

White Paper

First Trimester Screening with the ACUSON Sequoia™ Ultrasound System

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Introduction

Extensive evidence now exists that screening for Down syndrome can be provided to women in the first trimester of pregnancy that exceeds the effectiveness of current second trimester serum screening. Screening by a combination of nuchal translucency (NT) and two blood markers, free beta hCG and PAPP-A, have a Down syndrome detection rate approaching 90% for a 5% screen-positive rate. Two large NICHD-sponsored USA studies (BUN¹ and FASTER²) have produced results that support the effectiveness of first trimester screening. The American College of Obstetricians and Gynecologists released a Committee Opinion³ in July 2004 endorsing first trimester screening using a combination of NT, free beta hCG, and PAPP-A. More recently, the absence of the nasal bone, demonstrated by ultrasound in the first trimester and studied prospectively in over 15,000 pregnancies, has been shown to be a powerful marker for Down syndrome, on its own identifying 69% of the Down syndrome cases for a very low screen-positive rate of 1.4%⁴. However, investigators and professional societies agree that the effectiveness of NT depends completely upon its execution in a standardized and consistent fashion. This can only be accomplished with appropriate training, rigorous initial qualification, and ongoing oversight.

Techniques for measuring the NT and assessing the nasal bone have been developed by Prof. Kypros Nicolaides and his co-workers at the Fetal Medicine Foundation (FMF) in London. The FMF's program of education, training, and ongoing audit is in place in more than 16 countries worldwide, including the United States. More recently, the Society of Maternal Fetal Medicine Specialists has developed and instituted a program with similar goals. Both groups teach the FMF's single unified technique for NT measurement.

The basic principles of the FMF technique for measuring the NT are:

- The crown-rump length should be between 45.0 and 84.0mm.
- The fetal head, neck, and upper thorax should be magnified so that they fill the image area.
- The fetus should be viewed in the midsagittal plane, with the fetal profile, including the nose, clearly seen. The whole NT area, from the back of the head down to the mid-thorax, should be seen in one view.
- The amnion should be seen separate from the back of the fetal neck.
- The fetal head should be in a neutral position, neither flexed (curled) nor extended (arched).
- The lines that make up the NT should be sharp and clear.
- The calipers should be placed so that the horizontal crossbars of the calipers border the nuchal fluid space on either side. No part of the horizontal crossbar should lie within the nuchal fluid space, as this would cause an underestimate of the NT. Conversely, the horizontal crossbar should not lie entirely imbedded within the white line, as this would cause an overestimate of the NT.

The FMF protocol for assessing the nasal bone is:

- The crown-rump length should be between 45.0 and 84.0mm.
- The fetus should be viewed in the midsagittal plane.
- The nasal bone should be seen as brighter and thicker than the overlying skin.
- The angle of insonation should be perpendicular to the plane of the nasal bone.
- The fetus should be large enough in the image so that the skin and bone can be seen distinct from one another.

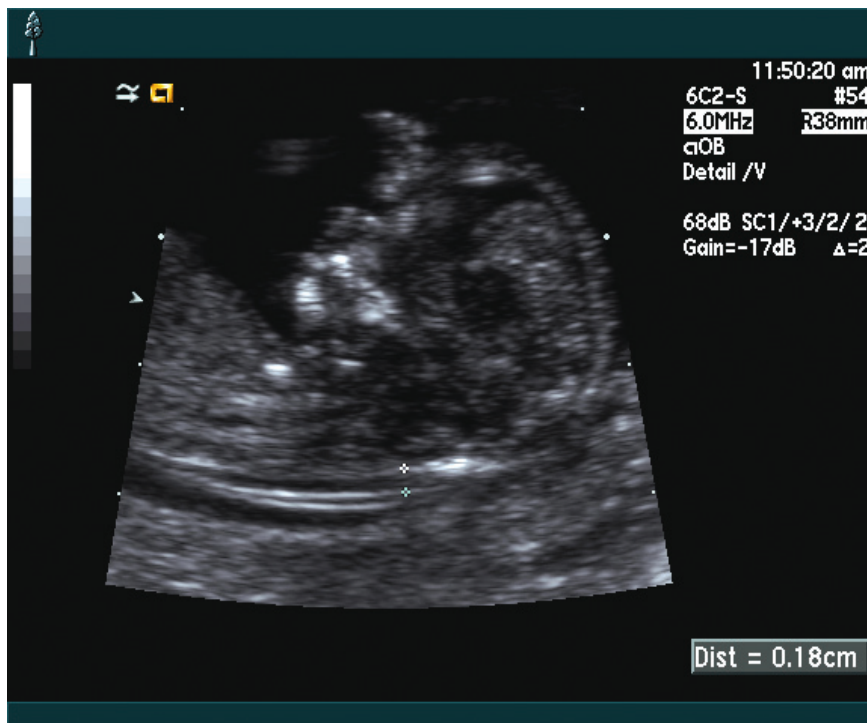
The purpose of this paper is to introduce a method of optimizing the Sequoia ultrasound system to produce accurate and consistent NT measurements and clear-cut assessment of the nasal bone.

Materials and Methods

The Sequoia system has many standard and optional features that can be utilized to produce ideal NT and nasal bone images in first trimester screening for aneuploidy. Settings can be created and stored for easy, one-step acquisition.

