

# **The Role of Medical Gloves in Infection Control**

**Eng Aik Hwee**

**Malaysia Rubber Export Promotion Council**

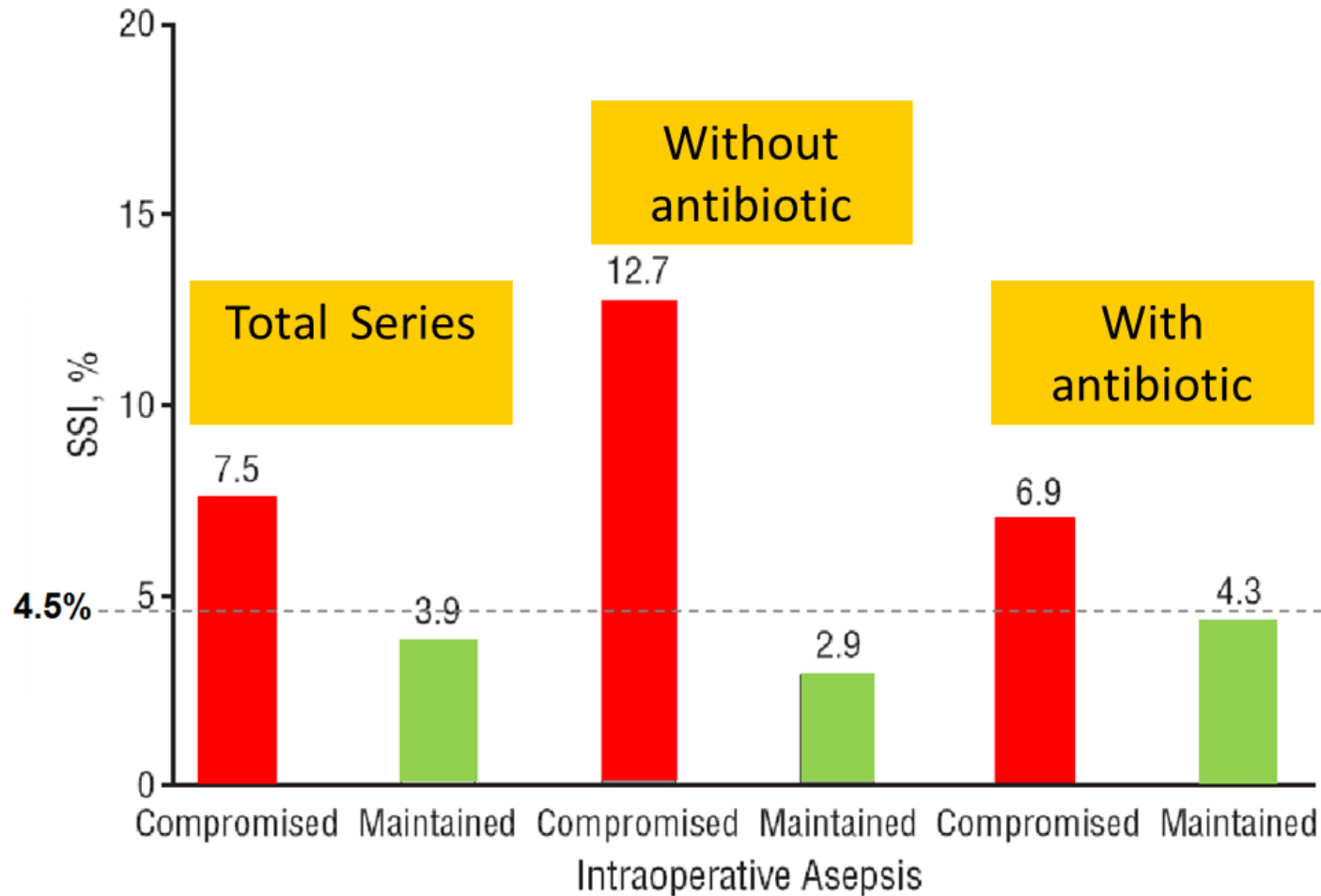
\*For educational purpose only

## Functions of Medical Gloves

- 1) Reduce the risks of cross contamination between the healthcare workers and patients.
- 2) A protective barrier when handling blood, body fluids, secretions, excretions, mucous membranes, and non-intact skin of patients.
- 3) Reduce the risks of hand flora migration from healthcare workers to patients
- 4) Reduce risks of transmitting pathogens from one patient to another patient by changing the gloves worn between patient contacts, followed by the hand hygiene procedures.

Gloves do not provide complete protection from cross-contamination or needle stick injuries. Small defects in gloves or inappropriate glove removal may transmit pathogens.

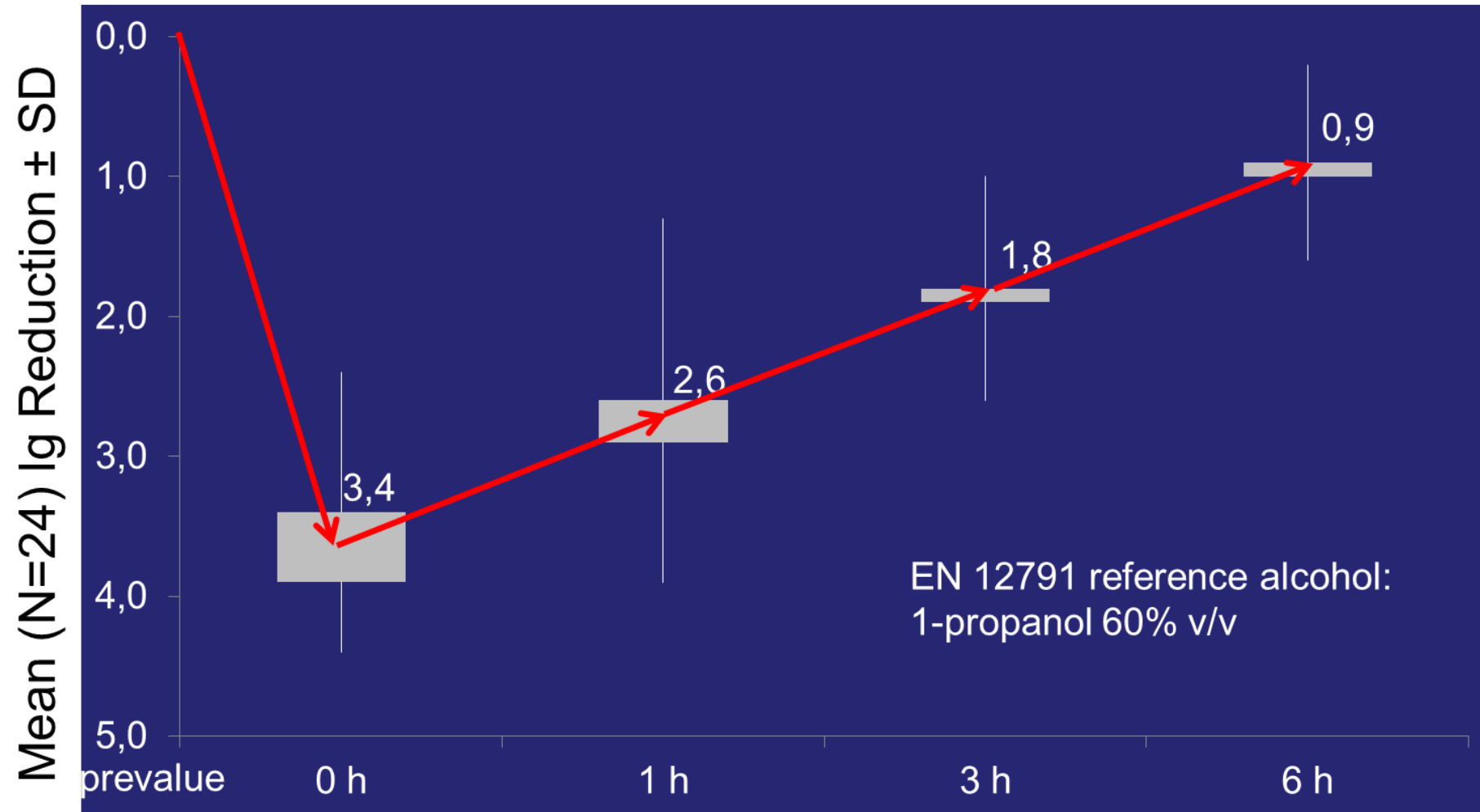
# Gloves & Surgical Site Infections



- Transfer of bacteria from the hand of wearer to patient can trigger a Surgical Site Infection (SSI)

# Hand Floral Growth After Gloving

- Hand floral in surgeon's hand can gradually grow during glove use.
- High hand floral poses a high risk in causing surgical site infections to patient when glove perforation occurs during glove use.



