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Fatigue Resistance of Medical Gloves

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Test equipment and a method for studying the fatigue resistance of medical gloves were developed. The method involves a continuous inflation and deflation of glove under a set of controlled conditions until the glove loses its integrity by the formation of a hole or a tear. Under the controlled conditions the deformation characteristic at certain critical parts of the glove during use was simulated. It was observed that the loss of glove integrity during the fatigue test occurred mostly at areas near the base and crotches of fingers. The type of fatigue failure displayed by natural rubber (NR) gloves, are holes and tears. The fatigue failure of nitrile and vinyl gloves was mainly by formation of tear. Fatigue lives of NR examination and surgical gloves at 50% strain measured at the base of the second finger, at an inflation-deflation frequency of 0.5 cycle per second were found to exceed 1000 cycles. Under similar conditions, the fatigue lives of nitrile and vinyl examination gloves were found to be less than 400 cycles. There was generally no clear relationship between the physical properties and the fatigue resistance of NR and nitrile gloves. For vinyl gloves, the fatigue resistance increased with decreasing stiffness of the glove. Depending upon the type of glove, the fatigue life of glove might increase or decrease after ageing. Rather unexpectedly, at a low strain of 50%, aged vinyl glove showed a significantly high fatigue life. This unexpected result was due to the relatively high permanent set that the aged vinyl glove experienced during the test. In general, aged natural rubber gloves regardless of the nature of their finish showed much superior fatigue life values when compared to unaged nitrile or vinyl gloves.

Key words: fatigue resistance, medical gloves, testing, equipment, NR nitrile, vinyl, ageing, strain, deformation

Medical gloves may tear, rip or puncture while in use. When this occurs, the glove ceases to function as a barrier device that protects the patient and the user from cross-contamination. Glove failures during use can be induced by forces exerted on the gloves during the handling of sharp objects such as instruments, knives, forceps, surgical needles *etc*.

It has been observed however, that gloves could still form a hole or a tear by mere movement of the hand and fingers. The tendency of nitrile gloves to tear at the crotches of fingers during use even in the absence of contact with sharp objects is a well-known problem in the glove industry. The tearing of glove during use gives an immediate, observable indication that the glove has lost its usefulness as a barrier device. The user could respond to this problem immediately by replacing the torn glove with a new one. However the tear may have started by the formation of a micro-sized crack which

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then develop into a pinhole-size crack during use and this is may not be visible easily It would therefore be useful for glove users if the minimum duration of glove integrity during use (due to fatigue stress) could be assured or predicted regardless of pinhole or tear failure

The requirements for the absence of holes and tensile properties of medical gloves that are specified in a number of standards[1-5] are unable to indicate glove barrier performance during use Admittedly, these tests are employed for quality assurance testing The water-tightness test only assures completeness in the integrity of glove before usage Besides, it cannot detect small holes that are still passable by certain type of virus[6] The tensile property or tear strength tests for gloves have several limitations in assessing the mechanical, and much less, the barrier performance of the whole glove during use This is due to a number of reasons Firstly, the test is carried out on test pieces taken from the palmar/back of glove areas whilst the relatively weak zones are in the curved parts of the glove such as the crotch of the fingers Secondly, the deformation, stress and failure characteristics of the standard test piece tend to be different than that experienced by the various parts of the glove during use Thirdly, the test piece does not undergo dynamic stress/strain changes such as that experienced by various parts of the glove during use

There have been studies on the loss of integrity of medical gloves under in-use conditions where gloved hands underwent a set of hand manipulations[7-9] after which their integrity was tested for water-tightness or bacterial penetration The results show that NR gloves have better barrier performance than other gloves The test however would not be suitable as a routine test for the barrier performance of gloves, partly due to the difficulty of maintaining consistency in test conditions

The Office of Science and Technology (U S A) carried out bi-axial flex-fatigue studies of a film test piece taken from a glove[10] The integrity of the film after flexing was determined using an electrical or viral permeability test An interesting observation in this study was that oven ageing resulted in a significant increase in the fatigue life of chlorinated NR gloves while the increase is marginal for non-chlorinated gloves One of the limitations of this test is that the test piece is subjected to bi-axial stress while that applied to a glove during use is multi-axial and the level of stress along different axis may be different It has been observed that if latex film is subjected to bi-axial stresses having different magnitude of stress in each stress direction, upon initiation of, the crack would tend to propagate more easily along the direction that had higher strain Another limitation is that the imperfections in gloves where small-scale crack could grow during fatigue stress are probably present in higher number at the crotches compared to the palmar areas The flaws/imperfections in gloves[11,12] can be associated with the structure of latex particulate, particulate impurities, film surface and network structure

This paper describes a glove fatigue test equipment that was developed at the Malaysian Rubber Board, a glove fatigue test-method and the fatigue behaviour of medical gloves made from natural rubber latex, nitrile latex and polyvinyl chloride dispersion The principle of the test was to flex the glove by inflating and deflating such that the critical areas around the base of the fingers were stretched and unstretched in the range that was close to that which might be experienced by the glove during use The glove inflation/deflation process was repeated until the glove lost its integrity. The expansion of the palmar areas and back of glove was controlled so as to promote the loss of glove integrity at these critical areas during the test.

EXPERIMENTAL

Glove Fatigue Test Equipment

The equipment assembly for the glove fatigue test is shown in *Figure 1*. A cylindrical collar that was fitted over the glove holder was used to hold the glove tightly. Any other suitable grip could be used. The solenoid valves, the timers and the air-flow rate regulators control the inflation of the gloves to a predetermined size within a predetermined time, and deflation of the same within a predetermined time.

