1	INCIDENCE AND RISK FACTORS FOR SURGICAL GLOVE PERFORATION IN
2	SMALL ANIMAL OPHTHALMIC SURGERY
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4	Paola A Massidda ¹ , Jesus Diaz ² , Roser Tetas Pont ² , Rachael Grundon ³ , Federico Corletto ¹ ,
5	Ben Blacklock ¹
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7	Ophthalmology Service, Dick White Referrals, Six Mile Bottom, Cambridgeshire CB8 0UH ¹
8	The Royal Veterinary College, Ophthalmology Service, University of London, North
9	Mymms, Herts, AL9 7TA ²
10	The Eye Vet Clinic, Marlbrook, Leominster, HR6 0PH ³
11	
12	Correspondence
13	Paola A Massidda DVM, MRCVS
14	The Royal (Dick) School of Veterinary Studies, University of Edinburgh, Easter Bush
15	Campus, Roslin
16	EH25 9RG, UK
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18	Email: azzurra.massidda@hotmail.com
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27 ABSTRACT

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29 **Objective:** To determine the incidence of perforation of surgical gloves and identify 30 associated risk factors that contribute to glove perforation in small animal ophthalmic 31 surgery. 32 Study design: Observational cohort study. 33 **Sample population:** Surgical gloves (n=2000) collected following 765 small animal 34 ophthalmic procedures. 35 **Methods:** All the gloves were tested for perforation at the end of the procedure using a water 36 leak test. The potential risk factors for glove perforation were recorded, and associations 37 between these risk factors and perforation were explored using univariable (Fisher's exact 38 test) and mixed effect logistic regression analysis. Results were considered significant if P < 39 0.05. 40 **Results:** Glove perforation was detected in 6% of procedures. Glove perforation was 1.97 41 (95% CI 0.98-4.22) times more likely in extraocular than in intraocular surgeries (7.3% vs. 42 3.9%; p=0.0462). The incidence of perforations was not statistically different between main 43 and assistant surgeon (p=0.86). No significant association was found between the risk of 44 glove perforation and duration of the procedure (p=0.13). Perforation of the non-dominant 45 hand was 2.6 (95% CI 1.38-4.98) times more likely than the dominant hand (74% vs. 26%; 46 p=0.0028). Only 22% of the perforations were detected intraoperatively. Multivariable 47 analysis identified only extraocular surgery as a risk factor for perforations. 48 **Conclusions**: There is a low incidence of glove perforation in small animal ophthalmic 49 surgery, but extra care of the non-dominant hand is required, especially during extraocular 50 procedures.

51 KEYWORDS: extra ocular, non-dominant, fore finger, thumb, needle, water leak test
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53 INTRODUCTION

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55 Surgical gloves are a protective barrier worn during surgical procedures to reduce the risk of 56 pathogen dissemination that can cause infections in the surgeon and the patient.¹ 57 Their integrity is therefore important in maintaining a sterile environment and reducing the 58 possibility of surgical site infections (SSI) that are a considerable concern in veterinary 59 medicine, having been described as a complication in 2.5% to 30% of small animal surgical procedures.²⁻⁶ Although a search of the veterinary and human ophthalmic literature via 60 61 Pubmed[®] resulted in no studies that specifically link glove perforation with infection of 62 ocular tissues, the integrity of surgical gloves is cited as a critical factor to prevent infections in surgery.⁷ Two large scale studies explored the correlation between glove perforation and 63 64 SSI and showed that, in the absence of antimicrobial prophylaxis, glove perforation is a risk factor for SSI.^{8,9} Furthermore, there are case studies in the literature that have implicated 65 surgical glove perforation with outbreaks of Staphylococcal infection in operated patients.^{10,11} 66 67 The incidence and risk factors contributing to surgical glove perforation have been largely investigated in many human medicine subspecialties and in a number of veterinary studies. 68 69 In small animal surgery performed at veterinary teaching hospitals, glove perforations were found following 22 and 26% of procedures.^{12,13} Amongst the risk factors described in 70 71 veterinary studies as contributing to surgical glove perforation, the type and the duration of 72 the procedure were the two most commonly identified.¹²⁻¹⁶ In ophthalmic surgery in humans the reported rate of glove perforation ranged from 0.3% to 21%.¹⁷⁻¹⁹ A recent study amongst 73 74 nurses scrubbed as assistant for the surgeon during ophthalmic surgery in humans, reported a rate of glove perforation of 4%.²⁰ To date, the occurrence of glove perforation in veterinary 75

ophthalmic surgeries has not been reported. Several methods have been described in the
published literature to test the integrity of surgical gloves, including: observation of skin
wetness after submersing a gloved hand under water;^{11,21} water inflation of the glove (water
leak test) with¹⁶⁻¹⁸ or without¹²⁻¹⁵ external compression; air inflation-water submersion with¹⁹
or without^{22,23} external compression; use of water soluble dyes to allow easier identification
of perforations such as fluorescein^{23, 24} or methylene blue;²⁵ and electrical conductance
methods.^{14, 26, 27}

The aim of this study was to elucidate the incidence of glove perforation in small animal ophthalmic surgery using a water leak test (WLT) modified by previous authors,^{13,18} and to explore potential risk factors. In addition, the ability of the wearer to detect glove perforation intraoperatively was investigated.

