13th Asian and Oceanic Society of Regional Anesthesia and Pain Medicine Congress

Combined with the 81st Annual Meeting of the Royal College of Anesthesiologists of Thailand

AOSRA-PM 2015

BIOLOGICAL EFFECTS OF ULTRASOUND

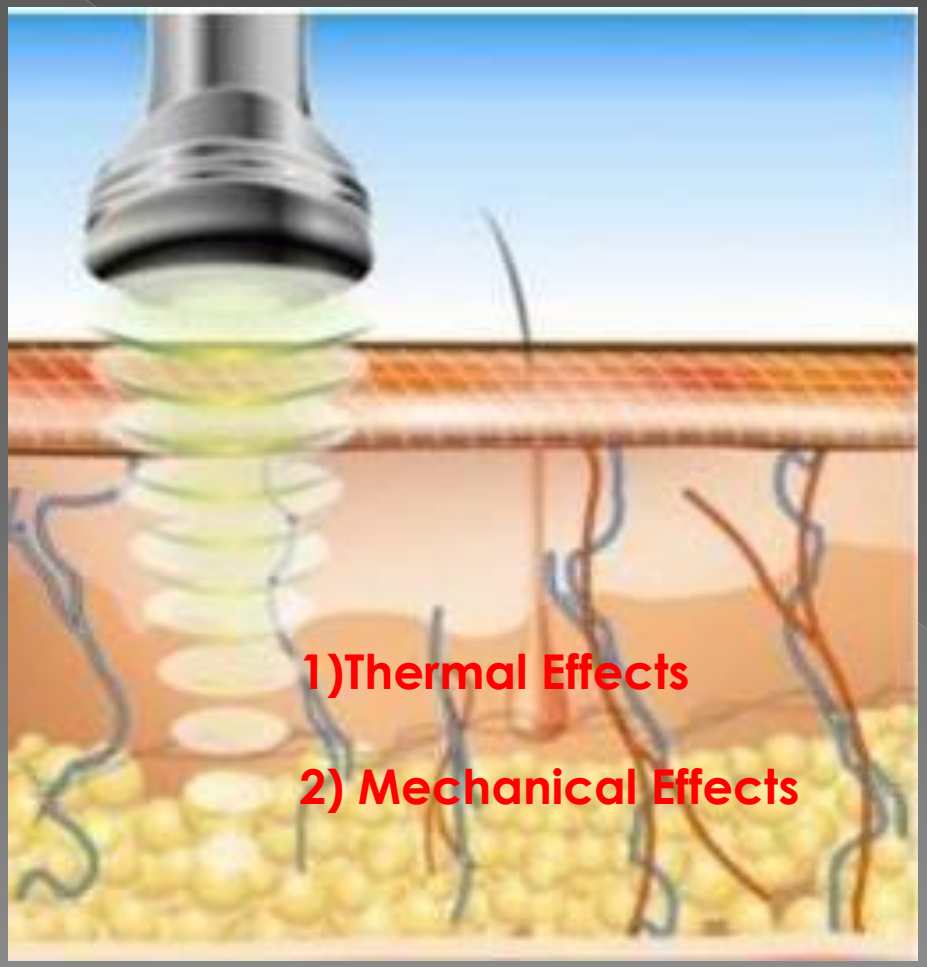
ARE THERE ANY SAFETY ISSUES?

(In collaboration with Malaysia SIGRA)

Dr Ling Kwong Ung,
Anaesthetist,
Ramsay-Sime Darby Medical Centre,
Ara Damansara,
Malaysia.
lingkupisces@yahoo.com

Ramsay-Sime Darby Medical Centre Ara Damansara, Selangor, Malaysia

Biological Effects of US

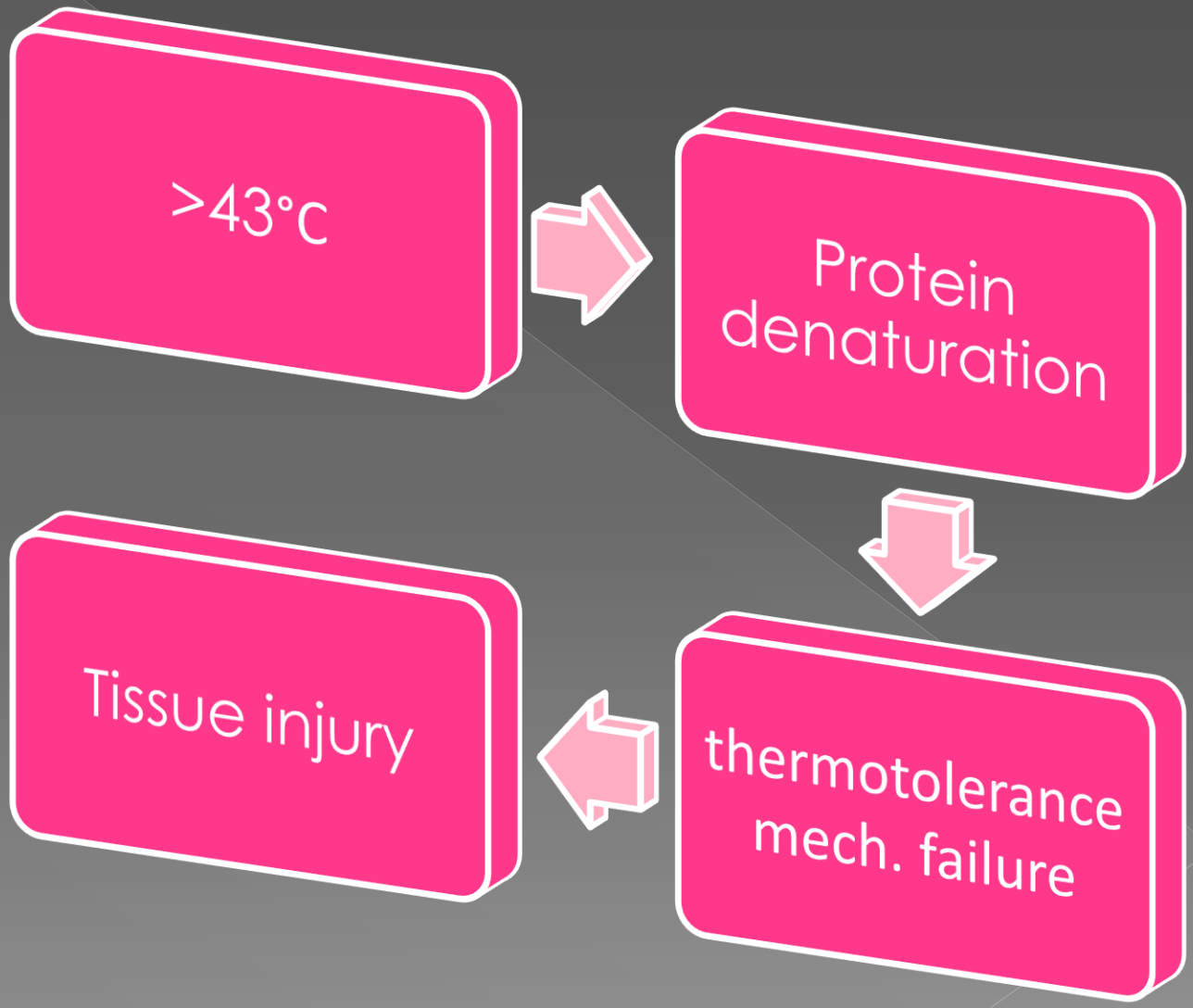


1) Thermal Effects

- When US travels through tissue, energy is absorbed by the tissue components and converted to heat.

Thermal Effects	=	Treatment Time	X	Heating rate per minute

Thermal Effects



1) Thermal Effects

Tissue injury caused by heat

- Necrosis
- Apoptosis (programmed cell death)
- Abnormal cell migration
- Altered gene expression/ teratogen
- Membrane dysfunction
- Changes in myelination
- Cell damage in neuronal cell

Thermal Effects

Table 3. Causes for Tissue Temperature Changes by Ultrasound

Ultrasound Parameters	Tissue Characteristics
Frequency	Attenuation
Focusing	Absorption coefficient
Pulse repetition frequency	Acoustic impedance
Pulse duration	Thermal conductivity
Transducer self-heating	Tissue perfusion
Exposure time	Nonlinear propagation
Intensity	Density
Beam width	Protein content

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Higher Frequency : less heat

Lower frequency : more heat

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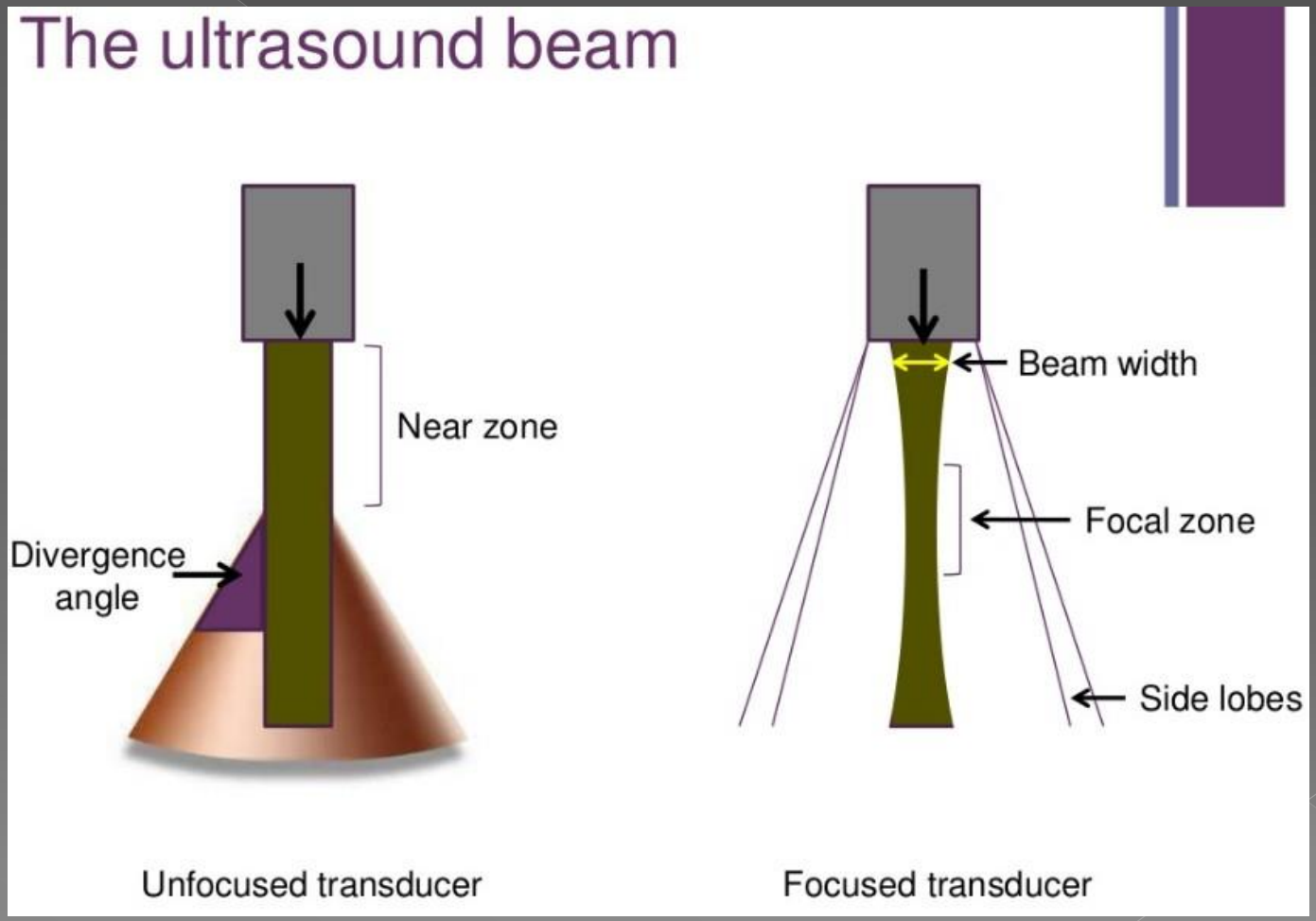
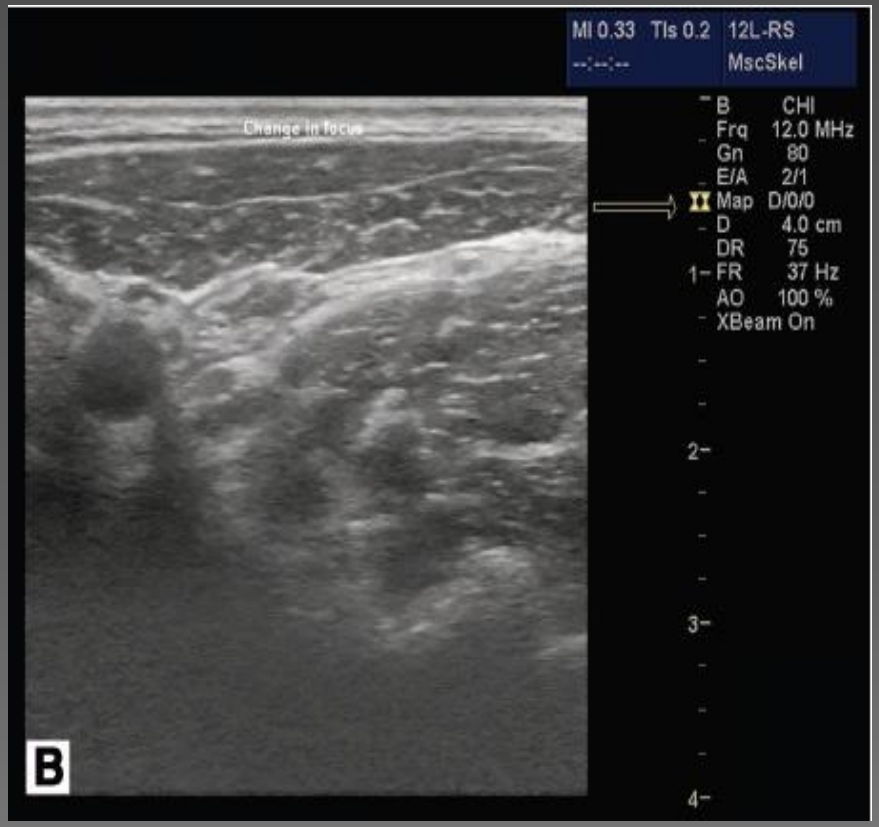
Deeper / focused : more heat