“Population kinetics of the skin flora on gloved hands following surgical hand disinfection..”  
*Infect. Control Hosp. Epidemiol.* 2007; 28, 346-50.

# ASTM Standards for Exam Gloves

	Natural Rubber		Nitrile Rubber		Chloroprene Rubber		
<b>Width by Size</b>	XS	L	XS	XL	XS	XXL	
	70	111	70	120	70	130	±10mm
<b>Palm and finger thickness</b>	0.08		0.05		0.05*		mm min

\*Chloroprene rubber glove also needs to meet cuff thickness of 0.05mm minimum

- For natural rubber glove, the size is up to L (large) due to its good elasticity
- For chloroprene rubber and nitrile rubber, they are less elastic, larger sizes are required
- The minimum thickness for chloroprene and nitrile is lower than NR as these materials can form a thinner film than NR

# EN Standard for Exam Gloves

Size	XS	S	M	L	XL
Median width, mm	≤80	80 <sub>+</sub> 10	95 <sub>+</sub> 10	110 <sub>+</sub> 10	≥110
Median length, mm	≥240				

## Mechanical Properties for Exam Gloves

Properties	NR Exam Glove	Nitrile & CR Exam Gloves
ASTM unaged tensile*	18 MPa min	14 MPa min
ASTM aged tensile*	14 MPa min	14 MPa min
ASTM unaged elongation	650% min	500% min
ASTM aged elongation	500% min	400% min
ASTM Modulus @ 500%	5.5 MPa max	N/A
EN Force @ break (FB) , U & A**	6N min	6N min
ISO 11193 FB unaged (aged)	7N min (6)	7N (6)
ISO 11193 Elongation (aged)	650% min (500)	500% min (400)

- ASTM set higher requirements in the tensile properties for NR glove than synthetic gloves because NR can easily achieve better mechanical properties than synthetic rubbers

# Standards for Surgical Gloves

## ASTM Standard

	5.5	9.0	
<b>Width All</b>	70	114	$\pm 6$ mm
<b>Length</b>	245	265	mm min

Thickness for finger, palm and cuff 0.1mm min for all sizes

## EN & ISO Standards

	5.0	9.5
<b>Width, mm</b>	67 $\pm$ 4	121 $\pm$ 6
<b>Length, mm</b>	$\geq$ 250	$\geq$ 280

# Major Standards for Surgical Gloves

<b>Properties</b>	<b>NR Surgical Glove</b>	<b>Synthetic Surgical Glove</b>
<b>ASTM unaged tensile*</b>	24 MPa min	17 MPa min
<b>ASTM aged tensile*</b>	18 MPa min	12 MPa min
<b>ASTM unaged elongation</b>	750% min	650% min
<b>ASTM aged elongation</b>	560% min	490% min
<b>ASTM Dimensions (L &amp;W)</b>	Same	Same
<b>ASTM Thickness, (FPC)</b>	0.1mm min	0.1mm min
<b>ASTM Modulus @ 500%</b>	5.5 MPa max	7.0 MPa max
<b>EN Force @ break, (FB) U&amp; A**</b>	9N min	9N min
<b>ISO 10282 Unaged (aged)</b>	12.5N min (9.5N)	9N min (9N)
<b>ISO 10282 Elongation (aged)</b>	700% min (550)	600% min (500%)
<b>ISO 10282 M300%</b>	2N min	3N min

\*Die C preferred; \*\*Die D

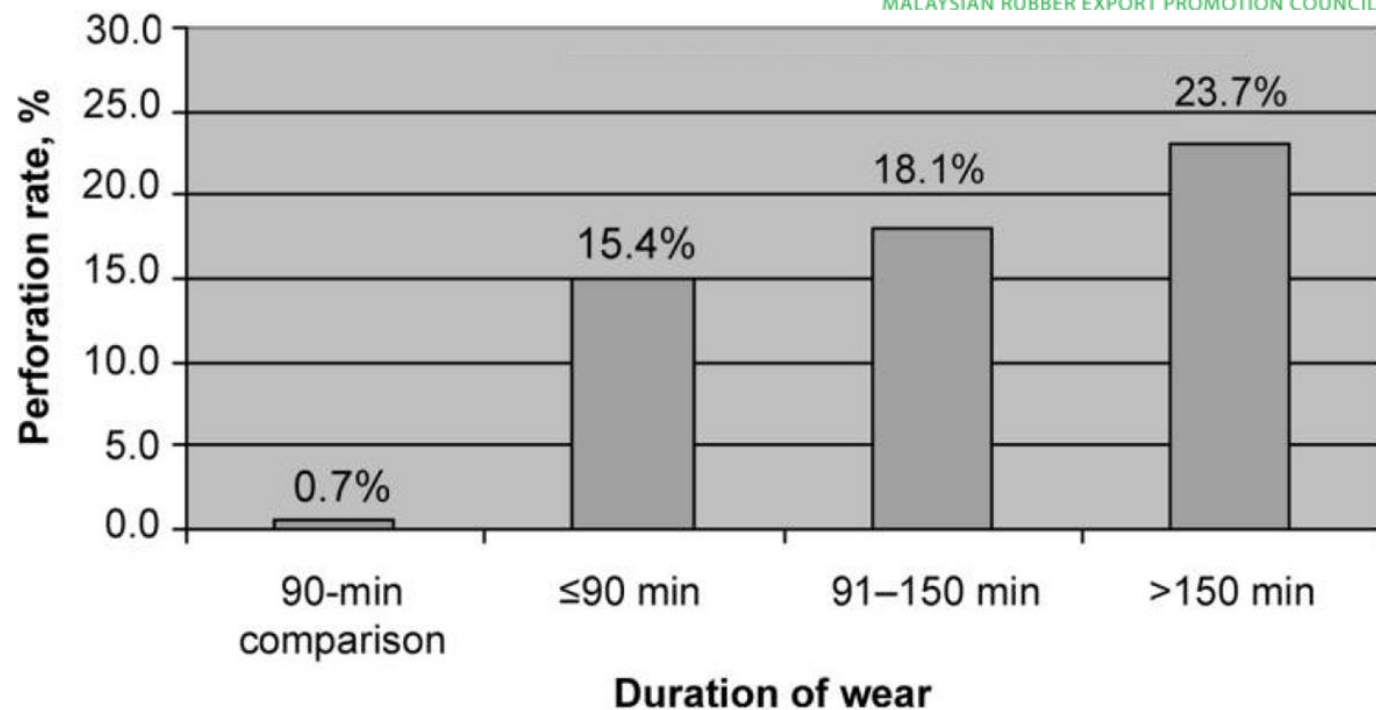


# Surgical Glove Perforation Rate and Wear Time

- Glove perforations during use are common (could be up to 70%\*) and often unnoticed

\* “Unnoticed Glove Perforation During Thoracoscopic and Open Thoracic Surgery” Ann. Thorac. Surg. 2005, 80, 1078–80

- Glove perforation risk increases with time (Less than 2hrs, <20% perforations).
- Generally, surgical gloves should be changed after 90 min of use



