf einem nicht linearen Regressionsmodell für die gestationsbezogenen Mittelwerte wurden verteilungsfreie Referenzbänder für die Parameter BPD, FOD, KU, ATD, ASD, AU, Fe, Ti, Fi, Hu, Ra und Ul berechnet. Die neuen Normkurven wurden mit den Normkurven, die wir 1996 publiziert hatten, wie auch mit verschiedenen in der Literatur publizierten Normkurven anderer Autoren verglichen.

Zusammenfassung 3D-Ultraschall gestattet eine kontrollierte Darstellung aller fetalen Ebenen, die für exakte biometrische Messungen erforderlich sind. Das fetale Wachstumsprofil, bestehend aus den 12 Biometrieparametern, gibt einen präzisen Überblick über ein normales oder abnormales fetales Wachstum.

Introduction

Fetal growth is associated with a number of factors: population characteristics, genetics, parity, nutrition, and environmental parameters. Various investigators have previously constructed fetal growth charts with the use of 2D ultrasound and the majority of these growth charts are integrated in the current ultrasound machines. However, the major part of these growth charts is not comparable due to the use of different study designs, data acquisition prior to 1990 (equipment with low image resolution), different types of measurement [i. e., BPD measurements: bone to bone as outer-to-inner [1–3], outer-to-outer [2–5], middle-to-middle measurements [7], or skin-to-skin measurements [8, 9]] derived from different populations [6, 10–12] and different statistical models and approaches [13, 14]. A systematic review of the methodology used by ultrasound studies of fetal biometry confirmed considerable methodological heterogeneity [15].

Since the publication of our first age-related reference graphs and tables for the head and abdomen parameters and the long limb bones in 1996 [8], the quality of ultrasound machines and abdominal and vaginal probes has improved continuously, enabling a more precise measurement of biometric parameters. Furthermore, 3D ultrasound [16] offers a major benefit over 2D ultrasound not only in the detection and assessment of fetal malformations [17] but also in controlling and correcting biometric planes by means of the two perpendicular planes in the multiplanar display.

Patients and methods

The study design was conducted as a prospective cross-sectional study from 2000 to 2020 and included only singleton pregnancies with gestational age confirmed by CRL measurements before 10 weeks of gestation. All patients were of Caucasian origin and each patient was included only once. Exclusion criteria were multiples, fetal malformations, chromosomal abnormalities, intrauterine growth restriction or macrosomia, oligo- or polyhydramnios, and maternal diseases (diabetes mellitus, hypertension, nicotine

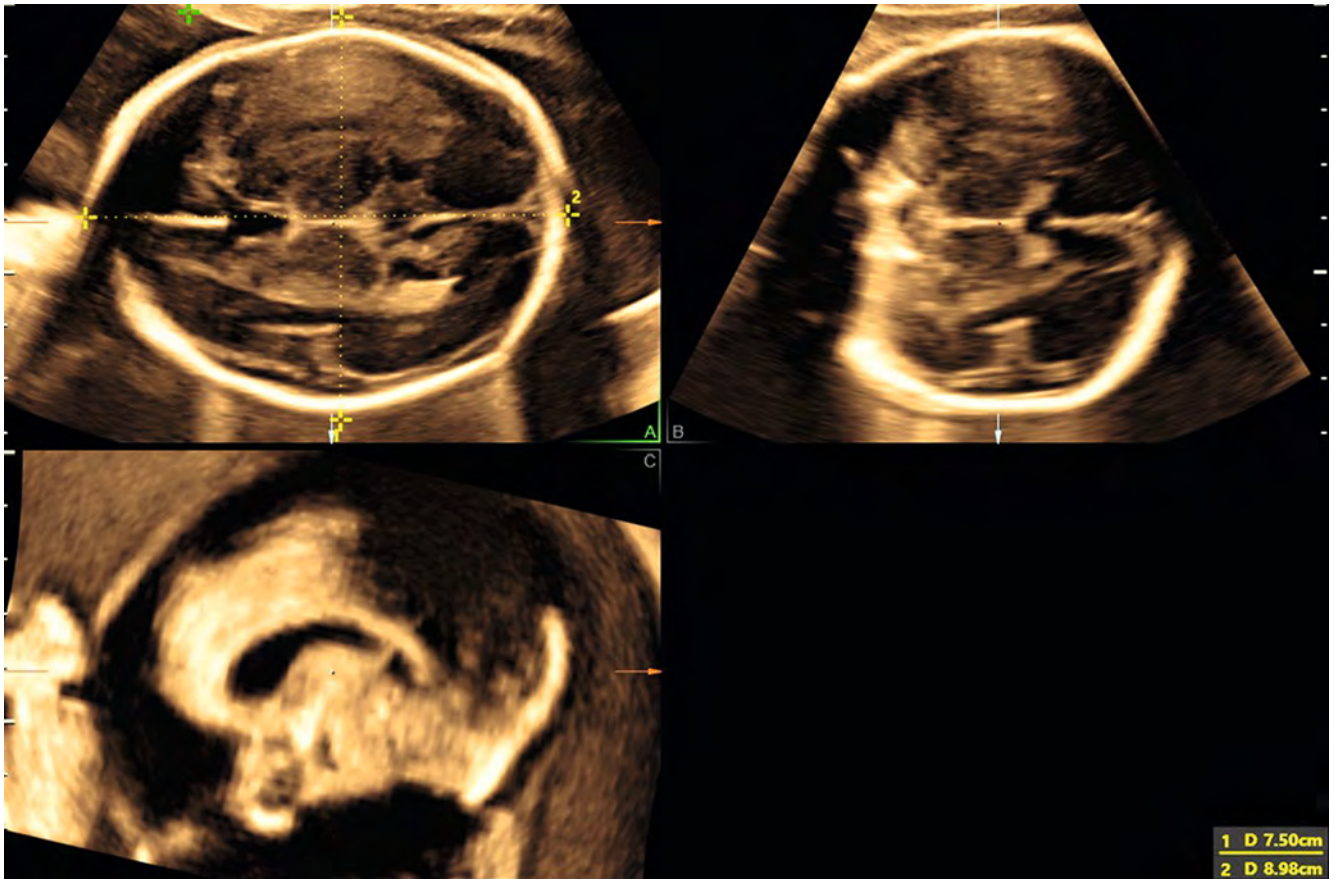
or alcohol abuse, and drug consumption). Informed consent was signed by all patients.