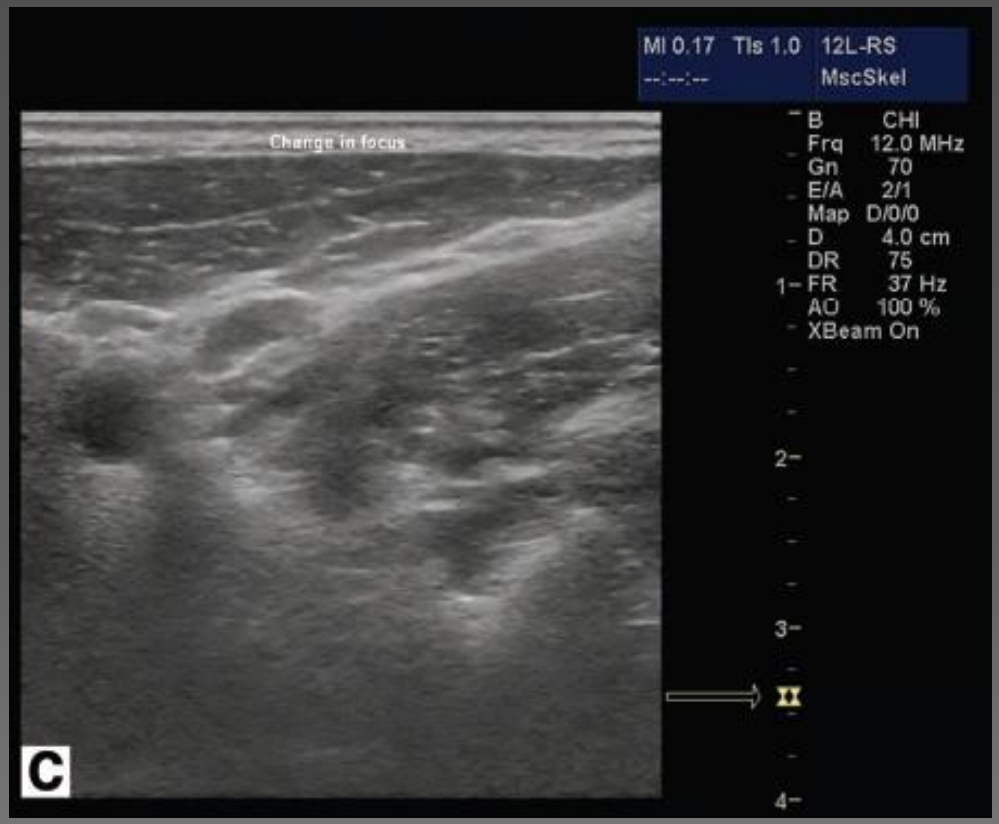
The ultrasound beam



Thermal Effects
-focusing

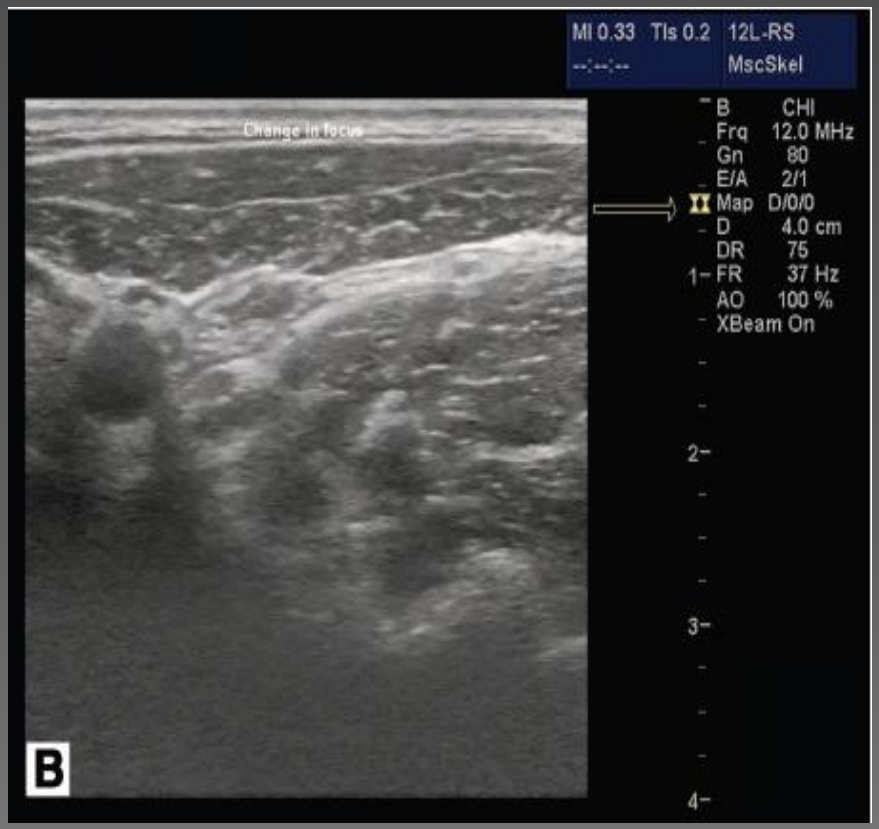


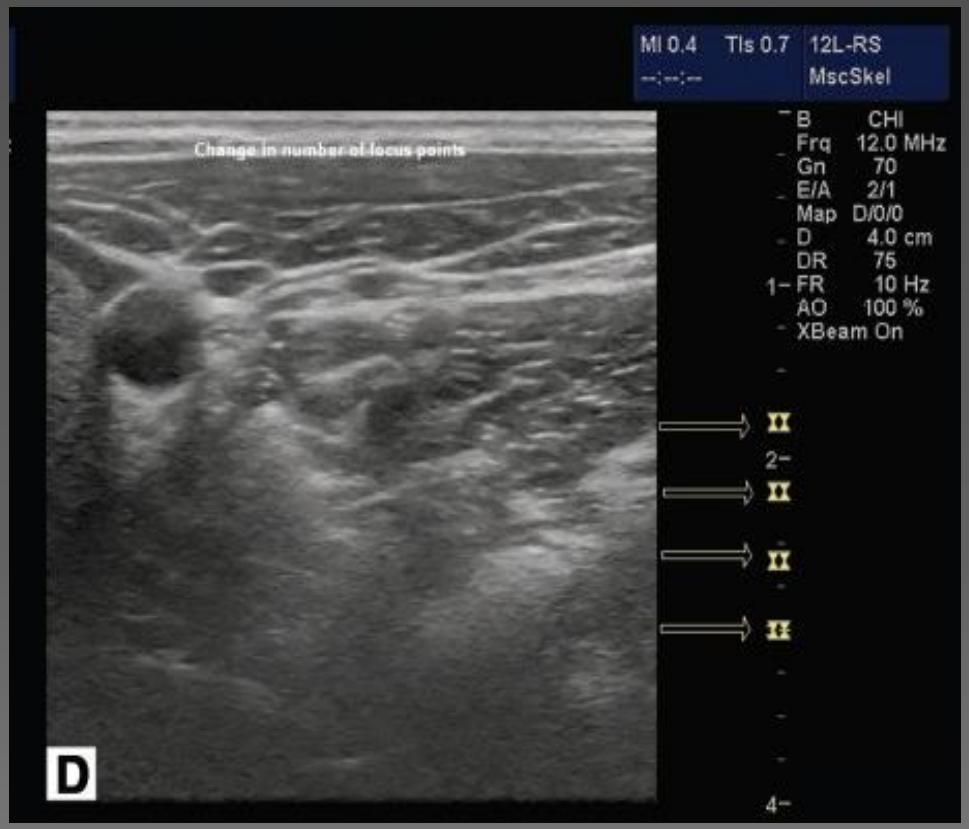
TIs o.2



TIs 1.0

Thermal Effects
-focusing





TIs o.2

TIs 0.7

Table 3. Causes for Tissue Temperature Changes by Ultrasound

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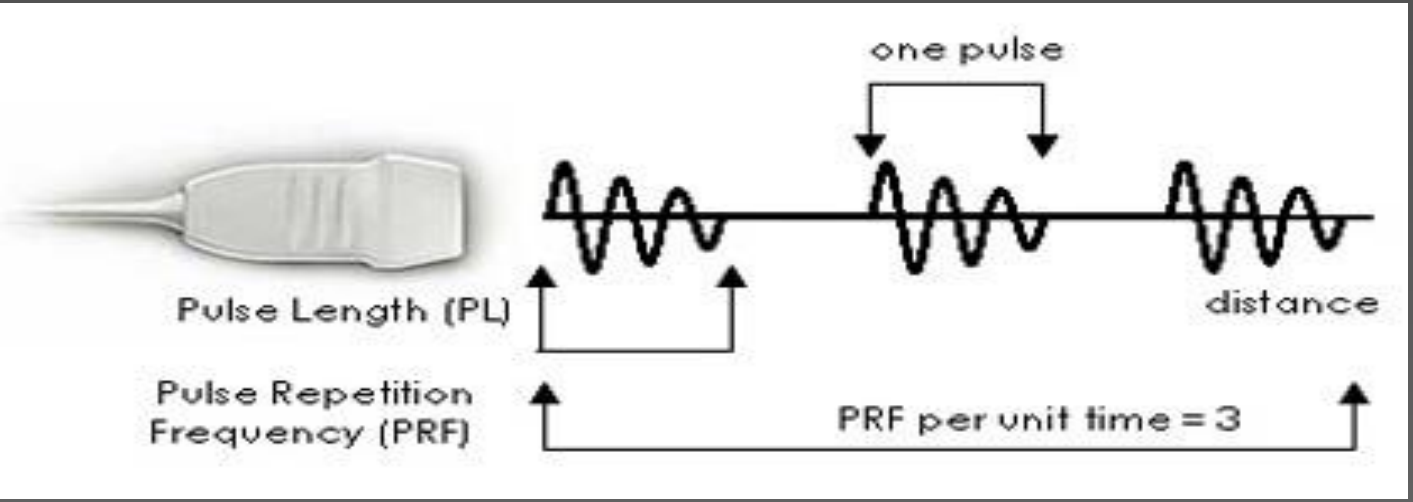
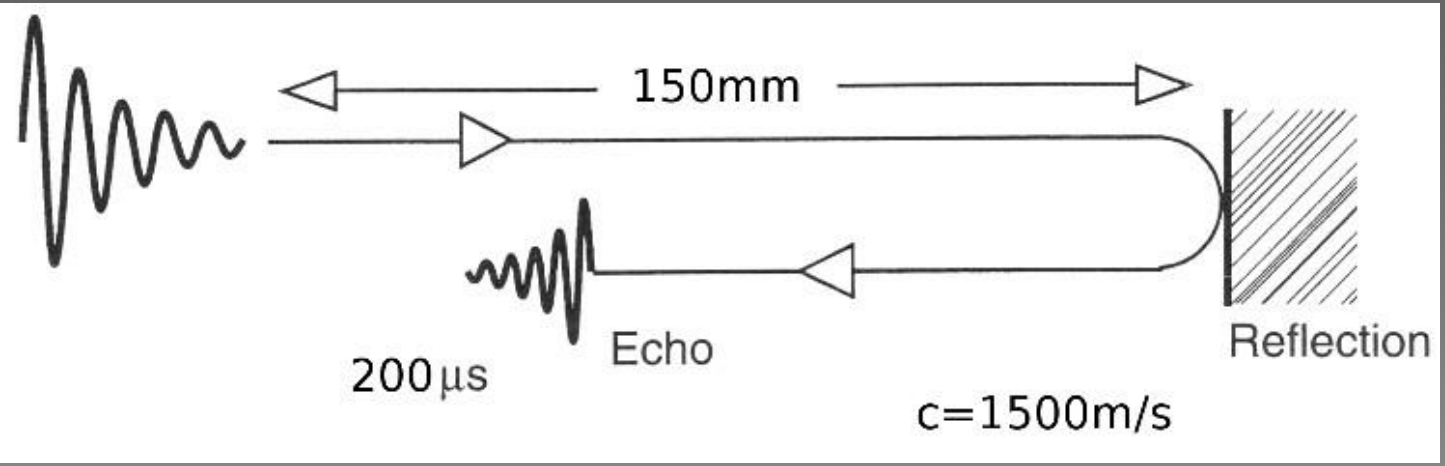
Exposure time	Nonlinear propagation
Intensity	Density
Beam width	Protein content

Higher PRF/ Pulse duration : more heat

Pulse Repetition Frequency (PRF)





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Intensity	Density
Beam width	Protein content

Higher exposure time / intensity : more heat

Intensity & Power output of US

- Intensity is defined as power per unit area
- mW/cm^2 or W/cm^2

- Power output is the total energy per unit time

Power Output/ Acoustic Power

US power output

Table 4. Factors Increasing Ultrasound Output

Parameter	Method of Increasing Output
Output power setting	Increased output power leads to an increase in peak pressure and energy
Deep transmission focus	Increases negative pressures and heating, secondary to increase in power
Color flow mapping and spectral Doppler imaging	High I_{SPTA} and power with a narrow and deep box
Spectral Doppler mode	Increase in Doppler frequency scale and pulse repetition frequency lead to increase in power and I_{SPTA}
M mode and spectral Doppler imaging	Larger negative pressures and I_{SPTA} are produced when the focus is close
Write zoom box	When narrow and deep, leads to a high pulse repetition frequency and negative pressure

I_{SPTA} = spatial peak, temporal average intensity.

Intensity levels

1. Pulsed doppler
2. Colour doppler
3. M-mode (Time Motion modulation)
4. B-mode (Brightness modulation)

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Beam width	Protein content

Narrow beam : more heat

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Higher attenuation coefficient
Higher absorption coefficient : more heat
Higher acoustic impedance
(attenuation= sound energy is weakened by reflection, scattered, absorbed, refracted or diffracted.)

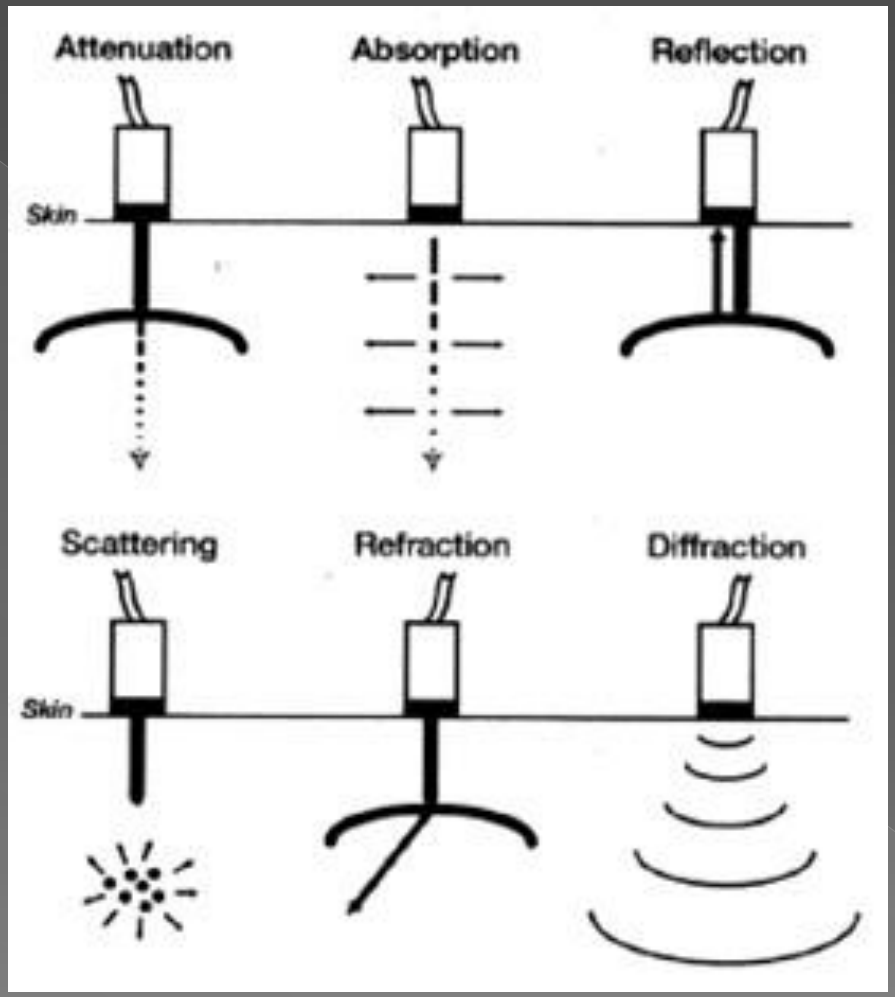
Attenuation
Absorption
Reflection
Skin
Scattering
Refraction
Diffraction
Skin

Table 2. Attenuation Coefficient and Acoustic Impedance of Various Tissues

Tissue/Medium	Attenuation Coefficient (dB/cm/MHz)	Acoustic Impedance (Mrayl)
Water	0.0022	1.5
Blood	0.15	1.6
Soft tissue	0.75	1.6
Air	7.50	0.00001
Bone	15.0	8.0
Fat	0.63	1.4
Kidney	1.0	1.6
Lens of eye	0.05	1.7

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Intensity	Density
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Higher tissue perfusion : less heat

Thermal Effects

- Less perfused tissues that are susceptible to thermal effect of US:
- Lens
- Cornea
- Tendon
- Adipose tissue

Table 3. Causes for Tissue Temperature Changes by Ultrasound

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Intensity	Density
Beam width	Protein content

Higher protein→ higher absorption coef. : more heat

Output Display Standard (ODS)- 1992 by FDA

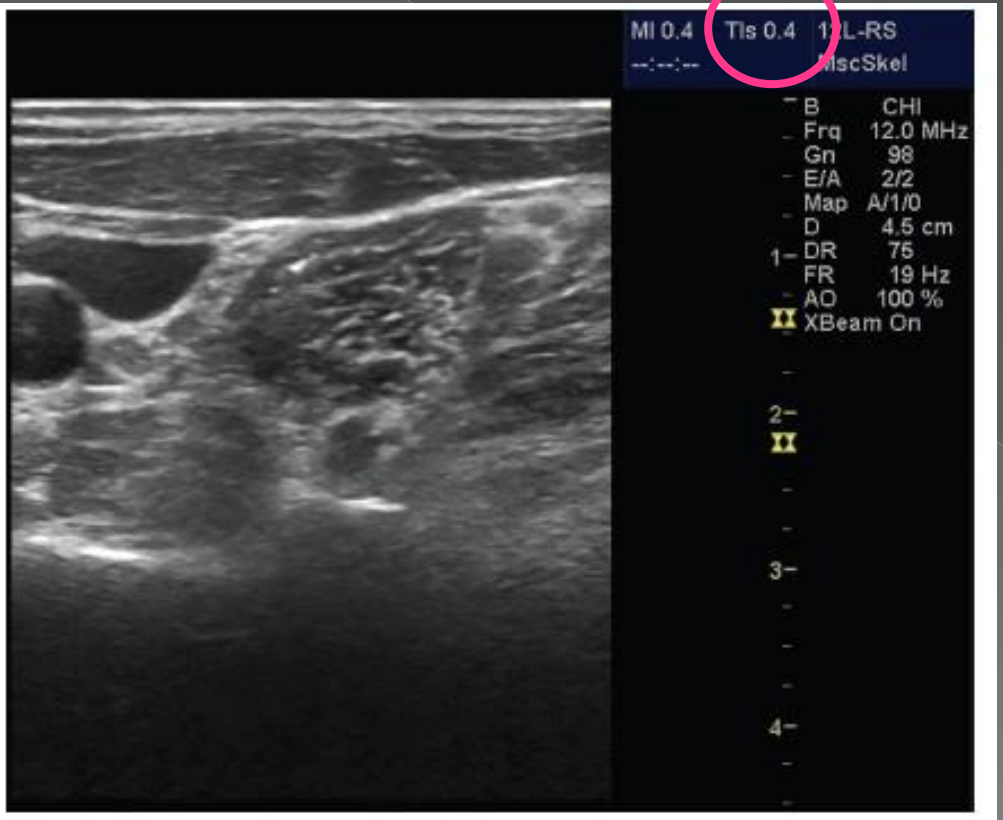


Fig. 1. Ultrasound image displaying the mechanical and thermal indices as MI and TIs, respectively. In this image the indices are displayed at the top right corner. The location may vary depending on the manufacturer.