The equipment controls allow for continuous inflation and deflation of the glove and, for automatic stoppage when the glove develops a tear or bursts. A counter displayed the number of inflation cycles. The equipment was also fitted with a pressure gauge that measured the inflation pressure of the glove. For glove failure due to the formation of a hole, the end point of the test could be detected by visual observation and/or from the reduction in the maximum inflation pressure.

A pipe with a diameter of about 108 mm was used to restrict the expansion of the palmar areas of the glove and to promote stretching at areas around the base of the fingers. The length of the pipe should be such that, when the glove is inflated to the required degree of stretching, the crotches of the fingers are not exposed. Pipe lengths of 20 cm – 30 cm would be suitable for gloves of various sizes and types.

Glove Samples

Glove samples were obtained from several Malaysian glove manufacturers and also through arrangements made by the Tun Abdul Razak Research Laboratory, UK. A wide range of glove samples were tested: surgical and examination, gloves made from natural rubber latex, nitrile latex and polyvinyl chloride; powdered, chlorinated and polymer coated; gloves having smooth and textured surface.

Determination of Strain Values for Fatigue Test

Different parts of a glove stretches at different degrees during use. However, they may not undergo the series of stretching and unstretching cycles. The degree of stretching at certain parts of the glove that undergo continuous stretching and unstretching during use was determined.

Lines of 10 mm lenght were drawn on several areas of the glove that were known to undergo substantial stretching and unstretching during use. The areas selected were near the crotches of fingers and at the knuckles. The crotch areas were avoided due to the difficulty in measuring the dimension of the lines. The glove was donned by a user and the dimension of the lines were measured when the hand was in stretched open position and clenched to form a fist. The percentage of stretching of these lines were calculated.

Table 1 shows the maximum degree of stretching at some critical areas of gloves under various conditions. The maximum degree of stretching at some critical areas of gloves varied over the 20% – 120% range. The stretching at the knuckles in the direction along the fingers was found to be around 20%. Stretching at certain palmar areas may be significant when the hand was clenched.

However, this could not be determined. The actual degree of stretching at various parts of the glove during use would depend upon the nature of task, size of glove, size of hand, as well as the type and design of glove. An undersized glove could undergo high degree of stretching during use.

Based on the data obtained as described above, the glove fatigue studies were carried out using three levels of glove inflation, equivalent to 50%, 75% and 100% stretching of a 10 mm strain mark drawn at the base of the second finger. This location was chosen because most of the glove failures occurred at the crotches and areas near the base of the fingers. The strain mark at this position also enables a convenient observation of the degree of stretching. The degree of stretching at the circumference of the palmar areas of the glove was in the range 60% – 110%, depending upon the size of the gloves and dimension of the restricting pipe.

Inflation-deflation Frequency for Glove Fatigue Test

Stretching-unstretching frequency at critical parts of the glove during use might vary in the range 0.25 to 3 cycles per second. Based on this observation, glove inflation-deflation frequency of 0.5 cycle per second was selected for the glove fatigue test. The use of a lower inflation-deflation frequency would require a

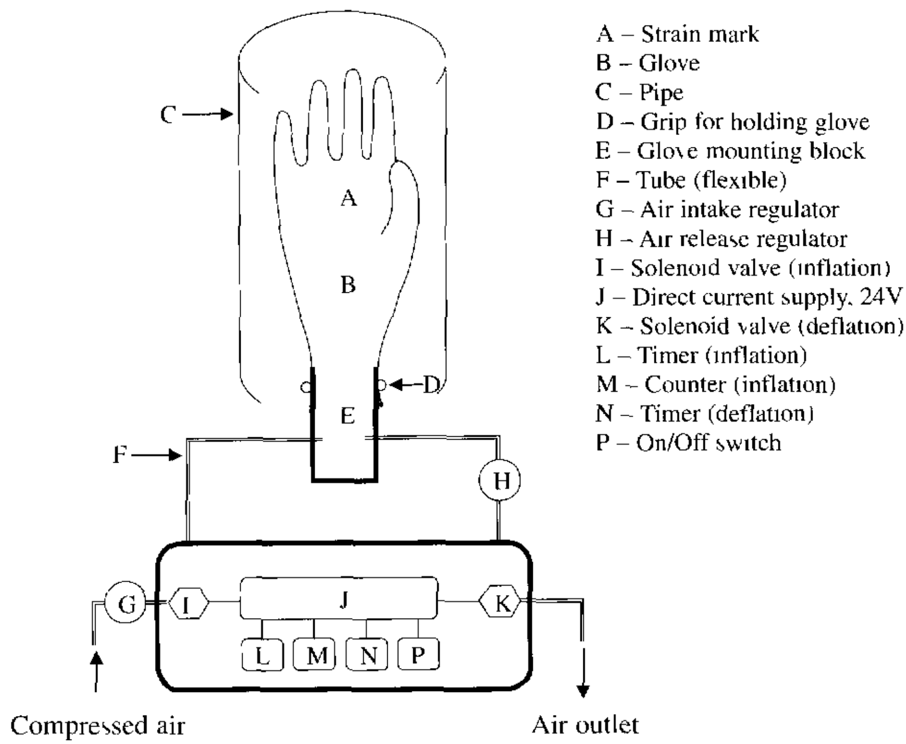

Figure 1. Glove fatigue test equipment assembly.

