



INSTITUTE FOR DEFENSE ANALYSES

**Predicting the Significance of Injuries Potentially  
Caused by Non-Lethal Weapons: Tympanic  
Membrane Rupture (TMR), Permanent Threshold  
Shift (PTS), and Photothermal Retinal Lesions**

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June 2016

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IDA Document NS D-8118

Log: H 16-000949



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#### About This Publication

This work was conducted by the Institute for Defense Analyses (IDA) under contract HQ0034-14-D-0001, Project DU-2-4040, "Significance of Tympanic Membrane Rupture (TMR) and Related Permanent Threshold Shift (PTS)," for the Joint Non-Lethal Weapons Directorate (JNLWD). The views, opinions, and findings should not be construed as representing the official position of either the Department of Defense or the sponsoring organization.

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Institute for Defense Analyses

21 June 2016

IDA is a set of Federally-Funded Research and Development Centers (FFRDCs). Our FFRDC is located in Alexandria, VA and supports the Office of the Secretary of Defense (OSD). We provide the DoD with independent, rigorous analyses on military systems.

Over the past year, our team at IDA has performed three separate analyses for the Joint Non-Lethal Weapons Directorate (JNWLD). All three analyses involved predicting the significance of injuries potentially caused by Non-Lethal Weapons (NLWs).

Our team consists of PhD-level biomedical engineers, biophysicists, biochemists, and molecular biologists, each with 5–20 years of analytical experience.

## IDA | Objective

For a given injury potentially caused by a NLW:

- Identify **attributes** of the injury that can quantitatively, accurately, and precisely **predict the significance** of the injury, per the definitions set forth in DoDI 3200.19 and
- Consider how these predictive attributes can be estimated **during the development acquisition phase** of a novel NLW.

$$\text{RSI} = P(\text{significant injury})$$

$$= P(\text{injury occurred}) \times P(\text{significant injury} \mid \text{injury occurred})$$

$$= P(\text{IO}) \times P(\text{SI} \mid \text{IO})$$

← This Analysis

The objective of each of our analyses was two-fold: For a given injury potentially caused by a NLW:

- Bin the injury into different types, where each type is defined by a physical characteristic or attribute– size, magnitude, location in the body, and so forth– such that these attributes can predict the significance of that injury type, per the definitions set forth in DoDI 3200.19.
- Consider how those predictive attributes could be estimated during the development acquisition phase of a novel NLW, such as a novel flashbang grenade, a novel dazzling laser, and so forth.

As we know, a NLW's Risk of Significant Injury (RSI) is the probability (or likelihood) that the NLW will cause a significant injury.

RSI can be estimated via two quantities:

- The probability that the injury occurred,  $P(\text{IO})$ , times
- The probability that the injury is significant, given that it has occurred,  $P(\text{SI}|\text{IO})$ .

Our analyses have focused on the second quantity,  $P(\text{SI}|\text{IO})$ .

## IDA | Bottom Line Up Front

- Permanent Threshold Shift (PTS)
  - PTS  $\geq 25$  dB: **Significant:  $P(SI | IO) \approx 1$**
  - PTS  $< 25$  dB: **Not Significant:  $P(SI | IO) \approx 0$**
- Tympanic Membrane Rupture (TMR)
  - TMR  $\geq 2$  mm (James Class 2 & 3): **Significant:  $P(SI | IO) \approx 1$**
  - TMR  $< 2$  mm (James Class 1): **Not Significant:  $P(SI | IO) \approx 0$**
- Photothermal Retinal Lesion
  - Suprathreshold: **Significant:  $P(SI | IO) \approx 1$**
  - Threshold inside the macula: **Significant:  $P(SI | IO) \approx 1$**
  - Threshold outside the macula: **Not Significant:  $P(SI | IO) \approx 0$**
  - Subthreshold: **Not Significant:  $P(SI | IO) \approx 0$**



We investigated three potential injuries caused by NLWs. Below is a quick preview of our results:

- Permanent Threshold Shift (PTS) in hearing sensitivity, which can be caused by a sound-based NLW such as a flashbang grenade. We binned PTS into two types based on the magnitude of the hearing loss:  $>$  or  $< 25$  dB:
  - We concluded PTS  $\geq 25$  dB was significant. That is, we approximated that  $P(SI|IO) \approx 1$  for this type of PTS.
  - We concluded PTS  $< 25$  dB was not significant. That is, we approximated  $P(SI|IO) \approx 0$  for this type of PTS.
- Tympanic Membrane Rupture (TMR), otherwise known as a burst eardrum, which can also be caused by a sound-based NLW like a flashbang grenade. We also binned TMR into two different types, based on the size of the TMR:  $>$  or  $< 2$  mm long:
  - We concluded TMR  $> 2$  mm was significant. That is, we approximated that  $P(SI|IO) \approx 1$  for this type of TMR.
  - We concluded TMR  $\leq 2$  mm was not significant. That is, we approximated  $P(SI|IO) \approx 0$  for this type of TMR.
- Photothermal Retinal Lesions, which can be caused by some laser pointers that are somewhat similar to dazzling lasers (although dazzling lasers are explicitly designed to be eye safe within intended use). We binned Photothermal Retinal Lesions into four classes, based on their clinical classification:
  - We concluded that suprathreshold lesions, as well as threshold lesions inside the macula, are significant, such that  $P(SI|IO) \approx 1$  for these types of lesions.
  - We concluded that threshold lesions beyond the macula, as well as subthreshold lesions, are not significant, such that  $P(SI|IO) \approx 0$  for these types of lesions.

The purpose of this briefing is to give an introductory overview of our rationale behind these conclusions. Our rationale is explained in more detail in three reports, each of which has been or will soon be approved for public release:

- King, Allison and Shelley Cazares. 2015. Significance of Permanent Threshold Shift Potentially Caused By Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.
- Cazares, Shelley, Leon R. Hirsch, and Allison King. 2016. Significance of Tympanic Membrane Rupture Potentially Caused by Flashbang Grenades. IDA Document D-5824. Alexandria, VA: Institute for Defense Analyses, May.
- Hirsch, Leon R., Jenny R. Holzer, Michael S. Finnin, and Shelley M. Cazares. 2015. Significance of Retinal Lesions Potentially Caused by Dazzling Lasers. IDA Document D-5691. Alexandria, VA: Institute for Defense Analyses, December.

# IDA | Agenda

- **Method**
- Results:
  - Permanent Threshold Shift (PTS)
  - Tympanic Membrane Rupture (TMR)
  - Photothermal Retinal Lesions
- Discussion

First, we will describe our approach. All three analyses used this same approach.

Next, we will describe the results of our three analyses, one by one.

Finally, we will provide the opportunity to discuss the results of all three analyses, from a broad perspective.

## IDA | Method: Literature Search

- DoDI 3200.19 defines:
  - **RSI** = “The potential of NLW to directly cause injury **requiring HCC Index 1 or higher** HCC index treatment, **permanent injury**, or death”
  - **Permanent Injury** = “Physical damage to a person that permanently impairs physiological function and **restricts the employment or other activities for that person for the rest of his or her life**”
- DoDI 3200.19 does not define “significant injury”
- We interpret DoDI 3200.19 as:
  - **Significant Injury** = an injury:
    - For which the **standard of care is HCC1+** treatment or
    - That leads to physical damage that permanently impairs physiological function and **restricts the employment or other activities for that person for the rest of his or her life** or
    - That leads to death.

Our method was based on searching the medical and other relevant literature to identify physical attributes of each injury that could be used to predict the significance of the injury.

We first considered the meaning of the term “significant injury”.

DoDI 3200.19 defines several terms, including RSI and Permanent Injury:

- RSI is the potential of a NLW to cause an injury requiring HCC1+ treatment (beyond buddy care), permanent injury, or death.
- Permanent injury is physical damage that restricts a person’s life.

Note, though, that DoDI 3200.19 does not explicitly define Significant Injury.

Therefore, we interpreted DoDI 3200.19 as follows:

- Significant Injury is:
  - An injury for which the standard of care is HCC1+ treatment (beyond buddy care), or
  - An injury that leads to physical damage that restricts a person’s life, or
  - An injury that leads to death.

Our interpretation of the definition of Significant Injury drove our approach to our three analyses.

## IDA | Method: Literature Search

1. Identify injury and limit scope: mechanism of injury
2. Review medical care to treat injury: **HCC0 vs. HCC1+**
3. Review medical care to treat complications of injury: **HCC0 vs. HCC1+**
4. Review permanent disabilities caused by injury or complication: **Restrictions on employment or other activities for the rest of a person's life**

Our approach consisted of four steps:

- Identify the injury and limit the scope of the analysis. This step involved reviewing the physics and physiology underlying the mechanism of injury.
- Review the medical care to treat the injury. This step involved classifying the medical care as HCC0 (buddy care, not significant) vs. HCC1+ (first responder or health care provider, significant)
- Review the medical care to treat complications of the injury (rather than the injury itself). This also involved classifying the medical care as HCC0 (not significant) vs. HCC1+ (significant).
- Review the permanent disabilities caused by the injury or complication. This involved reviewing the restrictions to life (significant vs. not significant) caused by those disabilities.

Each part of our analysis led directly back to our interpretation of the definition of Significant Injury in DoDI 3200.19.

## IDA | Agenda

- Method
- **Results:**
  - **Permanent Threshold Shift (PTS)**
  - Tympanic Membrane Rupture (TMR)
  - Photothermal Retinal Lesions
- Discussion



We applied our approach to PTS.

## IDA | PTS: mechanism of injury

**PTS = irreversible hearing loss caused by exposure to intense sound**

*Farlex Partner Medical Dictionary. 2012.*

- Our use of term “PTS”:
  - Sensorineural hearing loss caused by inner ear injury
  - Not conductive hearing loss caused by middle ear injury
  - ICD-10-CM codes:  
H90.3, H90.41, H90.42, & H90.5
- PTS can be caused by:
  - Disease
  - Blast (e.g., flashbang)

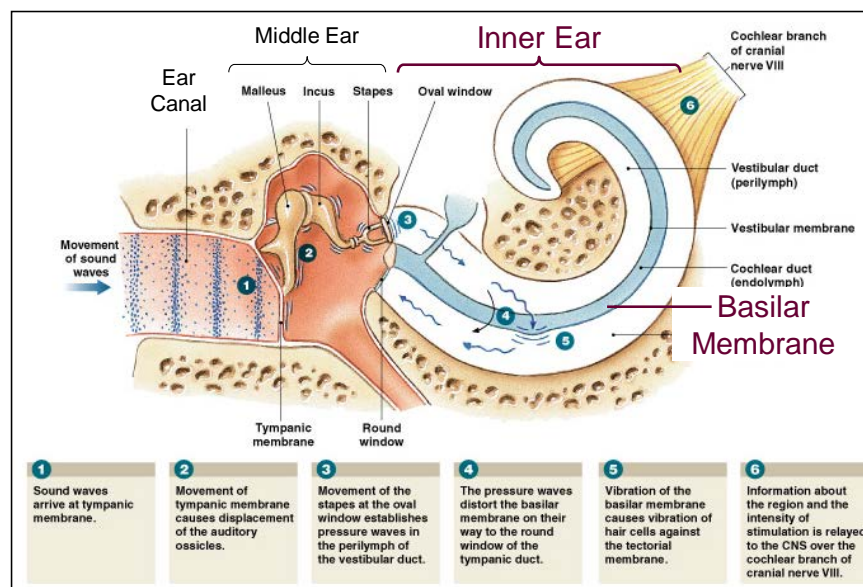


Figure from: van der Willigen. 2008. *Auditory Perception*. Nijmegen, Netherlands: Radboud University.