- **TI= Thermal index**

Thermal Index (TI)

- Def: the ratio of the total system power to the power required to cause a 1^0C increase in temperature
- TI = W^0/Wdeg

  W^0 – the power of the machine

  Wdeg – the power required to increase the tissue temperature by 1^0
- To estimate temperature increase associated with an US beam
- eg: TI 10 → temp rise of 10^0C

Thermal Index (TI)

- TIs- soft tissue TI
- TIb- bone TI
- TIc –cranium TI →neonatal brain/ where bone is superficial

Thermal Index (TI)

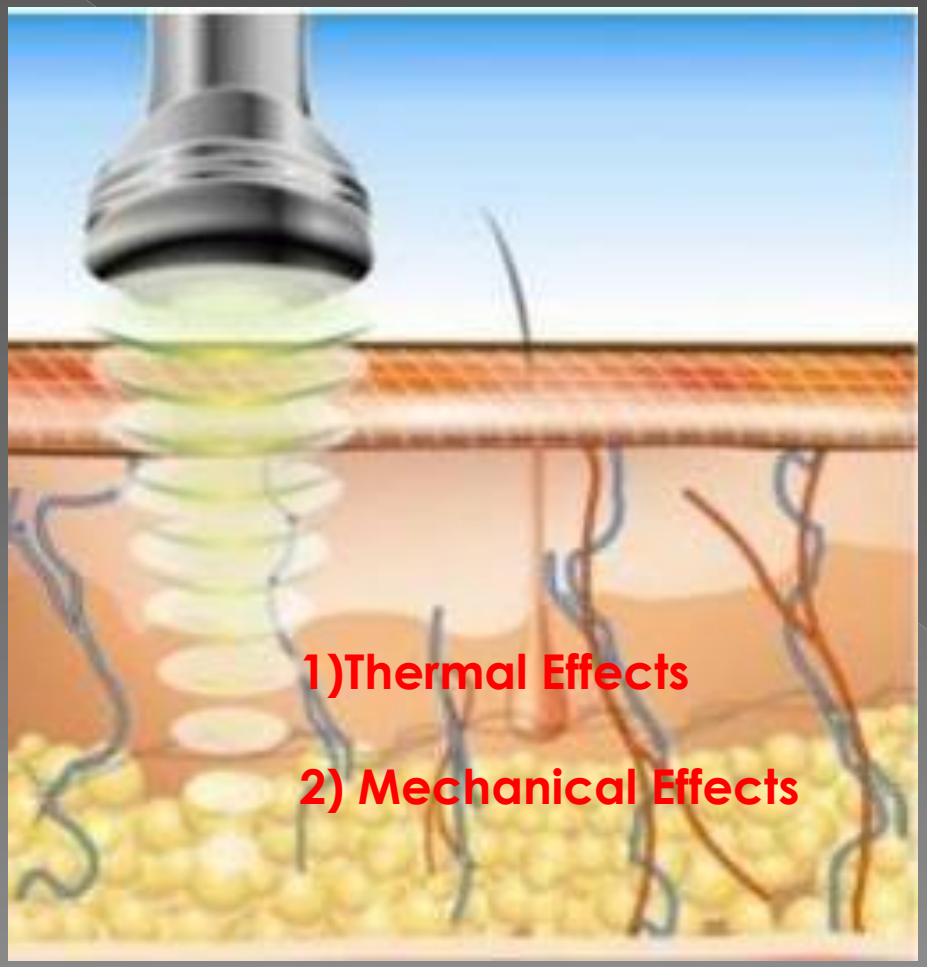
- Diagnostic US (Food & Drug Adm)