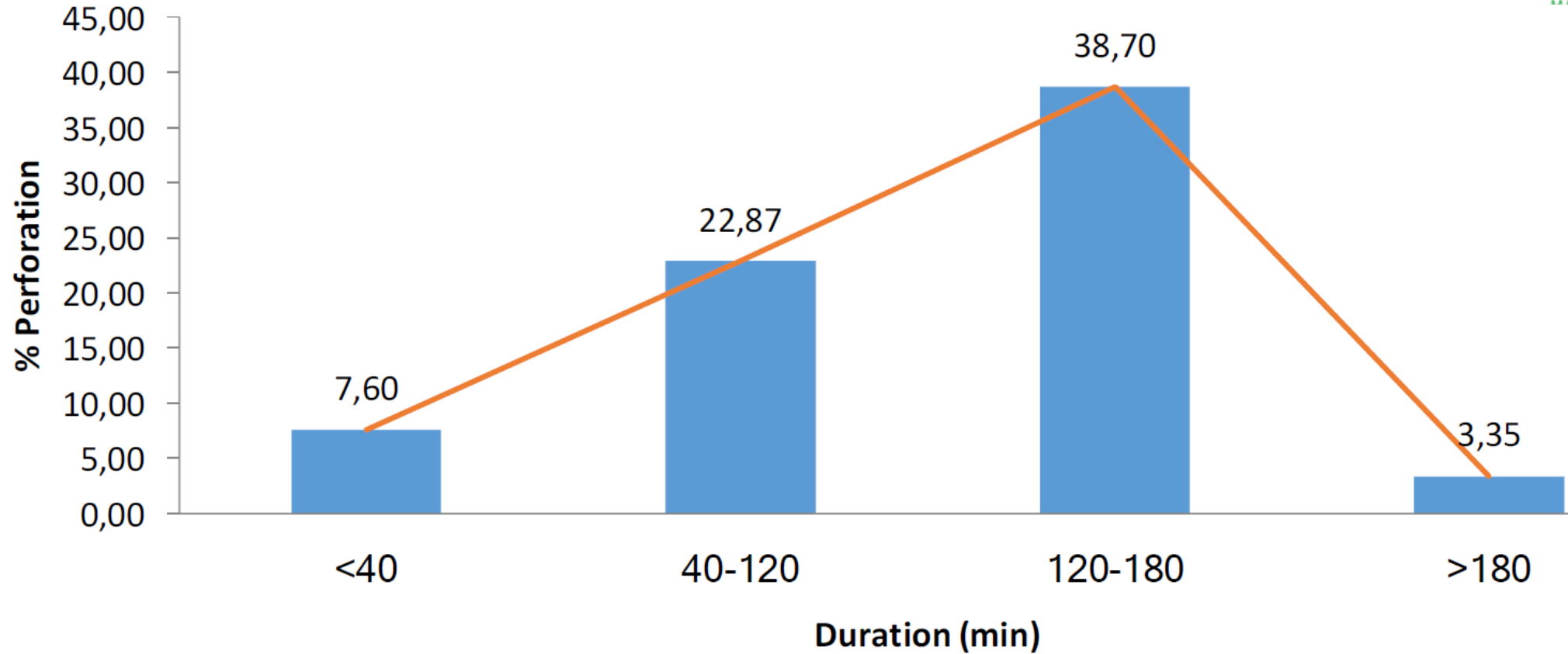
“Incidence of Micro-perforation for Surgical Gloves Depends on Duration of Wear”

Infect. Control Hosp. Epidemiol. 2009, 30, 409-414

- Double gloving reduces the perforation by >50%
- Injury during surgery: Risks HIV <0.4%; Hep B<30%, C < 10%
- Double gloving gives a better protection

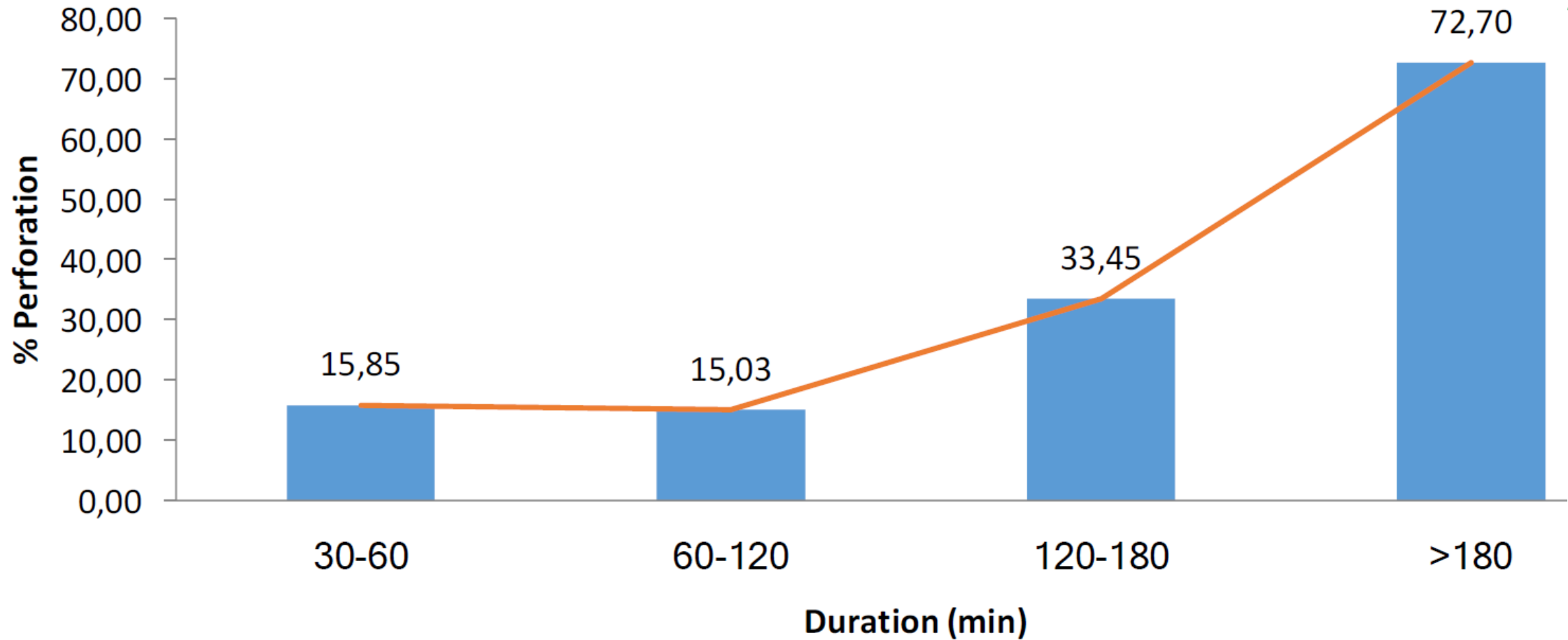
“Double gloving and practice attitudes among surgeons.” *Am J Surg.* 2003; 185:141-5.

# Perforation rate of surgical gloves in gynecology & obstetrics.



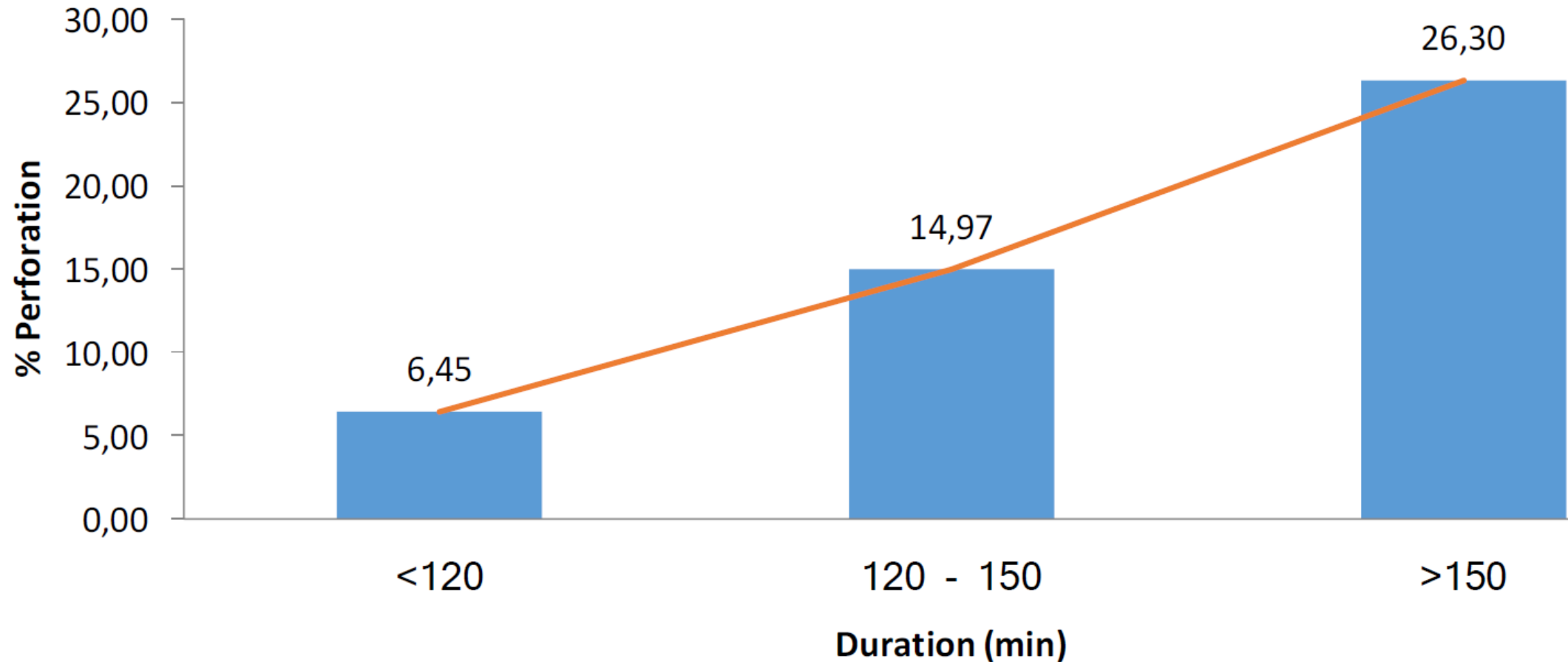
1. Manjunath AP, Sheperd JH, Barton DPJ, Bridges JE, Ind TEJ. Glove perforations during open surgery for gynecological malignancies. BJOG. 2008;115:105-19.
2. Malhotra M, Sharma JB, Wadhwa L, Arora R. Prospective study of glove perforation in obstetrical and gynecological operations: Are we safe enough? J Obstet Gynaecol Res. 2004;30(4):319-22.
3. Murta EFC, Silva CS, Júnior ORA. Frequency of glove perforation and the protective effect of double gloves in gynecological surgery. Arch Gynecol Obstet. 2003; 268(2):82-4.