**We focused on blast-induced PTS.**

The first step of our approach is to review the mechanism of injury.

We found that PTS is an irreversible hearing loss caused by exposure to intense sound.

We found that most papers in the medical and other relevant literature used the term “PTS” to refer to sensorineural hearing loss caused by injury to the inner ear– the hair cells lining the basilar membrane of the cochlea.

We note that this use of the term “PTS” does not refer to conductive hearing loss caused by injury to the outer or middle ear. We will refer to conductive hearing loss later in this briefing, in regards to TMR.

To be more specific about just what we mean by “PTS”, we refer to the ICD-10-CM codes for sensorineural hearing loss. The ICD-10-CM codes went into effect in American hospitals in October 2015.

We also found that PTS can be caused by:

- Disease,
- Chronic exposure to loud, continuous sounds, and/or
- Acute exposure to loud, impulse sounds, such as a blast. Flashbang detonations fall into this category.

Therefore we focused our analysis– we limited our scope– to blast-induced PTS, i.e., blast-induced sensorineural hearing loss.

## IDA | PTS: mechanism of injury

- Sound is often characterized by its Sound Pressure Level (SPL) in units of dB:

$$\text{SPL} = 20 \log_{10} \left( \frac{P}{P_o} \right)$$

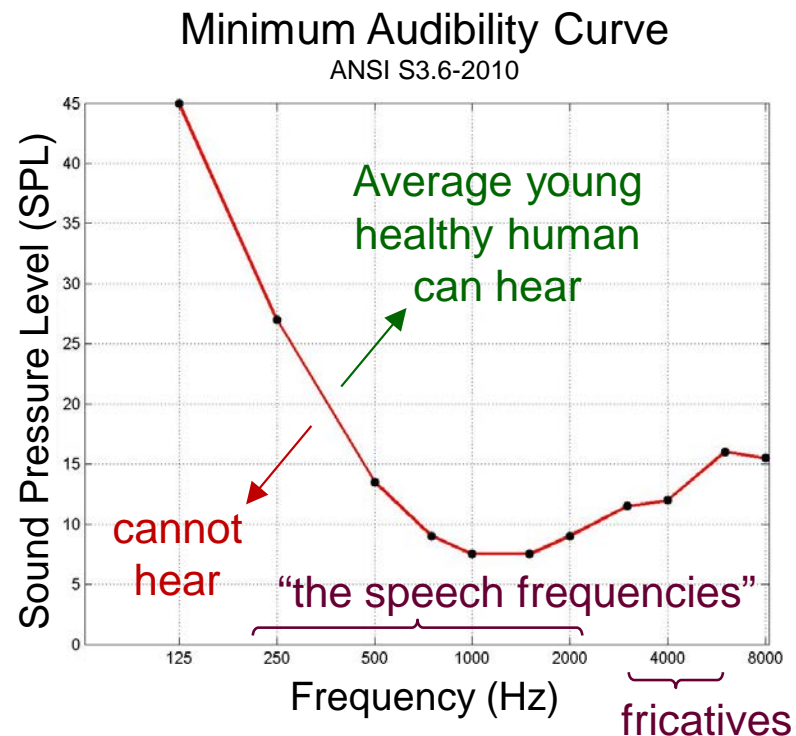
where

- P is the sound pressure and
- P<sub>o</sub> is a reference sound pressure

ANSI S1.1-2013.

- Humans are most sensitive to sounds at around 1000 – 2000 Hz.

ANSI S3.6-2010.



**Audiometric tests measure hearing loss w/r/t to the Minimum Audibility Curve at pure-tone frequencies b/t 125 – 8000 Hz.**

van der Willigen. 2008. *Auditory Perception*. Nijmegen, Netherlands: Radboud University.

We found that sound is often characterized by its Sound Pressure Level (SPL), measured in decibels (dB). SPL is related to the log of the sound pressure, with respect to a reference pressure (20 microPascals, the softest sound that the average, young, healthy human can detect).

We found that humans are most sensitive to sounds at around 1000 – 2000 Hz. That is convenient, since adult human speech normally falls in the frequency range of 250 – 2000 Hz. Note, though, that fricatives such as /ch/, /t/, and /f/ often contain higher frequencies, such as around 4000 Hz.

The American National Standards Institute (ANSI) has charted the Minimum Audibility Curve, the softest sound that the average, young, healthy human can detect at different pure tone frequencies, shown here in the plot:

- Sounds with SPLs above this curve are loud enough for the average, young, healthy human to detect
- Sounds with SPLs below this curve are not loud enough— the average, young, healthy human cannot detect them.

Audiometric tests can be done in the clinic to measure a person's hearing loss at individual pure-tone frequencies with respect to the Minimum Audibility Curve. This particular version of the Minimum Audibility Curve shows that the softest sound that the average young, healthy human can detect at 1000 Hz is 7.5 dB. However, consider an example in which audiometric testing is used to determine the softest sound that a particular human patient can hear. If the softest sound that our example person can hear at 1000 Hz is 20 dB, then an audiologist will take 20 dB and subtract out 7.5 dB, the value of the Minimum Audibility Curve at 1000 Hz. The difference is 12.5 dB, which is often rounded to the nearest integer: 13 dB. Thus our example person is said to have a hearing threshold of 13 dB at 1000 Hz.

This same method is used to find the hearing thresholds of the example person at other pure tone frequencies, as well: 250 Hz, 500 Hz, 1000 Hz (as was just explained), 2000 Hz, 4000 Hz, and so forth. One can then take the mean of these hearing thresholds over all pure tone frequencies under analysis. This mean hearing threshold is often used as an estimate of a person's PTS.

# IDA | PTS: medical care to treat injury

## World Health Organization (WHO)

Not Significant

??

Significant

Grade of Impairment	Audiometric Result (mean)	Performance	Recommendations
0: No impairment	≤25 dB	<b>No or very slight hearing problems</b> Able to hear whispers.	
1: Slight Impairment	26 – 40 dB	Able to hear and repeat words spoken in normal voice at 1 m.	Counseling. <b>Hearing aids <u>may</u> be needed.</b>
2: Moderate impairment	41 – 60 dB	Able to hear and repeat words spoken in raised voice at 1 m.	<b>Hearing aids usually recommended.</b>
3: Severe impairment	61 – 80 dB	Able to hear some words when shouted into better ear.	<b>Hearing aids needed.</b>
4: Profound impairment	≥81 dB	Unable to hear/understand even a shouted voice.	<b>Hearing aids may help understanding words.</b>

The second step of our approach is to consider the standard of care for a patient with PTS.

The World Health Organization (WHO) quantifies a person's PTS by his or her mean hearing threshold, as measured via audiometric test and averaged over all pure-tone frequencies under analysis:

- The WHO has declared that a mean PTS  $\leq 25$  dB indicates no or very slight hearing problems. In general, the person is still able to hear whispers. Therefore we concluded that a mean PTS  $\leq 25$  dB is not significant, since the person requires no medical care and has no restrictions on employment or other activities for the rest of his or her life.
- On the other end of the severity scale, the WHO has declared that a mean PTS  $\geq 41$  dB indicates that hearing aids are usually or always needed. In the United States, fitting a hearing aid requires a visit to a trained audiologist, which is beyond HCC0 care (HCC1+). Therefore we concluded that a mean PTS  $\geq 41$  dB is significant, since the standard of care (hearing aid fitting) is HCC1+.
- In the middle of the severity scale, the WHO has declared that a mean PTS of 26 – 40 dB, inclusive, indicates that hearing aids may (or may not) be needed. Therefore, we could not conclude that a PTS in this range is significant or not significant simply based on the standard of care— for these values of PTS, there is no particular standard of care in regard to hearing aids. Therefore, we had to further consider this particular range of PTS, as will be discussed on the next slides.

**IDA | PTS:** medical care to treat complications

**No complications that we know of.**



In the third step of our approach, we considered the standard of care for any downstream complications of a PTS of 26 – 40 dB. We could identify no particular complications.

## IDA | PTS: permanent disabilities

- We do not differentiate between PTS in target vs. operator.

→ We assume “failure to meet U.S. military enlistment criteria” is a surrogate for “restrictions on employment”.

- We have already concluded:
  - PTS  $\geq 41$  dB is significant, since hearing aids are recommended (HCC1+).
  - PTS  $\leq 25$  dB is not significant, since it is “no impairment”.

→ We consider “failure to enlist” for only PTS that is 26 – 40 dB.

- There are many combinations of hearing thresholds that fail to meet enlistment criteria but have an average between 26 – 40 dB.

**E.g.:** 0 dB @500 Hz, 30 dB @1000, 2000, 3000 Hz, 60 dB @4000 Hz → mean 30 dB

**We err on the side of caution and approximate  
PTS of 26 – 40 dB as significant.**

## Pre-Enlistment Hearing Standards

DoDI 6130.03 (2011)

Pure Tone (Hz)	Max Level Any Ear (dB)
500	$\leq 35$
1000	$\leq 35$
2000	$\leq 35$
3000	$\leq 45$
4000	$\leq 55$

In the fourth and final step of our approach, we considered the permanent disability caused by a PTS of 26 – 40 dB.

We first noted that a flashbang detonation could cause PTS to both the individuals targeted by the detonation and the military operators who employed the flashbang. Based on guidance from the JNLWD, we did not differentiate between PTS experienced by the target vs. the operators of the flashbang. This lack of distinction eased our analysis:

- It is difficult to quantify the restrictions on life that a PTS would impose upon a targeted individual, since it is difficult to anticipate all types of activities or functions a targeted individual would need to perform for the rest of his or her life.
- However, it is much more straightforward to quantify the restrictions on life that a PTS would impose upon a military operator, since the military has clear guidelines on hearing standards.

Therefore, we focused our analysis to the restrictions that a PTS would cause to a military operator. In particular, we assumed that failure to meet US military enlistment criteria is a surrogate for “restrictions on employment”, the term used in DoDI 3200.19. The chart on the right summarizes the pre-enlistment hearing standards for the US military, taken from DoDI 6130.03. A separate hearing threshold is stipulated for each pure tone frequency. To enlist in the US military, a person must have a hearing threshold  $\leq 35$  dB at 500, 1000, and 2000 Hz,  $\leq 45$  dB at 3000 Hz, and  $\leq 45$  dB at 4000 Hz.

