BMC Veterinary Research

STUDY PROTOCOL

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Drapes in Routine Aseptic Procedures for Environmental Sustainability (project DRAPES): a protocol for a multi-centre randomised controlled trial comparing post-operative wound complication rates following routine neutering of dogs and cats using reusable or disposable surgical drapes

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Abstract

Background Reusable surgical drapes have a lower lifetime environmental impact than disposable drapes in most cases. There is limited evidence regarding whether drape choice impacts patient outcomes including post-operative wound complications. The aim of this study is to compare wound complication rates following routine neutering surgeries in cats and dogs when reusable drapes are used as compared with disposable drapes.

Methods The trial will be conducted as a pragmatic, multi-centre, parallel group randomised controlled trial in the UK. Dogs and cats undergoing routine neutering will be randomised to disposable or reusable drapes with all other aspects of care occurring as they usually would at the practice. The required sample size is 2,850, with 4750 animals to be recruited from up to ten practices to allow for a 40% loss to follow-up. Demographic data and details on peri-operative care will be collected at the time of surgery. Post-operative wound complications will be assessed and recorded as usual at each practice using clinical codes. The post-operative wound clinical codes and any antibiotic use within 30 days of surgery will be retrieved from the practice management software. The primary outcome that will be compared between the two groups is the rate of post-operative wound complications within 30 days of surgery which will be analysed by multivariable logistic regression with a binary outcome of wound complication

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(yes/no). Secondary outcomes are the prevalence of different types of complications and antibiotic use within 30 days of surgery which will be compared between the two groups by chi square analysis.

Discussion Our hypothesis is that there will be no difference in post-operative wound complication rates between disposable and reusable drapes. If the likely rate of post-surgical wound complications with reusable drapes is similar to that with disposable drapes, then veterinary clinical teams can choose the more sustainable option, confident that their patients will not be impacted by this choice.

Trial registration We have retrospectively registered the protocol on the Open Science Framework on 14 Nov 2023 (Trial registration entry: https://doi.org/10.17605/OSF.IO/72HMA).

Keywords Sustainability, Neutering, Surgical drapes, Post-operative complications, Surgical safety, Randomised controlled trial, Wound complications, Surgical site infection

Background

Drapes are used during surgery ("surgical drapes") to protect the surgical site from contamination and reduce the risk of infection. They are used in virtually every sterile surgery in companion animals. Surgical drapes were initially made of cotton and washed and sterilised between uses. Over recent years, a range of drapes have been developed which are disposable. Practices may choose to use either type of drape, or a mixture of both, as there is no proof that either is superior.

In a 2019 British Veterinary Association (BVA) survey, 89% of vets stated they wanted to play a more active role in the UK's sustainability agenda. Some practices have therefore adopted the use of reusable surgical drapes to reduce waste volumes and resource consumption [11, 12]. Lifecycle analyses of reusable textile and single-use products in human hospitals demonstrate that in the majority of cases reusable surgical drapes substantially reduce energy consumption, greenhouse gas emissions, blue water consumption and solid waste generation compared with disposables [6, 13]. This suggests that using reusable drapes when appropriate may be preferable in practices looking to reduce their environmental footprint.

Wound complications, including surgical site infections, are an important consideration in routine surgical procedures. In dogs and cats undergoing ovariohysterectomy, reported incidence of surgical site infection ranges from 1.2 to 5.7% [1, 10]. Factors that have been identified as associated with increased surgical site infection include surgical time, American society of Anesthesiologists (ASA) status, wound contamination status and surgeon experience; but drape type was not recorded in any of these studies [3–5, 8]. A recent knowledge review concluded that there was insufficient evidence to make the statement that disposable drapes and gowns reduced the risk of surgical site infections, as the quality and outcomes of human studies were varied and there was no information in the veterinary literature [9].

Practitioners would like to know whether choosing a reusable drape is likely to result in changes to post-surgical wound complication rates as these can impact animal welfare, increase workload and can lead to significant cost increases for owners [3]. If the likely rate of post-surgical wound complications with reusable drapes is similar to that with disposable drapes, then they can choose the more sustainable option, confident that their patients, clients and the practice will not be impacted by this choice.

The aim of this study is to compare wound complication rates following routine neutering surgeries in cats and dogs when reusable drapes are used as compared with disposable drapes. Our hypothesis is that there will be no significant difference in the rate of wound complications between reusable and disposable drapes when used for dogs and cats undergoing routine surgical neutering procedures.