# Perforation rate of surgical gloves in pediatric orthopedics



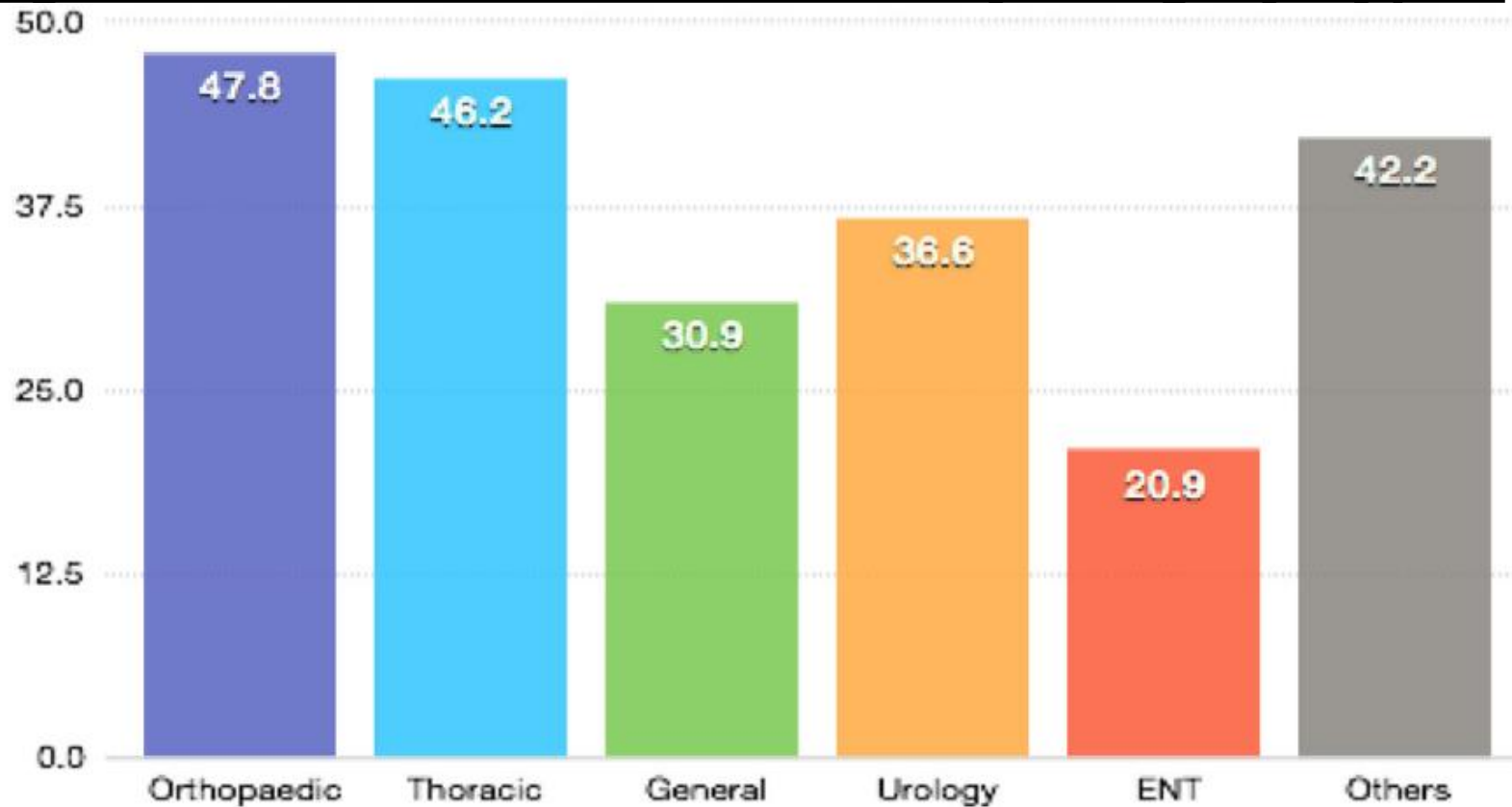
1. Yinusa W, Li YH, Chow W, Ho WY, Leong JCY. Glove punctures in orthopaedic surgery. *Int Orthop*. 2003;28(1):36-9.
2. Al-Habdan I, Sadat-Ali M. Glove perforation in pediatric orthopedic practice. *J Pediatr Orthop*. 2003;23(6):791-3.
3. Al-Habdan I, Corea R, Sadat-Ali M. Double or single gloves: which is safer in pediatric orthopedic surgery. *J Pediatr Orthop*. 2006; 26(3):409-11.

# Perforation rate of surgical gloves in digestion system



1. Harnoß JC, Partecke LI, Heidecke CD, Hübner NO, Kramer A, Assadian O. Concentration of bacteria passing through puncture holes in surgical gloves. *Am J Infect Control*. 2010;38(2):154–8.
2. Laine, T, Kaipia A, Santavirta J, Aarnio P. Glove perforations in open and laparoscopic abdominal surgery: the feasibility of double gloving. *Scand J Surg*. 2004; 93(1) 73–6.
3. Guo YP, Wong PM, Li Y, Or PPL. Is double-gloving really protective? A comparison between the glove perforation rate among perioperative nurses with single and double gloves during surgery. *Am J Surg*. 2012;204(2):210-5.

# Surgical Glove Perforation Rate by Surgery Types

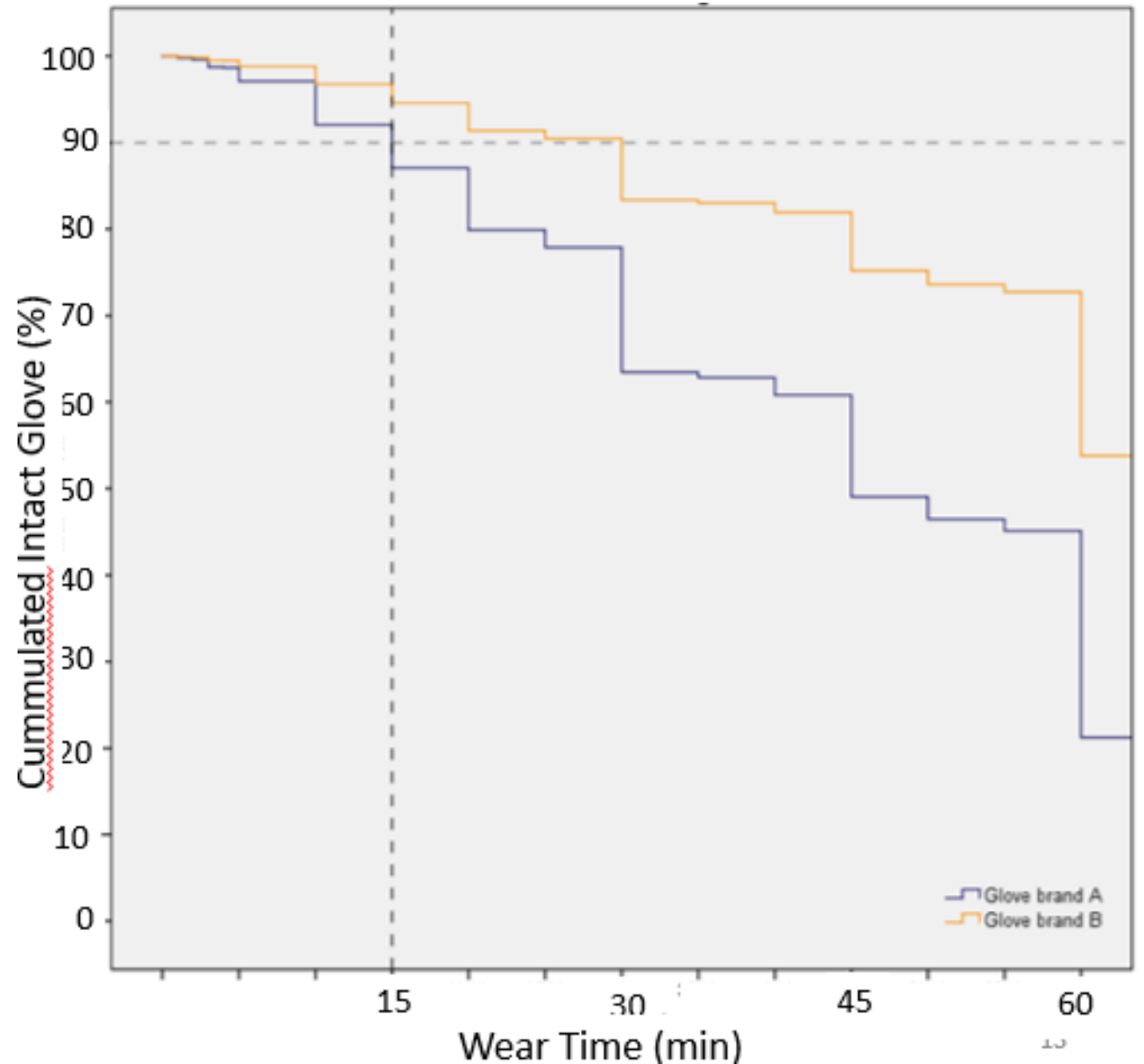


- Sample size of used gloves: 1588
- Perforation rate of both inner and outer gloves in double gloving cases: 0.4%
- Double gloving significantly reduces the risk of pathogen transmission