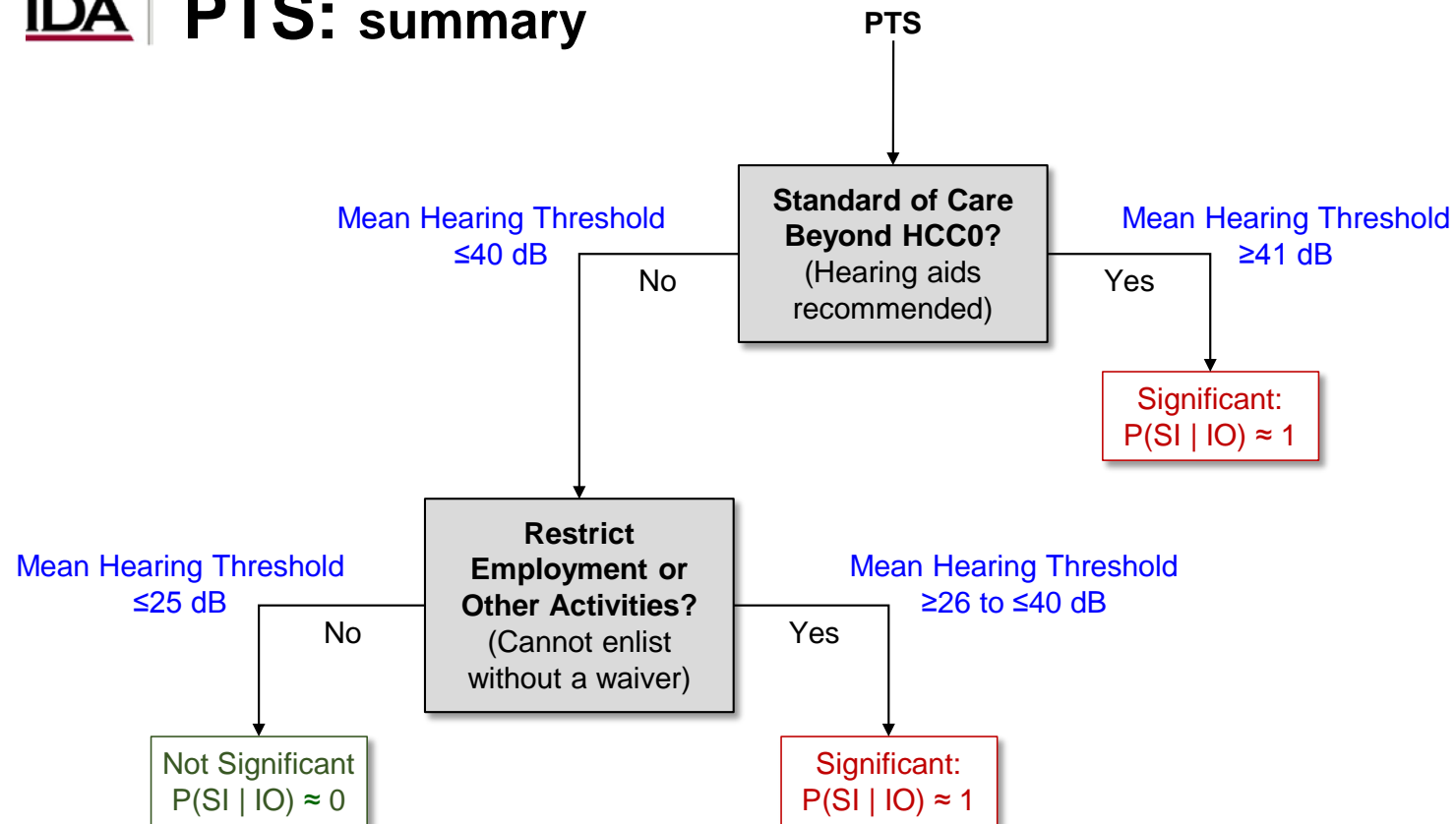
We have already concluded that:

- PTS  $\geq 41$  dB is significant, since hearing aids are the standard of care (HCC1+)
- PTS  $\leq 25$  dB is not significant, since this range of values represents no or mild impairment, for which whispers can still be heard.
- Therefore, we only considered “failure to meet US military enlistment criteria” for PTS of 26 – 40 dB, the remaining middle ground of severity. This middle ground is a “grey area”: One could conclude that a PTS of 26 – 40 dB is either significant or not significant, depending upon the assumptions one chooses to make when comparing mean hearing thresholds to the individual, frequency-specific hearing thresholds stipulated in DoDI 6130.03.

We note that there are many combinations of frequency-specific hearing thresholds that could fail the pre-enlistment criteria in DoDI 6130.03 and have a mean of 26 – 40 dB. One example is a hearing threshold of 0 dB at 500 Hz, 30 dB at 1000, 2000, and 4000 Hz, and 60 dB at 4000 Hz, leading to a mean value of  $(0 + 30 + 30 + 30 + 60)/5 = 30$  dB, within this 26 – 40 dB PTS range under analysis.

Therefore we erred on the side of caution and approximated a PTS of 26 – 40 dB as significant.

## IDA | PTS: summary



This flowchart summarizes our PTS analysis.

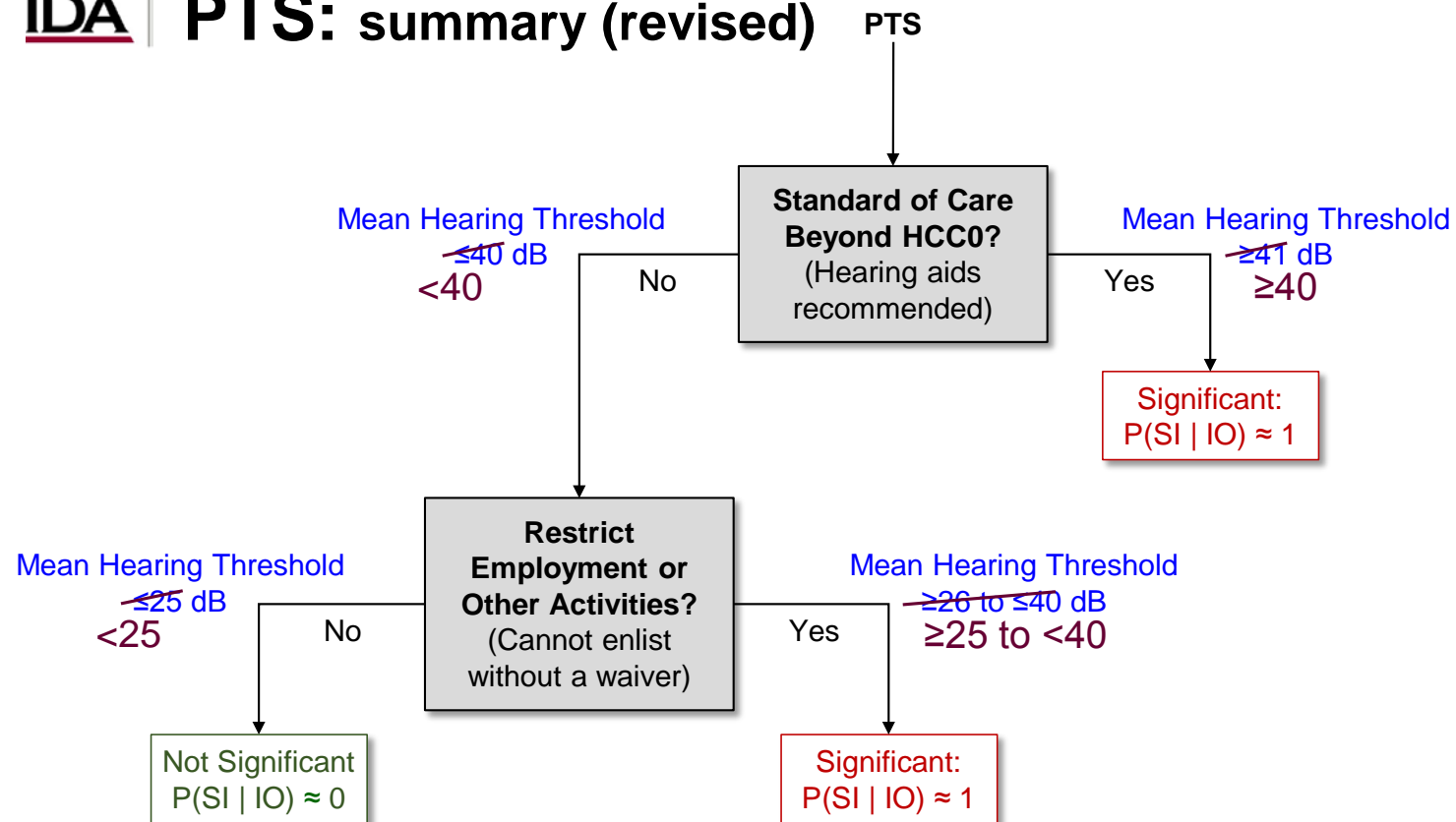
We first determine if the standard of care is beyond HCC0, i.e., if hearing aids are recommended.

- If so (if the mean hearing threshold is  $\geq 41$  dB), then the PTS is significant:  $P(SI|IO)$  is approximately 1.
- If not (if the mean hearing threshold is  $\leq 40$  dB), then we move to the next decision step in the flowchart...

In the next decision step, we determine if the PTS will restrict employment or other activities for the rest of the person's life, i.e., if the person cannot enlist in the US military:

- If so (if the mean hearing threshold is 26 – 40 dB, inclusive), then the PTS is significant:  $P(SI|IO)$  is approximately 1.
- If not (if the mean hearing threshold is  $\leq 25$  dB), then the PTS is not significant:  $P(SI|IO)$  is approximately 0.

## IDA | PTS: summary (revised)



**Auditory 4.0 computational model expects  
PTS threshold in 5-dB increments.**

Chan et al. 2016. *Mil Med*.181(5S): 59-69.

We made one revision to our conclusions.

We noted that Auditory 4.0 is a computational model that can be used to estimate that probability that an impulse sound causes a mean hearing threshold greater than or equal to a user-supplied dB value. This dB value must be specified in 5-dB increments. That is, one can use Auditory 4.0 to estimate the probability that an impulse sound causes a PTS  $\geq 25$  dB, but not  $\geq 26$  dB. We believe that the difference between 25 dB vs. 26 dB has approximately no effect on the overall RSI value, within the uncertainties (error bars) of the other quantities used by Auditory 4.0. Therefore, we revised our recommendations to use dB thresholds that are in 5-dB increments.

## IDA | Agenda

- Method
- **Results:**
  - Permanent Threshold Shift (PTS)
  - **Tympanic Membrane Rupture (TMR)**
  - Photothermal Retinal Lesions
- Discussion



We applied our same approach to TMR, otherwise known as a burst eardrum.

## IDA | TMR: mechanism of injury

**TMR = a disruption of the epithelium that separates the ear canal from the middle ear**

*Farlex Partner Medical Dictionary. 2012.*

- Our use of term “TMR”:
  - Tympanic membrane rupture *and* perforation
  - ICD-10-CM codes H72.00 – H72.93
- TMR can be caused by:
  - Penetrating objects
  - Blast (e.g., flashbang)

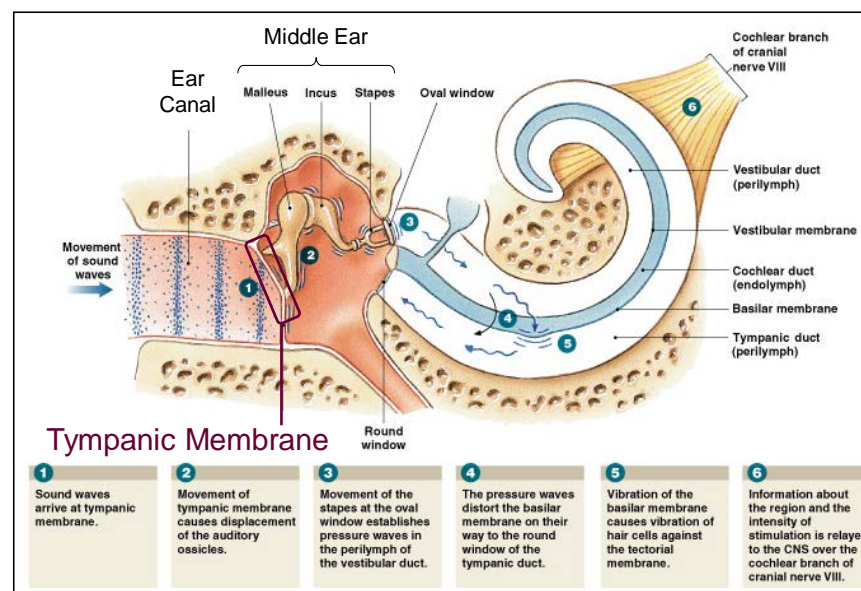


Figure from: van der Willigen. 2008. *Auditory Perception*. Nijmegen, Netherlands: Radboud University.