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88 MATERIALS AND METHODS

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90 The study was performed as an observational cohort study.

91 A total of 2000 gloves (1000 pairs) were collected between June 2017 and November 2018 92 following 765 ophthalmic procedures performed at three referral hospitals in the UK (Eye 93 Vet Clinic, Leominster; The Royal Veterinary College, London; Dick White Referrals, Six 94 Mile Bottom). The standard WLT described by the American Society of Testing and Materials²⁸ is the test most widely reported in the literature^{12-14,16,18-20} to estimate the 95 incidence of perforation in surgical gloves and relies on the pressure applied by 1000mL of 96 97 water inside the glove to detect perforations. The standard WLT was modified by Prendiville et al. and Hayes et al.^{13,18} (500mL of water) and this was the method used for the current 98 99 study.

100 The gloves were tested for perforations immediately after the end of the surgical procedures 101 by the glove wearers (37 different glove wearers across the 3 hospitals participated in this 102 study). Each glove was filled with 500mL of tap water and the cuff was occluded at its wrist 103 section with one hand, whilst the other hand squeezed the water filled glove; the body and the 104 fingers of the glove were visually inspected for leaks. Glove test results and potential risk 105 factors were recorded after each procedure. The potential risk factors included the type of 106 surgery (extra vs intra ocular), the role of the surgeon (main vs assistant) and the duration of 107 surgery. The hand that was perforated (dominant vs non-dominant), along with the number 108 and location of perforations was recorded. The authors recorded the location of the 109 perforations within each hand as follows: thumb, fore finger, middle finger, ring finger, little 110 finger, palm or dorsum as previously described by Miller et al.¹⁹ In case of observed 111 intraoperative perforation, the glove was removed and tested to confirm perforation. All 112 gloves worn were made of latex. Three different types of gloves from 2 manufacturers were 113 used: Biogel (powder-free, straight finger design, natural rubber latex surgical glove with 114 Biogel hydrogel polymer coating), Biogel Tech (powder-free, curved finger design, natural 115 rubber latex medical glove with Biogel hydrogel polymer coating) and Gammex (PF 116 Micro-thin powder-free latex surgical glove).

117 Normality distribution of duration of surgery was evaluated using the Shapiro-Wilk test. 118 Outcome was defined as any glove perforation in either the dominant or the non-dominant 119 glove in each pair. The relationship between the perforations and the risk factors was 120 explored using a Fisher's exact test for 2 by 2 tables and then calculating odds ratios (ORs) 121 and 95% confidence intervals (CI). A multivariable logistic regression was used to calculate 122 ORs and their CI for the predictor variables of perforation. The Hosmer-Lemeshow test was 123 used to assess the goodness of fit of the model. Statistical analysis was performed using R 3.6 124 for MacOS (R Core Team (2013). R: A language and environment for statistical computing.

126 <u>http://www.R-project.org</u>). Results were considered significant if P<0.05.

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128 RESULTS

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130 Overall, a glove perforation occurred during 46 of 765 procedures (6%), or in 2.3% of gloves.

131 Of the 765 procedures in our study, 60% were extraocular and 40% were intraocular.

132 The univariable analysis showed that glove perforation was 1.97 times more common in

133 extraocular procedures (CI 0.98-4.22) compared to intraocular procedures (7.3% vs 3.9%, p=

134 0.0462). There was not a significant difference in perforation rate between the main surgeon

and the assistant (4.7% and 4.3% respectively, p=0.86). (Table 1)

136 Perforation rate was not significantly different when considering procedure duration

137 (p=0.13): 0% for procedures lasting less than 15 minutes (n=69); 5.4% for procedures lasting

138 16 to 30 minutes (n=260); 6.3% for procedures lasting 31 to 45 minutes (n=218); 4.9% for

procedures lasting 46 to 60 minutes (n=121); 2.5% for procedures lasting 61 to 75 minutes

140 (n=40); 13.7% for procedures lasting 76 to 90 minutes (n=29) and 7.1% for procedures

141 lasting longer than 91 minutes (n=28).

