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RESEARCH ARTICLE

A sensorised surgical glove to improve training and detection of obstetric anal sphincter injury: A preclinical study on a pig model

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Abstract

Objective: To create a sensorised surgical glove that can accurately identify obstetric anal sphincter injury to facilitate timely repair, reduce complications and aid training.

Design: Proof-of-concept.

Setting: Laboratory.

Sample: Pig models.

Methods: Flexible triboelectric pressure/force sensors were mounted onto the fingertips of a routine surgical glove. The sensors produce a current when rubbed on materials of different characteristics which can be analysed. A per rectum examination was performed on the intact sphincter of pig cadavers, analogous to routine examination for obstetric anal sphincter injuries postpartum. An anal sphincter defect was created by cutting through the vaginal mucosa and into the external anal sphincter using a scalpel. The sphincter was then re-examined. Data and signals were interpreted.

Main Outcome Measures: Sensitivity and specificity of the glove in detecting anal sphincter injury.

Results: In all, 200 examinations were performed. The sensors detected anal sphincter injuries in a pig model with sensitivities between 98% and 100% and a specificity of 100%. The current produced when examining an intact sphincter and sphincter with a defect was significantly different ($p < 0.001$).

Conclusion: In this preliminary study, the sensorised glove accurately detected anal sphincter injury in a pig model. Future plans include its clinical translation, starting with an in-human study on postpartum women, to determine whether it can accurately detect different types of obstetric anal sphincter injury in vivo.

KEYWORDS
anal sphincter injury diagnosis, assisted birth, sensorised gloves, training

1 | INTRODUCTION

Obstetric anal sphincter injury (OASI) overall affects 2.9% of people in the UK,[1] but it can affect up to 12% of people having a forceps birth.[2] Diagnosis by digital rectal examination is highly subjective, with studies reporting misdiagnosis in 13–33% of patients.[3,4] Timely diagnosis is key to immediate postpartum repair so as to restore anatomical sphincter integrity and preserve function. If misdiagnosed, OASI can lead to faecal incontinence and rectovaginal fistula formation; in the USA, nearly 10% of rectovaginal fistula repairs are linked to obstetric trauma.[5,6] Even if diagnosed at a later stage, delayed repair has been associated with worse faecal incontinence.[7,8]

Missed diagnosis in the immediate postpartum period may result from poor training in its identification and subsequent management.[7] Missed diagnosis has significant medicolegal ramifications; in the UK alone, over £31million was paid to claimants with perineal injury over a 10-year period; principally those with OASI.[9] In addition to this, 24% of patients who undergo secondary repair will need further surgery after 5 years.[5]

One of the ways to reduce missed diagnoses is through ultrasound. Endoanal ultrasound (EAUS) is considered the gold standard to diagnose and assess OASI after primary repair.[10] There are conflicting studies on the utility of immediate postpartum EAUS to aid initial diagnosis of perineal trauma prior to repair.[11,12] One randomised control trial of 752 women who were randomised to routine examination or immediate EAUS found that EUAS before perineal repair may reduce rates of severe anal incontinence.[13] In contrast, another study reported that nearly 20% of scans performed immediately postpartum were 'non-assessable' due to poor image quality, and were difficult to perform on labour ward due to staff inexperience.[12] At present, there are no other widely used tests (both in the immediate postpartum period and in follow-up) that are conducted to diagnose OASI and to assess its consequences.

Therefore, in a collaboration between Obstetricians from University College London Hospital and Engineers from University College London, UK, we conducted a preclinical study to assess whether a low cost, simple to use sensorised glove could assess anal sphincter injury in a pig model, as it is closely related to human anatomy.[14] The ultimate aim is that this early, preliminary study will aid in the development of a glove that can objectively assess anal sphincter injury immediately postpartum, and support training of recognition of such injury in the future.

2 | METHODS

The design of the glove has been described in previous publications.[15,16] The glove is a routine surgical glove where triboelectric sensors were spray-coated onto the index finger and flexible electrodes and interconnects were screen-printed on the glove (Figure 1). Triboelectricity works by contact electrification, when a charge is created by rubbing two dissimilar materials against each other. This can be measured and analysed when connected to a signal acquisition device.[17–20] The mechanism of action and their potential to detect anal sphincter injury have been previously described.[16] A patient and public involvement (PPI) group, consisting of people with lived experiences of assisted vaginal and caesarean birth, were consulted and approved of its design and function.[15] There are no core outcome sets available for a device of this nature.