**We focused on blast-induced TMR.**

In the first step of our approach, we limited the scope of our analysis by reviewing the mechanism of injury.

TMR is a disruption of the epithelium that separates the ear canal from the middle ear. The middle ear is composed of the tympanic membrane (the eardrum) and the ossicles (the hammer, anvil, and stapes, three small bones).

The medical and related literature refers to both Tympanic Membrane Rupture and Tympanic Membrane Perforation. We use the term “TMR” to refer to both. These injuries are ICD-10-CM codes H72.00 – H72.93.

We found that TMR can be caused by:

- Penetrating objects, such as Q-tips, and/or
- Blasts, such as flashbang detonations

We limited the scope of our analysis to blast-induced TMR, since NLWs like flashbangs employ blast, rather than penetrating, mechanisms of injury.

## IDA | TMR: mechanism of injury

Small TMR:  
<25% of eardrum area



Large TMR:  
>50% of eardrum area



Figure from: Remenschneider et al. 2014. *Otol & Neurotol* 35(10): 1825-1834.

**Eardrum: area  $\approx 60 \text{ mm}^2$ , diameter  $\approx 10 \text{ mm}$**

van der Jeught et al. 2013. *JARO* 14(4): 483-494.

We show photographs of two different TMRs.

- The photo on the left, labeled A, shows a small TMR, one for which the area of the rupture is  $<25\%$  the area of the eardrum.
- The photo on the right, labeled B, shows a large TMR, one for which the area of the rupture is  $>50\%$  of the area of the eardrum. There are also burns to the ear canal.

Note that the eardrum area is approximately 60 square mm, with a diameter of approximately 10 mm.

## IDA | TMR: medical care to treat injury

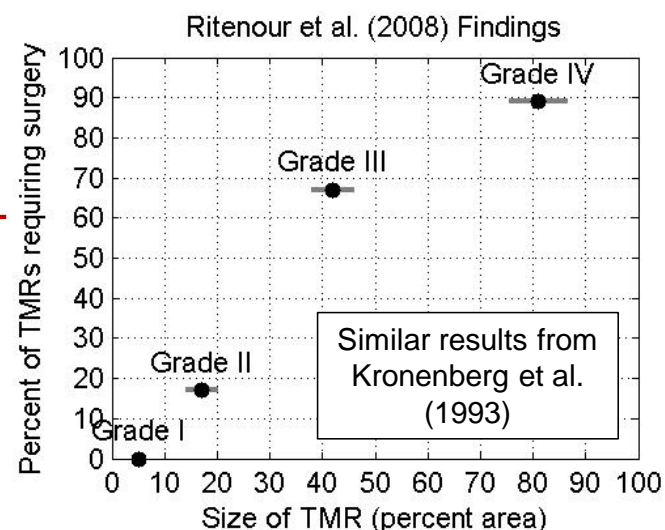
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Significant

TMR Size Grades (Percent of Eardrum Area)	
I: $\leq 2$ mm long ( $5 \pm 0$ )	
II: $>2$ mm long to $<25\%$ area ( $17 \pm 6$ )	
III: $25\% - 50\%$ area ( $42 \pm 8$ )	
IV: $>50\%$ area ( $81 \pm 11$ )	

Kronenberg et al. 1993. *Am J Otol* 14(1): 92-94.

Ritenour et al. 2008. *J Trauma Infection Crit Care* 64(2):  
S174-S178.



**We approximated that TMRs  $>2$  mm long are **significant** because a notable percentage require surgery (HCC1+).**

**However, we must further analyze TMRs  $\leq 2$  mm:**

Any complications? Any permanent disabilities?

In the second step of our analysis, we reviewed the standard of care for treating TMR.

Several studies published in the medical literature have shown that the size of the TMR is associated with the probability that the TMR will require surgery (HCC1+).

Both the Ritenour and Kronenberg research groups separated their TMRs into four grades:

- Grade I TMRs were very small– pinpoint TMRs or slit-like TMRs  $\leq 2$  mm long (remember, the diameter of the TMR is approximately 10 mm). All (or almost all) of the Grade I TMRs in these studies healed spontaneously (HCC0), meaning that none (or almost none) of them required surgery (HCC1+).
- On the other end of the size scale, Grade IV TMRs were very large, covering  $>50\%$  of the eardrum area. In the Ritenour study, only 11% of these Grade IV TMRs healed spontaneously (HCC0), meaning that 89% of them required surgery (HCC1+). The Kronenberg study had similar results.

In the end, we erred on the side of caution and concluded that TMRs in Grades II-IV ( $> 2$  mm) were significant, since a noticeable percentage required surgery (HCC1+).

However, further analysis was needed to conclude if TMRs in Grade I ( $\leq 2$ mm) were or were not significant. We first needed to consider the complications and permanent disabilities that might ensue after a Grade I TMR, discussed in the next slides.

## IDA | TMR: medical care to treat complications

- **Otitis Media** = inflammation of the inner ear. *Farlex Partner Medical Dictionary*. 2012.
- ICD-10-CM codes H65.00 – H65.07 and possibly H65.191 – H65.199.
- Severe cases require prescription antibiotics (HCC1+). Waseem. 2016. Medscape.
- Only  $\approx 8\%$  of all TMRs lead to otitis media. Lou et al. 2012. *Am J Otolaryn* 33(5): 549-555.
- We have already approximated TMRs  $>2\text{mm}$  as significant, since a notable percentage require surgery (HCC1+).
  - We consider otitis media resulting from only small TMRs ( $\leq 2\text{ mm}$ ), those that heal spontaneously.
- We have seen no reports of otitis media after spontaneous healing.
  - We approximate a  $\approx 0\%$  likelihood of otitis media resulting from small TMRs ( $\leq 2\text{ mm}$ ) that heal spontaneously:
    - Lower than the  $\approx 8\%$  likelihood resulting from all TMRs.
    - Zero, within the uncertainties of other quantities needed to estimate  $\text{RSI}_{\text{TMR}}$ .

**We disregarded the possibility of otitis media  
in TMRs  $\leq 2\text{ mm}$ .**



In the third step of our analysis, we considered the standard of care for treating complications of TMR.

One potential complication is Otitis Media, an inflammation or infection of the inner ear.

We found that severe cases of Otitis Media require prescription antibiotics (HCC1+).

We also found that only approximately 8% of all TMRs— including large and small TMRs— lead to Otitis Media.

Remember that we have already approximated TMRs  $> 2$  mm as significant, since a notable percentage require surgery (HCC1+). Therefore, we considered Otitis Media resulting from only small TMRs ( $\leq 2$  mm), those that we have already found heal spontaneously.

We have seen no reports of Otitis Media after spontaneous healing. Therefore, we approximate a 0% likelihood of Otitis Media resulting from small TMRs ( $\leq 2$  mm) that heal spontaneously. This value:

- Is lower than the approximately 8% value resulting from all TMRs, including large and small TMRs and
- Is approximately zero, within what we believe to be the uncertainties (error bars) of other quantities needed to estimate RSI for TMR.

Therefore, we disregarded the possibility of Otitis Media in TMRs  $\leq 2$  mm.

## IDA | TMR: medical care to treat complications

- **Cholesteatoma** = pieces of torn eardrum “seeding” in middle ear.
- ICD-10-CM codes H71.10 – H71.13.
- Severe cases require surgery (HCC1+). Ear Surgery Information Center 2016
- Only  $\approx 8\%$  of all TMRs led to cholesteatoma. Kronenberg et al. 1988. *Am J Otol* 9(2): 92-94
- We have already approximated TMRs  $>2\text{mm}$  as significant, since a notable percentage require surgery (HCC1+).
  - We consider cholesteatoma resulting from only small TMRs ( $\leq 2\text{ mm}$ ).
- We have seen only 1 report of cholesteatoma resulting from a small TMR ( $\leq 2\text{ mm}$ ). Kronenberg et al. 1988. *Am J Otol* 9(2): 92-94
  - We approximate a  $\approx 0\%$  likelihood of cholesteatoma resulting from small TMRs ( $\leq 2\text{ mm}$ ).
    - Lower than the  $\approx 8\%$  likelihood resulting from all TMRs.
    - Zero, within the uncertainties of other quantities needed to estimate  $\text{RSI}_{\text{TMR}}$ .

**We disregarded the possibility of cholesteatoma  
in TMRs  $\leq 2\text{ mm}$ .**

We also considered a second complication of TMRs, using the same type of argument we made for Otitis Media.

Cholesteatoma can occur when pieces of the torn eardrum “seed” inside the middle ear, impeding movement of the ossicles– the hammer, anvil, and stapes.

Severe cases of cholesteatoma require surgery (HCC1+).

Once again, only approximately 8% of all TMRs– including large and small TMRs– lead to cholesteatoma.

Once again, we have already approximated that large TMRs ( $> 2$  mm) are significant. Therefore we must only consider cholesteatoma in small TMRs ( $\leq 2$  mm).

The 8% number came from all TMRs, including large and small TMRs. We have only seen 1 report of cholesteatoma from a small TMR ( $\leq 2$  mm). Therefore, we approximate a 0% likelihood of cholesteatoma resulting from small TMRs ( $\leq 2$  mm). Although we recognize that this value is not exactly zero, we point out that:

- It is likely to be lower than the 8% reported for all TMRs, including large and small TMRs and
- It is likely to be approximately zero, within what we believe are the uncertainties (error bars) of other quantities needed to estimate RSI for TMR.

Therefore we disregarded the possibility of cholesteatoma for TMRs  $\leq 2$  mm.

## IDA | TMR: permanent disabilities

- **Conductive Hearing Loss (CHL)** = sound inadequately conducted through ear canal and middle ear to inner ear. *Mosby's Medical Dictionary* 9<sup>th</sup> ed. 2009.
- ICD-10-CM codes H90.0, H90.1, and H90.2.
- We have already approximated TMRs >2mm as significant, since a notable percentage require surgery (HCC1+).
  - We consider CHL resulting from only small TMRs ( $\leq 2$  mm), those that heal spontaneously.
- The World Health Organization (WHO) considers hearing loss  $\leq 25$  dB to be normal. WHO website: <http://www.who.int/mediacentre/factsheets/fs300/en/>
- Once a TMR has healed, CHL is usually fully recovered, “perhaps with a slight 5- to 10-dB drop due to scarring.” Taylor & Mueller. 2011. *Fitting and Dispensing Hearing Aids*. San Diego, CA: Plural Publishing.
  - We approximate a  $\approx 0\%$  likelihood of permanent CHL  $\geq 25$  dB after a small TMR ( $\leq 2$  mm) has spontaneously healed.

