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WHITE PAPER

The Clinical Usefulness of Volume NT™ Using Three-dimensional (3D) Ultrasound (US)

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INTRODUCTION & OBJECTIVES

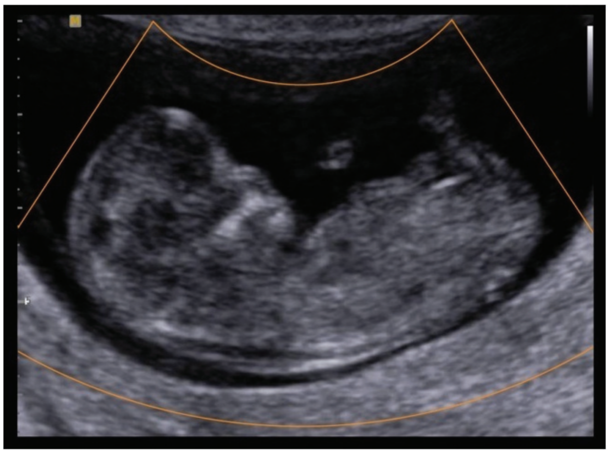
Nuchal translucency (NT) is a highly sensitive screening tool for both fetal aneuploidy and congenital structural anomalies including congenital heart defects; it is gaining in popularity and acceptance among both patients and clinicians.[1] In combination with maternal serum, PAPP-A and free beta-hCG, increased NT have been demonstrated to provide efficient Down's syndrome risk assessment, with a detection rate of 80-87% (5% false-positive rate), and it also allows earlier diagnosis of fetal aneuploidy.[2-3]

A correct NT measurement is determined by the quality of the image, the magnification, the angle of insonation, the B-mode image (gray scale) settings, and proper placement of the calipers.[4] Simple errors in measurement may have a significant effect on risk assessment. Therefore, to preserve the high efficacy of NT as a risk assessment tool, the ability and accuracy of operators in order to acquire a reliable measurement of NT is important.[5]

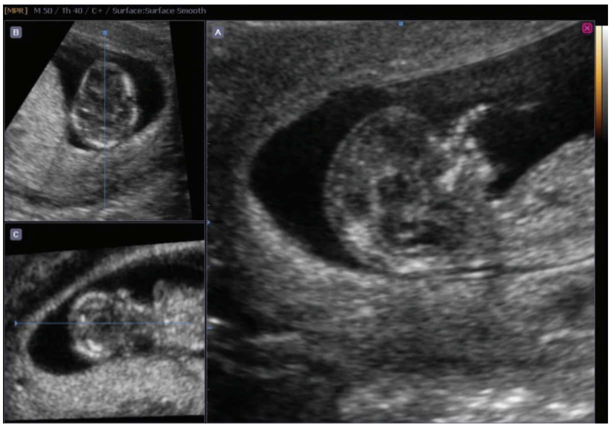
In this study, we used three-dimensional (3D) ultrasound (US) for the detection of the mid-sagittal section. The purposes of this study are to evaluate the clinical usefulness of semi-automated measurement of NT using 3D US and to investigate whether the clinical experience of the operators has an effect on the accuracy of the measurement of NT.

METHODS

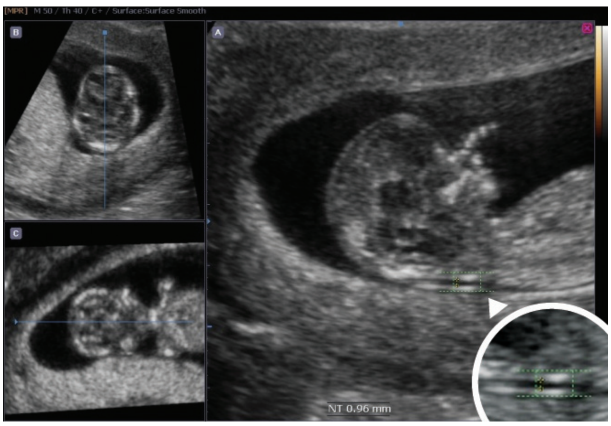
Between July and November 2010, ultrasound examination was performed on 107 pregnant patients at 11-13^{+6} weeks' gestation. Two experienced operators participated in this study. Each operator manually measured the nuchal translucency and also automatically using Volume NT™ software. One inexperienced operator then examined 10 of the pregnant patients. Each operator was blinded to any pre-existing measurements, all of which had been acquired trans-abdominally using an Accuvix V20 Prestige v2.03 with the V4-8 probe (MEDISON Co., Ltd, Seoul, Korea).