3D measurements were performed between 10 + 0 and 41 + 0 weeks+days of gestation by two experienced operators, using Voluson 730, Voluson E8, Voluson E8 Expert, or Voluson E10 (GE Zipf, Austria) ultrasound equipment with an abdominal 3D (4–8 MHz) or transvaginal 3D probe (5–9 or 6–12 MHz). The measurements were performed in the A-plane of the multiplanar display after aligning the planes under control of the two perpendicular planes into correct standard anatomical planes. BPD and OFD were measured in the exact axial plane of the fetal head at the level where the midline echo is broken by the cavum septi pellucidi in the anterior third and the anterior and posterior horns of the lateral ventricles are seen [4, 18]. ATD and ASD were measured through a transverse section of the fetal abdomen at the level of the stomach with a short demonstration of the umbilical vein entering the portal sinus as indicated by Hansmann [4] and Campbell and Wilkin [19]. Head and abdomen diameters were taken as outer-to-outer measurements, i. e., exactly from the outer boundary of the skin to the outer boundary of the skin (► Fig. 1, 2). Measurements of the long limb bones included the ossified shaft while the bone was visualized in a horizontal position to the probe (► Fig. 3). HC was computed using the formula $HC = 2.34 \times \sqrt{(BPD^2 + FOD^2)}$ [20, 21]. For AC the approximate elliptical formula $AC = (ATD + ASD) / 2 \times 3.142$ [8, 21] was used. Finally, only cases in which all 12 biometric parameters (BPD, OFD, HC, ATD, ASD, AC, Fe, Ti, Fi, Hu, Ra, and Ul) were recorded were taken into account.

Statistical Methods

The distribution-free method we used for the construction of reference bands consists of three major steps.

Step 1: Fitting a nonlinear regression model in order to determine a central line around which the band has to be spanned. The form of this regression function must reflect the way in which the age-specific mean values of the quantity Y under analysis change over time. The model which turned out to be particularly suitable for the fetal growth characteristics considered in this paper is given by the equation:



► **Fig. 1** Multiplanar demonstration of BPD and OFD measurement (a = axial plane, b = coronal plane, c = sagittal plane). 27 + 0 weeks of gestation.

$$y_{pred}(t) = c \cdot \left(d + I_{(t-t')/(t''-t')} (a, b) \right), \quad t' < t < t'' \quad (\star)$$

The symbols appearing in this formula have the following meaning:

$y_{pred}(t)$ = mean value of Y at gestational age t predicted according to the model;

(t', t'') = (smallest, largest) value of t in the population (in the database underlying this paper, the values of t' and t'' are 10.0 and 41.0 weeks);

c = scale parameter;

d = shift parameter;

$$I_x(a, b) = \frac{\Gamma(a+b)}{\Gamma(a)\Gamma(b)} \int_0^x u^{a-1} (1-u)^{b-1} du$$

= incomplete beta integral with parameters a, b evaluated at x .