  TIs 2.2-2.3

  TIb 2.8

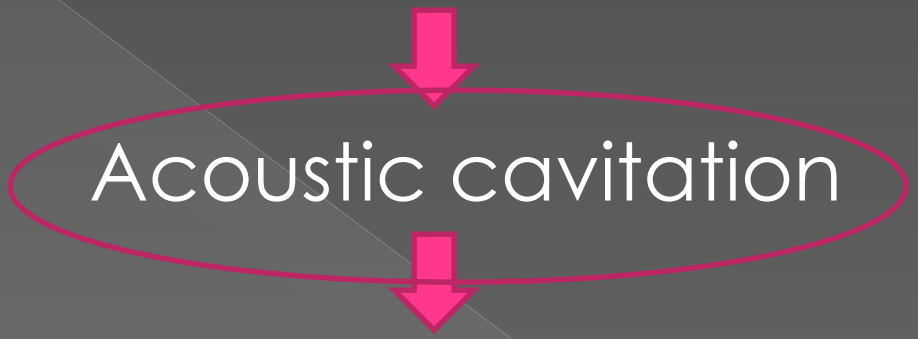
  Tic 3.0

2) Mechanical Effects



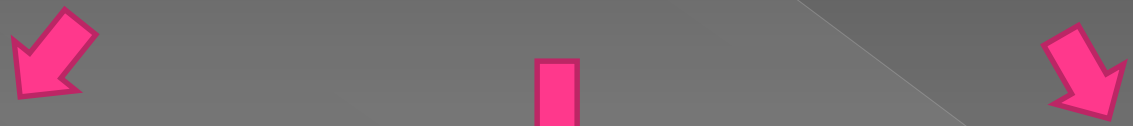
Mechanical Effects

Ultrasound energy interact with microbubbles



Acoustic cavitation

Mechanical Forces

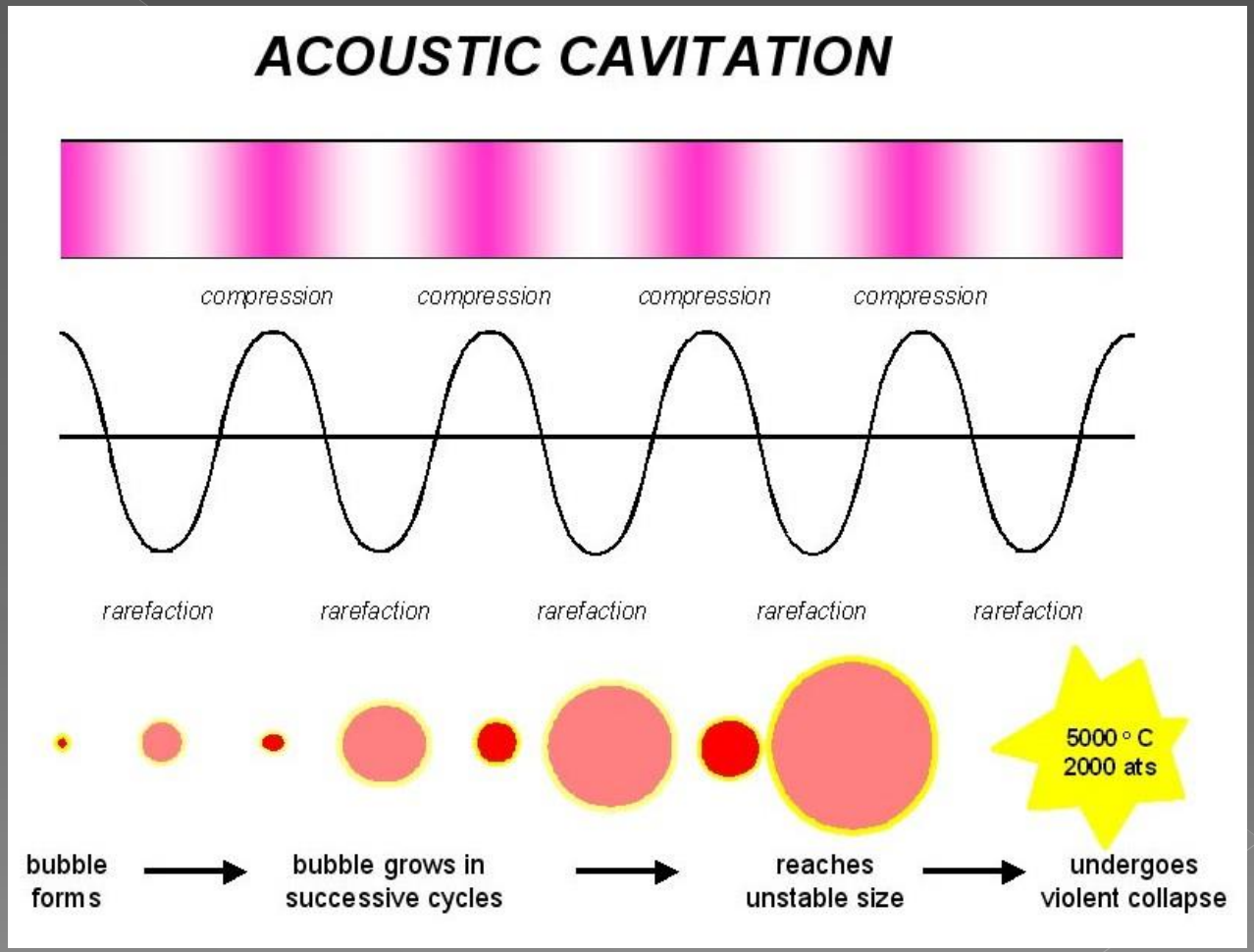


Shear force

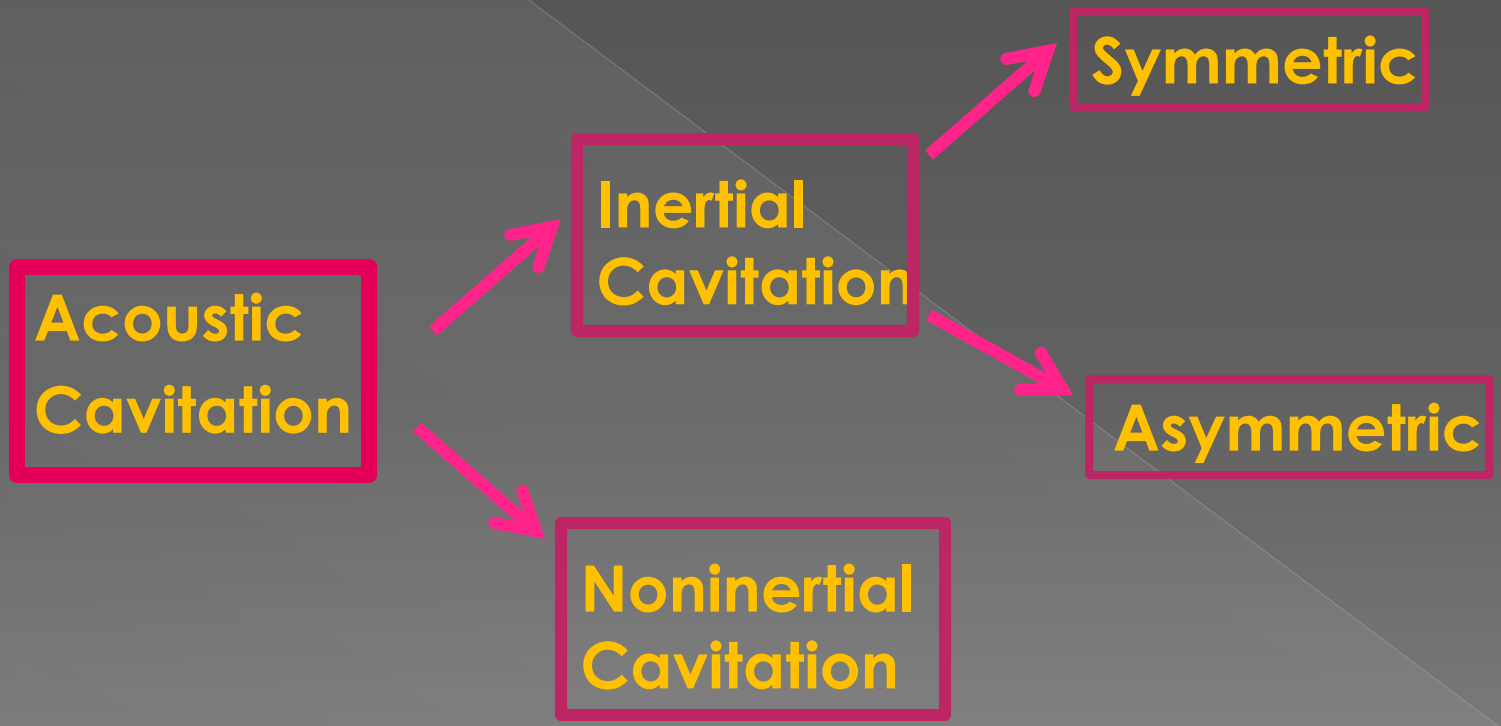
Pressure change

Free radical production

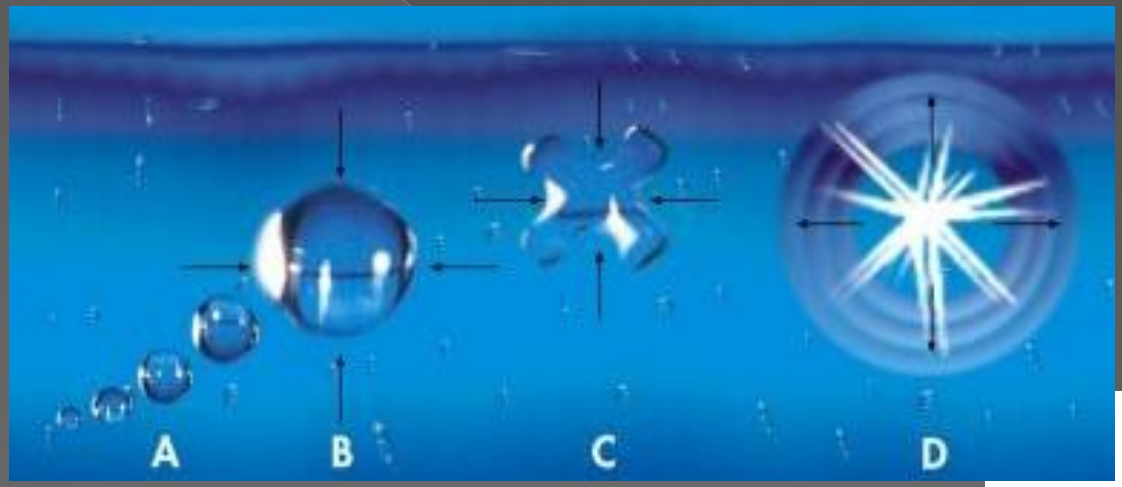
Mechanical Effects -Acoustic Cavitation



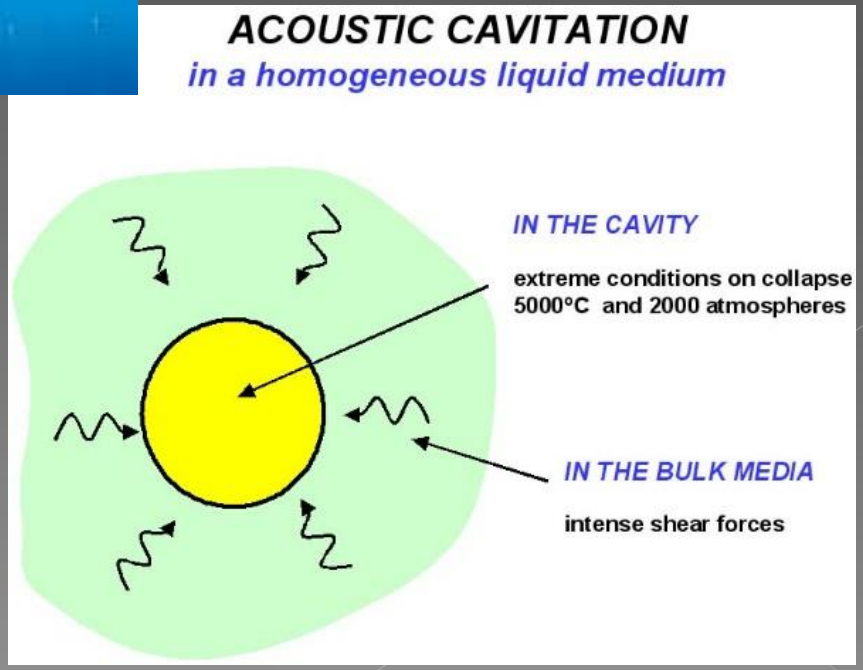
Mechanical effects
-Acoustic Cavitation



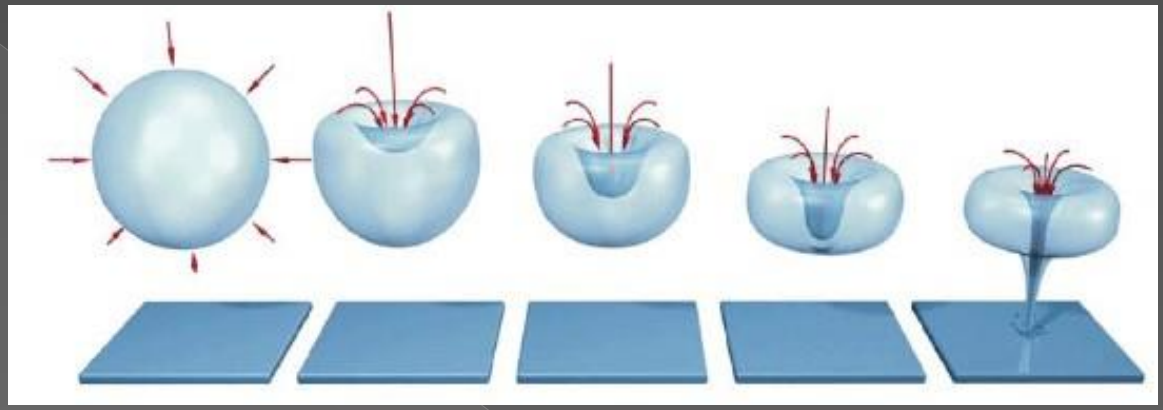
Mechanical effects
-Symmetric inertial cavitation

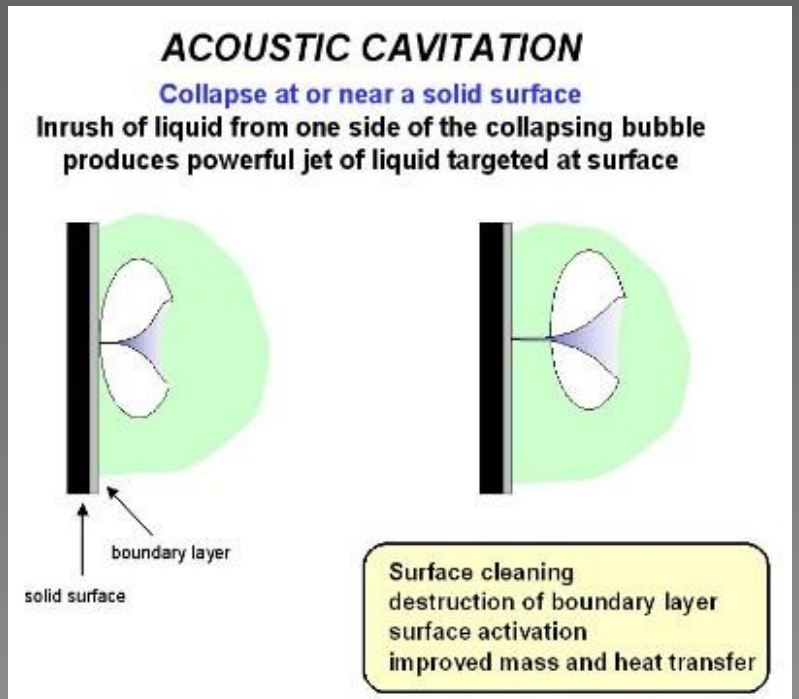


- Mechanical injury
- Shear force
- Internal thermal damage
- Highly reactive chemical intermediates



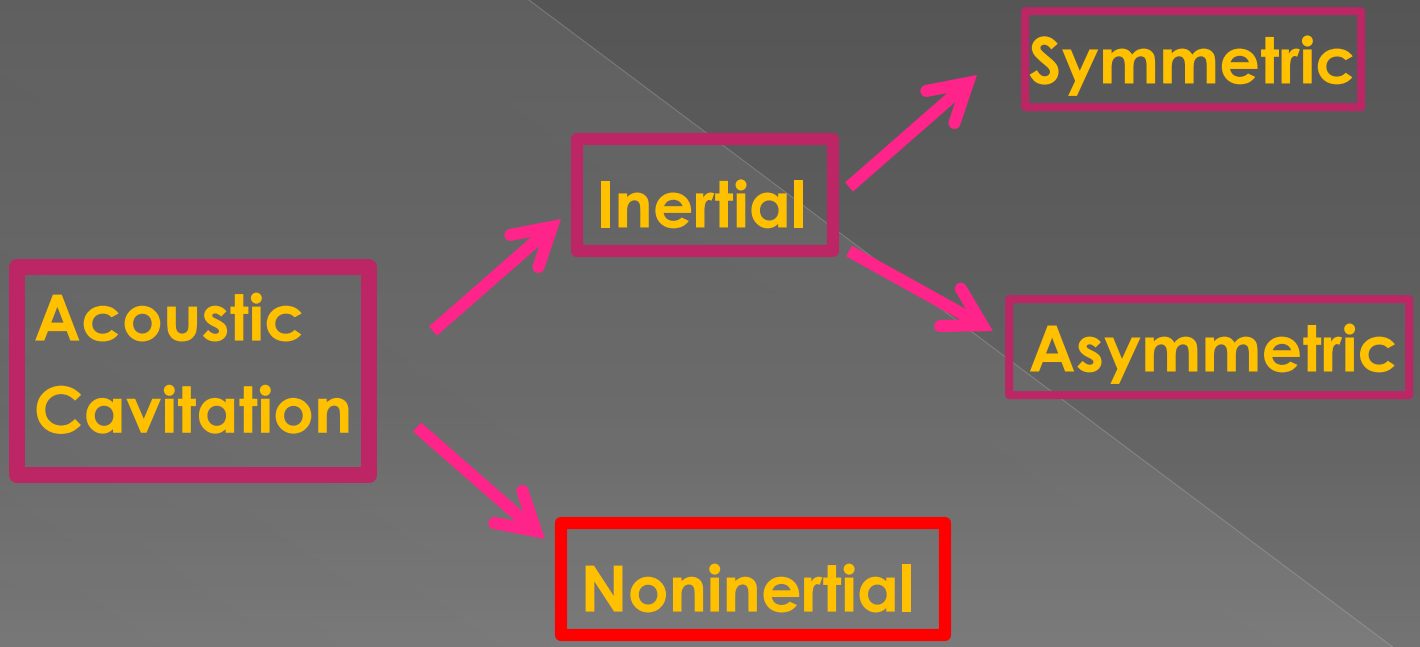
Mechanical effects
Asymmetric inertial cavitation





- High velocity liquid jets
- Direct mechanical damage to tissues

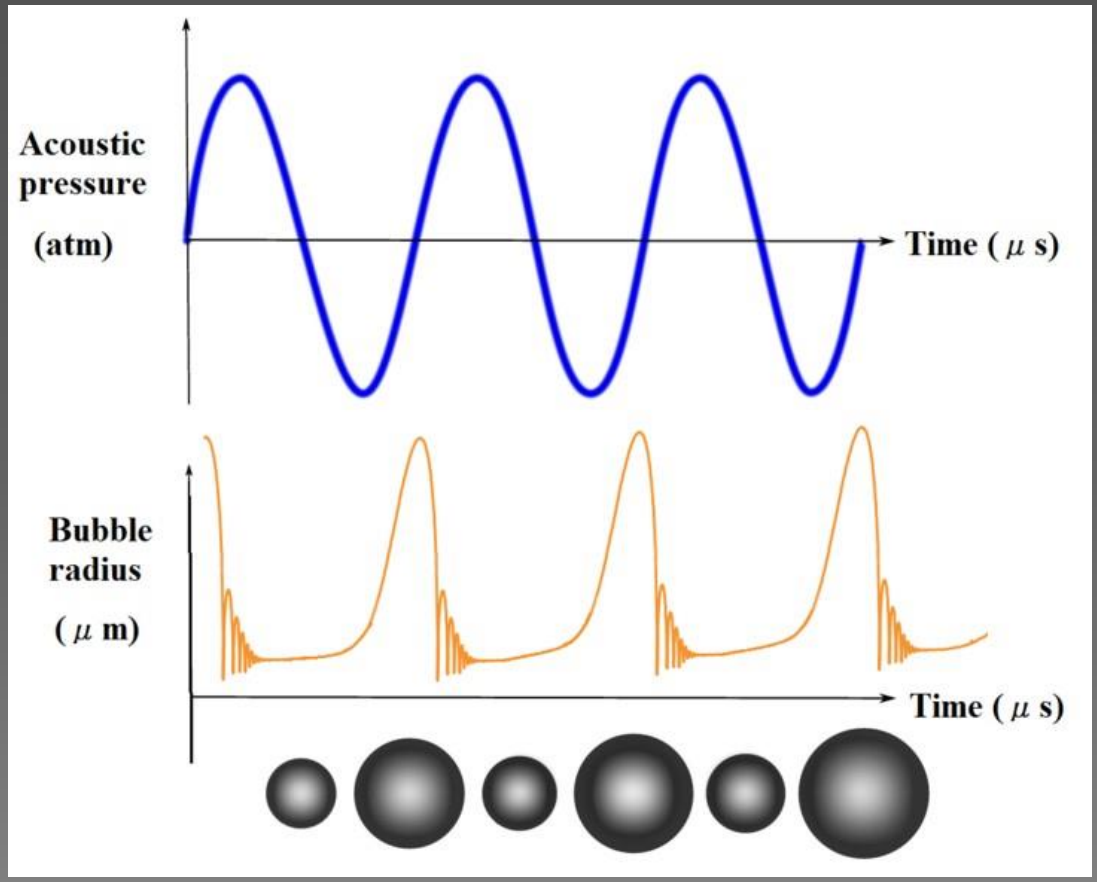
Mechanical effects
Noninertial Acoustic Cavitation



MECHANICAL EFFECTS
-NONINERTIAL ACOUSTIC CAVITATION

Repetitive bubble oscillation

Microstreaming
+
Mod. bubble cavity growth



Mechanical effects
-Acoustic Microstreaming

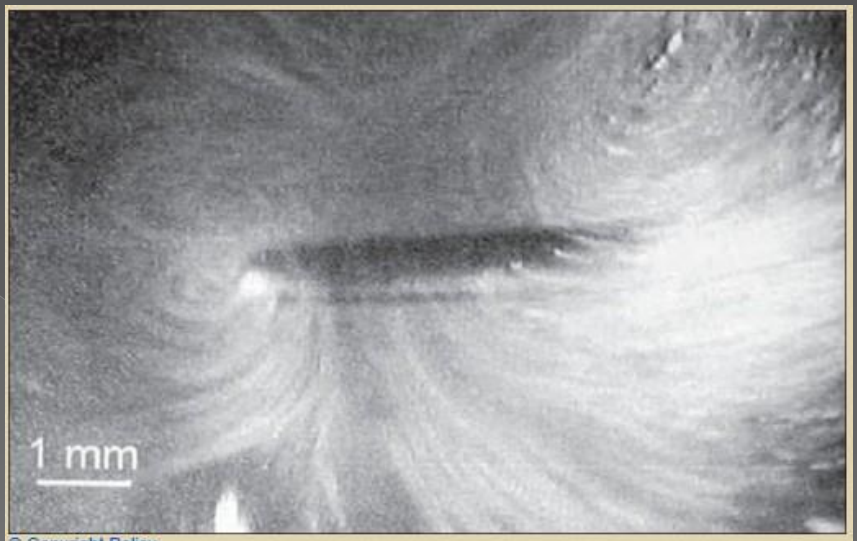
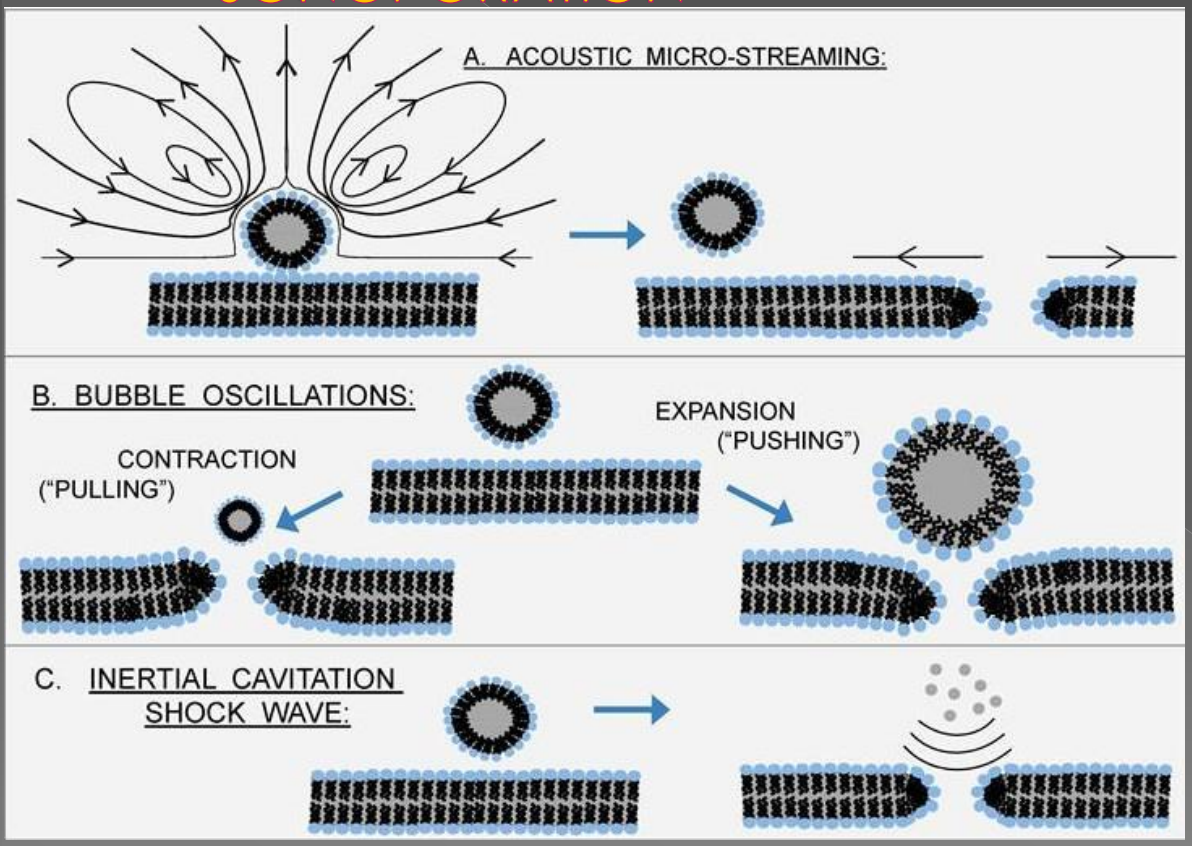