“Incidence and patterns of surgical glove perforations: experience from Addis Ababa, Ethiopia”. *BMC Surgery* 2017; 17, 26

# Examination Glove Perforation Rate and Wear Time

- Sample size of used gloves: 1500 pairs of NR & Nitrile examination gloves, about half for each type.
- 26% of the gloves were used for less than 15 minutes, with perforation rate 10.3% (308/3000).
- Of the perforated gloves, only 5.3% of the cases were noticed by the users (16/308).
- Perforation rate increased with wear time.
- Recommended to change examination glove every 15min for practicality and safety reasons.



## Double Gloving & Breach Detection

- Size of under glove varies, 31% same & larger, 35% smaller
- Breach detection:  
Under glove = a darker colour; Top glove = lighter colour
- The strong colour contrast > better breach detection  
79% versus 19% same colour.
- Other reasons are: weak/thin spots, punctured by sharp objects, weakened by solvents/oil/fat/hydration, repeated/ excessive stretching during use, rigorous surgical procedures, manufacturing defects



“Double gloving and a system for identifying glove perforation in maxillofacial trauma surgery”. *Br. J. Oral Maxillofac. Surg.* 1999; 37, 316-319.

# Puncture Resistance: Probe Vs Needle

Glove Type	Puncture force, N	
	Probe (ASTM F1342)*	0.4mm needle**
<b>NR Latex</b>	3.4	0.036
<b>Nitrile 1</b>	8.6	0.024
<b>Nitrile 2</b>	9.5	0.025
<b>Nitrile 3</b>	11.3	0.033

\*2mm Probe; \*\*Similar to ASTM F 2878, 28G needle

- Nitrile gloves have a higher puncture resistance than NR when probe is used
- Both NR and nitrile gloves are weak against sharp needle puncture

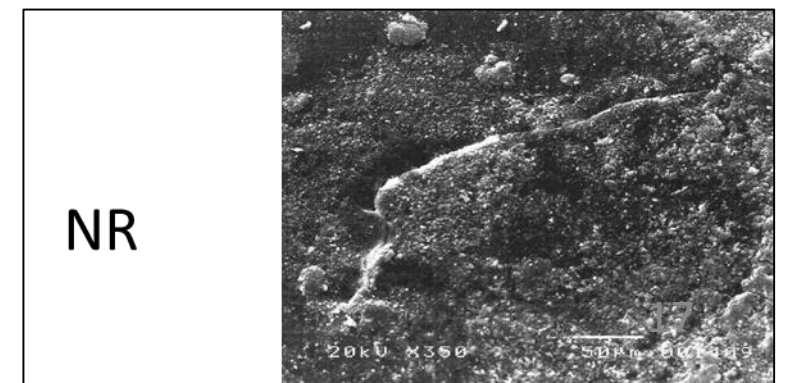
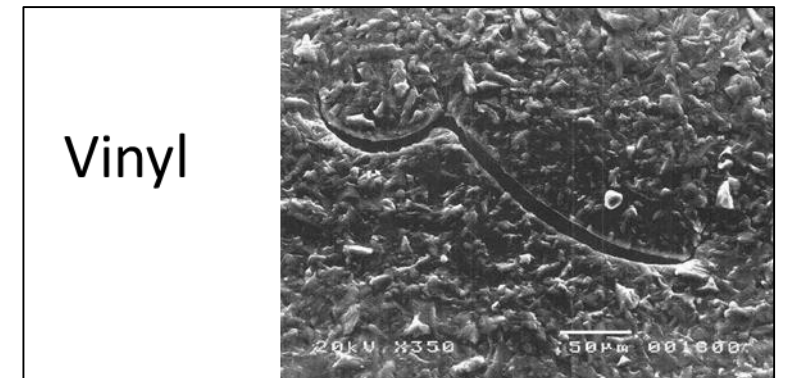
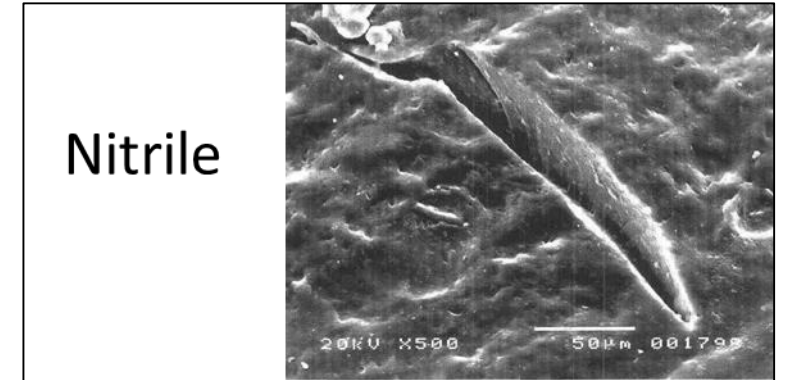


# Viral Penetration When Punctured\*

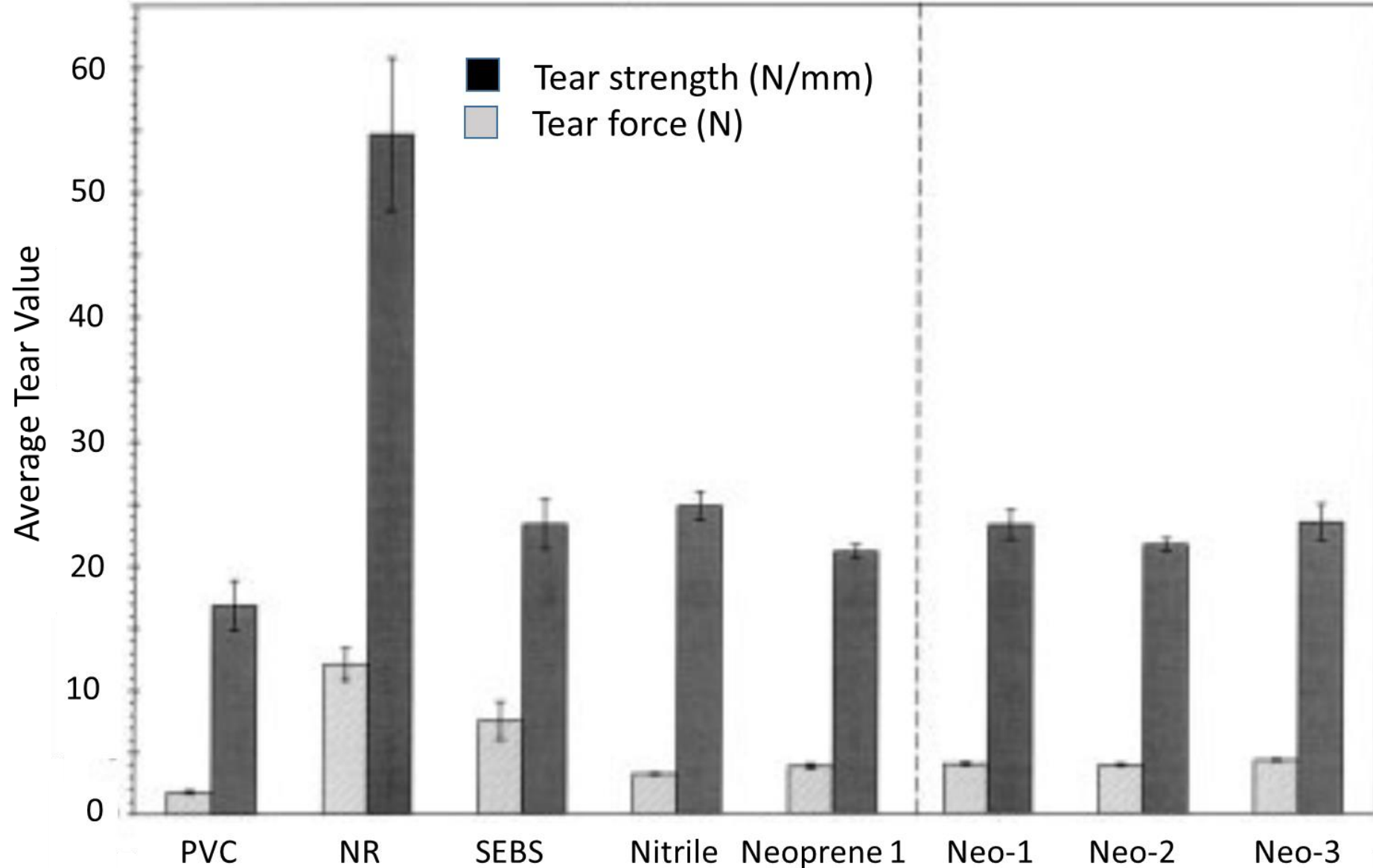
Glove Materials	Modulus (MPa)	Tear Strength (N/mm)	Virus Leak (ml)
PVC Glove 1	9.4	6	18
PVC Glove 2	7.4	4	10
PVC Glove 3	11.5	5	3
Nitrile Glove 1	2.9	5	22
Nitrile Glove 2	2.8	4	8
Nitrile Glove 3	4.7	5	10
Nitrile Glove 4	4.6	5	11
NR Glove 1	1.4	24	0.014
NR Glove 2	1.4	22	0.023
NR Glove 3	2.2	20	0.021
NR Glove 4	2.3	22	0.013