142 Multivariable analysis identified only extraocular surgery as a risk factor for perforations

143 (OR 1.98; CI 1.04-4.03; p= 0.0459). There was not a significant difference in perforation rate

between the main surgeon and the assistant (OR 1.15; CI 0.57-2.52; p= 0.71). (Table 2)

145 The Hosmer-Lemeshow test suggested the goodness of fit of the model (p=0.67) and the

146 model correctly predicted glove perforation in 95.4% of cases.

147 All the surgeons in this study were right-handed. The frequency of glove perforation was

significantly different between the dominant and the non-dominant hand: perforation on the

non-dominant hand was 2.6 times (CI 1.38-4.98) more common than the dominant hand

150 (72% of the perforated gloves were non-dominant gloves, p=0.0028). Of the 46 gloves that 151 were found to be perforated, 42 (91.3%) had a single perforation, whilst 4 gloves had 152 multiple perforations (giving a total of 50 perforations). Multiple perforation was not 153 associated with any variable and was not more likely to be noticed by the surgeon compared 154 to single perforation. The thumb and the fore finger were more commonly involved in 155 perforation (13 for the thumb and 14 for the fore finger; representing 26% and 28% of total 156 perforations respectively). The middle finger was involved in 9 perforations (18%), the palm 157 was involved in 6 perforations (12%), the ring finger in 5 perforations (10%) and the little 158 finger in 3 perforations (6%). No perforations were observed in the dorsum. (Fig 1) 159 Perforations were noticed intraoperatively in 10 cases (22%). 160

161 DISCUSSION

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163 This study reports the incidence and risk factors for surgical glove perforation during small 164 animal ophthalmic surgery. Ophthalmic procedures involve the utilisation of sharp 165 instruments in a dim light environment, those being factors that could potentially increase the 166 risk of glove perforation. On the other hand, ophthalmic procedures are often elective 167 procedures, less invasive and of a shorter duration compared to other surgeries and given the 168 results of previous ophthalmic studies in humans, the authors expected the perforation 169 incidence to be low. The present study found that the overall incidence of glove perforation 170 was relatively low, with 6% of procedures exposed to at least one glove perforation. This result was lower compared to those observed in previous studies in veterinary medicine,12-171 ^{14,16} but within the range reported in the ophthalmic literature in humans.¹⁷⁻¹⁹ The only 172 173 significant risk factor for glove perforation identified in this study was the type of surgery, 174 with extraocular procedures being more at risk for glove perforation. This finding was

similar to that documented in a previous ophthalmic study in humans.¹⁹ The authors 175 176 hypothesise that the nature of extraocular surgery, and the behaviour of surgeons performing 177 extraocular surgery could explain the higher incidence of glove perforations. Intraocular 178 surgery is generally more delicate, more precise and carries higher risks of serious 179 complications. As a result it seems logical that surgeons and assistants are more focused and 180 attentive during such procedures. Most intraocular surgery is performed via an operating 181 microscope – the hands are supported and steady, with small finger movements controlling 182 instuments in a small and well illuminated surgical field. In contrast, during extraocular 183 surgery, the surgical field may be larger which results in greater hand, arm and body 184 movements, and along with the use of larger instruments and needles, the opportunity for 185 glove perforation may be higher. It is possible that the surgeon and assistant may be less 186 focused during extraocular procedures, as absolute precision in surgical technique is less 187 critical to achieve a successful surgery. In addition, during extraocular procedures the fingers 188 are more likely to be used to load suture needles into the needle holders, increasing the risk of 189 injuries. Conversely, in intraocular surgery specialised instruments (suture forceps with tying 190 platform) to handle the sutures and load the small gauge needles into the needle holders are 191 routinely used, therefore the manual handling of suture needles is minimal. Further studies 192 would be required to confirm this hypothesis, for example by studying video recordings of all 193 surgeries and trying to pinpoint the moment any glove perforation occurs. 194 The present study found that the non-dominant hand was more likely to suffer perforations 195 and the thumb and fore finger were the fingers more commonly involved. Several researchers 196 have reported that gloves worn on non-dominant hands are more likely to sustain 197 perforations,^{12,14,16,19,29} and furthermore these are usually found in the thumb and the fore

198 finger, ^{12,14,16,19,29,30} most likely due to handling of suture needles by the non-dominant hand

during surgical procedures.^{29,30} A study in soft tissue surgery in humans about the influence

200 of suture technique on surgical glove perforation reported that avoiding manual handling of 201 needles by using a meticulous 'no touch' technique would much reduce the risk of surgical glove perforation.²¹ In another study, Corlett *et al.* compared a standard suturing technique 202 203 with a 'no touch' technique and reported that the latter minimise the risk of surgical glove 204 perforation during wound closure.³¹ The 'no touch' technique described by Orengo et al 205 requires the consistent use of mechanical assistance in the loading or adjustment of a suture 206 needle into the needle holder.³² Orengo *et al* emphasise that at no time the surgeon should use hands to place or adjust the needle into the needle holder.³² In light of the previous 207 studies^{21,31,32} and the current study, it would be sensible to always use an instrument to handle 208 209 the needles to minimise the risk of glove perforation, regardless the type of surgery (extra or 210 intraocular).