Figure 0006: Video captured digitalized image showing acoustic microstreaming at 47.5µm different displacement amplitudes (Khambay B S, Walmsley A D; 1999)

Mentions: The rapid cyclical volume pulsation of a gas bubble results in the formation of a complex steady state streaming pattern within the liquid close to the bubble surface.[1] Acoustic microstreaming is a phenomenon that exists in a fluid environment such as water and is characterized by the production of large shear forces.[30] It can be demonstrated around an oscillating solid cylinder within a fluid or a stationary cylinder within an oscillating fluid.[1] [Figure 4] Acoustic microstreaming occurring around ultrasonic scalers depends on displacement amplitude, tip orientation, and presence of water medium. It increases with increasing displacement amplitude, although it depends upon tip geometry, tip orientation, and distance from the oscillating tip.[30] [Figures 5 and 6]

Mechanical effects -Acoustic Microstreaming ---SONOPORATION



- Produces transient pores
- Increase cell mbr permeability

Mechanical effects -Acoustic Microstreaming

- Very little physiological effects

Output Display Standard (ODS)- 1992 by FDA

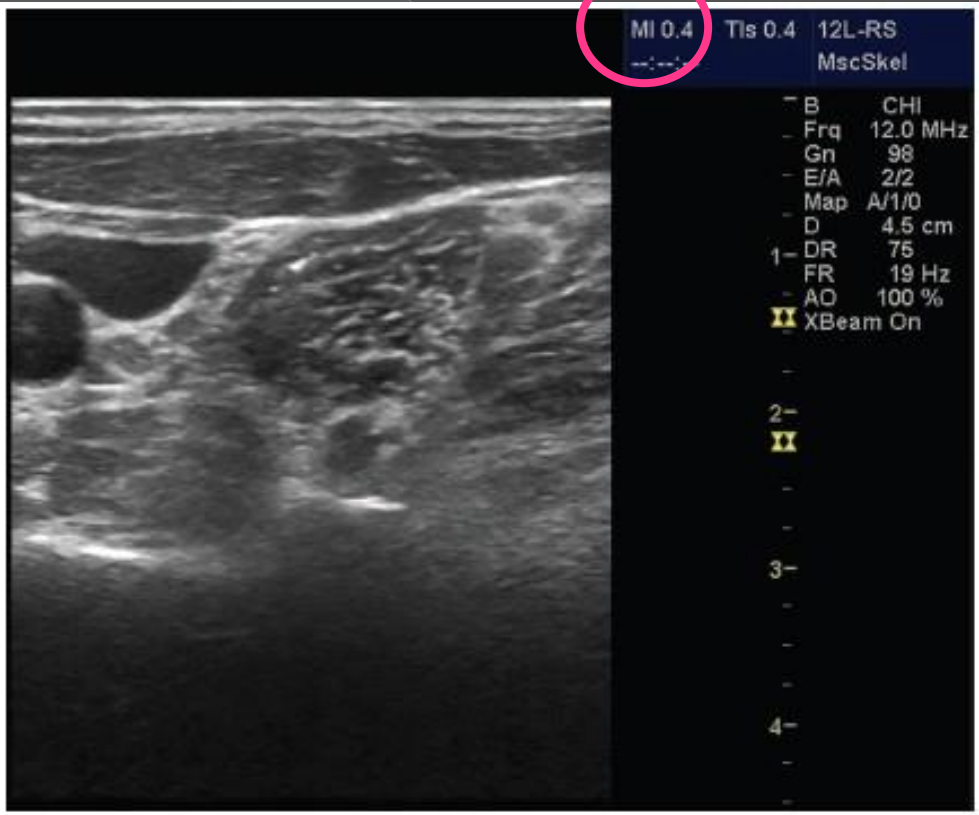


Fig. 1. Ultrasound image displaying the mechanical and thermal indices as MI and TIs, respectively. In this image the indices are displayed at the top right corner. The location may vary depending on the manufacturer.

- MI = mechanical indices

Mechanical Indices (MI)

- MI describes the relationship between cavitation formation and acoustic pressure
- MI is defined as the max value of the peak rarefactional negative pressures divided by the square root of the acoustic center frequency

$$MI = \frac{P_r}{\sqrt{f}}$$

Mechanical Indices (MI)

- MI gives an estimation of the risk of the mechanical effects (nonthermal effects),in relation to the intensity

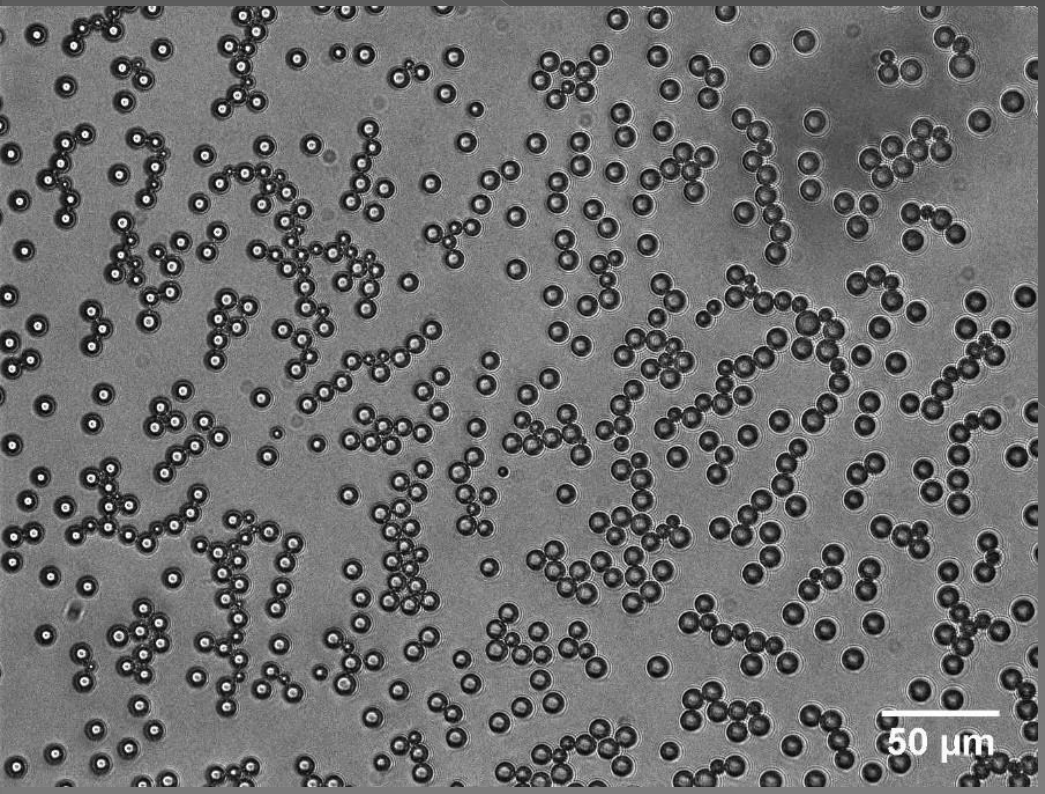
  – the potential to induce cavitation & streaming

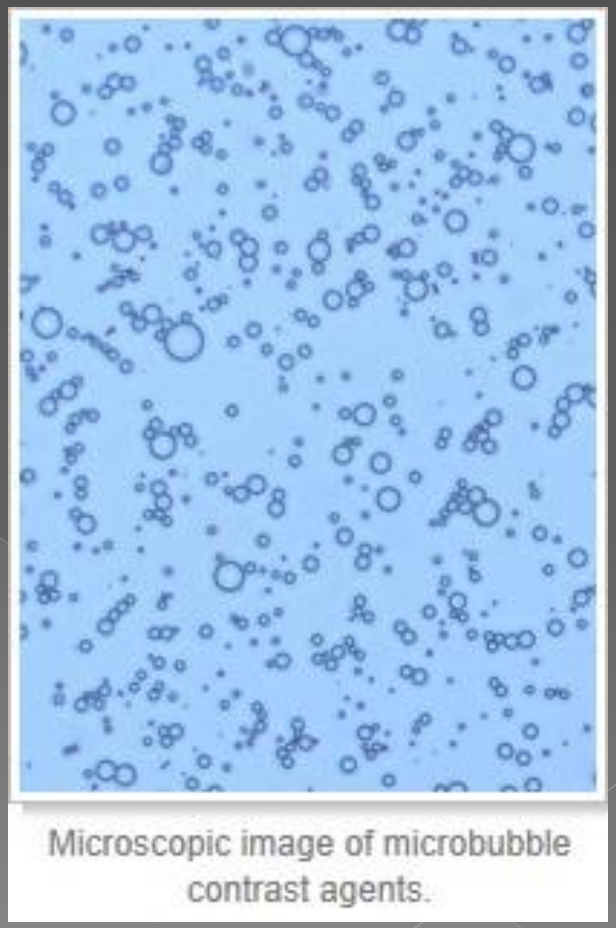
- MI is important for gaseous bodies:neonatal lung, bowel, US contrast agent

eg: (BMUS safety guide line)

- MI > 0.3 = risk of capillary bleeding in neonatal lung & intestine
- MI > 0.7 = cavitation risk in US contrast agent

US contrast agent



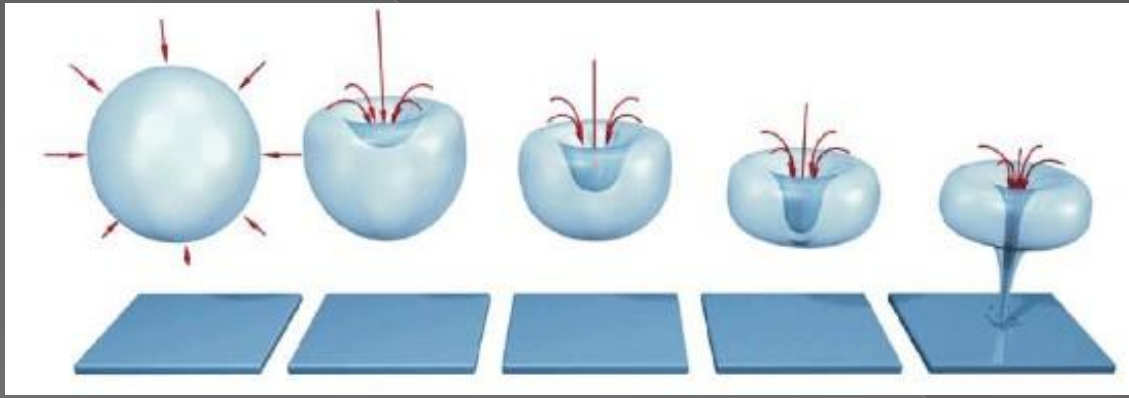


Microscopic image of microbubble contrast agents.

Biological Study

Cellular Effects of US

US induced
endothelial damage → thrombus formation



Asymmetric Acoustic Cavitation

Ultrasound Med Biol. 1974 Mar;1(2):133-48.

The production of blood cell stasis and endothelial damage in the blood vessels of chick embryos treated with ultrasound in a stationary wave field.

Dyson M, Pond JB, Woodward B, Broadbent J.

PMID: 4372758 [PubMed - indexed for MEDLINE]

Cellular Effects of US

- US facilitated an influx of Ca^{++} in fibroblast, &

Ultrasound Med Biol. 1988;14(6):499-506.

The effect of therapeutic ultrasound on calcium uptake in fibroblasts.

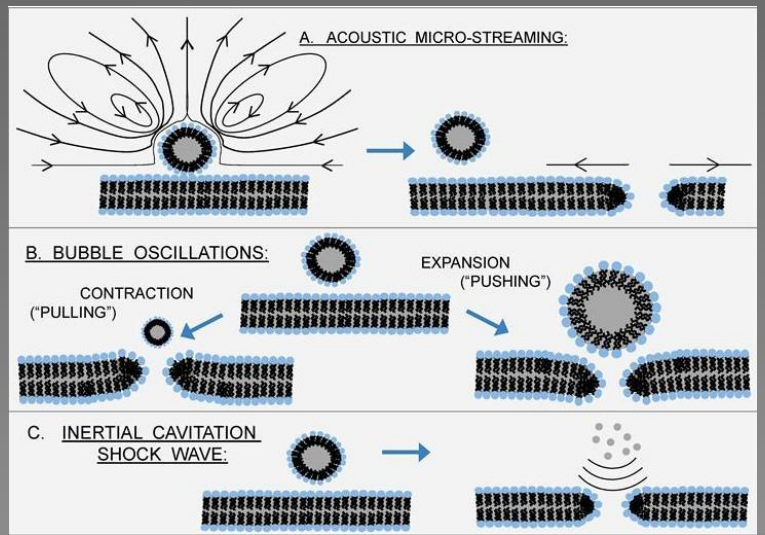
Mortimer AJ, Dyson M.

- efflux of intracellular K^{+} ions

Ultrasound-induced changes in rates of influx and efflux of potassium ions in rat thymocytes in vitro

I.V. Chapman, N.A. MacNally, S. Tucker

Department of Medical Biophysics, University of Dundee, Dundee, Scotland



Acoustic microstreaming

Cellular Effects of US

Hypotonicity (146 mOsm) + low intensity US (0.5 W/cm²)

Cell necrosis

Mol Cell Biochem. 2007 Jan;294(1-2):217-24. Epub 2006 Jul 20.

Evaluation of biological effects induced by diagnostic ultrasound in the rat foetal tissues.

Karaqöz I, Biri A, Babacan F, Kavutçu M.

Cellular Effects of US

US 20MHz

⬇

Inactivate enzymes

+

Free radical production

⬇

Cellular injury

Free radical formation induced by ultrasound and its biological implications

Peter Riesz [a,*,1], Takashi Kondo [†,2]

[a] Radiation Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD 20892, U.S.A

[b] Department of Experimental Radiology and Health Physics, Fukui Medical School, Matsuoka, Fukui 910-11, Japan

Cellular Effects of US

Doppler mode 3MHz	B mode 4MHz
↑antioxidant enzyme activities (rat fetal liver & brain)	↓antioxidant enzyme activity (fetal brain)

Alteration of antioxidant enzymes conc. may either protect against or further exacerbate US induced free radical damage

Mol Cell Biochem. 2007 Jan;294(1-2):217-24. Epub 2006 Jul 20.

Evaluation of biological effects induced by diagnostic ultrasound in the rat foetal tissues.

Karagöz I, Biri A, Babacan F, Kavutçu M.

Cellular Effects of US

30min US exposure at ISPTA1.2W/cm²

↓

↑heat-shock protein production

↓

Neuroprotective effect

Teratology. 1990 Sep;42(3):285-93.

Effects of pulsed ultrasound and temperature on the development of rat embryos in culture.

Angles JM, Walsh DA, Li K, Barnett SB, Edwards MJ.

Author information

Abstract

Rat embryos in culture were exposed to pulsed ultrasound at SPTA intensity of 1.2 W/cm2 for 5, 15, and 30 min on day 9.5 embryo culture system allowed precise temperature control for directly examining the effects of ultrasound on the developi

Cellular Effects of US

15min US exposure at
ISPTA1.2W/cm² at 40°C

↓

↓in somite numbers

(somite- bilaterally paired blocks of mesoderm in the vertebrate embryo, develop into muscle & vertebrae)

Teratology. 1990 Sep;42(3):285-93.

Effects of pulsed ultrasound and temperature on the development of rat embryos in culture.

Angles JM, Walsh DA, Li K, Barnett SB, Edwards MJ.