As dictated by the availability of appropriately sized pigs, the study was conducted in three parts.

2.1 | Study 1

To assess feasibility, the first study consisted of testing the glove on an ex vivo, pre-dissected pig anal sphincter. SRJ, an Obstetrics and Gynaecology ST5 trainee, wore the sensorised glove under a routine surgical glove and connected it to a software interface and signal acquisition device (Figure 2A). SRJ conducted a per rectum (PR) exam on an intact anal sphincter with the index finger in the rectum and thumb in the vagina. The sphincter was examined with the thumb moving from side to side. This PR examination was performed 30 times. A full-thickness 3b external anal sphincter (EAS) defect was then created by using a scalpel to cut into the full thickness of

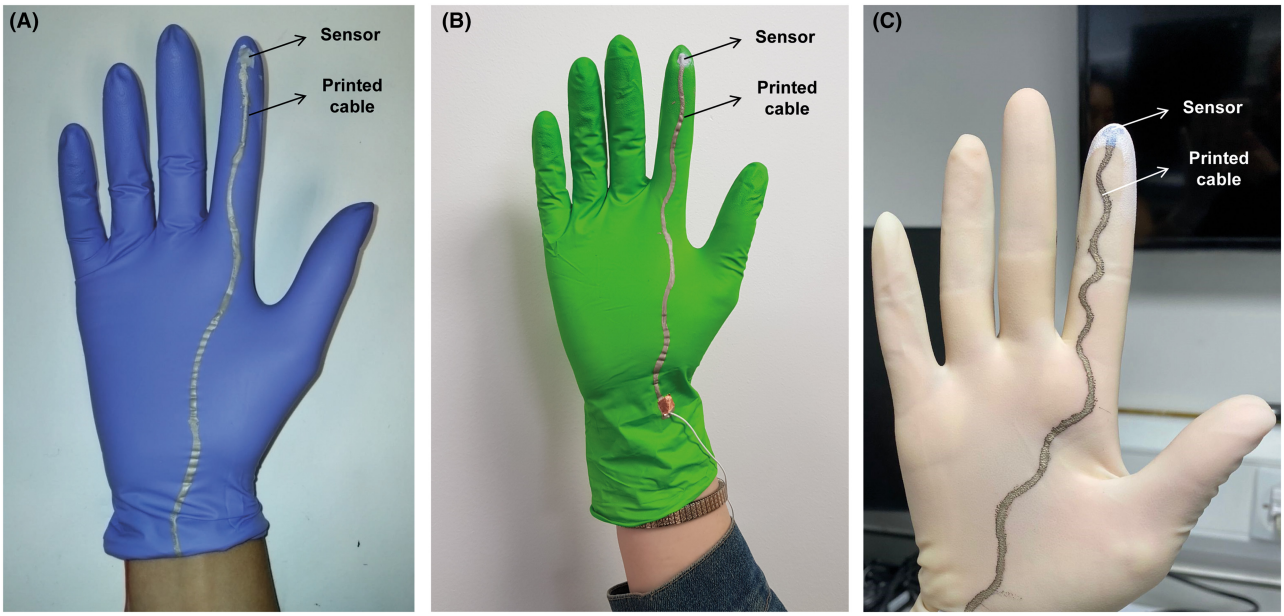

FIGURE 1 The sensorised surgical glove. (A) Glove used for Study 1: dissected pig's anal sphincter. (B) Glove used for Study 2: non-dissected pig's anal sphincter (30×). (C) Glove used for Study 3: non-dissected pig's anal sphincter (140×).