**We disregarded the possibility of a permanent, significant CHL in TMRs  $\leq 2$  mm.**

Now that we have considered the standard of care for treating both the TMR and its complications, we turned to the fourth and final step of our approach: We reviewed the permanent disability resulting from TMR.

We found that Conductive Hearing Loss (CHL) is a permanent disability that can result from TMR. CHL occurs when sound is inadequately conducted through the ear canal and/or middle ear to the inner ear. This can occur post-TMR. (Note that CHL is different from the sensorineural hearing loss discussed previously in relation to PTS, which is caused by damage to the inner ear, as opposed to damage to the middle ear.)

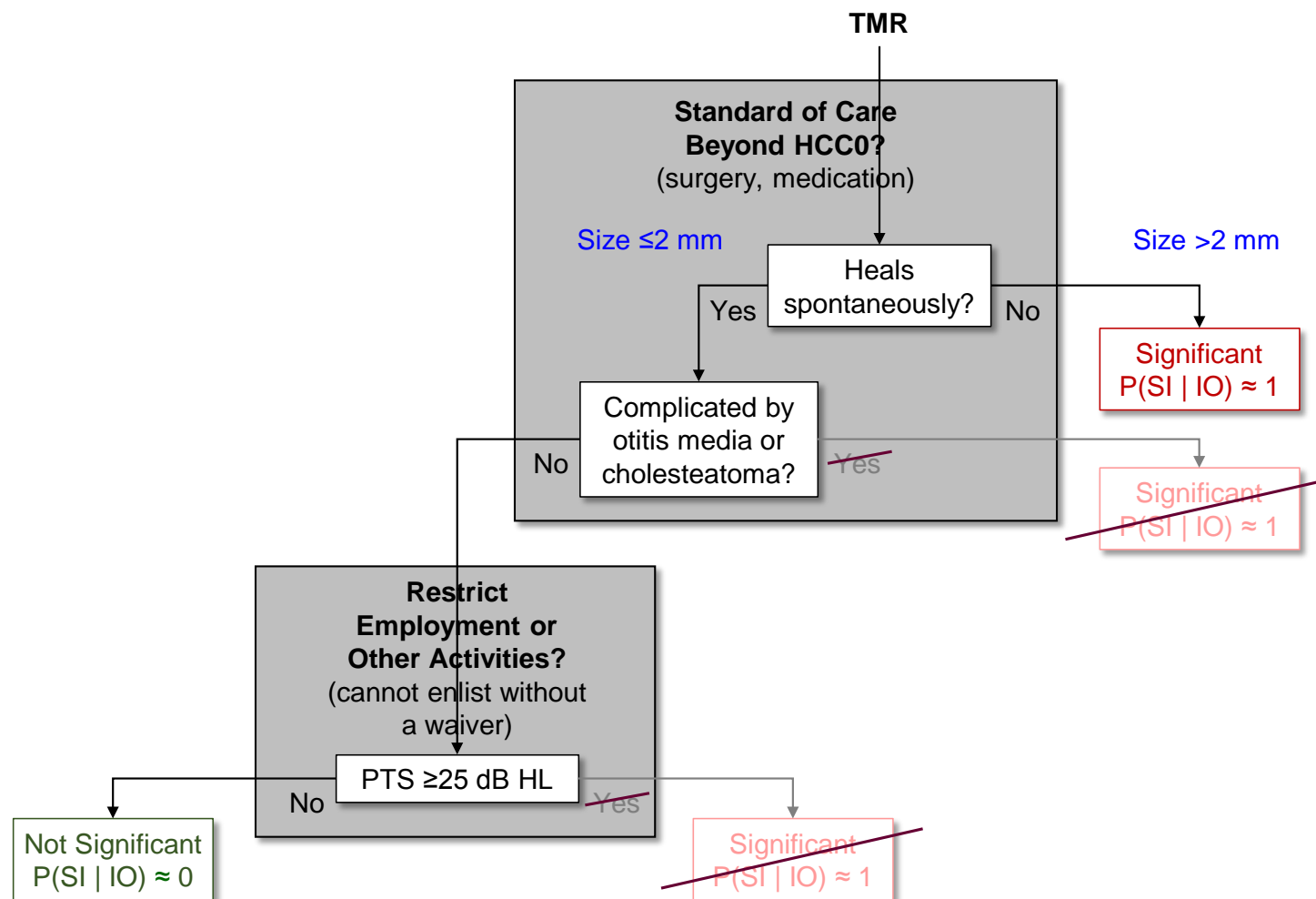
Once again, we must only consider small TMRs ( $\leq 2$  mm).

As we saw in our PTS analysis, the WHO considers hearing loss  $\leq 25$  dB (mean over all frequencies) to be normal.

We also found that once a TMR has healed (or has been surgically repaired), CHL is usually fully recovered, “perhaps with only a 5- to 10-dB drop due to scarring.” As such, we approximated a 0% likelihood of a permanent, significant CHL (mean CHL  $\geq 25$  dB) after a small TMR ( $\leq 2$  mm) has spontaneously healed.

Therefore, we disregarded the possibility of a permanent, significant CHL in TMRs  $\leq 2$  mm.

## IDA | TMR: summary



This flowchart summarizes our TMR analysis.

We first consider the standard of care for treating the TMR itself: Does the TMR heal spontaneously?

- If not (if the TMR  $> 2$  mm), then the TMR is significant:  $P(SI|IO)$  is approximately 1.
- If so (if the TMR  $\leq 2$  mm), then we move to the next step of the flowchart, still within our “standard of care” box...

In the next decision step, we consider the standard of care for treating complications of the TMR: is the TMR complicated by Otitis Media or Cholesteatoma that is severe enough such that prescription antibiotics or surgery is the standard of care?

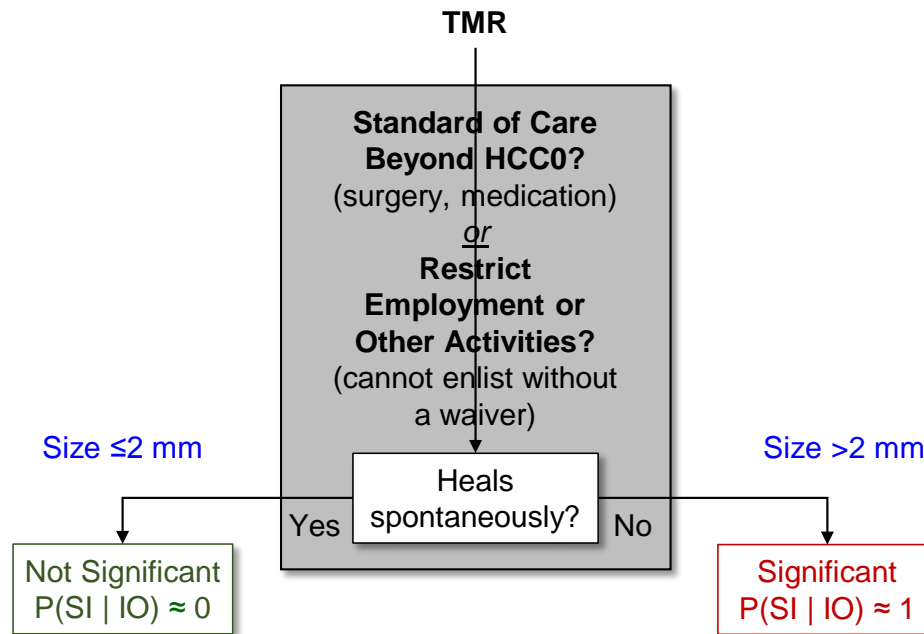
- We approximated a 0% likelihood that a small TMR ( $\leq 2$  mm) would lead to either of these two complications. Since the likelihood of these complications is approximately zero, we do not need to consider their consequence, i.e., significance. Therefore we greyed out this branch of the flowchart, such that all small TMRs ( $\leq 2$  mm) must move to the final branch towards the left...

In our final branch of the flowchart, we considered if TMR would restrict life: Will the TMR lead to a permanent, significant CHL?

- We approximated a 0% likelihood that a small TMR ( $\leq 2$  mm) that heals spontaneously would lead to this disability. Therefore, since the likelihood of this disability is approximately zero, we did not need to consider its consequence, i.e., significance (although if we had needed to consider its significance, we could have used the same rationale we used in the PTS analysis). Therefore we also greyed out this branch of the flowchart.
- As such, all small TMRs ( $\leq 2$  mm, those that heal spontaneously) are not significant:  $P(SI|IO)$  is approximately 0.

We consolidated the greyed-out branches to a simpler flowchart, shown on the next slide.

## IDA | TMR: summary (condensed)





The condensed flowchart consists of only one decision step: Does the TMR heal spontaneously?

- If no ( $\text{TMR} > 2 \text{ mm}$ ), then the TMR is significant:  $P(\text{SI}|\text{IO})$  is approximately 1.
- If yes ( $\text{TMR} \leq 2 \text{ mm}$ ), then the TMR is not significant:  $P(\text{SI}|\text{IO})$  is approximately 0.

Note, though, that there currently exists no computational model that can estimate the probability that a blast will create a  $\text{TMR} \geq 2 \text{ mm}$ .

Not Significant

## IDA | TMR: medical care to treat injury

TMR Size Grades (Percent of Eardrum Area)	TMR Size Classes (Subjective, Qualitative)
I: $\leq 2$ mm long ( $5 \pm 0$ )	1: Minor (small tears or slits)
II: $> 2$ mm long to $< 25\%$ area ( $17 \pm 6$ )	2: Moderate (large tears or multiple small tears)
III: $25\% - 50\%$ area ( $42 \pm 8$ )	
IV: $> 50\%$ area ( $81 \pm 11$ )	3: Major (complete tear)

Significant

Kronenberg et al. 1993. *Am J Otol* 14(1): 92-94.  
Ritenour et al. 2008. *J Trauma Infection Critical Care* 64(2): S174-S178.

James et al. 1982. *The Response of the Human Ear to Blast*. Aldermaston, UK: Atomic Weapons Research Establishment.

**We also considered a clinical classification scheme on which a new computational model has been based.**

Shelley and Chan. 2015. *Eardrum Rupture Phase-1 Final Report*. San Diego CA: L3 Applied Technologies.

However, we also reviewed plans for a new computational model that will predict the probability that a blast will produce a minor, moderate, or major TMR.

These “minor”, “moderate”, and “major” classes are based on a subjective and qualitative clinical classification scheme, using data published by the James research group in 1982.