Author information

Abstract

Rat embryos in culture were exposed to pulsed ultrasound at SPTA intensity of 1.2 W/cm2 for 5, 15, and 30 min on day 9.5 of development. The whole embryo culture system allowed precise temperature control for directly examining the effects of ultrasound on the developing neural plate. After exposure, embryos were maintained in culture for a further 48 hr. No major morphological abnormalities were observed but a reduction in somite number occurred in the group insonated for 30 min, which was equivalent to a 2 hr delay in embryonic development. Similar delay in growth and "blistering" in the prosencephalon region of some embryos were observed after insonation for 15 min at 40.0 degrees C, an elevation of 1.5 degrees C over the temperature used for controls. Exposure to ultrasound for 15 min at 40 degrees C caused significant reduction in the growth of the head compared with that of control embryos. Heat shock genes for hsps 71/73 and 88 kD were induced after insonation for 30 min at 38.5 degrees C. Insonation did not cause any temperature changes in the culture medium. However, when the temperature of the culture medium was increased during insonation, defective development occurred. The results of these in vitro experiments suggest that ultrasound if resulting in significant hyperthermia could affect the development during early organogenesis of the neural plate and in particular they suggest that the embryo is at greater risk of damage during hyperthermic conditions. These results should provoke discussion of the concept that ultrasound in the febrile patient may present an increased embryonic risk which should be considered when deliberating on the use of diagnostic ultrasound procedures in the pregnant patient.

Cellular Effects of US

- Affect cell regeneration
- Reduced leukocyte production
- Synaptic vesicles clumped (300W/cm²) for 0.5-3s

Genetic Effects of US in animal

Genetic Effects of US

- A small increase of sister chromatic exchanges (SCE) in Chinese hamster ovary cells when exposed to high intensity US

  (SCE – exchange of genetic material between 2 identical sister chromatic)

- However Miller cannot verified this his in study

Ultrasound Med Biol. 1989;15(3):255-62.

Sister chromatid exchanges in Chinese hamster ovary cells exposed to high intensity pulsed ultrasound: inability to confirm previous positive results.

Miller MW, Azadniv M, Pettit SE, Church CC, Carstensen EL, Hoffman D.

Author information

Abstract

This study was undertaken in an attempt to determine a physical mechanism of action for a recently published report of a small but statistically significant increase in sister chromatid exchanges (SCEs) in Chinese hamster ovary cells exposed to high-intensity pulsed ultrasound. The "positive" report's protocol involved a sizeable chance of ultrasound beam impingement on the side wall of the cell exposure chamber. Ten experiments per regimen were conducted; the regimens included exposures of (a) chamber center, (b) chamber wall, (c) nine grid sites, 0.5 mm between sites, and (d) nine grid sites, 1.5 mm between sites. The last was an exact replication of the conditions previously reported to induce the small SCE effect. The results did not support the postulate of an increase in SCEs with the ultrasound exposures.

PMID: 2741252 [PubMed - indexed for MEDLINE]

Genetic Effects of US

- Evidence of cell mutation
- Due to increased free radicals production and their action on nuclear material

Ultrasound Med Biol. 1990;16(7):699-705.

Confirmation of an ultrasound-induced mutation in two in-vitro mammalian cell lines.

Doida Y, Miller MW, Cox C, Church CC.

Author information

Abstract

In-vitro V79 and L5178Y cells were exposed in a rotating test tube to continuous-wave (CW) 1 MHz 35 W/cm2 ultrasound (0-4 or 0-3 min, respectively) and subsequently assayed for mutation as evidenced by resistance to 6-thioguanine (6-TG). There was a modest but statistically significant increase in mutation frequency in both cell types with increase in ultrasound exposure duration. X-ray exposures (3-9 Gy, a "positive control") yielded a large increase in 6-TG resistance. The data support an earlier report by Kaufman (1985) of an ultrasound-induced increase in mutation to 6-TG resistance in in-vitro mammalian cells.

PMID: 2281558 [PubMed - indexed for MEDLINE]

Genetic Effects of US

- Low frequency US → inertial cavitation → free radicals formation → cause double strand helical fractures → nonspecific DNA degradation

Free Radic Biol Med. 1992 Sep;13(3):247-70.

Free radical formation induced by ultrasound and its biological implications.

Riesz P, Kondo T.

Author information

Abstract

The chemical effects of ultrasound in aqueous solutions are due to acoustic cavitation, which refers to the formation, growth, and collapse of small gas bubbles in liquids. The very high temperatures (several thousand K) and pressures (several hundred atmospheres) of collapsing gas bubbles lead to the thermal dissociation of water vapor into .OH radicals and .H atoms. Their formation has been confirmed by electron spin resonance (ESR) and spin trapping. The sonochemistry of aqueous solutions of gases and of volatile and nonvolatile solutes is reviewed. The similarities and differences between sonochemistry and radiation chemistry of aqueous solutions are explained. Some unusual characteristics of aqueous sonochemistry can be understood by considering the properties of supercritical water. By the use of rare gases with different thermal conductivities, it is possible to distinguish between temperature-dependent processes such as redox reactions initiated by .OH radicals and .H atoms and pressure-dependent processes which lead to polymer degradation and cell lysis. The evidence for free radical formation in aqueous solutions by pulsed ultrasound is discussed. This subject is of interest because it is related to the possible deleterious effects of ultrasonic diagnostic devices. The role of free radicals and of mechanical effects induced by ultrasound in DNA degradation, inactivation of enzymes, lipid peroxidation, and cell killing is reviewed.

PMID: 1324205 [PubMed - indexed for MEDLINE]

Fetal Effects of US in Animal

Fetal Effects of US

- Rats exposed to US showed more vocalization and escape respond
- Low intensity US irradiation may influent the emotional behavior but not the cognitive behavior

Tohoku J Exp Med. 1975 Nov;117(3):225-35.

Effects of diagnostic ultrasound irradiated during foetal stage on emotional and cognitive behaviour in rats.

Murai N, Hoshi K, Kang DH, Suzuki M.

Abstract

Our previous work demonstrated that the prenatally irradiated ultrasound of even a low-intensity might affect the functional development of the brain of offspring in rats. In the present study, in order to investigate the emotional and cognitive behaviour of offspring of rats that received the irradiation of a diagnostic ultrasound on the 9th day of gestation, the following three experiments were carried out: 1) The emotional reactivity of the offspring was measured by the open-field technique. 2) The same reactivity was further evaluated in terms of the excape response from electroshock. 3) The cognitive function of the offspring was assessed through the discrimination learning and the discrimination reversal learning. The offspring of irradiated rats showed significantly more distinct vocalization response to handling in the open-field test and significantly more distinct escape response from the electroshock, when compared with the two control rats (untreated control and sham-irradiated control). From these findings it may be suggested that the emotional behaviour in rats can be influenced by a low-intensity ultrasound irradiated during foetal stage. On the other hand, as for the cognitive behaviour, the results of the present study suggest no adverse effect on it.

PMID: 1202656 [PubMed - indexed for MEDLINE] Free full text

Fetal Effects of US

- Prenatal exposure to US showed developmental delay
- No changes in physical dev or dev of orienting behavior
- But immobilization stress may contributed to this different

Tohoku J Exp Med. 1975 May;116(1):17-24.

Effects of diagnostic ultrasound irradiated during fetal stage on development of orienting behavior and reflex ontogeny in rats.

Murai N, Hoshi K, Nakamura T.

Abstract

The physical growth, the development of orienting behavior and neuromotor reflexes of offspring of rats that received an irradiation of a diagnostic level of ultrasound on the 9th day of gestation were estimated and compared with those of two control groups (untreated control and sham-irradiated or immobilized control). Results showed no significant group differences in terms of either physical development or development of orienting behavior. In the reflexological tests, however, a number of those reflexes that developed after 6 days of postnatal life of the offspring of irradiated rats showed significant delays in maturation when compared with those of the untreated control rats, but showed no difference from those of the sham-irradiated group. From these findings it is suggested that under certain circumstances such as in stress, the prenatally irradiated ultrasound of even a low-intensity may affect the development of the brain of offspring.

PMID: 1154372 [PubMed - indexed for MEDLINE] Free full text

Fetal Effects of US

- Prenatal US exposure did not cause gross developmental abnormalities in monkey except of an increase in muscle tone

Teratology. 1989 Feb;39(2):149-62.

Evaluation of the bioeffects of prenatal ultrasound exposure in the cynomolgus macaque (Macaca fascicularis): II. Growth and behavior during the first year.

Tarantal AF, Hendrickx AG.

Author information

Abstract

The extensive use of ultrasonography for the prenatal assessment of growth and development continues to present questions regarding biological effects. We are currently evaluating a nonhuman primate model (Macaca fascicularis) exposed to ultrasound from gestational day (GD) 21 to 152 +/- 2. Exposures were performed with a commercial real-time sector scanner (ATL, MK 600); animals were scanned five times weekly on GD 21-35 +/- 2, three times weekly on GD 36-60 +/- 2, and once weekly on GD 61-150 +/- 2. The length of exposure was approximately the same as human exposure (GD 21-60 +/- 2 = 10 min/exam and GD 61-150 +/- 2 = 20 min/exam) although the frequency of the examinations was considerably greater. Initial reports indicated differences between control and treated animals including lower birth weight, higher simian Apgar scores, and changes in select hematologic parameters. Follow-up evaluations of growth during the first year included measurements of body weight, hand and foot lengths, humerus and femur lengths, biparietal and occipitofrontal diameters, head circumference, arm circumference, chest circumference, skinfold thickness, and crown-rump length. Results indicated a significant reduction in body weight in treated animals during the first three months, with nonsignificant differences during the following nine months. Hematologic analysis including complete blood counts (CBC) and clinical biochemistry at 6, 9, and 12 months of age were not significantly different. A series of behavioral evaluations including a neurobehavioral test battery (NBT) and tests assessing motor and cognitive skills were included. The NBT revealed increased muscle tone in treated animals at one, two, and four days. In an observation cage (week 1-14) more quiet activities were displayed by treated animals. Group differences in performance of motor and cognitive tasks were observed and may be attributable to agitation and difficulties in adjusting to test environments. There were no group differences observed in discrimination learning. When considering the possible implications to the human population, it is important to consider the amount of exposure these animals received, and the fact that most of the effects observed appeared to be transitory. Although human epidemiological studies have not revealed any significant bioeffects, the "prudent use" of diagnostic ultrasound should still be kept in mind. This is especially significant with the current rise in the use of endovaginal scanning and pulsed Doppler.

PMID: 2648635 [PubMed - indexed for MEDLINE]

Fetal Effects of US

- Prenatal US exposure does not cause postnatal congenital malformation and neurobehaviour effects when used at recommended intensity levels

Teratology. 1999 Apr;59(4):240-51.

Intrauterine effects of ultrasound: animal studies.

Jensh RP, Brent RL.

Author information

Abstract

During the past several decades, the use of ultrasound technology in the clinical setting has greatly increased. Because nearly every pregnant woman receives at least one sonographic procedure today, there has been developing concern about the safety of such procedures. Since ultrasound exposure can result in hyperthermia and other physiological effects, the determination of a threshold or no-effect exposure has become a high-priority goal. Animal research has been important to the study of the effects of various exposures at all stages of pregnancy, since the clinical use of ultrasonography can occur during the preimplantation, organogenic, and fetal stages. Animal experiments using various mammalian species have been able to determine no-effect exposure levels for embryonic loss, congenital malformations and neurobehavioral effects. The preponderance of evidence from these studies indicates that, in the absence of a thermal effect, ultrasonography represents no measurable risk when used at recommended intensity levels.

PMID: 10331527 [PubMed - indexed for MEDLINE]

Genetic Effects of US

- From animals study, it remain unclear whether US contributes directly to genetic aberrations

Fetal Effects of US in Human

Fetal Effects of US in Human

- 297/ 1907 infants whose mothers had undergone US guided amniocentesis had abnormal grasp and tonic neck reflexes
- No other differences in motor, sensory, or other reflexes respond

Am J Obstet Gynecol. 1978 Aug 1;131(7):743-8.

One-year follow-up of infants exposed to ultrasound in utero.

Scheidt PC, Stanley F, Bryla DA.

Abstract

Neonatal and infant follow-up data from the Amniocentesis Registry of the National Institute of Child Health and Human Development were analyzed for possible effects of diagnostic ultrasound exposure in the second trimester of pregnancy. A total of 297 infants of mothers receiving both amniocentesis and diagnostic ultrasound were compared with a similar group of 661 infants of mothers who had amniocentesis but not ultrasound and with 949 infants exposed to neither amniocentesis nor ultrasound. Results of newborn and 1 year examinations were similar for the amniocentesis with ultrasound group when compared to the other two groups. However, in view of the small sample size and other limitations of these data, larger and more detailed studies are needed to adequately assess possible effects of ultrasound in pregnancy.

PMID: 686067 [PubMed - indexed for MEDLINE]

Fetal Effects of US in Human

- Retrospective study on children with and without in utero US exposure over a 4-yr period
- The incidence of dyslexia was modestly increased in children exposed to in utero US, otherwise no other biologically significant differences

Obstet Gynecol. 1984 Feb;63(2):194-200.

Short- and long-term risks after exposure to diagnostic ultrasound in utero.

Stark CR, Orleans M, Haverkamp AD, Murphy J.

Abstract

A total of 425 children exposed to diagnostic ultrasound at three Denver hospitals during the period May, 1968, through August, 1972, and 381 matched control children were studied for adverse effects at birth and again at a special examination between seven and 12 years of age. Apgar scores, gestational age, head circumference, birth weight, length, congenital abnormalities, neonatal infection, and congenital infection were measured at birth. At seven to 12 years of age, measurements included conductive and nerve measurements of hearing, visual acuity and color vision, cognitive function, behavior, and a complete and detailed neurologic examination. No biologically significant differences between exposed and unexposed children were found.

PMID: 6198611 [PubMed - indexed for MEDLINE]

Fetal Effects of US in Human

However, Salvesen KA and colleagues subsequently reported in two studies, that the in utero exposure to US does not increase the incidence of dyslexia.

Prog Biophys Mol Biol. 2007 Jan-Apr;93(1-3):295-300. Epub 2006 Aug 22.

Epidemiological prenatal ultrasound studies.

Salvesen KA.

Author information

Abstract

Epidemiological studies have indicated no association between diagnostic ultrasound e

Lancet. 1992 Jan 11;339(8785):85-9.

Routine ultrasonography in utero and school performance at age 8-9 years.

Salvesen KA, Bakketeig LS, Eik-nes SH, Undheim JO, Okland O.

Author information

Abstract

Most fetuses in developed countries are exposed in utero to diagnostic ultrasound examination. Many preg whether the procedure harms the fetus. Since most routine ultrasound examinations are done at weeks 16 rapidly, effects on neuronal migration are possible. We have sought an association between routine ultraso skills among children in primary school. At the age of 8 or 9 years, children of women who had taken part i ultrasonography during pregnancy were followed-up. The women had attended the clinics of 60 general pr The analysis of outcome was by intention to treat: 92% of the "screened" group had been exposed to ultra of controls had not been so exposed, but there was some overlap. 2428 singletons were eligible for follow- children (83%) was assessed by their teachers on a scale of 1-7; the teachers were unaware of ultrasound children underwent specific tests for dyslexia. There were no statistically significant differences between cl controls in the teacher-reported school performance (scores for reading, spelling, arithmetic, or overall per sample showed no differences between screened children and controls in reading, spelling, and intelligenc intelligence and reading or spelling. The test results classified 21 of the 309 screened children (7% [95% c controls (9% [4-12%]) as dyslexic. The risk of having poor skills in reading and writing was no greater for c routine ultrasonography than for those whose mothers had not been offered the procedure.

PMID: 1345870 [PubMed - indexed for MEDLINE]

BMJ. 1993 July 17; 307(6897): 159–164. PMCID: PMC1678377

Routine ultrasonography in utero and subsequent handedness and neurological development.

K A Salvesen, L J Vatten, S H Eik-Nes, K Hugdahl, and L S Bakketeig

Author information ▶ Copyright and License information ▶

See letter "Ultrasonography and handedness. Don't confuse direction with degree." on page 563.

This article has been cited by other articles in PMC.