A. Volume Scanning in the 3D Mode



B. Seed Point for the Mid-sagittal View;
Set a seed point in Diencephalon / Thalamus



C. Automatic NT Measurement;
Set an ROI box in the NT area
The NT value is the maximum value in of the ROI

***Figure 1.** Automatic NT measurement using Volume NT™*

The identical protocol was performed by each operator. Manual measurement of the NT was performed according to the FMF guidelines.

Automatic measurement of the NT with Volume NT™ from on to on of the two echogenic lines delineating the nuchal translucency, is demonstrated in Figure 1.

In an approximated, mid-sagittal section determined by conventional B-mode ultrasound, the operator pressed on the Volume NT button, after which the 3D volume data was obtained by a sweep of the transducer. When the most representative mid-sagittal section appeared, the operator placed the ROI box in the nuchal area and the scanner automatically selected the best measurement. The upper caliper was then placed automatically on the inner border of the upper echogenic line. The lower caliper was then placed automatically on the inner border of the lower echogenic line (on to on measurement).

The nuchal translucency was measured using 2D harmonic, 2D non-harmonic, 3D harmonic, and 3D non-harmonic US. Three attempts were made to obtain each nuchal translucency measurement (for a total of twelve measurements per patient). The mean and maximum of both the two- and three-dimensional measurements were then compared. The intraclass correlation coefficient (ICC) was used to assess the reliability and repeatability.

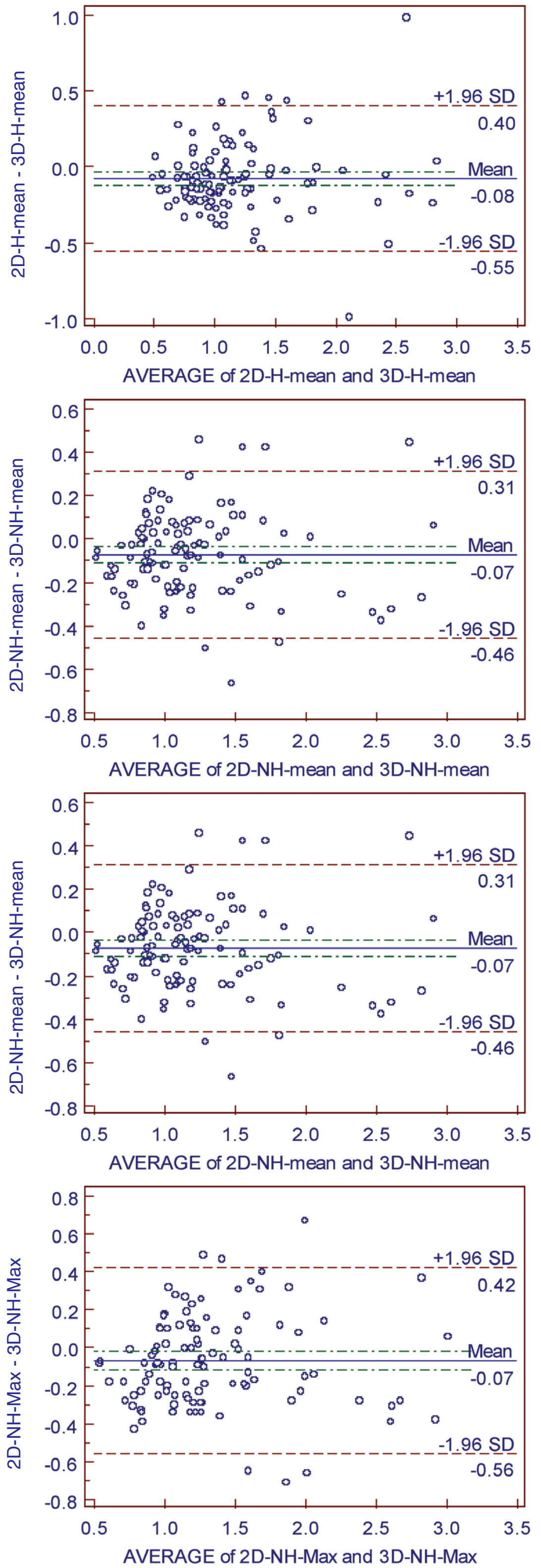


Figure 3. *Bland and Altman scatter diagrams showing the intra-operator difference in the means and the max between the 2D and 3D NT values (in mm).*