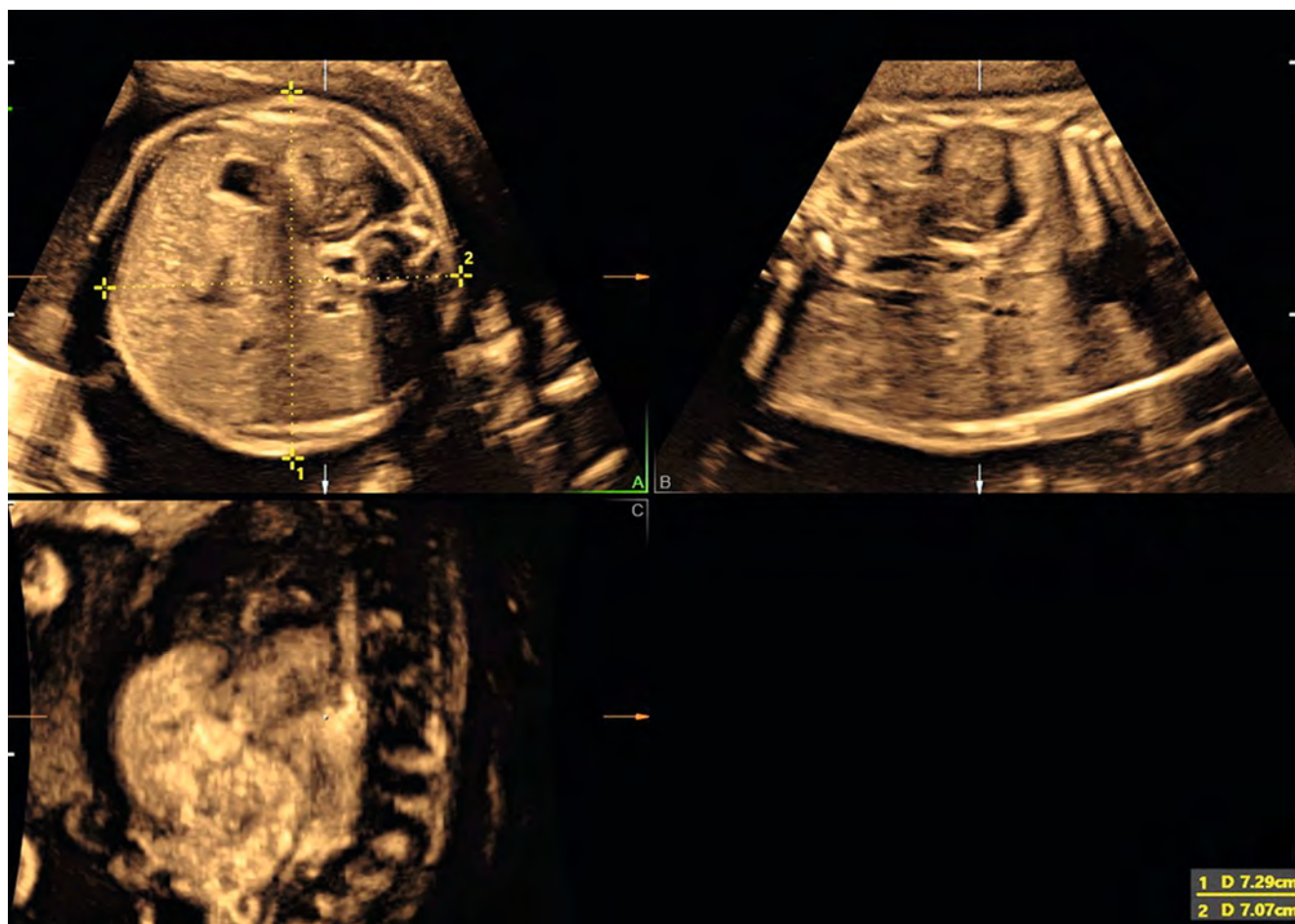
The model parameters a, b, c , and d have to be estimated by means of ordinary least squares fit from the data.

Step 2: Determining the ratio ρ between the width of the reference band at t'' and t' . This constant has to be chosen in a way reflecting possible differences in variability of Y at the boundaries of the time range.

Step 3: Calculating the lower and upper reference limit at time t from the formulae

$$y_*(t) = y_{pred}(t) - \lambda_l \left(1 + \frac{(\rho-1)(t-t')}{t''-t'} \right), \quad y^*(t) = y_{pred}(t) + \lambda_u \left(1 + \frac{(\rho-1)(t-t')}{t''-t'} \right),$$

where λ_l and λ_u are computed by means of an iteration algorithm as the smallest values for which the percentage of data points falling below and above the curve corresponding to $y(t)$ and $y^*(t)$, respectively, is at least 5%. In other words, the ordinates of the data points falling on the lower and upper boundary of the band correspond to smoothed 5th and 95th percentiles, respectively. A detailed description of the statistical method can be found in [14].



► **Fig. 2** Multiplanar demonstration of ATD and ASD measurement (**a** = axial plane, **b** = coronal plane, **c** = sagittal plane). 27 + 0 weeks of gestation.

Assessment of the reliability of the measurements making up our database was done calculating for the i th patient of a selected subsample of size $n = 100$ the quantity

$$\text{RelDev}_i = 100 * |X_i^{(1)} - X_i^{(2)}| / (X_i^{(1)} + X_i^{(2)}),$$

where $X_i^{(1)}$ and $X_i^{(2)}$ denotes the value noted by Examiner 1 and Examiner 2, respectively. The information contained in these percentage interobserver deviations was summarized by calculating their means and standard errors.

Results

A complete biometric profile including all 12 parameters was obtained in 10 225 fetuses with normal outcome.

The mean percentage of the interobserver deviation between the two examiners was 0.504 ± 0.04 , 0.534 ± 0.05 , and 0.554 ± 0.06 for BPD, ATD, and Femur, respectively.