Abstract

OBJECTIVE--To examine any associations between routine ultrasonography in utero and subsequent brain development as indicated by non-right handedness at primary school age and neurological development during childhood. DESIGN--Follow up of 8 and 9 year old children of women who took part in two randomised, controlled trials of routine ultrasonography during pregnancy. SETTING--Clinics of 60 general practitioners in Norway during 1979-81. Maternal and child health centres. SUBJECTS--2161 (89%) of 2428 eligible singletons were followed up, partly through a questionnaire to their parents and partly through information from health centres. MAIN OUTCOME MEASURES--The dominant hand of the child was assessed by 10 questions. Deficits in attention, motor control, and perception were evaluated by five questions. Impaired neurological development during the first year of life was assessed by an abbreviated version of the Denver developmental screening test. RESULTS--The odds of non-right handedness were higher among children who had been screened in utero than among control children (odds ratio 1.32; 95% confidence interval 1.02 to 1.71). No clear differences were found between the groups with regard to deficits in attention, motor control, and perception or neurological development during the first year of life. CONCLUSION--Our data suggest a possible association between routine ultrasonography in utero and subsequent non-right handedness, whereas no association with impaired neurological development was found. As the question on non-right handedness was one of six initial hypotheses, the observed results may be due to chance. None the less, the results suggest that the hypothesis may have some merit and should be tested in future studies.

Fetal Effects of US in Human

- The children with delayed speech had a higher rate of US exposure

CMAJ. 1993 Nov 15;149(10):1435-40.

Case-control study of prenatal ultrasonography exposure in children with delayed speech.

Campbell JD, Elford RW, Brant RF.

Author information

Abstract

OBJECTIVE: To determine whether there is an association between prenatal ultrasound exposure and delayed speech in children.

DESIGN: Case-control study.

SETTING: Network of community physicians affiliated with the Primary Care Research Unit, University of Calgary.

SUBJECTS: Thirty-four practitioners identified 72 children aged 24 to 100 months who had undergone a formal speech-language evaluation and were found to have delayed speech of unknown cause by a speech-language pathologist. For each case subject the practitioners found two control subjects matched for sex, date of birth, sibling birth order and associated health problems.

MAIN OUTCOME MEASURES: Rates of prenatal ultrasound exposure and delayed speech.

RESULTS: The children with delayed speech had a higher rate of ultrasound exposure than the control subjects. The findings suggest that a child with delayed speech is about twice as likely as a child without delayed speech to have been exposed to prenatal ultrasound waves (odds ratio 2.8, 95% confidence limit 1.5 to 5.3; $p = 0.001$).

CONCLUSION: An association between prenatal ultrasonography exposure and delayed speech was found. If there is no obvious clinical indication for diagnostic in-utero ultrasonography, physicians might be wise to caution their patients about the vulnerability of the fetus to noxious agents.

Fetal Effects of US

- Salvesen concluded that US exposure in utero is not associated with delayed speech in children

Ultrasound Obstet Gynecol. 1994 Mar 1;4(2):101-3.

Routine ultrasonography in utero and speech development.

Salvesen KA, Vatten LJ, Bakketeig LS, Eik-Nes SH.

Author information

Abstract

The purpose of this paper is to examine a possible association between prenatal ultrasonography and delayed speech among children. A follow-up study was carried out on primary school children born to women who took part in two randomized controlled trials of routine ultrasonography during pregnancy. Of 2428 eligible singletons, 2161 (89%) were followed up with a parental questionnaire and with information from maternal and child health centers. Parents assessed the development of speech during the childhood years and reported their observations in a questionnaire. Maternal and child health center records provided data on the children's development of speech and any referrals of children to a speech therapist. No significant differences between ultrasound-screened children and their controls were found in the parental assessment of speech development. According to health center records, screened children were less likely to be referred to a speech therapist (odds ratio, 0.51; 95% confidence interval 0.31, 0.85), but there were no other significant differences in speech development as reported in the health center records. We conclude that routine ultrasonography in utero is not associated with delayed speech in children.

Fetal Effects of US in Human

- Multiple prenatal US imaging and Doppler flow examination was associated with a small increase in the incidence of low birth weight.

Lancet. 1993 Oct 9;342(8876):887-91.

Effects of frequent ultrasound during pregnancy: a randomised controlled trial.

Newnham JP, Evans SF, Michael CA, Stanley FJ, Landau LI.

Author information

Abstract

Despite widespread application of ultrasound imaging and Doppler blood flow studies, the effects of their frequent and repeated use in pregnancy have not been evaluated in controlled trials. From 2834 women with single pregnancies at 16-20 weeks gestation, 1415 were selected at random to receive ultrasound imaging and continuous-wave Doppler flow studies at 18, 24, 28, 34, and 38 weeks gestation (the intensive group) and 1419 to receive single ultrasound imaging at 18 weeks (the regular group). Outcome data was obtained from 99% of women who entered the study. The only difference between the two groups was significantly higher intrauterine growth restriction in the intensive group, when expressed both as birthweight < 10th centile (relative risk 1.35; 95% confidence interval 1.09 to 1.67; p = 0.006) and birthweight < 3rd centile (relative risk 1.65; 95% confidence intervals 1.09 to 2.49; p = 0.020). While it is possible that this finding was a chance effect, it is also plausible that frequent exposure to ultrasound may have influenced fetal growth. Repeated prenatal ultrasound imaging and Doppler flow examinations should be restricted to those women to whom the information is likely to be of clinical benefit.

Fetal Effects of US in Human

- Newman f/u the children up to 8 yr old
- A delayed in language & speech dev at 1 yr in US exposed children
- But the differences was not observed during later development

Lancet. 2004 Dec 4-10;364(9450):2038-44.

Effects of repeated prenatal ultrasound examinations on childhood outcome up to 8 years of age: follow-up of a randomised controlled trial.

Newnham JP, Doherty DA, Kendall GE, Zubrick SR, Landau LL, Stanley FJ.

Author information

Abstract

BACKGROUND: Despite the widespread use of prenatal ultrasound studies, there are no published data from randomised controlled trials describing childhood outcomes that might be influenced by repeated ultrasound exposures. We previously undertook a randomised controlled trial to assess the effects of multiple studies on pregnancy and childhood outcomes and reported that those pregnancies allocated to receive multiple examinations had an unexplained and significant increase in the proportion of growth restricted newborns. Our aim was to investigate the possible effects of multiple prenatal ultrasound scans on growth and development in childhood. Here, we provide follow-up data of the childrens' development.

METHODS: Physical and developmental assessments were done on children whose pregnant mothers had been allocated at random to a protocol of five studies of ultrasound imaging and umbilical artery Doppler flow velocity waveform between 18 and 38 weeks' gestation (intensive group n=1490) or a single imaging study at 18 weeks' gestation (regular group n=1477). We used generalised logistic and linear regression models to assess the group differences in developmental and growth outcomes over time. Primary data analysis was done by intention-to-treat.

FINDINGS: Examinations were done at 1, 2, 3, 5, and 8 years of age on children born without congenital abnormalities and from singleton pregnancies (intensive group n=1362, regular group n=1352). The follow-up rate at 1 year was 85% (2310/2714) and at 8 years was 75% (2042/2714). By 1 year of age and thereafter, physical sizes were similar in the two groups. There were no significant differences indicating deleterious effects of multiple ultrasound studies at any age as measured by standard tests of childhood speech, language, behaviour, and neurological development.

INTERPRETATION: Exposure to multiple prenatal ultrasound examinations from 18 weeks' gestation onwards might be associated with a small effect on fetal growth but is followed in childhood by growth and measures of developmental outcome similar to those in children who had received a single prenatal scan.

PMID: 15582061 [PubMed - indexed for MEDLINE]

Fetal Effects of US in Human

- AIUM consensus in 2008 concluded that there was insufficient evidence of a direct link between US exposure in utero and subsequent biologic consequences in neonates & children

J Ultrasound Med. 2008 Apr;27(4):503-15.

American Institute of Ultrasound in Medicine consensus report on potential bioeffects of diagnostic ultrasound: executive summary.

Fowlkes JB; Bioeffects Committee of the American Institute of Ultrasound in Medicine.

Author information

Abstract

The continued examination of potential biological effects of ultrasound and their relationship to clinical practice is a key element in evaluating the safety of diagnostic ultrasound. Periodically, the American Institute of Ultrasound in Medicine (AIUM) sponsors conferences bringing experts together to examine the literature on ultrasound bioeffects and to develop conclusions and recommendations related to diagnostic ultrasound. The most recent effort included the examination of effects whose origins were thermal or nonthermal, with separate evaluations for potential effects related to fetal ultrasound. In addition, potential effects due to the introduction of ultrasound contrast agents were summarized. This information can be used to assess risks in comparison to the benefits of diagnostic ultrasound. The conclusions and recommendations are organized into 5 broad categories, with a comprehensive background and evaluation of each topic provided in the corresponding articles in this issue. The following summary is not meant as a substitute for the detailed examination of issues presented in each of the articles but rather as a means to facilitate further study of this consensus report and implementation of its recommendations. The conclusions and recommendations are the result of several rounds of deliberations at the consensus conference, subsequent review by the Bioeffects Committee of the AIUM, and approval by the AIUM Board of Governors.

Neural Effects of US - peripheral nerve

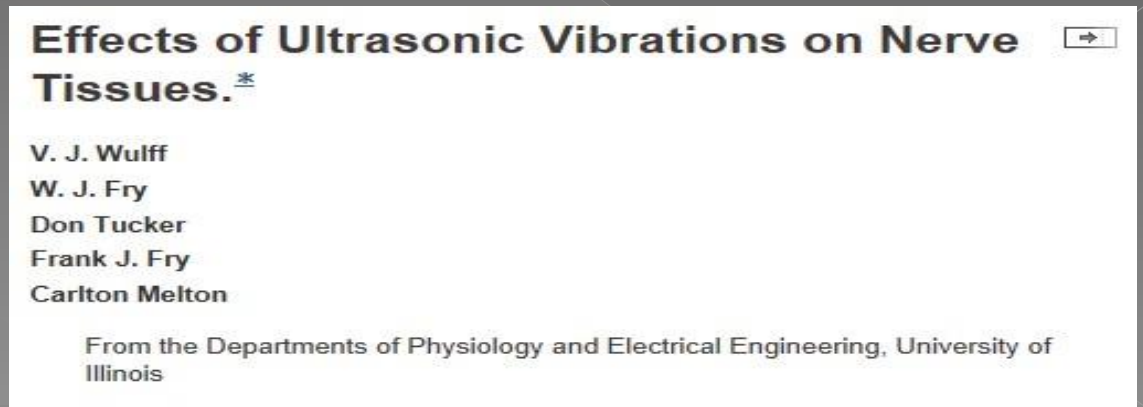
Neural Effects of US - peripheral nerve

- US exposure (35W/cm²) to the animal lumbar plexus at room temperature for 4.3s and at 1-2°C for 7.3s causes hind limb paralysis
- Histologic analysis

  - neuronal and myelin destruction in the spinal cord

  -axonal degeneration,chromatolysis, pyknosis & clumping of myelin in the peripheral nerve & cauda equina

(Chromatolysis- disintegration of the Nissl Bodies in a nerve cell body;
Pyknosis- degeneration of cell nucleus)



Effects of Ultrasonic Vibrations on Nerve Tissues.*

V. J. Wulff
W. J. Fry
Don Tucker
Frank J. Fry
Carlton Melton

From the Departments of Physiology and Electrical Engineering, University of Illinois

Neural Effects of US - peripheral nerve

- US exposure to the dorsal nerve root causes disruption of nodes of Ranvier and demyelination

Exp Neurol. 1987 Oct;98(1):78-92.

Diagnostic levels of ultrasound may disrupt myelination.

Ellisman MH, Palmer DE, André MP.

Author information

Abstract

Neonatal rats 3 to 5 days of age were exposed to the ultrasound beam from a medical ultrasound imaging system. Dorsal nerve roots were examined by electron microscopy. Comparison between exposed and sham-exposed controls revealed disruption of the nodes of Ranvier attributable to ultrasound. Morphologic changes ranged from vacuole formation in the paranodal region to frank demyelination and were still evident after 24 h of recovery. Rats of this age are at a stage of myelination similar to that of a human fetus 4 to 5 months. The ultrasound intensities used in this study are consistent with those used for human imaging (SPTA 0.135 mW/cm2, SATA 0.045 mW/cm2, SPTP 8.7 W/cm2, SPPA 1.9 W/cm2), but the relevance of these findings to clinical ultrasound will require further study.

PMID: 3308504 [PubMed - indexed for MEDLINE]

Neural Effects of US - peripheral nerve

- Reversible changes in conduction velocity & compound action potential, related to Na^{++} & K^{+} channels open with increase in temp. (Young RR et al, reversible block of nerve conduction by US. Arch neuro 1961)
- Increase in US intensity inactivate stretch sensitive channels and decrease the compound AP. (Tsui PH et al:In vitro effects of US with different energies on the conduction properties of neural tissue, Ultrasound 2005)
- Highly focused US decreased presynaptic activity and increased dendritic field potentials in hipocampal slices. (Bacthtold MR et al,:Focused US modifications of neural circuit activity in a mammalian brain, US Med Biol 1998)

Neural Effects of US - peripheral nerve

- Crush injury of the rat tibial nerves were exposed to US thermotherapy of 0.5 or 1.0 W/cm²
- Recovery rate of the nerve conduction velocity and compound action potential in the tibial nerve treated with US of 0.5 W/cm² were significantly faster .

Arch Phys Med Rehabil. 1988 Jun;69(6):410-4.

Ultrasound thermotherapy effect on the recovery of nerve conduction in experimental compression neuropathy.

Hong CZ, Liu HH, Yu J.

Author information

Abstract

Bilateral tibial nerves of 18 albino rats were mechanically compressed between knee and ankle. Beginning on the fifth day after compression, ultrasound thermotherapy of 0.5 or 1.0watt/cm2 was applied over the area of nerve compression in one limb for one minute three times per week. The other side (control) was not treated. Motor distal latency (DL), motor nerve conduction velocity (NCV) of the segment with nerve compression, and amplitude of the evoked compound muscle action potential (ACMAP) were measured before and immediately after nerve compression and two or three times per week after compression. The recovery rates of NCV and ACMAP of the tibial nerve treated with ultrasound of 0.5watt/cm2 were significantly faster than those of the control nerve. There was no significant change in the recovery rate of DL. However, if ultrasound of 1.0watt/cm2 was applied, the recovery rate of ACMAP of the treated nerve was slower than that of the control nerve. There were no significant changes in the recovery rates of DL and NCV. Low doses of ultrasound thermotherapy may facilitate recovery of compression neuropathy, but higher doses may induce an adverse effect.

PMID: 3377665 [PubMed - indexed for MEDLINE]

Neural Effects of US - peripheral nerve

- Injured rat sciatic nerves when exposed to therapeutic US showed histologic evidence of regeneration including increased nerve fiber density, prominent Schwann cell nuclei, and myelin formation

Ultrasound Med Biol. 2002 Oct;28(10):1335-41.

Low-intensity pulsed ultrasound accelerates the regeneration of the sciatic nerve after neurotomy in rats.

Crisci AR, Ferreira AL.

Author information

Abstract

The biophysical qualities of pulsed ultrasound (US) led us to appraise its effect on the regeneration of a peripheral nerve. In this study, our intention was to evaluate the effects of pulsed US on the axotomy of the sciatic nerve in rats. The proximal stump of the nerve was stimulated on 12 consecutive days with pulsed US and the effects of the sonication were evaluated through morphological and morphometric techniques. Our findings suggest that sonication leads to a rapid regeneration of the nerve after axotomisation. These affirmations are based on the counting of different types of fibre components in mixed nerves and the morphological recovery of the same in comparison with nerves of animals submitted to sham operation.