Methods

Overview

This study is a pragmatic, parallel group, two-arm, multicentre field-based randomised controlled trial that will be conducted within UK veterinary practices that are part of VetPartners. Ethical approval for the study has been granted by the Royal College of Veterinary Surgeons (RCVS) Ethics Review Panel. We have retrospectively registered the protocol on the Open Science Framework on 14 Nov 2023 (Trial registration entry: https://doi.org/10.17605/OSF.IO/72HMA).

Animals will be admitted, treated and discharged according to standard care at the site: i.e. all aspects of the anaesthetic, analgesia, the surgery itself and discharge conditions will be performed according to normal practice at the site and at the discretion of the attending clinicians. The only care that will differ according to the randomisation protocol is whether a disposable or reusable drape is used for the surgery. See Figs. 1 and 2 for the flow diagram of the study and SPIRIT schedule.

Primary outcome

- Wound complication rates within 30 days of routine surgical neutering.

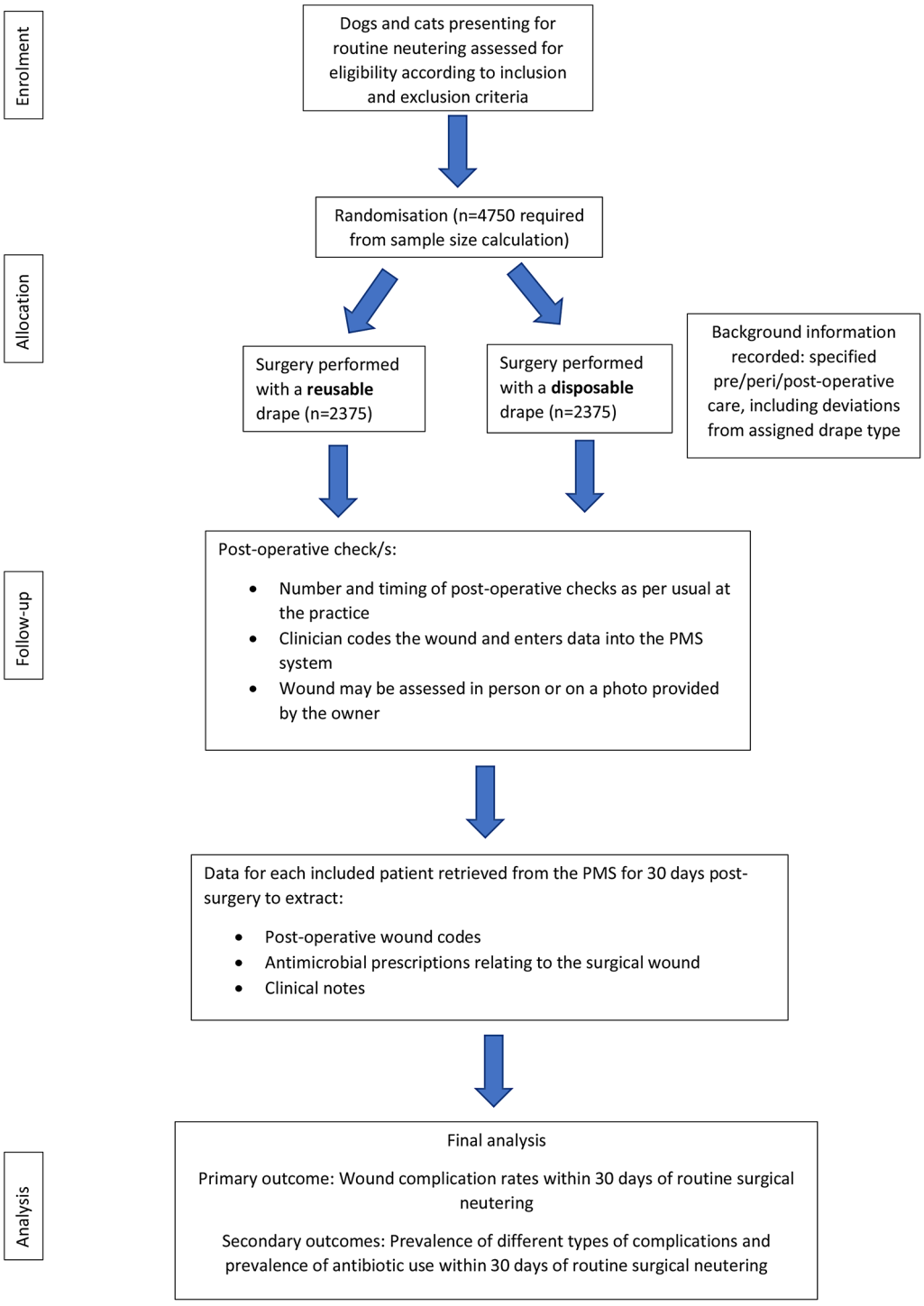

Fig. 1 Flow diagram of a prospective, multicentre, randomised controlled trial assessing wound complication rates in routine surgical neutering of dogs and cats using reusable versus disposable surgical drapes