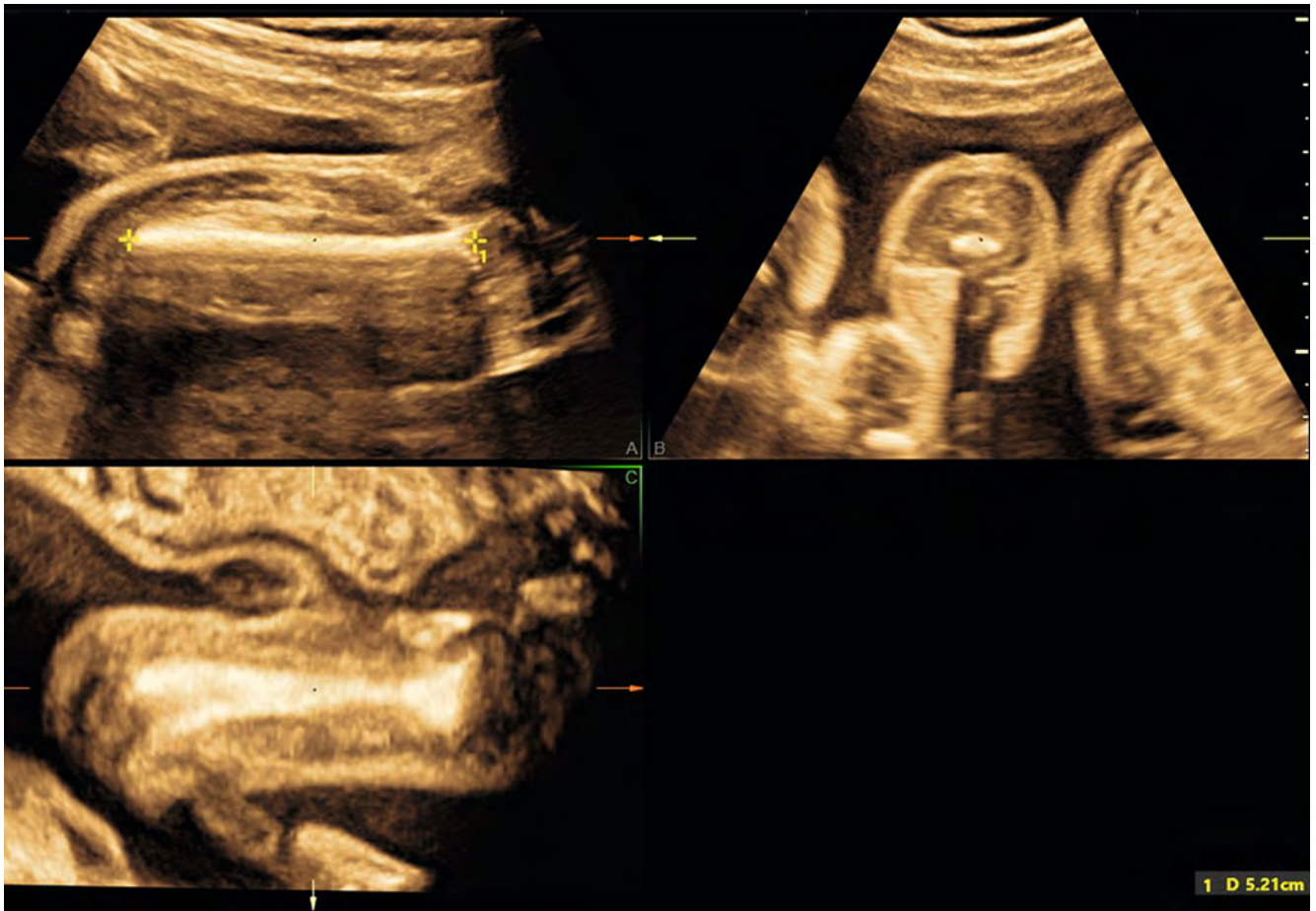
► **Fig. 4** shows the reference band constructed for HC, together with a scatterplot of all individual measurements contained in our database for this quantity. The 90% reference bands for 12 ultrasound parameters are shown in ► **Fig. 5a–f**, **6a–f**. A complete account of the numerical results behind these graphical representations can be found in ► **Table 1**.

The fitted values (5th percentile, mean, and 95th percentile) of all parameters are presented in **Appendix-Table 1, 2**.

The comparison of the described new growth charts with our charts published in 1996 (8) shows slightly higher values in the head and abdomen parameters after 24 weeks of gestation in the new charts but similar values in the long limb bones (► **Fig. 7a–c**).

The comparison of our new growth charts with a selection of growth charts published by other authors [1, 4, 5, 9] (► **Fig. 8a–c**) demonstrates higher mean values of the head parameters in our study, while the mean abdomen values are similar to the mean values reported by Hadlock [1], Knitzka [9] and Snijders [5], at apparently higher mean values reported by Hansmann [4]. The mean values of femur length are similar to the values reported by the compared other growth charts.

The comparison of the variability of our new growth charts with the data of Snijders et al. [5] confirmed a lower variation of the 90% range towards the right-hand boundary of the range of gestational age in the head and abdomen parameters as well as in the femur lengths in our charts (► **Fig. 9a–c**).

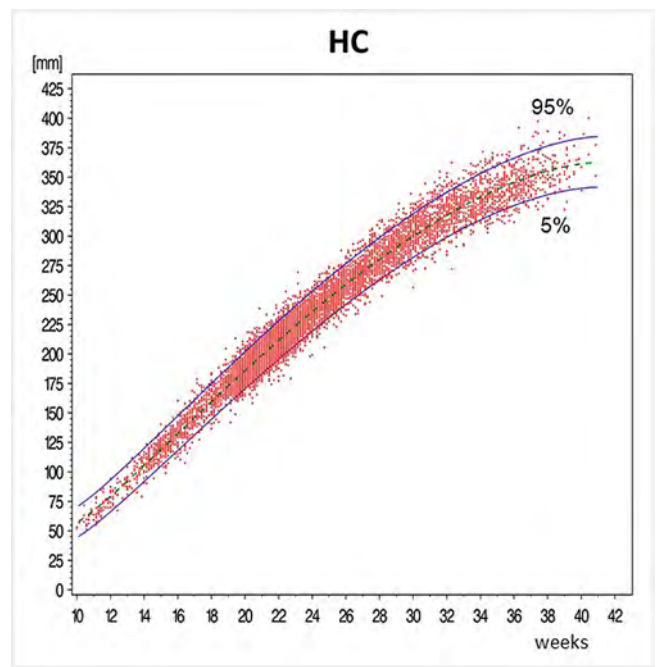


► **Fig. 3** Multiplanar demonstration of femur measurement (a = sagittal plane, b = axial plane, c = coronal plane). 27 + 0 weeks of gestation.

