New US techniques and applications and safety considerations

Jacques S. Abramowicz, MD
Professor of Ob/Gyn, Director of Ultrasound and co-Director of Rush Fetal and Neonatal Medicine Center
Rush University Medical Center
Chicago, IL

Disclaimer
I have no conflict of interest with respect to any of the material presented in this lecture. I am on the Ob/Gyn Board of advisors of Philips Medical and Siemens. I will not discuss off-label or unapproved uses of drugs or devices.

New technologies
“Is all this safe for my baby?”

New technologies
In general, all intended to improve diagnosis by improving resolution...

But there are others...

Elastography
Ultrasonic attenuation
Ultrasound contrast agents
Others...
...The xMatrix probe
Elastography

Dynamic technique that uses ultrasound to provide an estimation of tissue stiffness by measuring the degree of distortion under the application of an external force (ultrasound)


Ultrasound attenuation

Loss of energy as an ultrasonic wave propagates through tissue (by scattering and absorption)


Ultrasound Contrast agents


Abramowicz JS. Ultrasonographic contrast media: has the time come in obstetrics and gynecology? J Ultrasound Med. 2005;24:517-31

Ultrasound Contrast agents

Ovarian tumors


xMatrix technology

xMATRIX-the big words

9000 active elements
Ultrathin slices
Uniform (isovoxel) resolution
Artifact reduction
Fine details at depth

X-plane
Whole volume scanning (100°)
Fixed elevation focus
Very uniform thickness (determined by beam former)
Thick slice (elevation compounding): reduces speckle and increases contrast resolution
Two exactly orthogonal planes, hence best volume measurement
High quality MPR
The new iU22 system with xMATRIX technology—what does it do?

- All modes with one transducer – 2D, 3D/4D, Live xPlane, Live MPR, MPR, Doppler, color Doppler, CPA
- Save time – no changing transducers and no disruption of examination
- Easily integrate volume imaging into exam protocols
- Instantly interrogate regions of interest in any plane

**xMATRIX—the real stuff**

Single transducer for 2D, 3D, 4D, 5D
No loss of resolution
Very improved C plane resolution
Very fast acquisition [<1sec]
(important for fetal scanning)
Minimal movements (ergonomics)
Better assessment of anatomy/pathology

**Remember**

This is not a fast reconstructed plane
These are 2 planes being scanned and displayed simultaneously
What does the xMATRIX bring to me in my daily practice?

Simultaneous views of longitudinal and transverse planes of
1. Spine
2. Face(lips)
3. Palate
4. Heart
5. Limbs
6. Lost IUD
7. Pelvic organs/masses relations (although TV xMATRIX would be preferable...)

4D

5D
A miniresearch project

Whole spine (longitudinal and transverse views)

Number of movements (transducer or wrist)
Traditional probe  xMATRIX
8  1

Time  1min 12 sec  22sec

Let’s talk about STIC
Spatio-Temporal Image Correlation

Time: 12-14 seconds
Don’t all these technologies emit higher acoustic power and are they not more dangerous to the fetus?

Of course, ultrasound is safe. Why even speak about this at the 35th Annual Vanderbilt Diagnostic Sonography Symposium?

Ultrasound= Energy

Ultrasound=waveform with positive and negative pressures

Thermal energy (indirect)

Mechanical energy (direct): positive pressure causes movements, negative pressure can induce cavitation

So, ultrasound going through living tissues causes effects (bioeffects)... ...but there are no epidemiological studies demonstrating harmful bioeffects in humans

All epidemiological studies are about exposure before 1992

In 1992, maximal acoustic outputs for fetal applications were allowed to be increased by a factor of 8 (from 94mW/cm² to 720mW/cm², I₅₀TA)

FDA mandated (together with AIUM, NEMA, public representatives): the Output Display Standard (ODS)

Manufacturers may increase maximal output (up to 720mw/cm² for fetal use) on the condition that certain indices were displayed to somehow express the risk to the end-user:

• TI for thermal effects
• MI for non-thermal (a.k.a. mechanical) effects
• AND: a particular effort is to be made to educate the end-users about bioeffects, safety and the new indices

Thermal index (TI)
Unitless estimate of possible tissue temperature rise in °C under “reasonable worst-case conditions”

$$TI = \frac{\text{total acoustic power}}{\text{acoustic power needed to raise temperature by } 1 \, ^\circ C}$$

Predicts potential for temperature increase

Not a real temperature measurement

No time (duration of exposure) information
Thermal index

$T_{I_1}$: soft tissues

$T_{I_2}$: bones

$T_{I_3}$: cranium

Mechanical Index (MI)

MI expresses potential to induce inertial cavitation: bubbles must be present

No bubbles in fetal lungs or bowels

Hence, mechanical risk appears to be low

Manufacturers must display TI and MI on screen

Maximum recommended exposure times for embryo/fetus

<table>
<thead>
<tr>
<th>TI</th>
<th>Maximum exposure (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>60</td>
</tr>
<tr>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>1.5</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2.5</td>
<td>1</td>
</tr>
</tbody>
</table>


Sheiner E, Shoham-Vardi I, Pombar X, Hussey MJ, Strassner HT, Abramowicz JS: Increased thermal index can be achieved when performing Doppler studies in obstetrical ultrasound, J Ultrasound Med 26:71-6, 2007

Second part of the FDA mandate: 
education of the clinical user


Is Doppler worse?

Mean intensity (I_{SPTA})

B-mode: 34mW/cm^2
Color Doppler: 270mW/cm^2
Spectral Doppler: 1080mW/cm^2

About 25% of end-users know what TI and MI stand for and indicate

About 2/3 do not know where to find the indices during the examination

Marsal K, UOG 2006
Sheiner & Abramowicz, JUM 2008
NT, nasal bone, maxillary angle are obtained with B-mode (low ultrasound energy). For „entire assessment” tricuspid valve and ductus venosus have to be „Doppler’d”

Thank you