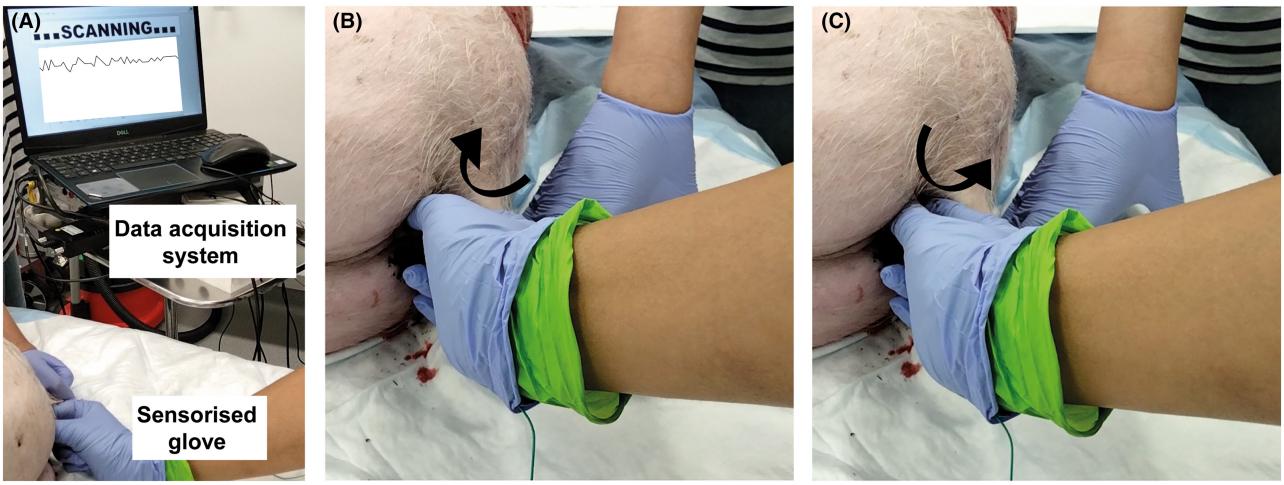

FIGURE 2 Test set-up. (A) Test set-up used to carry out the tests showing the obstetrician wearing the sensorised glove covered by another layer of surgical glove, the data acquisition system and the software interface showing the signals. (B, C) Obstetrician carrying out the test on the non-dissected pig's anal sphincter showing the protocol used when rolling the finger back and forth to examine the sphincter.

the external anal sphincter. A PR examination was conducted a further 30 times, with the thumb moving side to side and traversing the defect. The repeats were limited to 30 to preserve the rigidity of the unmounted sphincter.

2.2 | Study 2

Following encouraging results in the ex vivo study, the glove was tested on a terminally anaesthetised (not pre-dissected) pig weighing approximately 70 kg. SRJ and a pre-specialty training doctor with 3 years' clinical experience, with no prior experience of conducting PR exams (NA) examined the intact sphincter 15 times each (30 times in total). SRJ then created a full thickness 3b EAS defect with a scalpel. SRJ and NA examined this a further 30 times in total (Figure 2B,C). Lubricant was not used. We anticipate that lubrication would not interfere with the sensors, based on in-lab tests. Faeces were present in the rectum as is sometimes the case in routine examination. The perineal area was not cleaned. There was blood present in small amounts as the pig had been deceased for a number of hours.

2.3 | Study 3

In a third study to assess repeatability, SRJ and NA tested the glove 70 times each (140 in total) on another terminally anaesthetised pig that weighed approximately 70 kg. A full-thickness 3b EAS defect was created, and the sphincter was examined a further 70 times each (140 times in total). After 140 times the sphincter was subjectively considered to be starting to lose rigidity and the experiments were terminated.

Video and audio recordings were taken of the software interface and current peaks and the clinicians indicated when a sphincter defect was encountered by saying 'defect'. Signals were recorded for interpretation (Videos S1 and S2).

2.4 | Software interface

A virtual instrument (VI) interface was developed using LABVIEW®, which allows setting thresholds below which current peaks are detected and identified as an anal sphincter defect.

2.5 | Statistical analysis

Although a preliminary study, to ascertain whether the glove was truly able to detect sphincter injuries in this scenario, and that the differences in current were not due to chance, statistical analysis was utilised. IBM SPSS v29.0 software was used and the independent-samples Mann–Whitney *U*-test was employed to determine whether there was statistical significance between these differences. A p-value of <0.05 was deemed statistically significant. The specificity of the glove in each of the three tests was determined by calculating the percentage of peaks in the intact sphincter tests that exceeded the predefined detection threshold. Sensitivity was calculated by determining the percentage of peaks generated by the sensor when encountering the defect that did not surpass the detection threshold.