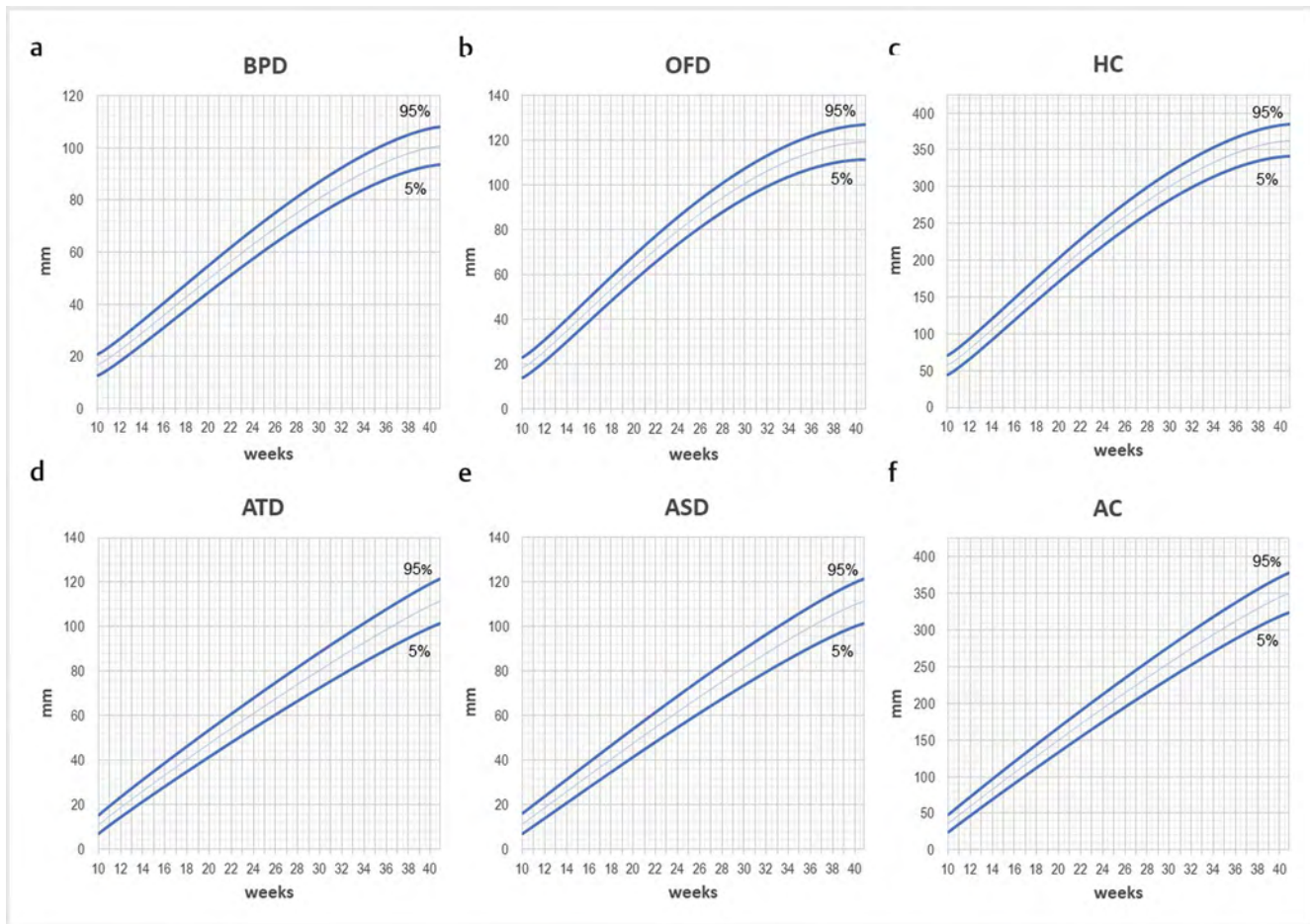
Discussion

Ultrasound has undergone tremendous improvement with regard to 2D and 3D technology and image quality over the past three decades. This has had a significant impact on the delineation of fetal structures, enabling more precise biometric measurements. Furthermore, 3D ultrasound permits storage of volumes and volume manipulation with the use of the multiplanar mode. The demonstration of all three perpendicular 2D planes (A, B, and C plane) on the monitor allows identification of the correct biometric plane, and correction of the A plane with the rotation controls in all three dimensions. Consequently, control of the A plane by the two perpendicular planes enables the operator to detect and correct any imprecise standard plane before performing the measurement.