\*26G (0.46mm diameter)

“Barrier Integrity of Punctured Gloves....”. *J. Rubb. Res.* 2003; 4, 231-240



# Tear Properties of Different Rubber Gloves



# Penetration of *Escherichia coli* bacteria when punctured\*

Glove type	Material	Model	Median barrier efficiency (Ln)	Median fluid transfer (µL)
Examination	Nitrile	Stretch Nitrile	1.05	770
	Nitrile	Super Stretch Nitrile	1.07	345
	Nitrile	Micro-Touch Nitrile	1.35	770
	Nitrile	Micro-Touch Nitra Tex EP	0.72	305
	Latex	Premium	18.90	0
	Latex	Micro-Touch Latex Ultra	18.76	0
	Latex	Med-Comfort	2.53	55
	Neoprene	Micro-Touch Affinity	2.09	10
	Neoprene-composite	Neotril	2.67	20
	Surgical	Latex	Gammex PF with Antimicrobial Technology*	18.50
Latex		Gammex PF	20.91	0
Thermoplast		G-Derm	22.27	0

\*0.6mm diameter needle (23G); Repeated stretching up to 2.5 times of length for 4 cycles over a period of 66 seconds.

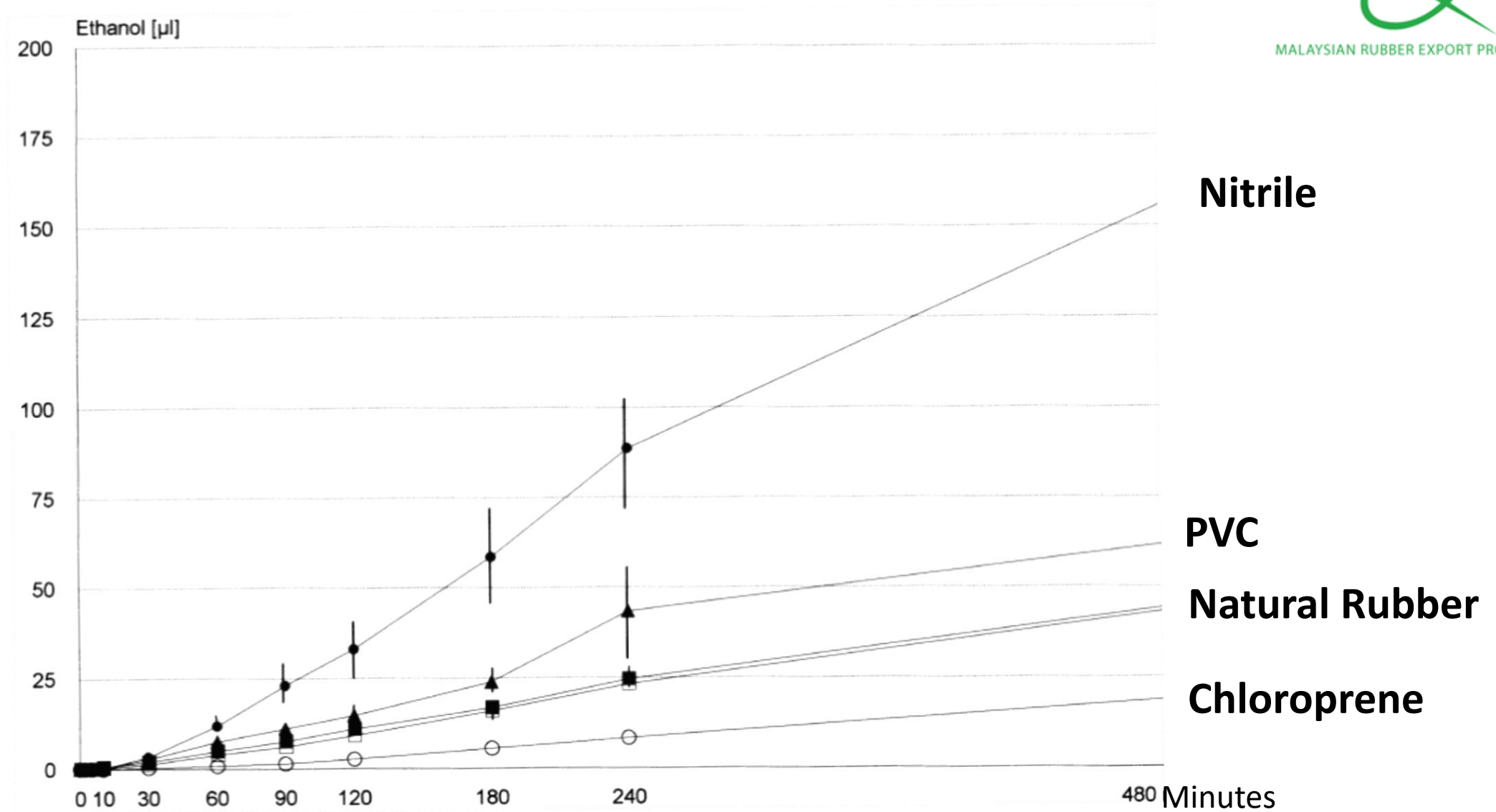
- NR latex may have an increased protective effect due to resealing
- A risk-benefit assessment should be considered, balancing the risk of allergy against the degree of required protection in case of a glove puncture.

# Perforation Occurrence

<b>Gloves</b>	<b>NR</b>	<b>Neoprene</b>	<b>Nitrile</b>	<b>Total</b>
<b>Number</b>	2647	3624	215	6486
<b>Defective rate</b>	5.6%	7.4%	9.3%	6.7%