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT	*At admission for surgery*	*After admission for surgery*	*On the day of surgery*	*Post op check/s (number and timings will vary by practice)*	*30 days post-surgery*
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation; block randomisation		X			
INTERVENTIONS:					
[Surgery performed with a reusable drape]			X		
[Surgery performed with a disposable drape]			X		
ASSESSMENTS:					
[Baseline variables and pre/peri and post operative care details collected]			X		
[Primary Outcome: Post-operative wound code]				X	X
[Secondary outcomes: antibiotic prescriptions, severity of complications]				X	X

Fig. 2 SPIRIT (Standard Protocol Items Recommendations for Interventional Trials) schedule of enrolment, interventions, and assessments for the DRAPES study

Secondary outcomes

- Prevalence of different types of complications.
- Prevalence of antibiotic use within 30 days of surgery.

We will also descriptively present data on the timeframe in which complications occur, other treatments administered, and the number of post-operative checks patients have.

Patient inclusion criteria

To be eligible for inclusion animals must meet the following criteria at the time of randomisation:

- Dogs and cats presented to participating clinics for routine spay (cats) or spay/castrate (dogs).
- American society of Anesthesiologists (ASA) status 1 or 2 [2].
- Owner provided informed consent for participation in the trial.
- Surgeon consent.

Patient exclusion criteria

Animals will be excluded from the study if they meet any of the following criteria:

- Species other than dogs or cats.
- Cats being castrated.
- Non-routine neuter surgery (e.g. pyometra, Caesar-spay, cryptorchid castration, known pregnant spay).
- Laparoscopic spay.

- Concurrent additional procedures e.g. any dental procedures/any additional surgical procedures but microchipping and nail clipping are allowed.
- ASA status greater than 2 (i.e. significant comorbidity [2])
- Owner declined consent for participation in the trial.
- Surgeon declined consent.
- Patient has received treatment with systemic antibiotics or corticosteroids in the previous 2 weeks.
- Patients receiving peri-operative antibiotics.
- Procedure not completed, including anaesthetic death.

Due to the pragmatic nature of the trial being conducted in busy veterinary clinics with high routine neutering loads we will not collect information on the number of animals excluded and for what reasons.

Practice recruitment

Practices (estimated to need between 5 and 10 practices) will be recruited from within VetPartners via expressions of interest following advertising of the trial in internal communications and via direct approach to practices with a high neutering caseload. Final selection of practices for involvement will be based on agreement to participate within the whole practice team; capacity to carry out the research (including use of pre-existing post-operative check coding systems), and suitable caseload of included surgeries.

Patient recruitment

Information will be provided in the form of leaflets, posters and social media posts, targeted at owners planning to have their pets neutered. All owners of qualifying pets will be provided with study information including a leaflet and/or weblink (https://vetpartners.co.uk/clinical-insights/project-drapes/) and given time to consider whether they wish to participate. On admission of their animal for neutering, they will then be taken through an information sheet (see Additional file 1) and consent form detailing the study and all predicted outcomes of relevance and significance.

Consent

Informed consent for participation in the trial will be obtained in addition to routine informed consent for the surgery. All owners will be informed that participation is voluntary, and that refusal to participate will in no way prejudice or influence the care of their pets. Owners will be guided through the consent form, invited to ask questions and, where owners agree to participate, will be asked to sign to indicate this. Owners will be provided with material (printed and/or online) which will supply further details about the study, and a point of contact for queries or if they would like to withdraw at any point before the data is anonymised.

Allocation concealment and randomisation

Once recruited and owner consent given, included patients will be randomised to the two study groups in a 1:1 ratio. The randomisation code will be generated centrally and correspond to sequentially numbered opaque sealed envelopes held at each practice site. When an animal is admitted to the trial, the next envelope will be opened by a member of the team at the practice, and the envelope number and assigned drape type (reusable or disposable) recorded on the consent form that remains with the animal. Randomisation will be blocked by practice site to ensure an approximately even distribution of patients within study groups.