TABLE 1 DEGREE OF STRETCHING OF GLOVES IN USE

No	Gloves Type	Palm width (mm)	Palm width of glove user (mm)	Percentage of stretching (%) Location[c] A	B	C
1	Surgical, NR	95	85[b]	20	20	30
2	Surgical, NR	82	90[a]	110	50	120
3	Surgical, NR	85	90[a]	70	40	80
4	Surgical, NR	90	90[a]	50	20	50
5	Surgical, NR	90	90[a]	40	20	40
6	Surgical, NR	95	90[a]	50	20	30
7	Surgical, Neoprene	86	90[a]	50	30	50
8	Examination, NR	94	90[a]	40	30	30
9	Examination, NR	90	90[a]	50	40	40
10	Examination, NR	94	85[b]	30	70	70
11	Examination, NR	95	85[b]	20	60	60
12	Examination, Nitrile	76	90[a]	60	60	70
13	Examination, Nitrile	90	90[a]	60	50	80
14	Examination, Nitrile	76	85[b]	50	60	90
15	Examination, Nitrile	77	85[b]	40	80	90
16	Examination, Nitrile	79	85[b]	50	80	90
17	Examination, Nitrile	92	85[b]	50	50	70
18	Examination, Nitrile	93	85[b]	40	80	90
19	Examination, Vinyl	90	85[b]	40	60	60
20	Examination, Vinyl	92	85[b]	40	50	50
21	Examination, Vinyl	93	85[b]	30	40	40

[a] User with slim fingers, [b] User with thick fingers
[c] Location of strain measurement

A – At the back of glove, near the crotch of the index-middle fingers, in widthwise direction, with the fist stretched open

B – At the back of glove, near the crotch of thumb-index fingers, in approximately lengthwise direction, with the fist clenched

C – At the palm of glove, near the crotch of thumb-index fingers, in approximately lengthwise direction, with the fist stretched open longer time to complete the test. On the other hand, a much higher inflation-deflation frequency could not be used with the present equipment as this might result in incomplete deflation of glove during the deflation cycle. If this occurs, the glove would inflate to a bigger size in the next inflation cycle. The rate of glove deflation dependes mainly on a combination of two factors: the elastic force of the inflated glove body and the size of air release tube of the test equipment.

Fatigue Test Procedure

A 10 mm strain mark was drawn at the base of the middle finger of the glove. The glove was attached on to the glove mounting block. A suitable grip was used to hold the glove to prevent leakage of air at the grip areas during inflation of the glove. The compressed air supply and the power supply to the test equipment were then turned on.

Talc was lightly applied on the inside wall of the restricting pipe to reduce friction between the glove and the inside wall of the pipe during the test. The glove was inflated slightly and the restricting pipe was then placed over the glove as shown in *Figure 1*. The slight inflation of the glove before fixing the pipe was to prevent the glove from folding during inflation.

The glove inflation and deflation timers were both set at one second. This is equivalent to glove inflation-deflation frequency of half cycle per second. The auto glove inflation/deflation switch was turned on. The glove was inflated such that the strain mark was stretched by 50%, 75% or 100%, as required. The stretched strain mark was measured using a suitable strain gauge. The rate of air supply was adjusted to meet the requirement on glove inflation time and degree of glove inflation. The rate of air release was also adjusted to obtain the required glove deflation time. After this initial settings, only minor adjustments of the equipment controls were needed in order to test other gloves. The glove was inflated and deflated until the glove lost its integrity. The number of inflation cycles when the glove lost its integrity was recorded as the fatigue life of the glove.

Any fatigue life cycle that was found to be abnormally high compared to the average value of other samples from the same batch was rejected, as this high result might be due to an oversight in detecting failure due to a pinhole or a leak at the glove-holder areas. In such a situation, the glove might have been inflated to a lesser degree than required.

The fatigue life could also be expressed in terms of fatigue life time. This was the total time (in seconds) that the glove could maintain its integrity during the test and was equal to twice the maximum number of inflation cycles.

Fatigue Test for Aged Gloves

Selective glove samples were aged in hot air at 70°C for 168 h ± 2 h. The gloves were hung with the fingers in a downward position in an ageing oven using a string that passed through the edge of the cuff termination. Glove fatigue tests on the aged gloves were carried out in a similar manner as described above.

Determination of Glove Dimensions and Physical Properties

The palm width of the glove and a single-wall thickness of glove at the point where the strain mark was drawn were determined. The unaged tensile properties[13] and the tear strength[14] of test pieces taken from the gloves were determined according to *ISO 37* and *ISO 34*, respectively. For aged tensile properties, dumb bell test pieces were taken from the gloves which had been aged as described above.

RESULTS AND DISCUSSION

Stretching Characteristics during Use and Requirements for Fatigue Test

Comparison of data obtained from gloves of similar palm width shows that the degree of stretching of NR surgical gloves measured under conditions *B* tend to be lower than that of NR examination gloves (*Table 1*). This can be explained by the difference in the design of the thumb of surgical and examination gloves. However, the difference in the degree of stretching between the two types of gloves was not significant at positions *A* and *C*. Thus, if the glove fatigue test was to be used as a standard test requirement for gloves, the degree of stretching or inflation should be the same for different type of glove designs.

Data for NR surgical gloves show that the gloves which had smaller palm width than the palm width of user's hand tended to stretch more at positions *A*, *B* and *C* than those with larger palm width. However, this relationship did not appear to be true for the group of nitrile examination gloves which had smaller palm widths than did the user's hand. Perhaps it was the actual dimensions of the fingers and areas near positions *A*, *B* and *C* rather than the palm widths that had greater influence on the degree of stretching at these locations.

It was noteworthy that the range of the degree of stretching calculated for the palmar areas (60% – 110%) during the glove fatigue test was similar to the range used in this study as determined at a location near the base of the second finger (50% – 100%). This could simplify data analysis irrespective of the location of fatigue failures.