Updates in growth charts are not only useful with regard to an improvement of the conditions for measurements to obtain more precise data, but also in the detection of fetal growth alterations when comparing the new charts with the older ones. In a recently published study, Knitza et al. [9] found an increase in fetal growth within one generation. A similar finding was noted in our study due to the fact that we used the same standard measurements with the same caliper placements as in our previous study. Comparing our new charts with the growth charts we published in



► **Fig. 4** Scatterplot of head circumference raw data between 10 and 41 weeks of gestation with superimposed fitted 5th percentile, mean, and 95th percentile.



► **Fig. 5** Fetal head and abdomen parameters (a BPD, b FOD, c HC, d ATD, e ASD, f AC) with fitted 5th percentile, mean, and 95th percentile from 10 to 41 weeks of gestation.

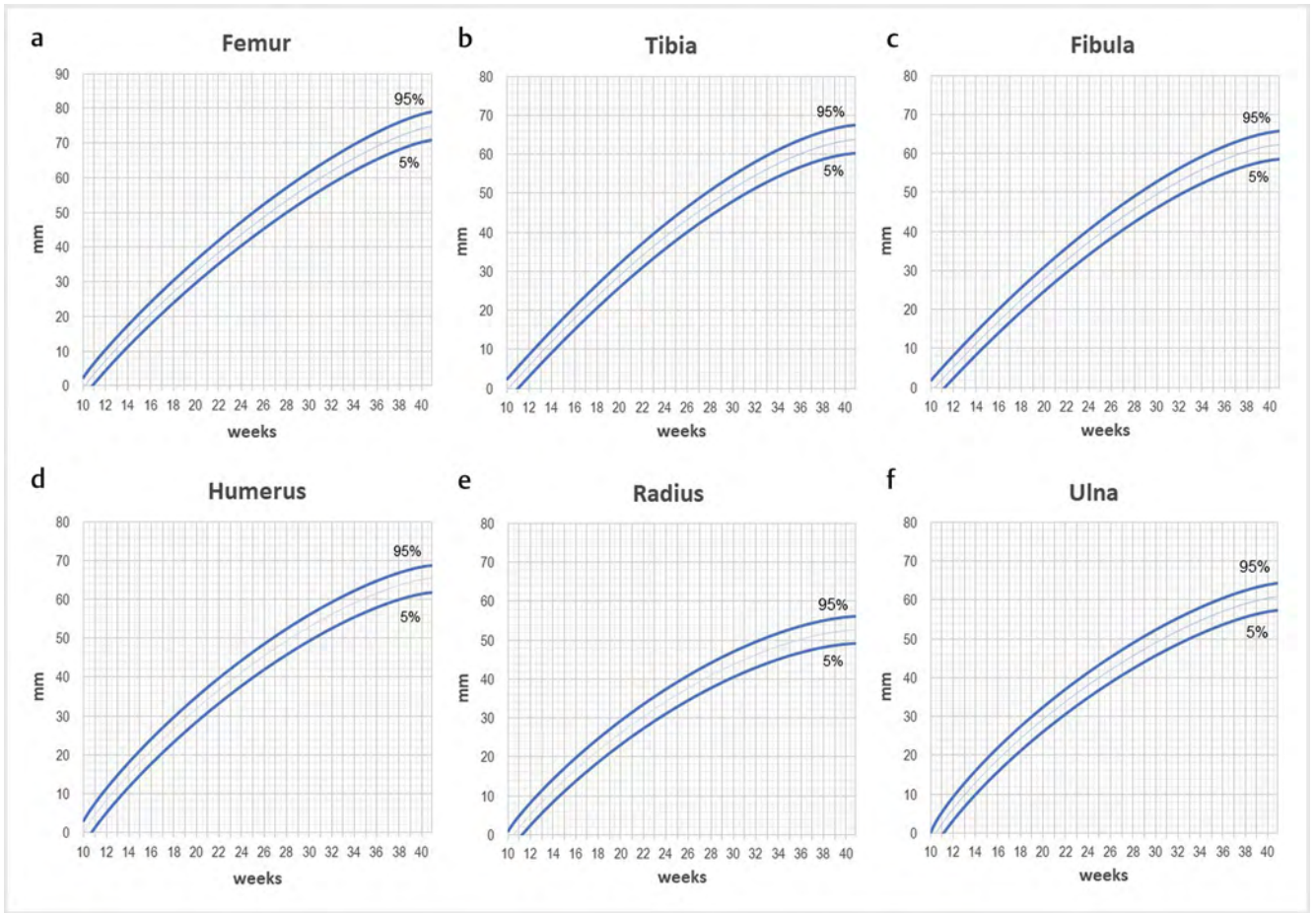
1996 [8], we identified a slight increase in head and abdomen circumference but not in the long limb bones.

The comparison of our new growth charts with charts published in the literature is shown in ► **Fig. 8, 9**. The greatest difference is found in HC, due to different measurements recorded for the biparietal diameter (BPD) ► **Fig. 8** as well as for the range of the reference bands ► **Fig. 9**.