3 | RESULTS

3.1 | Study 1

3.1.1 | Ex vivo, pre-dissected pig anal sphincter

Positive peaks formed when the sensor made contact with the sphincter, and negative peaks were formed when contact ceased due to the relative positions of the tissue in contact with the sensor and the sensor itself in the triboelectric series (Figure 3A). When moving between the intact sphincter

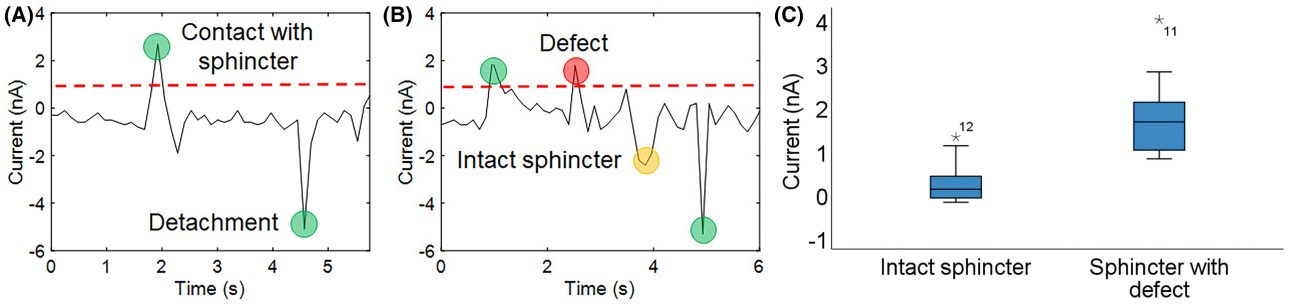

FIGURE 3 Study 1 results. (A) Control test result from one examination on the intact pre-dissected anal sphincter in Study 1. (B) Test result from one examination showing accurate detection of the defect in the dissected anal sphincter in Study 1 (peak shown in red surpasses threshold represented by the dashed red line). (C) Boxplots showing the values of the maximum current peak obtained throughout the anal sphincter detection tests on the intact sphincter versus sphincter with a defect in Study 1 (excluding the peak created upon initial contact).