Under the test conditions chosen for this study, the rate of stretching of the strain mark was in the range 300 mm/min – 600 mm/min. For comparison, the pulling rate of test piece for the tear strength determination[14] using a trouser test piece was 100 mm/min ± 10 mm/min and for tensile property determination[13] it was 500 mm/min.

General Characteristics of Fatigue Behaviour

Table 2 shows some of the glove fatigue test results obtained in this study and the following observations were noted:

- More than 95% of gloves tested lost their integrity at areas near the base or crotch of fingers either due to a pinhole or a tear. The remaining failures occurred at the palm or at the wrist.

- NR gloves showed both types of fatigue failure, that is, formation of a hole or a tear. Nitrile and vinyl gloves invariably showed fatigue failures by the formation of a tear. *Figures 2a* and *2b* are pictures of NR and nitrile gloves showing a similar type of fatigue failure.

- Gloves that were taken from the same batch, regardless of the type of material, film surface treatment and film surface texture, inclined to show similar type of failure. Thus, for a given batch of NR gloves, most of it might have failed due to holes or tear formation.

- The fatigue life of gloves made from different materials was in the order: NR > nitrile > vinyl.

TABLE 2. NATURE OF THE FATIGUE FAILURE OF GLOVES

Glove sample[a]	Strain (%)	Fatigue life (Cycles)	Nature and location of glove failure
NREG A (pf)	75	495	Tear at the base of 2nd finger to cuff
NREG A (pf)	75	944	Tear at the palm near the 2nd finger to cuff
NREG A (pf)	75	569	Tear at the palm near the 2nd finger to cuff
NREG A (pf)	100	465	Tear from the base of 2nd finger to cuff
NREG A (pf)	100	234	Tear at the palm near the 2nd finger to cuff
NREG A (pf)	100	319	Tear from the base of thumb to the rear
NREG L (pf)	50	1800	A hole at the edge of wrist
NREG L (pf)	50	1550	A hole at the crotch of 2nd and 3rd finger
NREG L (pf)	50	1280	A hole at the crotch of 2nd and 3rd finger
NREG L (pf)	75	625	Tear at the base of palm
NREG L (pf)	75	750	A hole at the crotch of 2nd and 3rd finger
NREG L (pf)	75	450	A hole at the edge of wrist
NREG L (pf)	100	455	Tears at both side of palm
NREG L (pf)	100	669	A hole at the crotch of 1st and 2nd finger
NREG L (pf)	100	450	Tear at the palm
NEG N (pf,t)	50	169	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	50	312	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	50	226	Tear at the crotch of thumb and 1st finger
NEG N (pf,t)	75	85	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	75	78	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	75	183	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	100	35	Tear at the crotch of thumb and 1st finger
NEG N (pf,t)	100	141	Tear at the crotch of 2nd and 3rd finger
NEG N (pf,t)	100	45	Tear at the crotch of 2nd and 3rd finger
VEG V (p)	50	580	A hole at the crotch of 2nd and 3rd finger
VEG V (p)	50	117	Tear at the crotch of 2nd and 3rd finger
VEG V (p)	50	129	Tear at the base of 2nd finger
VEG V (p)	75	35	Tear at the crotch of 2nd and 3rd finger
VEG V (p)	75	47	Tear at the crotch of thumb and 1st finger
VEG V (p)	75	63	Tear at the crotch of thumb and 1st finger

[a]p = powdered; pf = powder free; t = textured
NREG = NR examination glove; NEG = Nitrile examination glove
VEG = Vinyl examination glove

- Fatigue life of glove decreased in a generally non-linear manner with increasing degree of stretching of the glove. However, it should be noted that, as the glove inflation-deflation frequency was fixed at half cycle per second, the rate of stretching of the glove increased with increasing degree of stretching. Apart from the degree of stretching, the rate of stretching might also influence the fatigue life of gloves.

- Textured gloves or chlorinated gloves might show a similar fatigue life compared to smooth-powdered gloves. *Table 3* shows fatigue life results for different types of NR examination gloves produced by a single manufacturer. The basic formulation and manufacturing process used in the manufacture of these gloves may probably be similar. Textured gloves would be expected to have more flaws compared to those with smooth finish and consequently it would be expected that the former would have a lower fatigue life compared to the latter. However, the generally thicker gauge of textured gloves compared to the smooth ones probably compensated for this weakness. Also, the dipping former used by this manufacturer might have produced textured gloves that had gentle dips and peaks.

- NR surgical gloves generally showed a slightly higher fatigue life compared to NR examination gloves (*Table 4*). This could be due to the fact that they were generally thicker than examination gloves. The difference in the design of the gloves probably did not influence the results very much because the locations where both the surgical and examination gloves lost their integrity during the test were rather similar.

Relationship between Test Conditions and Fatigue Life

Effect of inflation-deflation frequency on fatigue life. The effect of glove inflation-deflation frequency was not studied. Fatigue studies on dry rubber vulcanisates showed that, for a flexing frequency in the range 10^{-3} cycle per second – 50 cycles per second, the crack-growth resistance of the vulcanisates increased slightly with increasing frequency[15–17]. It might be deduced that, the fatigue resistance of gloves might not be significantly affected by a small variation in the inflation-deflation frequency of gloves. Assuming this is the case, the fatigue life time would, however, decrease with increasing deformation frequency.