A strength of our study is the homogeneity of the population from which the sample was taken. The resulting reference bands are comparatively narrow and allow early detection of deviations from a normal growth process. This is in contrast to the results of the fetal growth longitudinal study of the INTERGROWTH-21st project [6], a multiethnic, population-based project intending to ensure worldwide applicability of reference limits. However, pooling biometric measurements from different ethnic groups with anthropological differences resulted in reference bands of increased width as compared with the bands obtained in our study. Therefore, it seems doubtful whether basing reference limit estimation on mixed populations is suitable for establishing reference percentiles of worldwide applicability for purposes of early detection of growth abnormalities. A key feature and major strength of the statistical approach used in this study for the construction of reference bands is that it provides direct control over the proportions of data points

to be rated as being either abnormally small or large. This means that the specificity of the diagnostic procedure relying on the age-specific reference limits established here in the (very large) sample of observed pregnant women precisely represents the targeted value of 95% (except for slight, practically irrelevant exceedances due to the discreteness of observed proportions). In contrast, other well-established statistical approaches to the estimation of age-dependent reference limits [22–25] have to rely on a specific model for the distribution of the measured quantity Y under assessment in order to enable maintenance of specificity at least in the long run (i. e., in terms of the distribution of the coverage proportion arising from a large number of repeated applications of the procedure to different datasets).

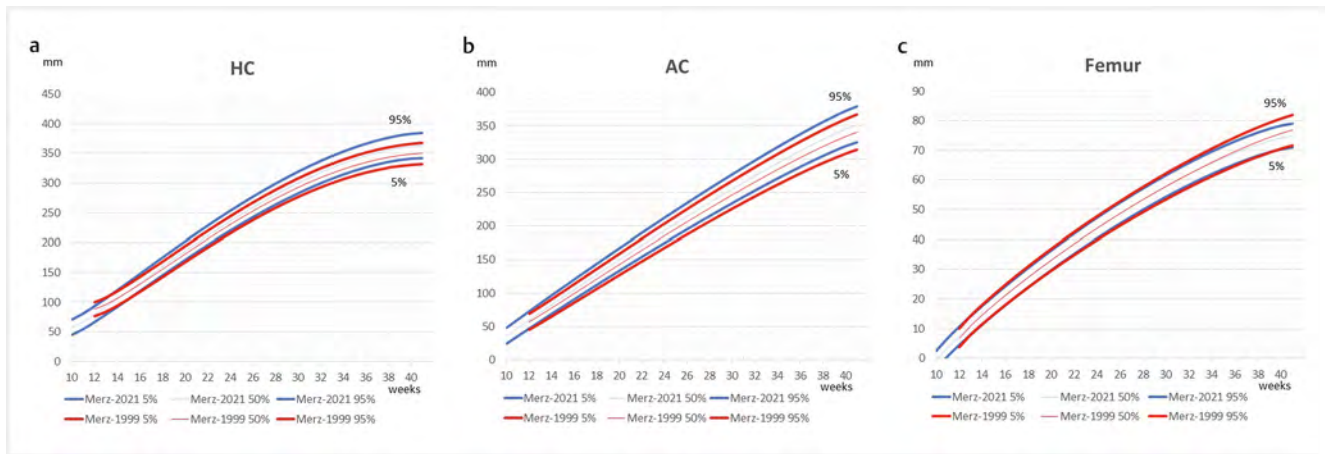
The model given by Equation (★) used to determine the regression line about which the reference band is spanned, showed reasonably good fit for all measurements, with a mean squared error being almost identical to that of a 3rd degree polynomial. In contrast to a polynomial, functions of that form are monotonic which makes the corresponding model perfectly suitable for the analysis of data on variables subject to a growth process.



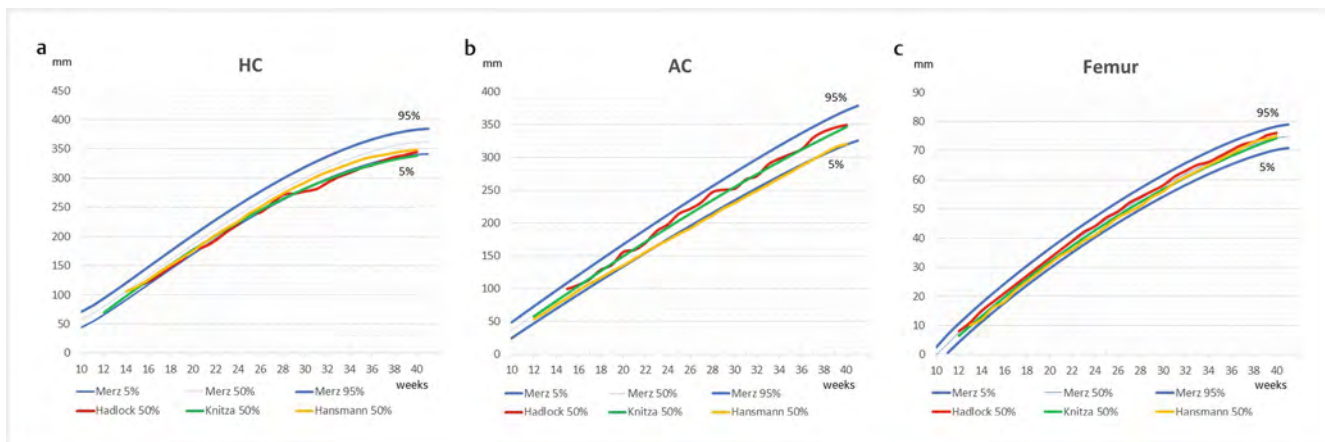
► **Fig. 6** Fetal long bones (a Femur, b Tibia, c Fibula, d Humerus, e Radius, f Ulna) with fitted 5th percentile, mean, and 95th percentile.