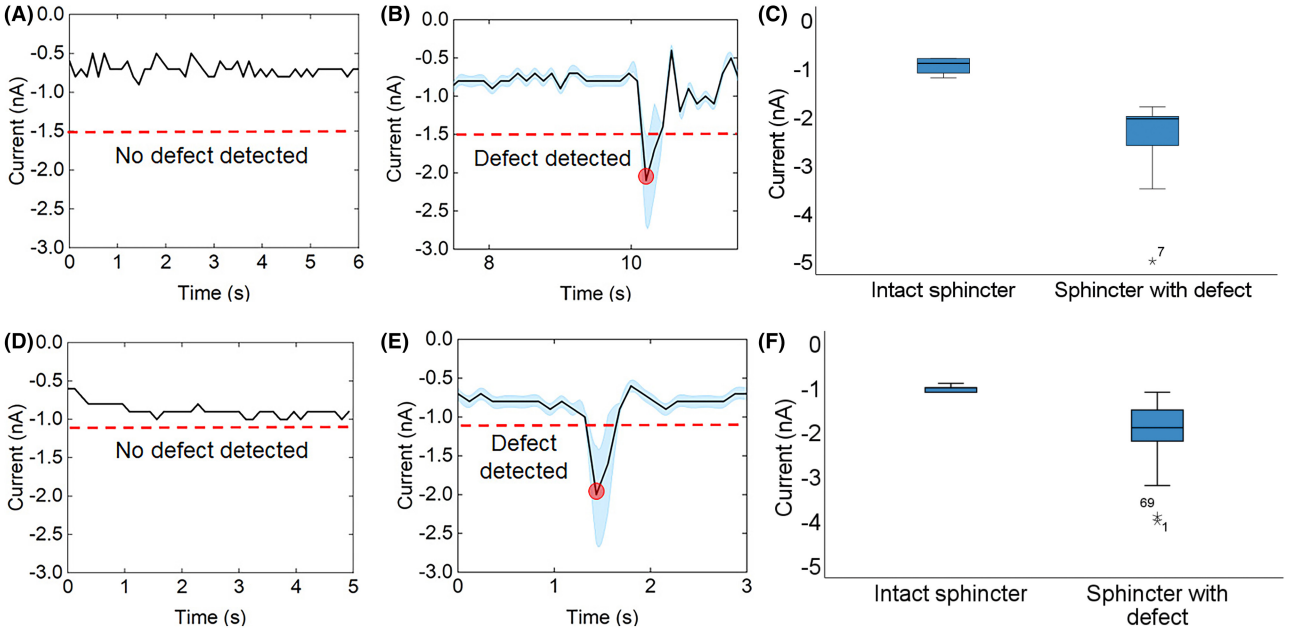

FIGURE 4 Study 2 and 3 results. (A) Control test results from one examination on the intact non-dissected anal sphincter in Study 2. (B) Test result from one examination showing accurate detection of the defect in the non-dissected anal sphincter in Study 2 (peak shown in red is below the threshold represented by the dashed red line) including standard deviation area for both the intact sphincter section and the encountered defect. (C) Boxplots showing the values of the minimum current peak obtained throughout the anal sphincter detection tests on the intact sphincter versus sphincter with a defect in Study 2. (D) Control test result from one examination on the intact non-dissected anal sphincter in Study 3. (E) Test result from one examination showing accurate detection of the defect in the non-dissected anal sphincter in Study 3 (peak shown in red is below the threshold represented by the dashed red line) including standard deviation area for both the intact sphincter section and the encountered defect. (F) Boxplots showing the values of the minimum current peak obtained throughout the anal sphincter detection tests on the intact sphincter versus sphincter with a defect in Study 3.

to the defect, where the sensor came into closer contact with the softer internal anal sphincter (IAS) and anal mucosa at the base of the defect, the peak formed was in the positive y-direction, due to the increased contact, deformation and strain gradients associated with it (Figure 3B). When moving from the defect to the intact sphincter, a negative peak was formed, due to decreased deformation fields in the intact sphincter relative to the softer IAS/anal mucosa beneath the defect.[16]

The glove attained 86% sensitivity and 79% specificity when setting the peak detection threshold at 1.0 nA (any peaks that surpassed this threshold were identified as defects, excluding the initial peak created upon contact with the sphincter) (Figure 3C).

3.2 | Studies 2 and 3

3.2.1 | Examination on pig cadavers

In the tests carried out on the intact sphincter of a pig cadaver, the peak produced when encountering the defect was in the negative direction (Figure 4). The restricted space and limited manoeuvrability, coupled with the creation of a finer incision in the sphincter to produce the defect seemed to lead to the formation of a 'slot' in the sphincter and a small air gap between the sensor (together with the obstetrician's fingertip) and the skin. Consequently, the sensor failed to establish complete contact with the IAS/anal mucosa underneath and

instead was subject to contact separation due to the small gap created instantaneously when rubbing through the sphincter.[16] This contact separation resulted in negative peaks in the recorded data.

In Study 2 (Figure 4A,B), the peak detection threshold was set as −1.5 nA (any peaks found below this threshold were identified as defects). Sensitivity was 100% and specificity was 100% in detecting the sphincter defect (Figure 5C), with distinct peaks formed in all 30 examinations (Figure 4B).

In Study 3, where the sphincter was examined a total of 140 times, sensitivity was 98% and specificity was 100% when setting the peak detection threshold at −1.1 nA (Figure 4D,E). To assess the statistical significance between the peaks recorded when encountering a defect versus those occurring in an intact sphincter (Figure 4F), *p*-values were calculated, and were <0.001.

It is important to note that the peak detection thresholds differed between Study 2 and 3 (−1.5 and −1.1 nA, respectively). This is to be expected, as each sensor needs to be individually calibrated before being used.[16]

3.3 | Software interface

The LABVIEW interface indicated 'DEFECT' when an anal sphincter defect was encountered in real time (Figure 5A,B).

4 | DISCUSSION

4.1 | Main findings

In this pilot study, the sensorised glove gave promising preliminary results, and detected the majority of anal sphincter defects in a pig model. We also created a software interface to display when a sphincter defect is encountered in real time.

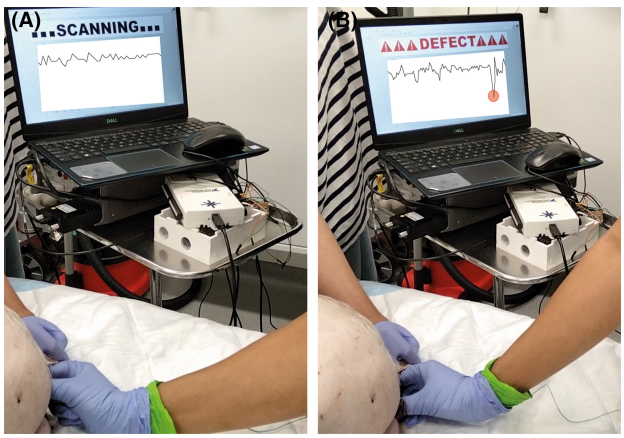

FIGURE 5 Software interface. Study 3: Obstetrician carrying out the test on the non-dissected pig's anal sphincter wearing the sensorised glove covered by a second surgical glove and the software interface showing: (A) signals produced by the sensor when scanning for a defect and (B) peak produced by the sensor when encountering the defect and interface successfully displaying the 'DEFECT' alert.