Effect of the degree of stretching on fatigue life. Table 5 shows fatigue resistance for all samples in this study, while *Figure 3* shows the relationship between the degree of stretching and fatigue life for some medical gloves. The fatigue life decreased with increasing strain. For most of the samples, the relationship between fatigue resistance and strain appeared to show a logarithmic relation.

The fatigue life of gloves determined using the present test method is very much lower than the tensile fatigue life of dry rubber vulcanisates[16,17]. The fatigue life of dry rubber vulcanisates at strains in the range 100% – 300% is in the range 10^3 cycles to 10^7 cycles. The difference between the fatigue life of NR and nitrile or vinyl gloves become more significant with decreasing strain.

Relationship between Physical Properties and Fatigue Life

It would be most convenient if any one of the physical properties of a glove had a clear and simple relationship with fatigue life. The

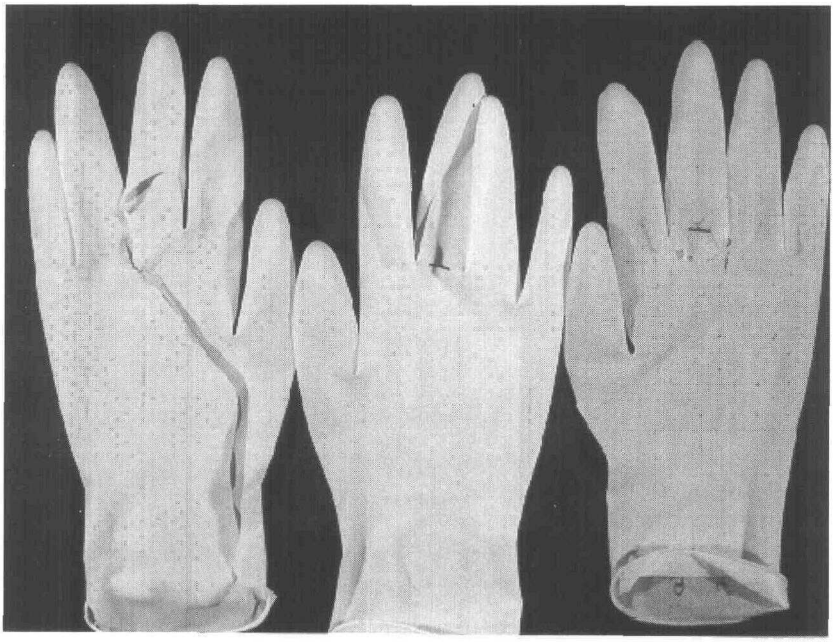

Figure 2a. NR gloves showing tear failure after fatigue test.

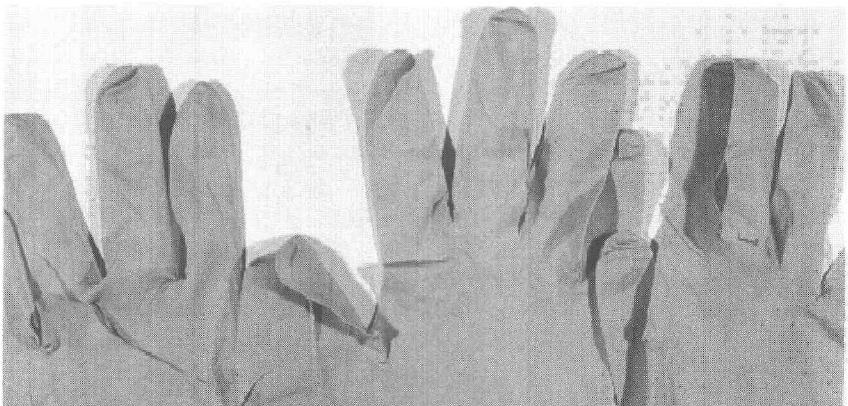

Figure 2b. Nitrile gloves showing tear failure after fatigue test.

TABLE 3. EFFECT OF SURFACE TEXTURE AND FILM TREATMENT ON FATIGUE LIFE OF NR EXAMINATION GLOVES

Type of NR examination gloves[a]	Palm width (mm)	Thickness at strain mark (mm)	Fatigue life at 75 % strain (Cycle)	Nature and location of glove failure
Powdered	97	0.142	735	Tear from the base of 1st finger to 2nd finger
Powdered	94	0.141	1037	Tear at the crotch of 2nd and 3rd finger
Powdered	92	0.152	1298	Tear from the palm near the thumb to 3rd finger
Chlorinated	95	0.151	1198	A hole at the crotch of 2nd and 3rd finger
Chlorinated	92	0.146	921	Tear from the base of 2nd finger to base of thumb
Chlorinated	94	0.155	1430	A hole at the crotch of 2nd and 3rd finger
Chlorinated, textured	93	0.177	1018	A hole at the crotch of 2nd and 3rd finger
Chlorinated, textured	92	0.178	1287	A hole at the crotch of 2nd and 3rd finger
Chlorinated, textured	92	0.170	1285	Holes at the palm near 2nd and 3rd finger

[a] The gloves were supplied by the same manufacturer

TABLE 4. DIFFERENCE IN FATIGUE LIFE OF NR SURGICAL AND EXAMINATION GLOVES

Type of NR gloves[a]	Palm width (mm)	Thickness at strain mark (mm)	Fatigue life at 75 % strain (cycle)	Nature and location of glove failure
Examination	93	0.177	1018	A hole at the crotch of 2nd and 3rd fingers
Examination	92	0.178	1287	A hole at the crotch of 2nd and 3rd fingers
Examination	92	0.170	1285	Holes at the palm near 2nd and 3rd fingers
Surgical	93	0.196	1560	Holes at the palm near the first and 2nd finger
Surgical	94	0.194	1490	A hole at the centre of palm
Surgical	92	0.202	1860	Holes at the centre of palm