► **Table 1** Estimated model parameters and numerical results determining the reference bands shown in ► Fig. 4–6. (For the definition of the symbols appearing in the column headings, see the statistical methods section.)

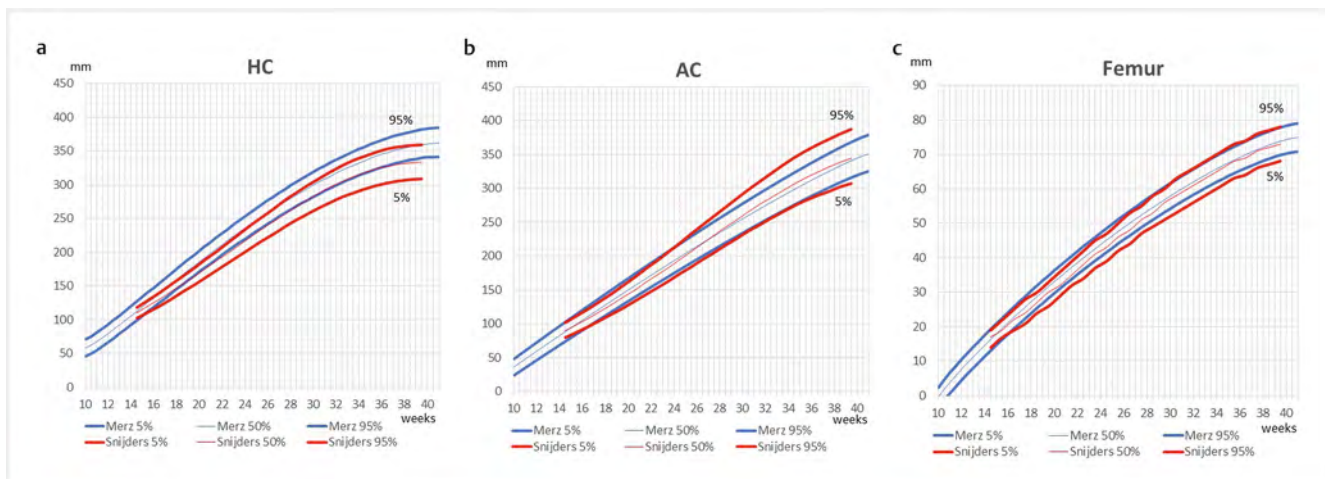
Y	a	b	c	d	ρ	λ_l	λ_u
BPD	1.14943	1.52649	84.0244	0.19919	1.72041	4.1650	4.1719
OFD	1.18451	1.82477	100.730	0.18258	1.73397	4.4766	4.6094
ATD	0.96609	1.10274	100.748	0.11067	2.36895	4.2346	4.2031
ASD	1.01940	1.18073	100.158	0.11562	2.28844	4.5117	4.4277
HC	1.16200	1.69207	305.053	0.18792	1.65794	12.6719	13.2891
AC	0.99287	1.14246	315.606	0.11314	2.20884	11.8350	12.3223
Fe	0.91345	1.35330	75.5703	-0.00847	1.38145	2.9467	3.0211
Hu	0.85826	1.43654	66.1801	-0.01244	1.12215	3.1406	3.0684
Ti	1.00207	1.57249	64.2636	-0.00593	1.25579	2.8223	2.8438
Fi	0.98402	1.52876	63.2465	-0.01658	1.23750	2.8887	2.8330
Ra	0.88751	1.62679	54.6429	-0.03555	1.19848	2.8699	2.8906
Ul	0.81378	1.42009	63.6335	-0.04321	1.12596	3.0898	3.0749



► **Fig. 7** Comparison of our old fitted growth charts of **a** HC, **b** AC and **c** Femur (red color) [7] with the new fitted growth charts (blue color) (5th percentile, mean, and 95th percentile).



► **Fig. 8** Comparison of our new growth charts for **a** HC, **b** AC and **c** Femur (5th percentile, mean, and 95th percentile (blue color)) with the corresponding growth charts (50th percentiles) of Hadlock [1] (red color), Hansmann [4] (yellow color), and Knitza [8] (green color).



► **Fig. 9** Comparison of our new growth charts for **a** HC, **b** AC and **c** Femur (blue color) (5th percentile, mean, and 95th percentile) with the 5th, 50th and 95th percentiles of the growth charts of Snijders et al. [5] (red color).

Conclusions

The new reference charts for fetal head and abdomen parameters as well as for the long limb bones derived from our prospective cross-sectional study enable the operator to closely observe the growth profile of fetuses (12 growth parameters) from 10 to 41 completed weeks of gestation. Three-dimensional ultrasound – in comparison to 2D ultrasound – allows the demonstration of the different biometric parameters in exactly controlled standard planes and thus enables precise measurements.

The comparison of the new charts with our charts published in 1996 [8] reveals a slight increase in head and abdomen size over the past two decades, while no significant differences were observed for the limb bones over this time.

The comparison of our new growth charts with a selection of charts published in the literature demonstrates a difference in mean values and variation within the 90% range.

The data from this study could be an integrative component in future automated measurement programs controlling fetal growth profiles.

Conflict of Interest

The authors declare that they have no conflict of interest.

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