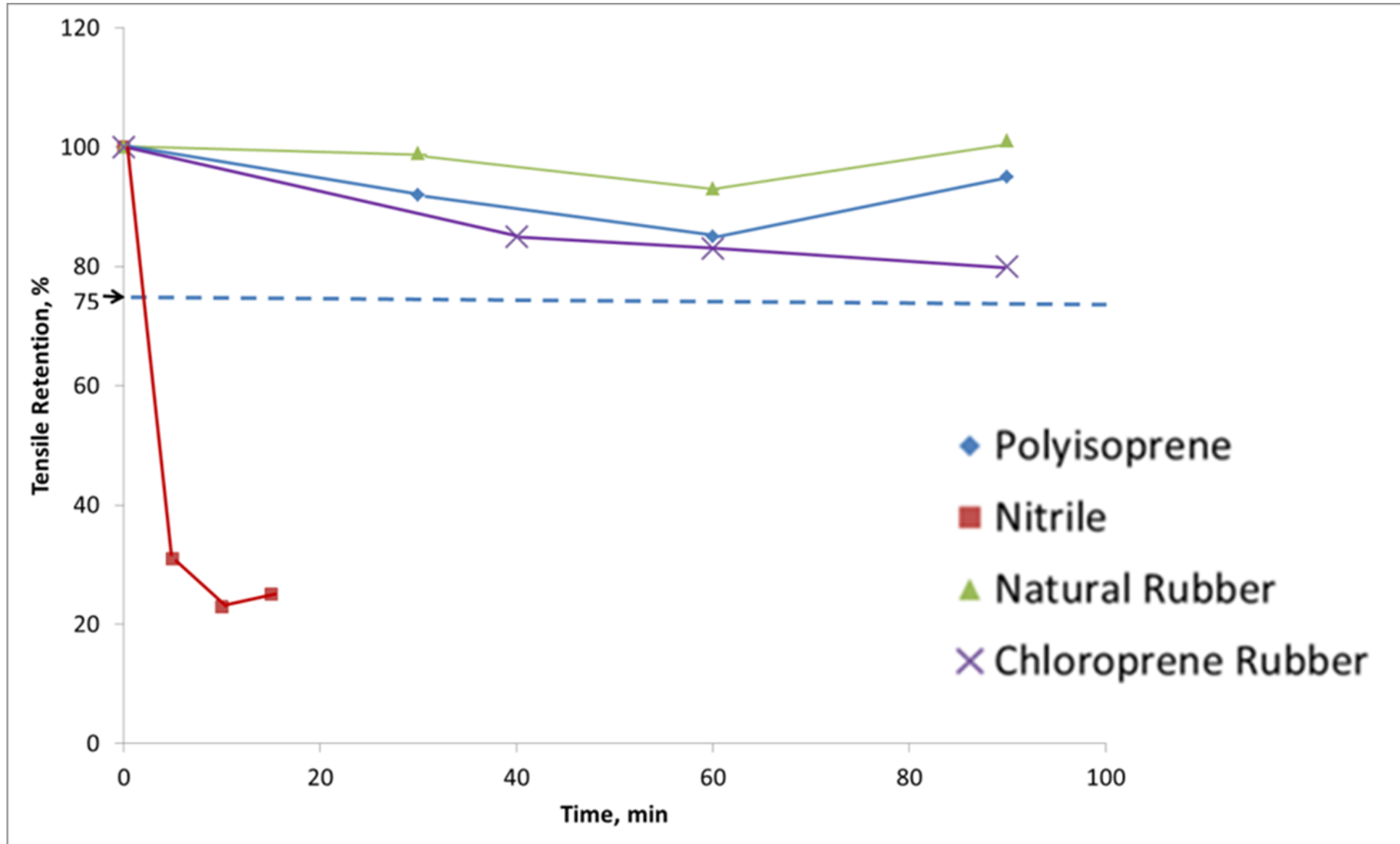
- 6,486 gloves were tested after being used for 15 different surgeries
- Non-latex gloves had higher visible defects
- There was no difference in no visible defects (water leak test)
- Rates of defects increased with the duration of glove use
- Surgeons and residents were more satisfied with latex than nonlatex (ie, nitrile and neoprene) gloves (F = 21.98; df= 2,367; P < 0.0001).

# Alcohol Permeation



“The permeability of dental procedure and examination gloves by an alcohol based disinfectant” *Dental Materials* 2000; 16, 139–144

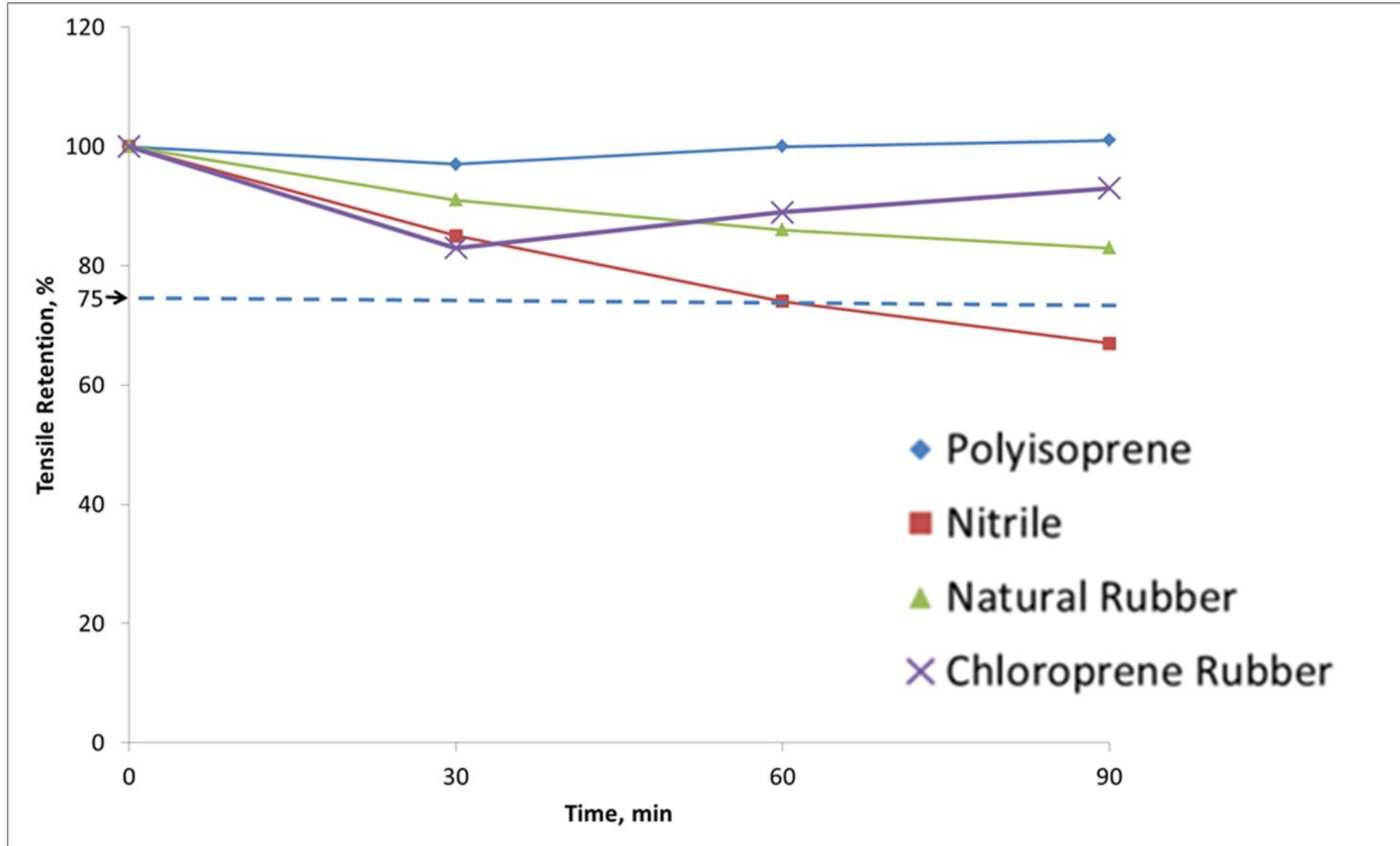
# Effects of Alcohol on Glove Strength Retention



“Effects of Several Liquids on Tensile Properties of Rubber Gloves”. *Chemistry in Malaysia* 2015; page 4-8.