[a] The chlorinated and textured gloves were supplied by the same manufacturer

TABLE 5. FATIGUE LIFE OF MEDICAL GLOVES

Glove sample's code	Gloves Type	Gloves Material	Finish[a]	Fatigue life at 50% strain (Cycles)	Fatigue life at 75% strain (Cycles)	Fatigue life at 100% strain (Cycles)
A	Examination	NR	c	> 1000	944	319
B	Examination	NR	c	> 1000	> 1000	> 1000
C	Examination	NR	p	> 1000	> 1000	394
D	Examination	NR	p	–	754	600
E	Examination	NR	c	–	–	324
F	Examination	NR	c,t	–	1198	846
G	Examination	NR	c,t	–	1285	995
H	Examination	NR	p	–	1037	847
I	Examination	NR	pc	1489	1200	1090
J	Examination	NR	c,t	> 2000	860	846
K	Examination	NR	c	1670	1268	809
L	Examination	NR	c	1550	625	455
M	Examination	NR	p	> 2000	1059	763
N	Examination	Nitrile	c,t	226	85	45
P	Examination	Nitrile	p	213	102	26
Q	Examination	Nitrile	p	355	207	130
R	Examination	Nitrile	c,t	329	135	162
S	Examination	PVC	p	183	54	13
T	Examination	PVC	p	130	–	11
U	Examination	PVC	p	350	–	52
V	Examination	PVC	p	129	47	8
W	Surgical	NR	c,t	> 2000	1560	623
X	Surgical	NR	p,t	> 2000	1532	903
Y	Surgical	NR	p	> 2000	1078	984
Z	Surgical	NR	c,t	1600	1034	427
AA	Surgical	NR	c,h	1230	958	734

[a] c = chlorinated; t = textured: p = powdered; pc = polymer-coated; h = other surface treatment
PVC = polyvinyl chloride

fatigue life of a glove might then be roughly estimated from these physical properties. More importantly, enhancement of fatigue life of gloves could then be made through the use of appropriate manufacturing conditions.

Table 6 shows the physical properties of some of the gloves used in this study. The analysis of the relationship between glove properties and fatigue resistance of gloves was limited by the narrow range of property values. For NR gloves, the linear correlation coefficients (R^2) of physical properties and fatigue resistance, generally indicated a large non-linear correlation. For nitrile gloves, there was little linear correlation between physical properties and fatigue resistance of gloves. For vinyl gloves, there was a high linear correlation (R^2 equal or close to 1) between M100 and fatigue resistance or between elongation at break and fatigue resistance, at both strain values of 75% and 100%. The fatigue resistance of vinyl gloves increased with decreasing M100 value.

Fatigue Life of Aged Medical Gloves

Table 7 shows the fatigue life of aged medical gloves. Some of the percentage retention of fatigue resistance after ageing at 50% strain are not shown, either because the test on unaged gloves was not carried out or the test values exceeded 2000 cycles.

The fatigue life of NR medical gloves inclined to decrease after ageing. The shape of the relationships between fatigue resistance and strain (*Figure 4*) is such that aged NR gloves tend to show lower fatigue resistance at the higher range of strains compared to that of unaged NR gloves. At the range of strains that are lower than those used in this study, it seems that aged NR gloves could have higher fatigue resistance than those of unaged NR gloves.

NR *Glove W* is a chlorinated glove while NR *Glove X* is polymer-coated, both supplied by the same manufacturer. The chlorinated Glove showed higher retention of fatigue resistance after ageing compared to the non-chlorinated. This observation is consistent with earlier studies[10]. Results in *Table 7* shows that the M100 value for *Glove W* decreased to a low value of 0.51 MPa after ageing. The NR Glove AA is chlorinated on one side. Its M100 value decreased whilst its retention of fatigue resistance at 50% strain after ageing was found to be more than 100%. These results indicated that, at a lower range of modulus, the fatigue resistance of gloves might increase with decreasing M100 value. This situation might arise regardless of the cause that led to the gloves having very low modulus. Low modulus indicates that the glove may have a low level of elasticity, and this could cause the glove to undergo a certain degree of permanent set and/or to experience a non-relaxing stress[21,22] situation during the fatigue test. A non-relaxing stress is a condition where the stress does not return to zero for part of each deformation cycle.

Aged nitrile examination gloves have the tendency to tear at the cuff when mounting onto the glove holder of the fatigue test equipment. The M100 values of the gloves after ageing are rather similar to those of the unaged gloves (*Table 7*). However, the strength of the gloves decreased quite substantially after ageing. The fatigue resistance of aged nitrile gloves was lower than that of unaged gloves. The percentage retention of fatigue resistance of nitrile gloves after ageing was generally lower than that of NR gloves.