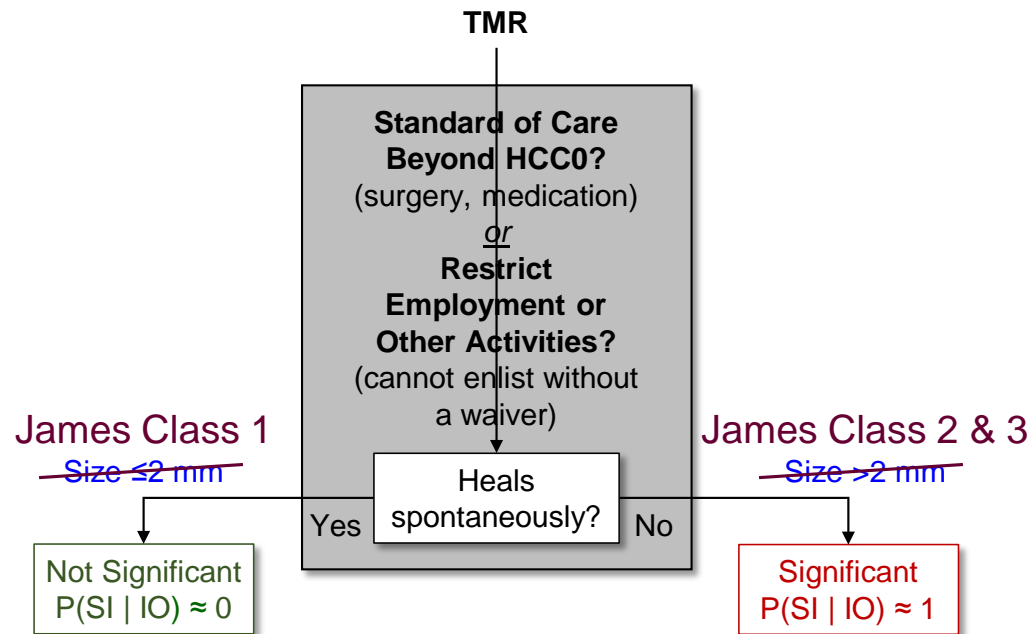
The James research group defined three types of TMRs:

- Minor TMRs were “small tears or slits”. We believe these minor TMRs fall into the quantitatively-defined Grade I on which we based our previous conclusions.
- Moderate TMRs were “large tears or multiple small tears”. We believe these moderate TMRs fall into the quantitatively-defined Grades II or III.
- Major TMRs were “complete tears”. We believe these major TMRs fall into the quantitatively-defined Grade IV.

That is, we believe that the qualitatively-defined James Class 1 is the same as the quantitatively-defined Grade I on which our previous conclusions were based. We also believe that the qualitatively-defined James Classes 2 and 3 are the same as the quantitatively-defined Grades II – IV.

The new computational model will be able to estimate the probability that a blast will cause a James Class 2 or 3 TMR. Therefore, we revised our flowchart on the next slide.

## IDA | TMR: summary (condensed, revised)



**We also considered a clinical classification scheme on which a new computational model has been based.**

Shelley and Chan. 2015. *Eardrum Rupture Phase-1 Final Report*. San Diego CA: L3 Applied Technologies.

Our revised flowchart is based on the James clinical classification scheme. The single decision point remains the same: Does the TMR heal spontaneously? Only the attributes used to make that decision have been revised:

- If so (TMR is in James Class 2 or 3), then the TMR is significant:  $P(SI|IO)$  is approximately 1.
- If not (TMR is in James Class 1), then the TMR is not significant:  $P(SI|IO)$  is approximately 0.

## IDA | Agenda

- Method
- **Results:**
  - Permanent Threshold Shift (PTS)
  - Tympanic Membrane Rupture (TMR)
  - **Photothermal Retinal Lesions**
- Discussion

Finally, we applied our same approach to a third injury: Photothermal Retinal Lesions.

# IDA | Retinal Lesions: mechanism of injury

**Lesion = a pathologic change in tissues**

*Farlex Partner Medical Dictionary. 2012.*

- Types of retinal lesions:

- **Photomechanical:**  
High energy dose over short time (e.g., Q-switched/mode-locked near-IR lasers)
- **Photothermal:** >5mW dose in <seconds (closest to regime used for **dazzling lasers**)
- **Photochemical:** Low energy dose over long time (e.g., eyelids forced open)

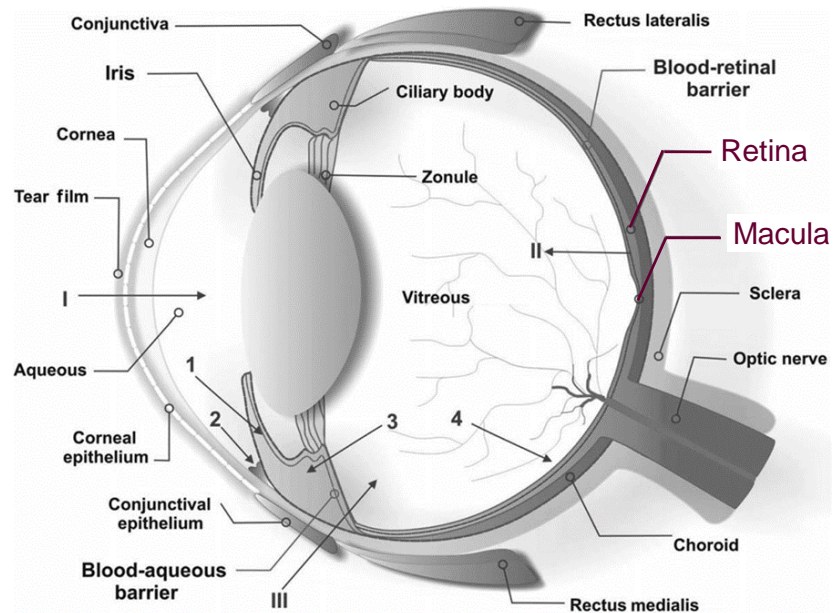


Figure from: Willoughby et al. 2010. *Clin Exp Opth.* 38: 2-11

**We focused on photothermal retinal lesions.**



In the first step of our approach, we reviewed the mechanism of injury.

A lesion is a pathologic change in tissues— here, retinal tissues. The retina is photosensitive tissue that lines the inner rear of the eye. The macula is the area of the retina that is most rich in photosensitive cells.

We found that there are three main mechanisms by which laser light can injure these cells:

- A high energy dose of light, such as from a Q-switched or mode-locked near-infrared laser, can cause photomechanical injury to the retinal cells. At high electromagnetic strengths, a dielectric breakdown occurs inside the eye, resulting in an ionized gas (plasma) formation. The rapid formation and expansion of this gas introduces a local disruption of tissue. Sometimes even a popping noise can be heard. Lasers that can cause photomechanical lesions employ much higher powers than dazzling lasers.
- At the other end of the scale are photochemical lesions, caused by a low energy dose applied over long exposure times, such as if the eyelids were forced open and not allowed to blink. When visible light is used, photochemical effects are associated with the bleaching of sensory pigments and oxidative stress leading to cell damage. This effect can reverse itself over seconds or minutes and is the effect and recovery sought by military operators employing dazzling lasers. It is intended that the targeted individual is allowed to blink or look away from the dazzling laser, limiting the exposure duration and thus ensuring that the photochemical damage is minor enough to be temporary and to recover.
- In the middle of this scale are photothermal lesions. Such lesions can be caused by visible, continuous-wave lasers with powers just above 5 mW and exposure durations less than a few seconds. This is the regime of lasers closest to those used for dazzling lasers (although dazzling lasers are designed to have lower powers— often orders of magnitude lower, such that they are easily considered to be eyesafe, within intended use).

Therefore, one could say that none of these mechanisms of injury are relevant to RSI from dazzling lasers. However, just to be overly conservative, we erred on the side of caution and continued our analysis. We limited the scope of our analysis to photothermal retinal lesions, since these are permanent lesions produced by lasers closest to dazzling lasers.

This analysis proved to be much more challenging than the PTS and TMR analyses, due a lack of consistent terminology and consistent quantitative data in the medical and related literature. In the absence of clear definitions and quantitative studies with large sample sizes (as opposed to case studies with a sample size of  $n = 1$ ), we were forced to make many assumptions and approximations.

# IDA | Retinal Lesions: mechanism of injury

Cones (color vision) are concentrated in macula

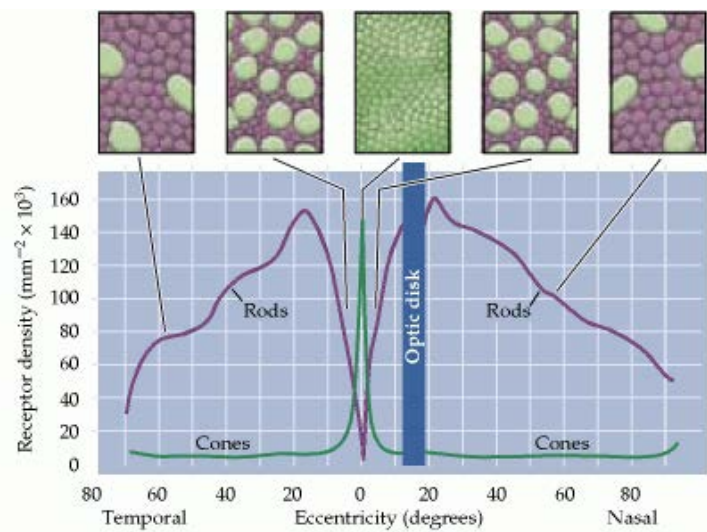


Figure from: Purves. 2001. *Neuroscience* 2<sup>nd</sup> ed. St. Louis, MO: Elsevier.

1 degree Eccentricity ≈ 0.3 mm

Wandell. No date. Stanford University Center for Cognitive and Neurobiological Imaging

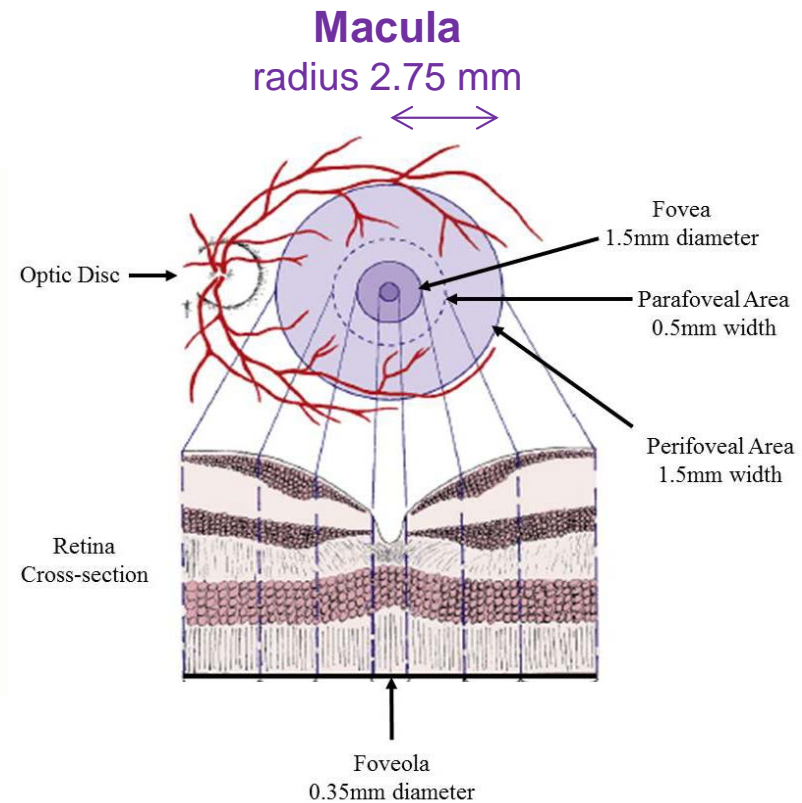


Figure from: Remington. 2012. *Clinical Anatomy and Physiology of the Visual System* 3<sup>rd</sup> ed. St. Louis, MO: Elsevier.