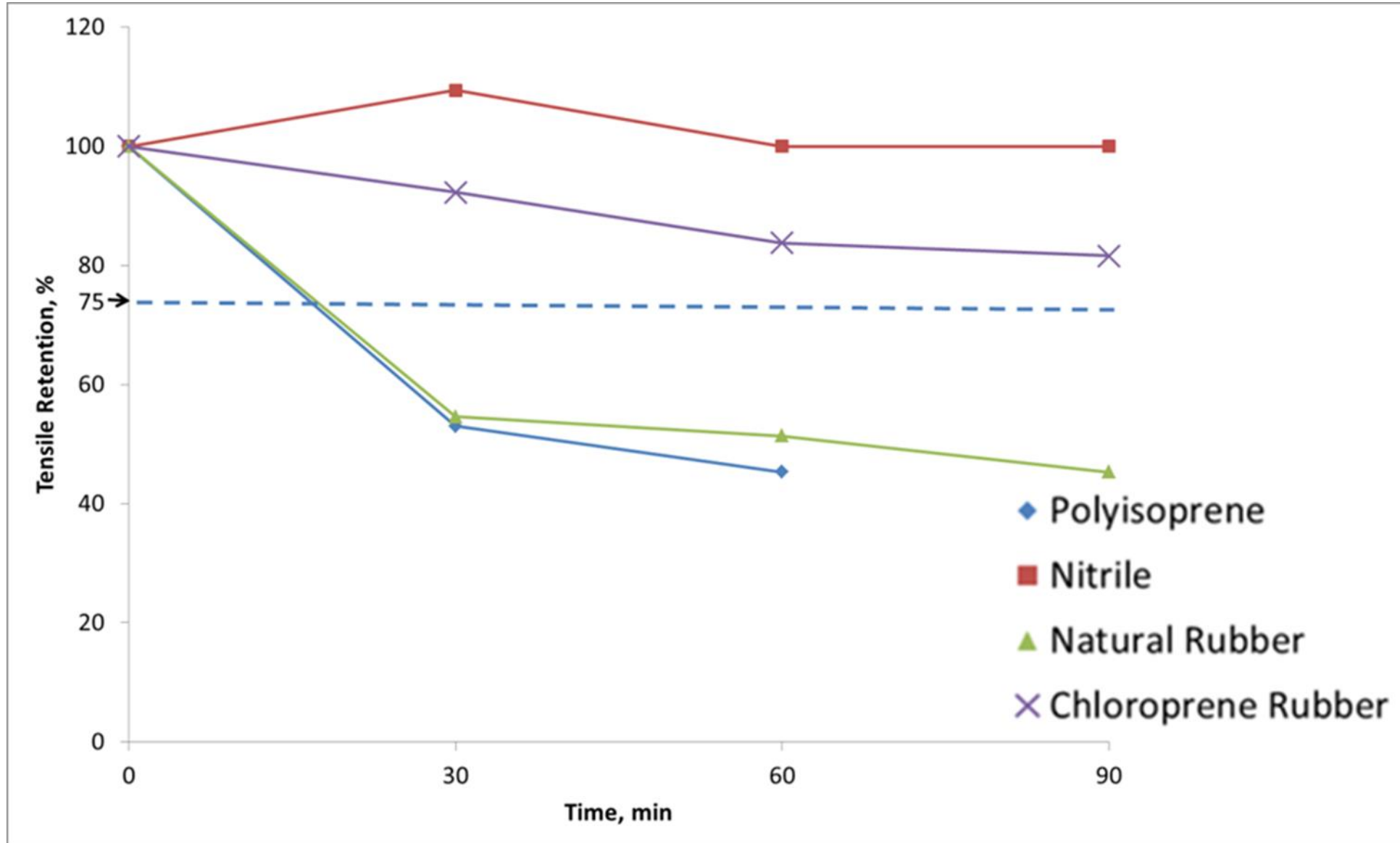


# Effects of Artificial Sweat on Glove Strength Retention



“Effects of Several Liquids on Tensile Properties of Rubber Gloves”. *Chemistry in Malaysia* 2015; page 4-8.

# Effects of Fat on Glove Strength Retention



“Effects of Several Liquids on Tensile Properties of Rubber Gloves”. *Chemistry in Malaysia* 2015; page 4-8.



# Summary of Properties Different Glove Materials



	<b>Natural Rubber</b>	<b>Nitrile</b>	<b>Chloroprene Rubber</b>	<b>PVC</b>
<b>Durability</b>	★★★★	★★★★	★★★★	★
<b>Tear resistance</b>	★★★★	★★★	★★★	★
<b>Puncture resistance</b>	★★★	★★★★	★★★	★★
<b>Comfort and fit</b>	★★★★	★★★	★★★	★★
<b>Flexibility</b>	★★★★	★★	★★★	★★
<b>Tactile sensitivity</b>	★★★★	★★	★★★	★★
<b>Grip</b>	★★★	★★★★	★★★	★★★
<b>Alcohol resistance</b>	★★★★	★★	★★★★	★★★
<b>Oil resistance</b>	★★	★★★★	★★★	★★★

## Risks of Re-using Single Use Medical Gloves

- 1) Soiled used medical gloves are usually highly contaminated, difficult to clean.
- 2) Used gloves may contain prions that can cause transmissible spongiform encephalopathies (TSE) which are resistant to heat and sterilisation .
- 3) Used gloves also contain different levels of soiled biological and chemical materials which can make cleaning and sterilisation of the reprocessed gloves difficult. Sterility can only be assured when the bioburden is below 1000cfu/unit product.
- 4) Certain chemicals may be released during reprocessing, which could cause adverse irreversible chemical reactions to the gloves such as dissociation of crosslinks.
- 5) Reprocessing could cause deterioration in the glove performance properties.
- 6) Reprocessed gloves may also contain endotoxins from the dead bacteria found in the soiled gloves.

Currently, there is no validated appropriate method available for reprocessing medical gloves. Healthcare workers are advised against the use of reprocessed medical gloves.

# Summary

- Medical gloves do not provide complete protection from cross-contamination
- Proper use of medical gloves can reduce the risk of cross contamination.
- One should frequently check for glove perforations during use.
- Double gloving can reduce the risk of exposure to pathogens.
- Donning a darker under glove and a lighter outer glove can enhance the breach detection.
- Double glove should be practised especially the duration of use exceeds 30min.
- Change both gloves when the outer glove is perforated
- Durability of medical gloves depends on many factors such as the glove materials, types of liquid exposed, types of medical procedure, duration of use.
- Certain glove materials, such as natural rubber, have the ability to reseal which could reduce the risk of cross contamination in the event of micro-perforation.
- Single use medical gloves should not be reprocessed for reuse to avoid the risk of pathogen transmission

Thank you



Table I. Sample Size Code Letters

Lot or Batch Size	Special Inspection Levels				General Inspection Levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and Over	D	E	H	K	N	Q	R



# SINGLE SAMPLING PLANS FOR NORMAL INSPECTION

Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)																					
		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																				0	1	
B	3																				0	1	
C	5																	0	1				
D	8													0	1								
E	13													0	1					1	2	2	3
F	20													0	1			1	2	2	3	3	4
G	32													0	1			1	2	3	4	5	6
H	50													0	1			1	2	2	3	5	6
J	80													0	1			1	2	2	3	7	8
K	125													0	1			1	2	2	3	10	11
L	200													0	1			1	2	2	3	14	15
M	315													0	1			1	2	2	3	21	22
N	500													0	1			1	2	2	3		
P	800													1	2			2	3	3	4		
Q	1250													2	3			3	4	5	6		
R	2000													3	4			5	6	7	8		

↑ Use first sampling plan above arrow, if sample size equals or exceeds lot or batch size, do 100 percent inspection.

↓ Use first sampling plan below arrow

AC : Acceptance number      Re : Rejection number

# ASTM Performance Requirements for Examination Gloves

Characteristics	Failure	Inspection Level	AQL	Sample Size*	Max Failure Rate
<b>Sterility</b>	Fails sterility	U.S. Pharmacopeia	N/A	N/A	$\leq 1 / 10^6$
<b>Freedom from holes</b>	Holes	G-I	2.5	N	$\leq 21 / 500$
<b>Dimensions</b>	Width, length, thickness	S-2	4.0	E	$\leq 1 / 13$
<b>Physical properties</b>	Before & After A. aging	S-2	4.0	E	$\leq 1 / 13$
<b>Powder (Free) residue</b>	Exceeds limit	N=5	N/A	N/A	$\leq 2\text{mg/glove}$
<b>Antigenic proteins</b>	Exceeds limit	N=3	N/A	N/A	$<10 \mu\text{g/dm}^2$
<b>Extractable proteins</b>	Exceeds	N=3	N/A	N/A	$50 \leq \text{EP} \leq 200 \mu\text{g/dm}^2$

\*Assuming order quantity of  $\geq 500,000$  pieces;

## Sampling

For referee purposes, gloves shall be sampled and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in the Table, or as agreed between the purchaser and the seller, if the latter is more comprehensive.

# ASTM Performance Requirements for Surgical Gloves

Characteristics	Failure	Inspection Level	AQL	Sample Size*	Max Failure Rate
<b>Sterility</b>	Fails sterility	U.S. Pharmacopeia	N/A	N/A	$\leq 1 / 10^6$
<b>Freedom from holes</b>	Holes	G-I	1.5	M	$\leq 10 / 315$
<b>Dimensions</b>	Width, length, thickness	S-2	4.0	E	$\leq 1 / 13$
<b>Physical properties</b>	Before & After A aging	S-2	4.0	E	$\leq 1 / 13$
<b>Powder (Free) residue</b>	Exceeds limit	N=5	N/A	N/A	$\leq 2\text{mg/glove}$
<b>Antigenic proteins</b>	Exceeds limit	N=3	N/A	N/A	$<10 \mu\text{g}/\text{dm}^2$
<b>Extractable proteins</b>	Exceeds	N=3	N/A	N/A	$50 \leq \text{EP} \leq 200 \mu\text{g}/\text{dm}^2$

\*Assuming an order quantity of  $\sim 360,000$  pairs for a 40' container

## Sampling

For referee purposes, gloves shall be sampled and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in the Table, or as agreed between the purchaser and the seller, if the latter is more comprehensive.