Fatigue testing of aged vinyl examination gloves inclined to be very difficult especially at strains of 75% and 100%. This was because the glove had the tendency to slip off the glove holder. This was due to the problem of

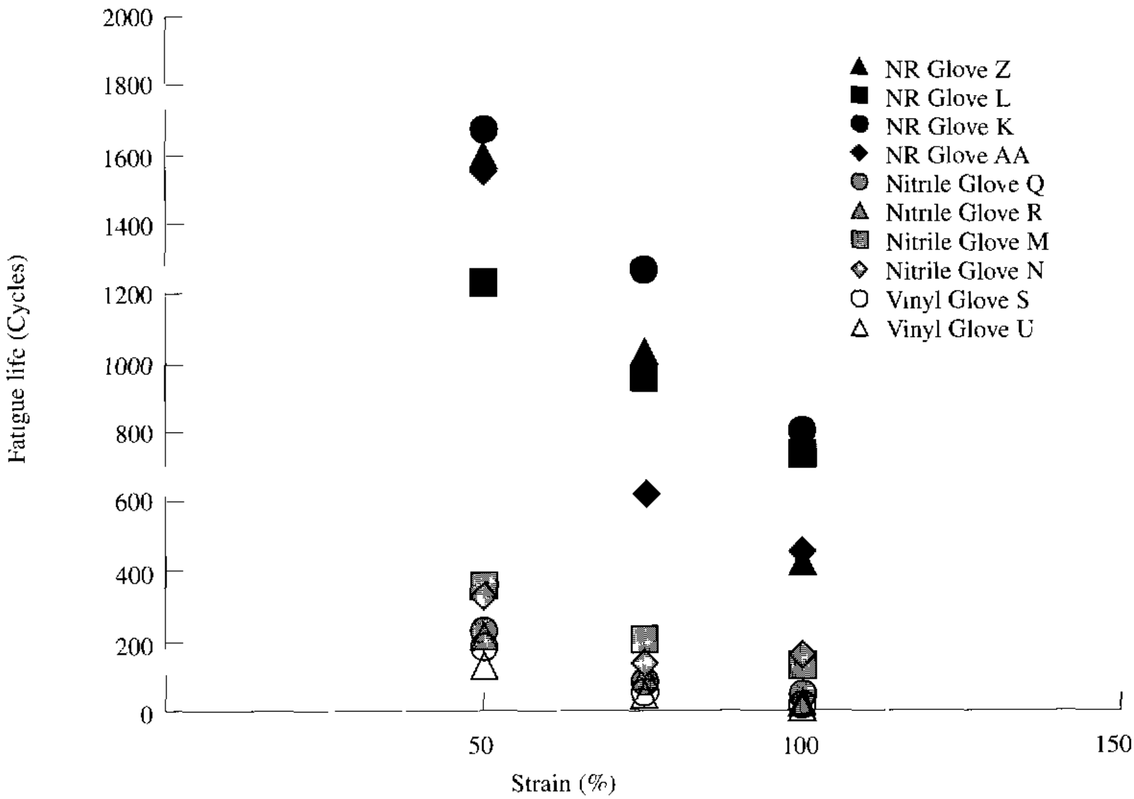

Figure 3 Relationship between strain and fatigue life of medical gloves.

permanent set, thining of the cuff areas and also to a very high inflation pressure developed during the test as a consequent of its stiffness. Vinyl examination gloves showed poor fatigue resistance after ageing when tested at 75% strain. However, at 50% strain the aged gloves apparently had excellent fatigue life of greater than 1000 cycles. The reason for this behaviour was that aged vinyl gloves tend to undergo permanent set during the test, in the range 20% – 50% measured at the location of strain mark. The strain mark became longer after the first cycle of inflation. Thus, after the first cycle of inflation, the parts of the glove that were actually stretched and unstretched were much smaller than that was evident initially. However, the increase in the fatigue resistance after ageing might also be due to insufficient time for the stress to relax completely after each inflation-deflation cycle.

Accelerated Fatigue Resistance Test and Specification for Medical Gloves

Determination of fatigue resistance for NR medical gloves by the above method at 50% strain might take too long for the estimation of barrier performance of gloves or for routine quality assurance testing or for setting a specification in glove standards. Carrying out the test at a higher strain would enable more rapid generation of results. With this

TABLE 6 RELATIONSHIP BETWEEN TENSILE PROPERTIES AND FATIGUE RESISTANCE OF MEDICAL GLOVES

Glove Sample	M100[a] (MPa)	Elongation at break (%)	Tensile strength (MPa)	Tear strength (N/mm)	Fatigue life at 75% strain (Cycles)	Fatigue life at 100% strain (Cycles)
NR Glove F	0.72	800	19.3	26.1	1198	846
NR Glove G	0.76	890	27.4	21.0	1285	995
NR Glove H	0.75	840	21.4	17.8	1037	847
NR Glove I	0.70	790	18.5	16.9	1200	1090
NR Glove J	0.75	730	15.4	13.7	860	809
NR Glove K	0.97	830	23.9	23.9	1268	846
NR Glove M	0.76	850	28.4	21.2	1059	455
NR Glove W	0.93	830	24.9	20.1	1560	623
NR Glove X	0.80	820	23.8	21.0	1532	903
NR Glove Y	0.67	900	25.4	17.8	1078	984
NR Glove Z	0.83	900	27.9	15.6	1034	427
NR Glove AA	0.70	870	20.8	14.2	958	734
Nitrile Glove N	2.96	500	30.4	1.8	85	45
Nitrile Glove P	2.66	480	22.4	2.7	102	26
Nitrile Glove Q	2.83	510	22.2	2.7	207	130
Nitrile Glove R	1.34	650	21.5	2.9	135	162
Vinyl Glove S	4.50	430	10.7	4.4	54	13
Vinyl Glove T	5.13	390	12.3	8.6	–	11
Vinyl Glove U	0.64	870	20.9	4.0	–	52
Vinyl Glove V	5.40	410	15.2	–	47	8

[a] M100 is modulus or stress at 100% elongation

condition, the median or the average fatigue resistance values could be obtained using a larger sample size. From the observations, a logarithmic relation between fatigue life and strain could be applied for all gloves. This relation could then be used to predict the fatigue life of gloves at strain levels that are normally encountered during use. For glove specification, specifying a single fatigue life value at a selected strain value might also be adequate, because the general trend of fatigue resistance and strain was known from this study.