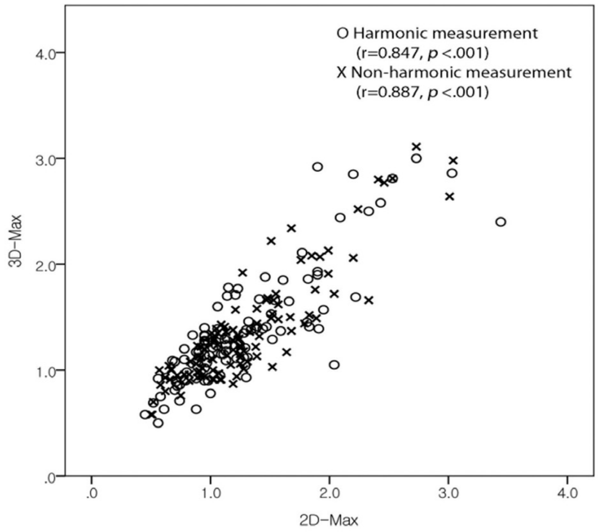


Figure 2. *Pearson's correlation coefficient test of 2D maximal value and 3D maximal value*

RESULTS

1. The correlation coefficient for the max 2D and 3D harmonic measurements was 0.847 ($p<.001$); for the max 2D and 3D non-harmonic measurements it was 0.887 ($p<.001$) (Fig. 2).

2. The nuchal translucency using three-dimensional ultrasound was significantly greater than that using two-dimensional ultrasound (Table 1).

3. The intra-operator repeatability was assessed using intraclass correlation coefficients (ICC) varying from 0.941 to 0.967 for the experienced operators (Table 2).

4. The inter-operator difference in nuchal translucency for the experienced operator and the inexperienced operator was significant using two-dimensional ultrasound (0.072 ± 0.081 vs. 0.131 ± 0.065, $p=0.022$), unlike that using three-dimensional ultrasound (0.191 ± 0.106 vs. 0.166 ± 0.071, $p=1.0$) (Table 3).

Table 1. *Comparison of the value of 2D and 3D measurement by experienced operators*

Variable		Mean ± 2SD (mm)	Mean Difference (mm)	*p*-value
Harmonic Mean	2D 3D	1.24 ± 0.84 1.31 ± 0.81	0.073	.003
Harmonic Max	2D 3D	1.36 ± 0.91 1.44 ± 0.87	0.095	.002
Non-harmonic Mean	2D 3D	1.28 ± 0.85 1.29 ± 0.61	0.076	<.001
Non-harmonic Max	2D 3D	1.40 ± 0.89 1.40 ± 0.64	0.077	.003

Table 2. *Intra-operator repeatability with experienced operators; Intraclass Correlation Coefficient (ICC)*

Variable	N	ICC
2D Harmonic	107	0.963
2D Non-Harmonic	107	0.967
3D Harmonic	107	0.959
3D Non-Harmonic	107	0.941

Table 3. *Difference of 2D and 3D NT measurement by operators with different levels of related clinical experience*

Variable	Experienced	Inexperienced	*p*-value
2D (mm)	0.131 ± 0.065	0.072 ± 0.081	.022
3D (mm)	0.166 ± 0.071	0.191 ± 0.106	1.0

CONCLUSION

In this study, the results of the measurements were highly correlated. However, a significant difference in the means and the max between the 2D and 3D results was observed. This suggests that the Volume NT™ provides a more accurate, mid-sagittal section and detects the deepest pocket of NT.

The intra- and inter-operator reproducibility of Volume NT™ is high. Therefore, automation of the nuchal translucency measurement may substantially reduce the within and between operator variation in the measurement of NT achieved using the traditional, manual approach. In particular, it may be useful for inexperienced operators in order to improve the intra- and inter-operator reliability.

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