PMID: 12467860 [PubMed - indexed for MEDLINE]

Neural Effects of US - peripheral nerve

- Therapeutic US on ulnar nerve:
  - ≤ 1.9 W/cm² = ↓ temp & ↓ nerve conduction velocity (NCV)
  - ≥ 1.9 W/cm² =↑ temp & ↑ NCV

  (Madsen PW Jr, Gersten JW: The effects of US on conduction velocity of peripheral nerves, Arch Phys Med Rehabil 1961)

- Bimodal distribution in US-induced NCV
  - 1 - 2 W/cm² = ↓ NCV
  - ≤ 0.5 W/cm² = ↑ NCV
  - ≥ 3 W/cm² = ↑ NCV

(Farmer WC: Effect of intensity of US on conduction of motor axons, Phys Ther 1968)

Neural Effects of US - peripheral nerve

- No documented US-induced biologic consequences in patients during use for RA.
  - Coupling gel reduced the thermal effects
  - Use of B-mode US
  - Frequent transducer movement & adjustment
  - Conduction of heat by the needle
  - Heat dissipation by blood vessels close to nerves

Neural Effects of US - peripheral nerve

- USGRA appears to be relatively safe

Ocular Effects of US

- Collagen in the cornea and lens are efficient absorbers of US energy and have the potential to increase in temp.
- Prolonged exposure may produces cataract

Ocular Effects of US

- Focused US exposure(3 & 7 MHz at peak intensity of 58 & 135 W/cm²) can cause
  - transient chemosis
  - Conjunctiva injection
  - corneal clouding
  - lens opacities
  - reduction in intraocular tension
  - destruction of the ciliary body

Ocular Effects of US

- High frequency US (> 50 MHz) for ant chamber imaging
- Theoretic concern for thermal effects at this frequency
- But this energy is rapidly dissipated, and exposure is usually only a few second

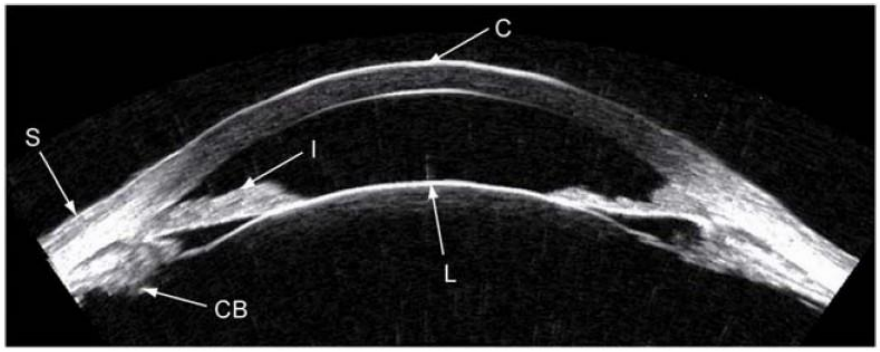


FIGURE 3.4 High resolution ultrasound image of the anterior segment of the eye obtained with arc-scan geometry. Visualised structures include the cornea (C), sclera (S), iris (I), anterior lens surface (L) and ciliary body (CB). (Image reproduced courtesy of Dr R H Silverman, Department of Ophthalmology, Weill Medical College of Cornell University, New York)

Ocular Effects of US

Table 5. FDA Recommendations on Acoustic Output Exposure Levels

Use	$I_{SPTA.3}$ (mW/cm^2)		$I_{SPPA.3}$ (W/cm^2)	MI
—	Track 1	Track 3	Tracks 1 and 3	
Peripheral vessel	720	720	190	1.9
Cardiac	430	720	190	1.9
Fetal imaging and other	94	720	190	1.9
Ophthalmic	17	50 and TI ≤ 1	28	0.23

The limits vary depending on the on-screen display of the indices. Track 1 limits are used when there is no display of indices. Track 3 limits are used when there is a visual display of indices. FDA = Food and Drug Administration; $I_{SPPA.3}$ = derated spatial-peak, pulse-average intensity; $I_{SPTA.3}$ = derated spatial-peak, temporal-average intensity; MI = mechanical index; TI = thermal index.

Pulmonary Effects of US

- US induced lung hemorrhage is common in experimental animals, but not in human
- However, neonates & patients with pulmonary disease may be theoretically vulnerable to this process

Limitations of Studies Examining Biologic Effects of US

- Core temperatures of experimental animals are different from those of human
- Restraint animals is a known teratogen
- Unrecognized maternal or congenital disease or toxin exposure
- Experimental models and methods varied substantially between studies
- Lack of standardized US exposure protocols
- Use of baseline anesthesia

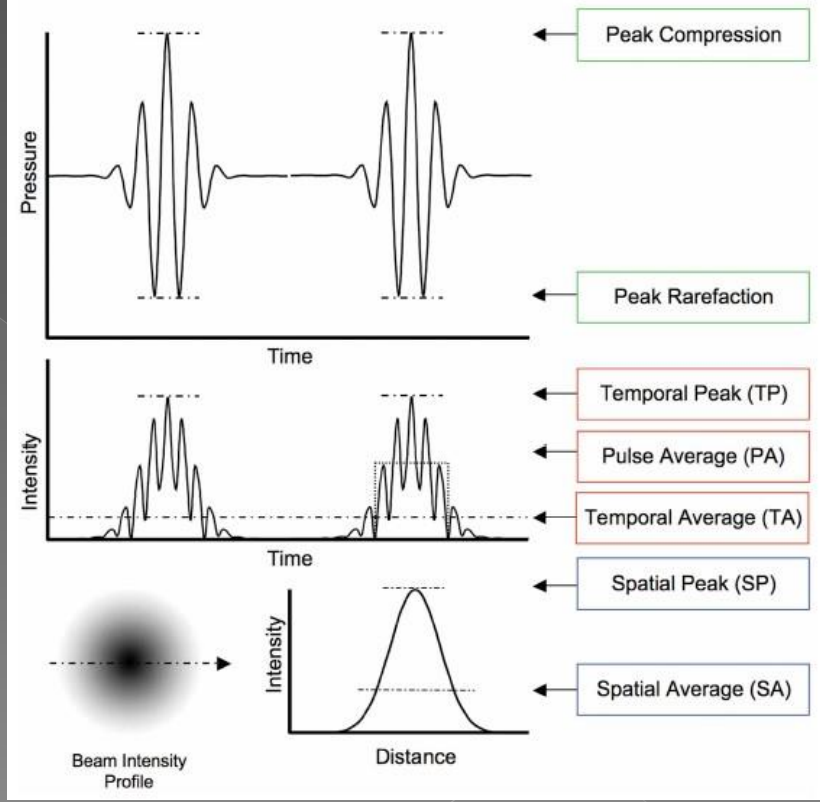
Current Recommendation
-Limiting the US acoustic power

Table 5. FDA Recommendations on Acoustic Output Exposure Levels

Use	$I_{SPTA.3}$ (mW/cm^2)		$I_{SPPA.3}$ (W/cm^2)	MI
—	Track 1	Track 3	Tracks 1 and 3	
Peripheral vessel	720	720	190	1.9
Cardiac	430	720	190	1.9
Fetal imaging and other	94	720	190	1.9
Ophthalmic	17	50 and TI ≤ 1	28	0.23

The limits vary depending on the on-screen display of the indices. Track 1 limits are used when there is no display of indices. Track 3 limits are used when there is a visual display of indices. FDA = Food and Drug Administration; $I_{SPPA.3}$ = derated spatial-peak, pulse-average intensity; $I_{SPTA.3}$ = derated spatial-peak, temporal-average intensity; MI = mechanical index; TI = thermal index.

Figure 1. Acoustic pulses showing where and how acoustic output is measured and reported for a single scan line at the focus of a diagnostic medical ultrasound system.



Output Display Standard (ODS)-1992 by FDA

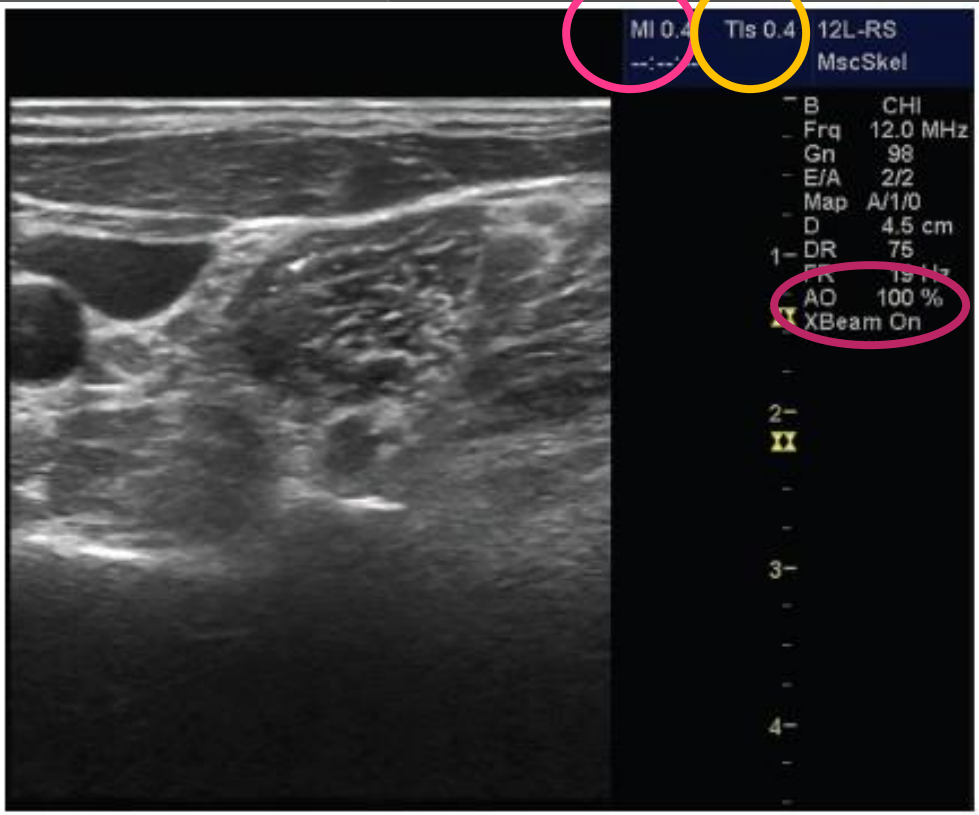
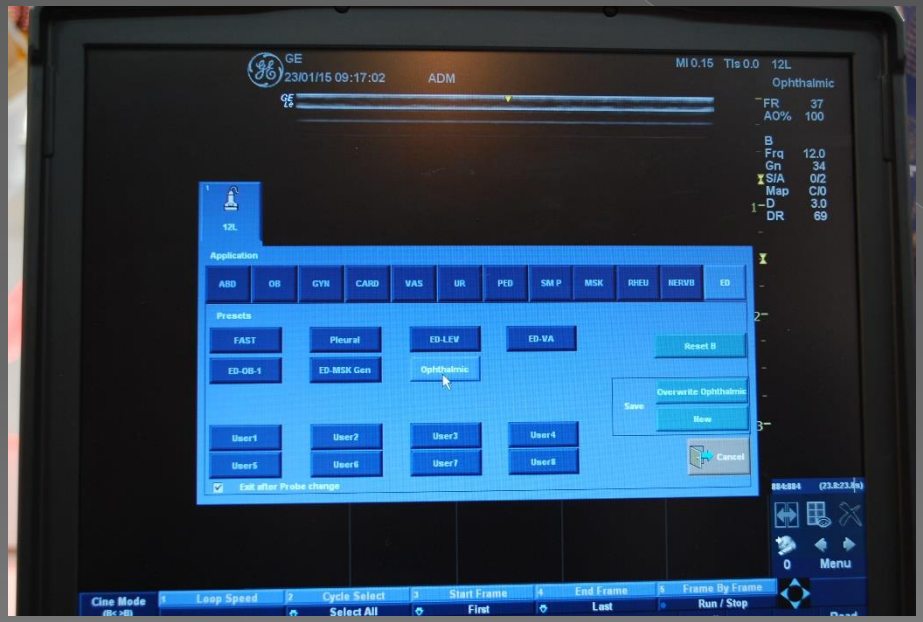


Fig. 1. Ultrasound image displaying the mechanical and thermal indices as MI and TIs, respectively. In this image the indices are displayed at the top right corner. The location may vary depending on the manufacturer.

- MI = mechanical index
- TI= Thermal index


GE
23/01/15 09:17:02
ADM
MI 0.15 TIs 0.0 12L
Ophthalmic
FR 37
AO% 100
B
Frq 12.0
Gn 34
S/A 0/2
Map C/0
D 3.0
DR 69
12L
Application
ABD OB GYN CARD VAS UR PED SM P MSK RHEU NERVB ED
Presets
FAST Pleural ED-LEV ED-VA
ED-OB-1 ED-MSK Gen Ophthalmic
Reset B
Save
Overwrite Ophthalmic
New
User1 User2 User3 User4
User5 User6 User7 User8
Cancel
Exit after Probe change
0
Menu
Cine Mode
Loop Speed
Cycle Select
Select All
Start Frame
First
End Frame
Last
Frame By Frame
Run / Stop


GE
23/01/15 09:18:14
ADM
MI 1.2 TIs 0.5 12L
NER-Superfici
FR 34
AO% 100
CHI
Frq 12.0
Gn 37
S/A 3/4
Map B/0
D 3.0
DR 69
12L
Application
ABD OB GYN CARD VAS UR PED SM P MSK RHEU NERVB ED
Presets
NER-Superficial NER-Average NER-Deep Spine
Reset HAR
Save
verwrite NER-Superfici
New
BLOCK User2 User3 User4
User5 User6 User7 User8
Cancel
Exit after Probe change
0
Menu
Cine Mode
Loop Speed
Cycle Select
Select All
Start Frame
First
End Frame
Last
Frame By Frame
Run / Stop

Current Recommendation

- **Limiting the US exposure time**

Table 7. Recommended Exposure Times for Nonobstetric and Nonfetal Ultrasound Imaging at Various Thermal Indices in Bone and Cranium

Maximum Exposure Time	TI_B	TI_C
5 s	5.0–6.0	Not recommended
15 s	4.0–5.0	Not recommended
1 min	3.0–4.0	2.5–3.0
4 min	2.5–3.0	2.0–2.5
15 min	2.0–2.5	1.5–2.0
30 min	—	1.0–1.5
60 min	1.5–2.0	0.7–1.0
120 min	1.0–1.5	—

Adapted with permission from the 2009 recommendations provided by the British Medical Ultrasound society at their Web site: http://www.bmus.org/policies-guides/pg-safety03.asp. Accessed April 24, 2010.

TI_B = thermal index bone; TI_C = thermal index cranium.

Current Recommendation

- **Output Display Standard (ODS)**

TABLE A3 Levels of the safety indices for which user action is recommended by the British Medical Ultrasound Society (Hoskins et al, 2003)

Safety index	User action
MI > 0.3	Reduce duration of exposure to neonatal lung or intestine
MI > 0.7	Potential hazard with gas contrast agents
TI > 0.7	Restrict exposure times of embryo or fetus
TI > 1.0	Eye scanning not recommended (not applicable for fetal scanning)
TI > 3.0	Use not recommended for embryo or fetal scanning

Current Recommendation

- **ALARA (as low as reasonably achievable) by AIUM**

The ALARA principle:

A. Controlling energy;
B. Controlling exposure time;
C. Controlling scanning technique;
D. Controlling system setup;
E. Effects of system capabilities;
F. Effects of operating mode (learn to distinguish);
G. Effects of transducer capabilities.

Current Recommendation

- **Limiting the US scanning time in fetus**

SUGGESTED SCANNING GUIDELINES BASED ON ACOUSTIC OUTPUT

Target	Index	Value	Duration
Fetus (1st trimester)	MI	<0.5	unlimited
Fetus (1st trimester)	TI	<0.5	unlimited
Fetus (2nd / 3rd trimester)	MI	<1.0	unlimited
Fetus (2nd / 3rd trimester)	TI	<1.0	unlimited
Neonate, pediatric, adult	MI	<1.0	unlimited
Neonate, pediatric, adult	TI	<1.0	unlimited
Fetus (1st trimester)	MI	>0.5	<5 minutes
Fetus (1st trimester)	TI	>0.5	<5 minutes
Fetus (2nd / 3rd trimester)	MI	>1.0	<5 minutes
Fetus (2nd / 3rd trimester)	TI	>1.0	<5 minutes
Neonate, pediatric, adult	MI	>2.5	<1 minute
Neonate, pediatric, adult	TI	>2.5	<1 minute
Eye	MI	<0.32	<unlimited

International Guideline

- World Federation of US in Medicine and Biology (WFUMB)
- British Medical US Society
- European Federation of Societies for US in Medicine and Biology (EFSUMB)
- Australian Society for US in Medicine (ASUM)
- The American Institute of US in Medicine

conclusions

- No confirmed biological effects on patients or operators caused by exposure to diagnostic US that complies to FDA regulation
- …….minimizing the exposure time is probably the single most important factor…
- …..current data indicate that the benefit outweigh the risks.


ROOTS


ABSA

(In collaboration with Malaysia SIGRA)