NT Measurement using the 6C2 transducer

- Select the OB Exam Preset.
- Select "Detail" image preset from the Options menu.
- Using MultiHz key, select the highest fundamental frequency (the highest number without an "H").
- Using the Space Time control, select Spatial Compounding (SC1). Spatial Compounding is an optional feature that improves resolution by reduction of image speckle. If Spatial Compounding is not available, select S2.
- Using the Edge control, select +3.
- Set Persistence to 0, 1, or 2 — depending on the patient.
- Set Postprocessing to 2.
- The overall depth should be decreased such that the bottom of the image area coincides with the posterior uterine wall. The sector width should be narrowed. The Sequoia system is designed to allow sector narrowing and then steering to follow the fetus within the original sector. The narrowed sector should contain the fetus from crown to rump.

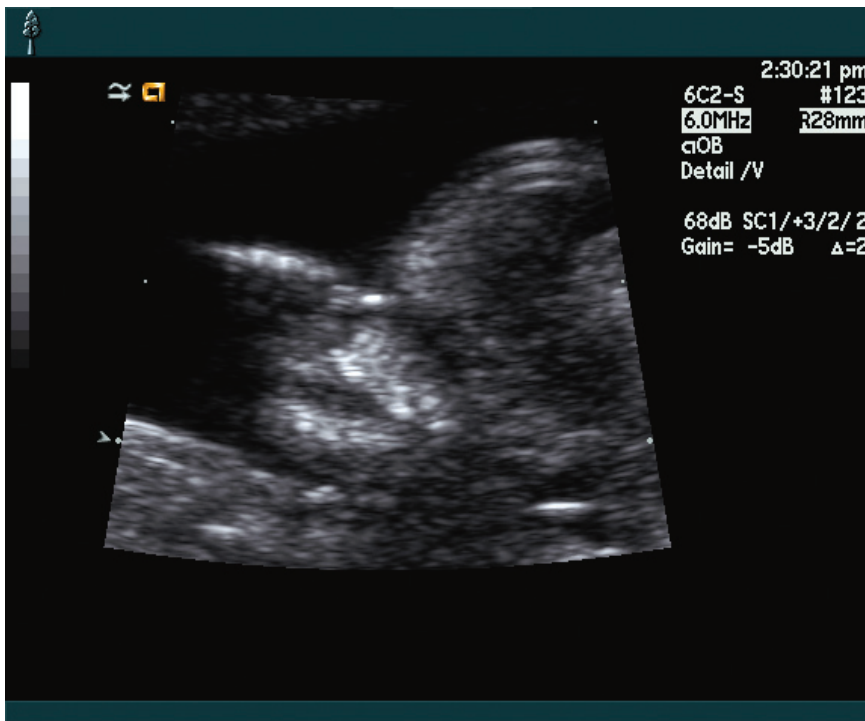


Nuchal Translucency with optimized settings and proper placement of calipers

- The RES control should now be activated. The box size should be adjusted so that there is approximately 1cm above (anterior to) and below (posterior to) the fetus. The width of the box should include the area from the top of the head through the mid-thorax. RES™ enhanced resolution imaging will not only enlarge the area of interest, but will increase image resolution allowing accurate placement of calipers.
- Activate the “+” caliper. Set the top caliper: move from above the fetus in a downward sweep until the horizontal crossbar of the caliper faces the nuchal fluid space. No part of the crossbar should be in the nuchal fluid and, conversely, it should not be entirely imbedded within the white line. Repeat for the bottom caliper, but this time sweep upward from below the fetus.

Nasal bone assessment using the 6C2 transducer

- The same settings can be used for assessing the nasal bone as those described above for NT measurements.
- The angle of insonation should be perpendicular to the plane of the nasal bone. It is possible that an image used to assess the nasal bone will not be appropriate for measuring the NT, due to the angle of insonation.



Nasal Bone seen during 12-week fetal assessment

Discussion

Calculation of patient-specific risk of Down syndrome in the first trimester uses maternal and gestational age along with NT measurements and the presence/absence of the nasal bone. The Fetal Medicine Foundation's risk calculation algorithm was developed on the basis of information gathered from more than 100,000 pregnancies, with all NTs measured using the same technique as described above. Therefore, it is imperative that all practitioners who wish to provide their patients with accurate individualized risk estimates based on first trimester ultrasound and biochemical markers are certain they are obtaining NT measurements in the same way the original data was obtained. The most important element of the accreditation process is the submission of images for review and feedback. Images are submitted in batches of 10 initially; then in subsequent sets of 5 until such time as the practitioner demonstrates consistent conformity with the technique. In some cases, a videotape or CD with video clips is requested to give the reviewer a closer vantage point of the applicant's real-time approach to obtaining the measurement.

It is projected that the above guidelines for optimizing the Sequoia system for first trimester aneuploidy screening will reduce the number of images that users will need to submit and thereby shorten the accreditation process. In addition, storing the settings suggested in the preceding paragraphs as an NT Image Preset will facilitate consistency over time, as the practitioner moves forward with incorporating NT into everyday clinical practice. Ongoing quality assurance for NT measurements is a vital part of the Fetal Medicine Foundation's process, ensuring that providers do not drift from the correct technique over time. With Image Presets, conformity of the appearance of the NT in images over time will enable users to stay on target with measurements and continue to provide accurate individualized aneuploidy risks to their patients.

REFERENCES

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2. Submitted for publication
3. ACOG Committee Opinion Number 296, July 2004
4. Nicolaides KH; Nuchal translucency and other first-trimester sonographic markers of chromosomal abnormalities. Am J Obstet Gynecol. 2004 Jul;191(1):45-67. Review.

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