As part of the first step of our approach, we reviewed the anatomy and physiology of the retina.

We found that the retina contains two types of photosensitive cells: rods and cones. The left figure shows a plot of the concentration of rods and cones vs. eccentricity– the degree or distance from the center of the foveola, the spot on the retina to which the center of the visual field is projected:

- Rods are the cells responsible for black-and-white vision. Rods (purple line) are not concentrated in the area surrounding the foveola.
- Cones are the cells responsible for sharp, color vision. Cones (green line) are concentrated in the area surrounding the foveola.

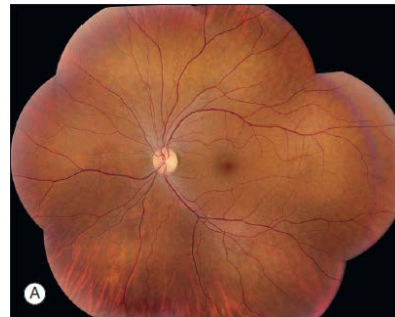
We also found that according to the histological definitions of retinal anatomy, the area surrounding the foveola is called the macula, consisting of concentric rings called the fovea, parafovea, and perifovea. The macula has a radius of approximately 2.75 mm.

## IDA | Retinal Lesions: mechanism of injury

Clinical Characterization	
-	
-	visible

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

Color Fundus Photography

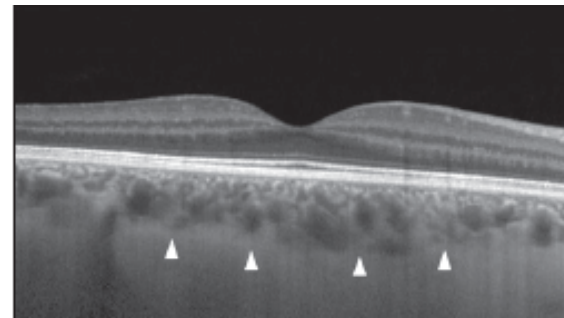


Fluorescein Angiography



Johnson et al. 2012. "Fluorescein Angiography: Basic Principles and Interpretation." In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis, MO: Mosby.

## Optical Coherence Tomography (OCT)



Filho et al. 2012. "Optical Coherence Tomography". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

We also reviewed the techniques physicians use to monitor retinal lesions:

- Traditional techniques are only a few steps removed from the tools that optometrists use to view the inside of your eye during an eyeglasses appointment. These methods include color fundus photography and its slightly more complex sister method, fluorescein angiography. Both provide mostly a surface view of the retina.
- A more novel technique is optical coherence tomography (OCT), which provides a view down into the various layers of the retina.

We found that physicians often classify retinal lesions based on whether they can be viewed via traditional techniques vs. OCT:

- Suprathreshold lesions are obvious in all methods.
- At the other end of the severity scale, subthreshold lesions are only visible in OCT. They are not visible with traditional techniques.
- In the middle of the severity scale, threshold lesions are just barely visible with traditional techniques. They appear white in color fundus photographs– similar to when egg whites turn white during cooking.

## IDA | Retinal Lesions: medical care

Significant ?? ??	Clinical Characterization	
	Supra-threshold	Obvious in all methods
	Threshold	White in photographs
	Sub-threshold	Only visible in OCT

Mainster and Turner. 2012. "Photoc Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

- Suprathreshold lesions can lead to complications like hemorrhage, macular holes and neovascularization. Barkana and Belkin. 2000. *Survey of Ophth* 44(6): 459-478.
- These complications can benefit from HCC1+ treatment like surgery and prescription medications. Alsulaiman. 2015. *Am J Ophth* 160(1): 107-113. Grossniklaus and Green. 2004. *Am J. Ophth* 137(3): 496-503.
- We found very little data to explore exactly how often these complications occur, or for how often HCC1+ is the standard of care.
  - We erred on the side of caution and assumed the worst case scenario: suprathreshold lesions lead to complications for which HCC1+ is the standard of care.

**We approximated suprathreshold lesions as significant.**

We performed the second and third steps of our approach simultaneously: We reviewed the standard of care in treating retinal lesions and their complications.

We found that suprachreshold lesions can lead to complications like retinal hemorrhage, macular holes, and neovascularization.

We also found that these complications can benefit from HCC1+ treatment such as surgery and prescription medications.

However, we found very little data to quantify exactly how often these complications occur, or for how often HCC1+ is the standard of care.

Therefore, we erred on the side of caution and assumed the worst case scenario: suprachreshold lesions lead to complications for which HCC1+ is the standard of care.

As such, we approximated suprachreshold lesions as significant.

## IDA | Retinal Lesions: medical care

Significant ?? ??	Clinical Characterization	
	Supra-threshold	Obvious in all methods
	Threshold	White in photographs
	Sub-threshold	Only visible in OCT

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby

- Threshold and subthreshold lesions do not often lead to complications for which HCC1+ could be considered the standard of care.

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

→ In the absence of further data, we assumed threshold and subthreshold lesions do not lead to complications for which HCC1+ is the standard of care.

**We must further analyze subthreshold and threshold lesions:**  
**Any permanent disabilities?**



In contrast, we found that threshold and subthreshold lesions do not often lead to complications for which HCC1+ could be considered the standard of care.

Once again, we could find little quantitative data regarding exactly how often these complications (do not) occur.

In the absence of further data, we assumed that threshold and subthreshold lesions do not lead to complications for which HCC1+ is the standard of care. Although some of these lesions could potentially benefit from HCC1+ care, we have not seen medical recommendations or articles suggesting that HCC1+ is the standard of care for these lesions.

However, we must further analyze threshold and subthreshold lesions to determine if they lead to permanent disabilities that restrict life.

## IDA | Retinal Lesions: permanent disabilities

Significant	Clinical Characterization	
	Supra-threshold	Obvious in all methods
??	Threshold	White in photographs
Not Significant	Sub-threshold	Only visible in OCT

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

- Photocoagulation therapy is often used to create subthreshold lesions to treat retinal disorders. Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds Ryan et al. St. Louis: MO: Mosby.
  - These lesions are intended to improve vision, w/r/t the vision experienced prior to treatment.
  - We found little quantitative data comparing
    - Vision pre- to post-treatment
    - Vision post-treatment to normal vision
- We assumed subthreshold lesions do not cause a permanent, significant vision loss:
  - Visual acuity worse than 20/40 or
  - Visual field worse than 60° or large/central scotoma

**We approximated subthreshold lesions as not significant.**

In the fourth and final step of our analysis, we reviewed the permanent disability caused by threshold and subthreshold lesions.

We found that photocoagulation therapy is often used to explicitly create subthreshold lesions in order to treat retinal disorders, such as diabetic retinopathy.

- These lesions are intended to improve vision, with respect to the vision experienced prior to treatment.
- We found little quantitative data comparing:
  - Vision pre- vs. post-treatment
  - Post-treatment vision vs. normal vision

In the absence of further data, we assumed that subthreshold lesions do not cause a permanent, significant vision loss, since these lesions are explicitly caused, by design, via photocoagulation therapy. Therefore we approximated subthreshold lesions as not significant.

Note that we performed a separate analysis, not shown here, to define significance thresholds for vision loss. We defined a significant vision loss as:

- Visual acuity worse than 20/40, since the International Council on Ophthalmology (ICO) recommends no driving restrictions for visual acuity 20/40 for better, and since the Veterans Affairs Schedule for Rating Disability (VASRD) rates a veteran as 0% disabled if he or she has 20/40 vision or better in both eyes, or
- Visual field worse than 60 degrees or a large or central scotoma. A scotoma is a spot in the visual field for which vision is absent or deficient. We chose this definition of significance since the VASRD rates a veteran as 0% disabled if he or she has an average visual field of 60 degrees or better (larger numbers are better) and no large or central scotomas.

We discuss our rationale for choosing these significance thresholds in the following report:

- Hirsch, Leon R., Jenny R. Holzer, Michael S. Finnin, and Shelley Cazares. 2015. Significance of Retinal Lesions Potentially Caused by Dazzling Lasers. IDA Document D-5691. Alexandria, VA: Institute for Defense Analyses, December.

At this point, we have made conclusions regarding the significance (or non-significance) of suprathreshold and subthreshold lesions. We must now further consider threshold lesions.

## IDA | Retinal Lesions: permanent disabilities

Significant	Clinical Characterization	
	Supra-threshold	Obvious in all methods
	Threshold within macula	White in photographs
Not Significant	Threshold beyond macula	White in photographs
	Sub-threshold	Only visible in OCT

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

- Threshold lesions can lead to noticeable visual impairment. Mainster et al. 2004. *ARCH Ophthalm* 122:1210-1217.
- Cones are important for visual acuity and their distribution differs throughout the retina. Purves. 2001. *Neuroscience* 2<sup>nd</sup> ed. St. Louis, MO: Elsevier. Remington. 2012. *Clinical Anatomy and Physiology of the Visual System* 3<sup>rd</sup> ed. St. Louis, MO: Elsevier.

→ We assumed the location of the threshold lesion affects its significance.

We found that threshold lesions can lead to noticeable visual impairment.

We also found that cones (one of the two types of photosensitive cells in the retina) are important for visual acuity and that their distribution differs throughout the retina, such that they are most concentrated within the center of the macula.

Therefore, we assumed that the location of the threshold lesion affects its significance: within vs. beyond the macula.

## IDA | Retinal Lesions: permanent disabilities

Clinical Characterization		
Significant	Supra-threshold	Obvious in all methods
	Threshold within macula	White in photographs
Not Significant	Threshold beyond macula	White in photographs
	Sub-threshold	Only visible in OCT

Mainster and Turner. 2012. "Photic Retinal Injuries: Mechanisms, Hazards, and Prevention". In *Retina* 5<sup>th</sup> ed, eds. Ryan et al. St. Louis: MO: Mosby.

- Threshold lesions in the peripheral retina may produce no noticeable effect on vision. Harris et al. 2003. *Aviation, Space, Env Med* 74(9): 947-952. Marshall. 1989. *Health Physics* 56(5): 617-624.

→ We assumed threshold lesions beyond the macula ( $\geq 2.75$  mm from center of foveola) do not cause a permanent, significant vision loss.

- A foveal lesion can lead to noticeable visual impairment. Marshall. 1989. *Health Physics* 56(5): 617-624.

→ We assumed threshold lesions in the macula ( $< 2.75$  mm from center of foveola) cause a permanent, significant vision loss.

**We approximated threshold lesions within / beyond the macula as not significant / significant.**

We found that threshold lesions in the peripheral retina may produce no noticeable effect on vision. However, we found few reports quantifying this loss in vision using Snellen notation (20/XX) or other quantitative scales of vision loss.

Therefore, in the absence of further data, we assumed that threshold lesions beyond the macula ( $\geq 2.75$  mm from the center of the foveola) do not cause a permanent, significant vision loss.