4.2 | Strengths and limitations

The strengths of this study lie in the number of examinations performed (200 in total) and the recording of data during each examination, which have allowed statistical analysis.

In Study 1, precision was low. Our interpretation is that this is due to the increased laxity and degrees of freedom introduced in the dissected anal sphincter, which are likely unrealistic in a usual PR exam.

Sensitivity was lower in Study 3 than in Study 2 (98% versus 100%). The slightly lower rates were thought to be due to the number of examinations, leading to an increase in laxity and damage to the anal sphincter and surrounding tissues. This would likely not be the case in a clinical situation where the sphincter has to be examined a handful of times.

Limitations of the study overall include the fact that only two clinicians tested the device, and that a true OASI was not replicated after a vaginal birth. As well as this, only a 3b defect was created; it remains to be confirmed whether the glove can detect more superficial tears. As SRJ was one of the examining clinicians and created the defect, there may be an element of unconscious bias when examining the sphincter (e.g. pressing harder over the defect); however, this was unlikely to have had a significant effect, as NA, a different junior clinician with no prior experience at all of PR examination, produced similar currents during their examination (Figure S1). Moreover, the mechanism of injury was with a scalpel, so a clean surgical cut was created, with only one site of injury, and wider defects were not created/examined.

The glove was tested on pig cadavers that had been dead for 2–3 hours, so the way in which the sensors interacted with the tissue is likely to differ from that in a living being. Furthermore, in real-life, clinical assessment might be compromised by the perineal and vulva oedema that occurs after vaginal birth, as well as the presence of active bleeding. Patient discomfort and movement artefacts may also have an impact. This further supports an in-human study to ensure that this works for true OASI in vivo.

4.3 | Interpretation

This is the first study that has developed a sensorised glove that has the potential to be used in detecting OASI, which is intended for use immediately postpartum. Sensorised gloves have been used in other obstetric applications, such as measuring the force applied on the maternal abdomen during external cephalic version (ECV) with a glove mounted with piezoresistive pressure sensors.[21] Another work measured the force applied during perineal support during childbirth.[22] However, to our knowledge, no sensorised gloves have been used for diagnostic purposes in obstetrics or maternity care.

5 | CONCLUSION

We have developed a novel, sensorised surgical glove that shows promise in detecting anal sphincter defects. In this preliminary study, the glove has demonstrated 100% specificity and 98–100% sensitivity in a porcine model.

The sensorised glove has significant clinical potential. At the time of publication, the glove costs <£1 to make,[15] is simple to use (like a normal surgical glove) and does not require in-depth training for interpretation of the results. Due to its low cost, it could be used in low- and middle-income countries. If it can detect OASI in vivo, it has the potential to reduce the complications associated with OASI, the substantial litigation costs associated with missed diagnosis, and the associated social stigmas in low/middle-income countries.[23] Most importantly, it could lead to an improved quality of life for sufferers of such injuries. It is important to state that it does not replace clinical judgement and training, and rather should act as an adjunct and complementary diagnostic tool.

While the preliminary results of the glove are exciting, clinical translation is ongoing and needs to be tested in vivo in humans to ascertain that it works in the presence of oedema, blood and true OASI. This requires an in-human feasibility study on labouring and postpartum women, which necessitates stringent safety testing of the glove for in vivo use. In the future, the team plan to move forward with clinical trials to assess whether the glove can accurately detect different types of OASI, increase the rates of timely repair and ultimately increase women's quality of life by reducing complications associated with missed injury or delayed repair.

AUTHOR CONTRIBUTIONS

DS, MKT, ALD, AD, SRJ and CSF were involved in the conception and design of the study. SRJ, CSF, and NA acquired, interpreted and analysed the data. SRJ, CSF and NA wrote the draft. DS, MKT, ALD and AD revised the paper critically.

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CONFLICT OF INTEREST STATEMENT

SRJ, CSF, AD, MKT, ALD and DS are co-inventors on a patent filed on sensorised surgical gloves and are involved in clinical translation of the technology.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS APPROVAL

The protocol and scientific rationale for the supply and use was approved by the Royal Veterinary College's (RVC) Ethical Review Board (request number 48, approved 25 May 2021). The guidelines for the care and use of animals approved by the institution were followed.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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