

LIFE TIME OF SURGICAL GLOVE

1. Background

Surgical gloves were first introduced in the 1870's. Surgical gloves constitute a barrier between the surgeon and the patient that prevent each other from contamination of body fluids. During surgery, intact gloves act as a protective barrier against blood borne pathogens.

The characteristics and performances surgical gloves must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated when the device is subjected to the stresses which can occur during normal conditions of use.

Hence, literature survey on in-use performance was studied to ascertain the lifetime of surgical gloves.

2. Intended Use

Glove shelf life depends on how products are stored and the materials used to manufacture the products. To maximize the useful life of any type of gloves, the products should be stored in a cool, dark environment where they are shielded from ozone and UV light. Gloves that have deteriorated during storage will have definite signs of deterioration e.g. tear easily when stressed and cracks when stretched (Schlatter, 2005).

In view of the protection against infectious agents the barrier function of gloves is an important aspect of glove quality. Glove barriers must provide an effective two-way barrier between the patient and the healthcare provider when used in clinical setting.

According to the literature by European Commission Health & Customer Protection Directorate-General (2003), when medical gloves are stressed during use, the quality of the barrier may become compromised. Therefore, when gloves are assessed for barrier effectiveness for leakage of biological agents through gloves, the following variables must be taken into account:

- The glove material (natural rubber latex, synthetic latex e.g. nitrile)
- The task to be performed whether clinical or non-clinical
- The length of time the glove is used
- The exposure of the glove to chemicals, blood or other body fluids
- The quality of the glove

According to the literature by European Commission Health & Consumer Protection Directorate-General (2003), intrinsic chemical structure of the material could inherently allow agents to pass through it over a period of time. Nonetheless, the properties of the material could change on contact with a fluid or chemical used in the handling of the product e.g. oils and solvents such that it became permeable to the agent during use. A defective product e.g. pinholes, in which case there could be a direct route for agent transmission other than permeation through the molecular structure of the material. Finally, the product itself could suffer some damage (tearing) during use, providing a clear pathway for fluid transmission, this risk of being controlled by the mechanical properties of the material, the quality of the manufacture and the nature of the procedures being undertaken.

The rate of glove perforations in the different fields of surgery (Rutkow, 1999; Hollaus et al., 1999; Yinusa et al., 2004):

	Perforation rate (%)
Vascular surgery	7.50
Orthopaedics and traumatology	8.54
Urology	4.24
Gastrointestinal surgery	8.72
Thoracic surgery	9.46
Others	3.87

The highest frequencies of perforations have been reported in Orthopaedics, traumatology and thoracic surgery, because in those fields the surgeon faces sharp fractured bones or bony structures.

According to the literature by Laine & Aarnio (2001), if the duration of the operation was longer than 2 hours, the perforation rate is higher 11.69% compared to when the duration was less than 2 hours which is 4.21%. The rate of perforation seems to be depend on the duration of the operation; the longer the operation time, the greater the possibilities of needle sticks or tears in the gloves.

As per the literature by Murta et al. (2003), the use of double glove method in surgery gives an additional level of protection against blood borne infections and greatly reduces the risk of glove penetration. In gynaecological surgery, found that 10.4% of single gloves perforated during use, as did 9.8% of the outer double gloves whereas there was no perforation of any inner double glove. In general surgery found a 6.2% incidence of puncture of the inner glove of a double glove compared to an overall 18.3% of total operations resulting in perforation. In open lung surgery, Hollaus et al. (1999) reported a 78% incidence of perforation of gloves, but the inner glove only perforated in 1.1%, double gloving effectively protecting against cutaneous blood contact. Nonetheless, glove changing frequency is typically based on institutional policy.



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All WRP surgical gloves are manufactured to harmonized standards with criteria in place (i.e. force at break) to ensure they are fit for their intended use.

Based on above literature, as the potential gloves failure increases significantly on surgical procedures that last more than 2 hours, it recorded that the gloves must be changed at maximum 2 hours once.

3. Conclusions/ recommendations

WRP has emphasized the need for regular glove changes and recommends changing surgical gloves after a maximum of 2 hours usage. Therefore, the lifetime of the product shall be recommended as 2 hours.

4. References

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