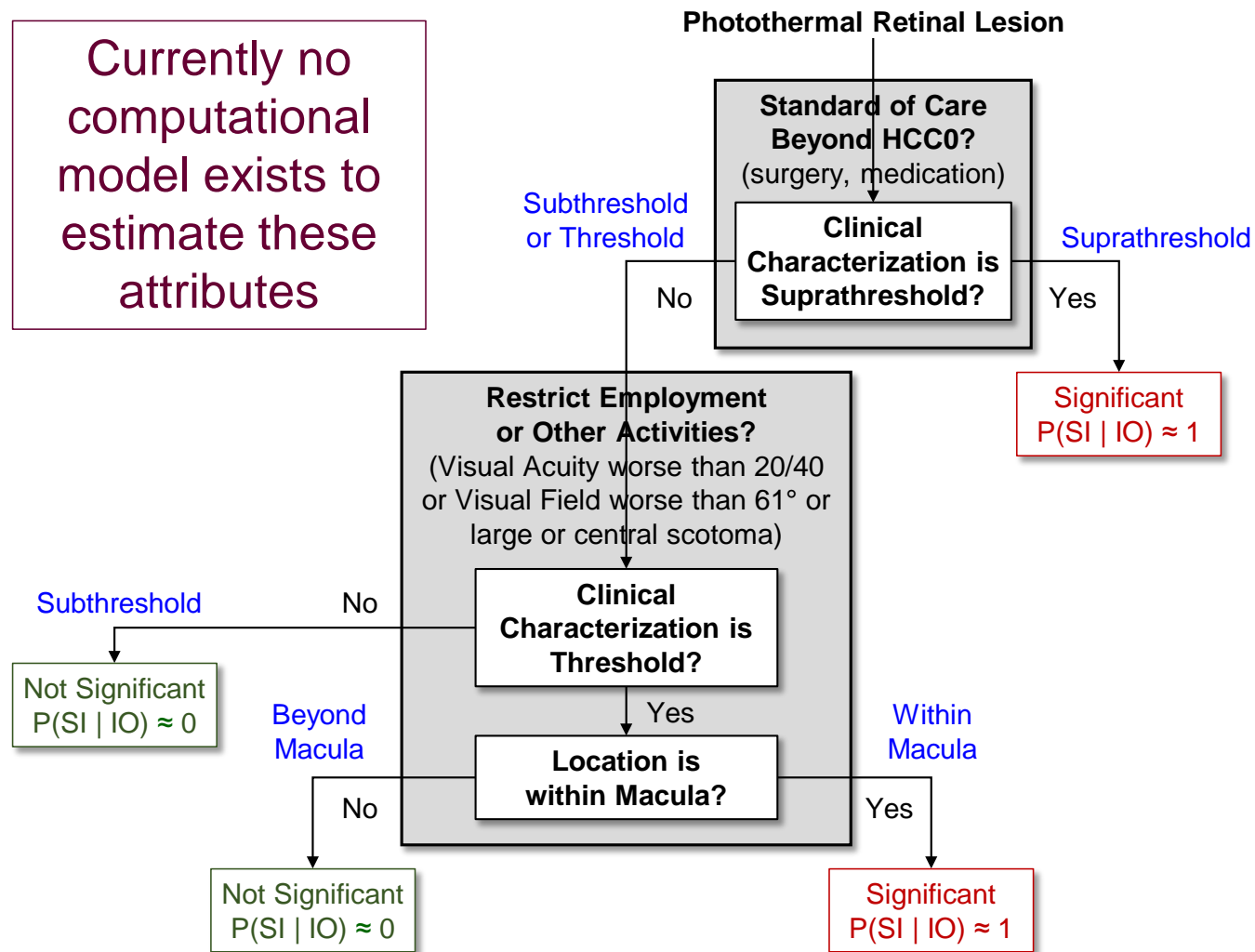
In contrast we found that a foveal lesion can lead to noticeable visual impairment.

In the absence of further data, we erred on the side of caution and assumed that threshold lesions within the macula ( $< 2.75$  mm from the center of the foveola) cause a permanent, significant vision loss.

Therefore, we approximated threshold lesions within vs. beyond the macula as not significant vs. significant, respectively.

# IDA | Retinal Lesions: summary

Currently no computational model exists to estimate these attributes





This flowchart summarizes our analysis:

In the first decision step, we consider the standard of care for treating the lesion and its complications: Is the lesion suprathreshold?

- If so (suprathreshold), then we approximate the lesion as significant, since we assume complications for which HCC1+ is the standard of care:  $P(SI|IO)$  is approximately 1
- If not (subthreshold or threshold), then we assume HCC1+ is not the standard of care, and we must move to the next decision step in the flowchart...

In the next two decision steps, we consider if the lesion will restrict life. First: Is the lesion threshold?

- If not (if it is subthreshold), then we approximate the lesion as not significant, since we assume no noticeable vision loss:  $P(SI|IO)$  is approximately 0
- If so, (if it is threshold), then we must consider its location: Is it within the macula?
  - If so, then we approximate the lesion as significant, since we assume a permanent, significant vision loss:  $P(SI|IO)$  is approximately 1
  - If not, then we approximate the lesion as not significant, since we assume no permanent, significant vision loss:  $P(SI|IO)$  is approximately 0

Unfortunately, no existing computational model can estimate the probability that a dose of laser light will cause suprathreshold, threshold, or subthreshold lesions. Therefore, the significance of a retinal lesion, given that it has occurred, cannot be quickly or easily estimated during the development acquisition phase of a novel dazzling laser. In our report (Hirsch et al. 2015), we discussed additional experiments that could be done to map the suprathreshold / threshold / subthreshold clinical characterizations to a quantitative metric: the temperature incident on the retina. If this is possible, then existing computational models such as Buffington, Thomas, Edwards, and Clark (BTEC) could then be used to estimate the temperature incident on the retina due to a dazzling laser, which can then be mapped to the suprathreshold / threshold / subthreshold clinical classifications which, in turn, can be mapped to our significant / not-significant approximations.

We note, that many of our approximations are likely over-conservative (i.e., not all suprathreshold lesions will lead to complications for which HCC1+ is the standard of care, and not all threshold lesions in the macula will cause a permanent, significant vision loss). However, we note that even if our approximations of  $P(SI|IO) \approx 1$  are too high for these types of lesions, the associated term  $P(IO)$  is very small, since the laser power needed to produce a photothermal retinal lesion ( $> 5$  mW) is orders of magnitude larger than the powers used by dazzling lasers. Therefore, once these two numbers are multiplied together, the resulting RSI will also be very low. That is good news for dazzling laser designers.

## IDA | Agenda

- Method
- Results:
  - Permanent Threshold Shift (PTS)
  - Tympanic Membrane Rupture (TMR)
  - Photothermal Retinal Lesions
- **Discussion**

To finish this briefing, we now provide the opportunity to discuss all of our results together.

## IDA | Discussion

- Permanent Threshold Shift (PTS)
  - $\text{PTS} \geq 25 \text{ dB HL}$ : Significant:  $P(\text{SI} | \text{IO}) \approx 1$
  - $\text{PTS} < 25 \text{ dB HL}$ : Not Significant:  $P(\text{SI} | \text{IO}) \approx 0$
- Tympanic Membrane Rupture (TMR)
  - $\text{TMR} \geq 2 \text{ mm}$  (James Class 2 & 3): Significant:  $P(\text{SI} | \text{IO}) \approx 1$
  - $\text{TMR} < 2 \text{ mm}$  (James Class 1): Not Significant:  $P(\text{SI} | \text{IO}) \approx 0$
- Photothermal Retinal Lesion
  - Suprathreshold: Significant:  $P(\text{SI} | \text{IO}) \approx 1$
  - Threshold inside the macula: Significant:  $P(\text{SI} | \text{IO}) \approx 1$
  - Threshold outside the macula: Not Significant:  $P(\text{SI} | \text{IO}) \approx 0$
  - Subthreshold: Not Significant:  $P(\text{SI} | \text{IO}) \approx 0$

This slide summarizes the results of our three analyses, and is identical to the summary slide showed at the beginning of this briefing.

## IDA | Questions

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For further questions, or to obtain copies of our reports, please contact Dr. Shelley Cazares at IDA.

Reports:

- King, Allison and Shelley Cazares. 2015. *Significance of Permanent Threshold Shift Potentially Caused By Sound-Based Non-Lethal Weapons*. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.
- Cazares, Shelley, Leon R. Hirsch, and Allison King. 2016. *Significance of Tympanic Membrane Rupture Potentially Caused by Flashbang Grenades*. IDA Document D-5824. Alexandria, VA: Institute for Defense Analyses, May.
- Hirsch, Leon R., Jenny R. Holzer, Michael S. Finnin, and Shelley M. Cazares. 2015. *Significance of Retinal Lesions Potentially Caused by Dazzling Lasers*. IDA Document D-5691. Alexandria, VA: Institute for Defense Analyses, December.





REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE June 2016		2. REPORT TYPE Final		3. DATES COVERED (From-To) May 2016 – Jun 2016	
4. TITLE AND SUBTITLE  Predicting the Significance of Injuries Potentially Caused by Non-Lethal Weapons: Tympanic Membrane Rupture (TMR), Permanent Threshold Shift (PTS), and Photothermal Retinal Lesions				5a. CONTRACT NUMBER HQ0034-14-D-0001	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Cazares, Shelley M. King, Allison L. Hirsch, Leon R. Holzer, Jenny R. Finnin, Michael S.				5d. PROJECT NUMBER DU-2-4040	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)  Institute for Defense Analyses 4850 Mark Center Drive Alexandria, VA 22311-1882				8. PERFORMING ORGANIZATION REPORT NUMBER  IDA Document NS D-8118 Log: H16-000949	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)  Joint Non-Lethal Weapons Directorate 3097 Range Road Quantico, VA 22134-5100				10. SPONSOR/MONITOR'S ACRONYM(S)  JNLWD	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT  Approved for public release; distribution is unlimited.					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT <p>On June 21, 2016, the Institute for Defense Analyses (IDA) presented the results of three of its recent analyses to the Health Effects Review Board (HERB). Members of the multi-service HERB include health care professionals and safety officers. The purpose of IDA's analyses was to predict the significance of injuries potentially caused by Non-Lethal Weapons. Three specific injuries were considered: (1) Permanent Threshold Shift (PTS) in hearing sensitivity (often referred to as sensorineural hearing loss caused by damage to the inner ear), (2) Tympanic Membrane Rupture (TMR) (often referred to as a burst eardrum) and resultant conductive hearing loss, and (3) Photothermal Retinal Lesions. Based on guidance from DODI 3200.19, IDA performed a search of the medical literature to assess the significance of each of these three injuries based on the medical care required to treat the injury, the medical care required to treat any potential complications of the injury, and the physical damage caused by the injury or complication that restricts the person's employment or other activities for the rest of his or her life. IDA organized its findings into flow diagrams. In summary, a PTS &lt; 25 dB is not significant, a TMR ≤2 mm is not significant, and a threshold photothermal lesion beyond the macula or a subthreshold photothermal lesion anywhere in the retina is not significant. Computational models currently exist for estimating the attributes associated with PTS and TMR, but not for Photothermal Retinal Lesions.</p>					
15. SUBJECT TERMS Non-Lethal Weapon; NLW; Risk of Significant Injury (RSI); Health Care Capability; HCC; Permanent Threshold Shift; PTS; sensorineural hearing loss; conductive hearing loss; Tympanic Membrane Rupture; TMR; eardrum; photothermal; retina; macula					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT  SAR	18. NUMBER OF PAGES  80	19a. NAME OF RESPONSIBLE PERSON Dr. Shannon Foley
a. REPORT Uncl.	b. ABSTRACT Uncl.	c. THIS PAGE Uncl.			19b. TELEPHONE NUMBER (include area code) (703) 432-0916