CONCLUSIONS

The Malaysian Rubber Board developed a glove fatigue test equipment which could

TABLE 7. AGED TENSILE PROPERTIES AND FATIGUE RESISTANCE OF GLOVES

Glove sample[a]	M100		Tensile strength		Fatigue life at 50% strain		Fatigue life at 75% strain		Fatigue life at 100% strain	
	Aged value (MPa)	Retention of unaged value (%)	Aged value (MPa)	Retention of unaged value (%)	Aged value (Cycles)	Retention of unaged value (%)	Aged value (Cycles)	Retention of unaged value (%)	Aged value (Cycles)	Retention of unaged value (%)
NR Glove H (p)	0.91	121	23.1	108	> 2000	–	1050	101	635	75
NR Glove J (c,t)	0.69	92	16.2	105	1980	–	797	92	530	62
NR Glove W (c,t)	0.51	54	14.5	58	1962	–	1020	65	398	64
NR Glove X (p,t)	0.84	105	13.5	57	1959	–	754	49	424	47
NR Glove AA (c,h)	0.51	73	14.5	64	1549	125	599	62	322	44
Nitrile Glove N (c,t)	3.2	108	18.3	60	133	58	70	82	30	66
Nitrile Glove P (p)	2.6	98	16.2	72	156	73	41	40	10	23
Vinyl Glove V (p)	5.5	102	8.9	58	> 1000	–	10	21	–	–

[a] p = powdered; c = chlorinated; t = textured; h = other film surface treatment

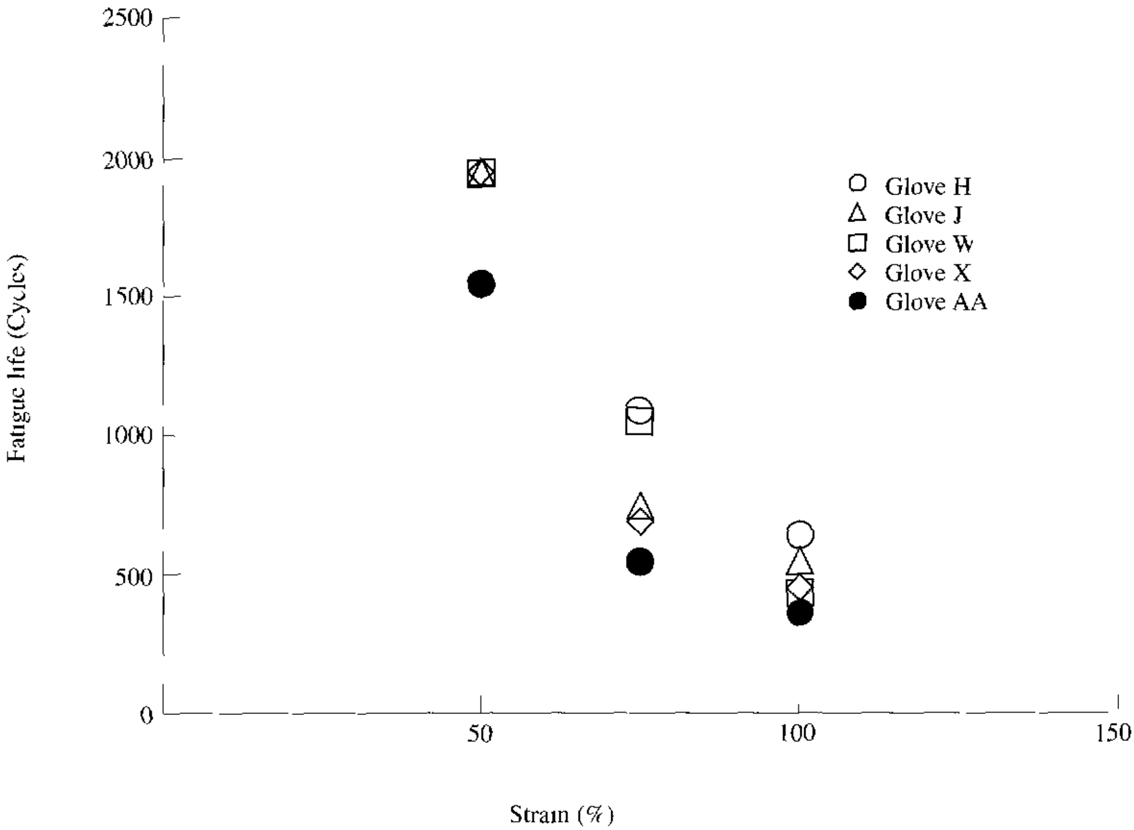

Figure 4 Relationship between strain and fatigue life of aged NR examination and surgical gloves

simulate deformation behaviour of gloves during use, especially at the critical parts The equipment was of simple design and easy to operate

The test equipment and the test method developed were able to distinguish the fatigue life behaviours of different types of gloves and to give an estimate of how long a glove would maintain its integrity when subjected to fatigue stress alone Unaged and aged NR gloves had superior fatigue resistance to nitrile and vinyl gloves

There was no clear relationship between physical properties and fatigue resistance of NR or nitrile gloves For vinyl gloves, fatigue resistance decreased with increasing M100 value, but increased with increasing elongation at break

The use of a correct sized glove or one size larger would prolong its fatigue life

The pattern of relationship between glove fatigue resistance and strain, and between tensile fatigue resistance of dry rubber vulcanisates and strain was generally similar

However, the fatigue resistance of gloves was considerably lower than that of dry rubber vulcanisates

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