211 There was not a significant difference between the main and assistant surgeon's frequency of 212 glove perforation in the present study, while other veterinary medicine studies found the primary surgeon more likely to have glove perforations.¹²⁻¹⁴ One explanation for this could 213 be that the previous studies¹²⁻¹⁴ involved more invasive procedures, where the gloves of the 214 215 primary surgeon may experience more stress, caused by increased tissue and instrument 216 handling, than the gloves of other team members. Ophthalmic procedures, on the other hand, 217 involve minimal tissue handling and this could explain why no significant difference between 218 the main and assistant surgeon's frequency of glove perforation was found in the present 219 study.

Interestingly, unlike previous studies, no significant association was found between glove
perforation and duration of surgery in the current study.^{12-16,19} This could possibly be
explained by the relatively low number of surgeries lasting over 46 minutes included in this
study.

The present study found that the ability of the glove wearer to detect perforations intra

225 operatively was quite poor with 78% of perforations unnoticed. This data was similar to the 226 low detection rates documented in previous studies.^{12-14,16,27} Burrows *et al* suggested that this 227 might be due to the lack of awareness within the surgeons of how frequently surgical gloves may be damaged during operations.¹² It has also been suggested that the focus of the operator 228 on the procedure precludes awareness of glove perforation.²⁷ To address this problem, double 229 230 gloving puncture indicator systems that include differently coloured under and over gloves have been developed to facilitate detection for glove perforation intraoperatively.^{15,33,34} 231 232 There were several limitations to the present study. Previous studies suggested that the WLT 233 might not be as sensitive as an alternative method, the electroconductivity test (ECT), in 234 detecting micro perforations.^{14,26,27} The ECT relies on a decrease of electrical resistance of 235 the glove barrier to detect micro perforations, however, despite being more sensitive than the 236 WLT, this method may produce false positive results due to the hydration of the latex.^{14,35} 237 Although the WLT has a low sensitivity for micro perforations detection and could 238 underestimate the true incidence of glove perforation, it was selected by the authors over the 239 ECT because it has been widely validated and is the most commonly used test to estimate the incidence of surgical glove perforation.^{12-14,16,18-20} In addition, given the multicenter nature of 240 241 the study, the time, the costs and the additional equipment required, performing ECT would 242 not have been feasible.

Another possible limitation could be that the gloves were tested by the main surgeon or the assistant, rather than an independent assessor, and this may have resulted in a bias toward under detecting perforations because the WLT might not have been performed in the standardised way by all the glove wearers (i.e. differences in the pressures applied on gloves by different surgeons). Furthermore, the temperature of the water and the duration of the WLT (i.e. the amount of time the glove was filled with water) were not recorded, and these could be additional limitations of the study. A further limitation could be that the amount of water used to fill the gloves in this study
(500mL) might generate insufficient pressure to provoke leakage and confirm perforation
from a very small hole. The authors decided to use the WLT modified by Prendiville *et al.*and Hayes *et al.*^{13,18} because the amount of water used by the standard WLT described by the
American Society of Testing and Materials (1000mL)²⁸ would not fit the surgical gloves
without the use of special equipment.

During the data collection in this study one of the surgeons suffered an intraoperative needle stick injury of the finger with a 30-gauge insulin needle, which resulted in a small amount of haemorrhage within the glove. The glove was changed and submitted for the WLT, but no leakage was observed. This incident appeared to confirm the limitations of the WLT as described above.

The association between glove perforation and SSI in veterinary medicine has not yet been investigated. On the other hand, in the human surgical literature there is evidence of strong statistical association between glove perforation and SSI (in the absence of antimicrobial prophylaxis)^{8,9} and glove perforation is considered a potential source of infection in surgery.⁷ The association between glove perforation and SSI was not investigated by the present authors and additional studies to assess the influence of glove perforation on SSI in small animal ophthalmic surgery is warranted.

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269 CONCLUSIONS

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This study concluded that the incidence of glove perforation in small animal ophthalmicsurgery was low. When perforation was detected, it most commonly affected the thumb and

273 fore finger of the non-dominant hand during extra-ocular procedures.

274	Extra care of the non-dominant hand while handling sharp instruments and avoiding handling		
275	the needles with fingers could help minimise the risk of glove perforation.		
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277	CONFLICT OF INTEREST		
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279	The authors declare no conflicts of interest and they are the only responsible for the content		
280	and writing of this manuscript.		
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