Intervention

The two study groups will be animals that have their routine surgery carried out using either a sterilised reusable cotton/polycotton drape or sterile disposable drape of an appropriate size for the patient. Practices can choose the specific reusable or disposable drapes they prefer, however adhesive drapes are not allowed. A member of the research team will visit each practice before the trial commences to deliver training in correct use and protocol, and practices will be provided with VetPartners' Surgical Drape Sterilisation Standard Operating Procedure (SOP; see Additional file 2) which details correct sterilisation technique of reusable drapes to minimise the risk of infection.

Blinding

Due to the nature of the intervention, it will not be possible to blind team members within the practice to study group allocation. For practical reasons it is also not possible to ensure the team members assessing the outcomes are blinded. Owners will not be informed of which group their animal was allocated to. Those involved in extracting the outcome data from the practice management system and the statistician will be blinded to treatment allocations until the analysis is completed.

Background data to be collected at the time of surgery

The following data will be collected for each animal at the time of surgery:

- Patient unique identification number.
- Drape type assigned.
- Drape type used – and why it was not the assigned type if applicable.
- Surgery type - cat spay/dog castrate/bitch spay.
- Bodyweight.
- ASA status.
- ID of colleague performing surgical preparation.
- Surgeon ID.
- Whether the usual practice SOP was followed for skin preparation.
- Whether sterile gloves were worn by the surgeon.

- Surgical approach (e.g. flank vs. midline for cat spay, open vs. closed castrate for dogs).
- Pre-medication and anaesthetic agents used.
- Additional peri-operative treatments (e.g. pain relief, antibiotics).
- Any known break in aseptic technique.
- Any surgical complications.
- Suture materials used in all layers of closure.
- Skin closure type – glue/intradermal/subcuticular sutures/staples/external skin sutures.
- Deviations from study protocol e.g. drapes changed and why.
- Presence and type of surgical site dressings.
- Surgical time.
- Post-operative treatments (e.g. pain relief, antibiotics).
- Provision of collar or shirt for patient.
- Unexpected events e.g. general anaesthetic death.

These data will be entered into an online, secure data collection form (survey monkey; see Additional file 3) by practice colleagues, accessed via a tablet provided for the purpose of the study. Survey responses from each participating site can be identified separately and each recruited patient will be uniquely identified by its patient number. This will later be used as a cross-reference when extracting post-operative codes for study participants.

Outcome measurements

Routinely practices will check animals post-operatively once or twice during the approximately 10 days after surgery. During this routine post-operative follow-up and care, vets or nurses assess the patient's surgical site and assign a post-operative code to describe their findings. These post-operative codes are recorded in the practice management system (PMS). Animals participating in the study will be followed up post-operatively as they usually would be within that practice, meaning the way this is done will likely vary between participating practices in terms of timings, whether it is performed by vet nurses or vets and whether it is done face-to-face or via a photo of the surgical site. The post-operative codes used vary between practices. Here is an example of one coding system:

Description	Code given
Post op 0: No complication	PO
Post op 1: Minor complication, no treatment	PO1
Post op 2: Minor complication, treatment required	PO2
Post op 3: Major complication	PO3

The post-operative codes and clinical notes (including age of the animal) will be extracted from the PMS for all participating animals. Patients with no post-operative code assigned will be considered as lost to follow up. If animals have been assigned more than one post-operative code within 30 days of surgery (usually due to multiple post-operative checks), the most severe code will be used for analysis.

Complications requiring some form of treatment (including topical/systemic/surgical treatment) related to the original surgical wound which commence within 30 days of the surgery will be classified as a post-operative complication for the primary outcome.

- If no treatment was required (in this example codes PO or PO1) this will be classed as no complication for the primary outcome.
- If treatment was required (in this example codes PO2 or PO3) this will be classed as a complication for the primary outcome.

For some of the coding systems this will require manual checking of the clinical records to assign a yes/no outcome for whether a complication occurred. Interventions considered 'standard care' e.g. buster collar or wound dressings will not be considered as 'treatment' if they occur at a post-operative check.

Records of all animals assigned as having a complication will be manually checked to verify if the complication is related to the wound as some coding systems record all post-operative complications e.g. vomiting. Any animals found to have been miscoded during these manual checks will be reassigned accordingly. Where ambiguity exists, codes will be checked against free-text clinical records for the patient by two independent, blinded assessors with a third assessor resolving any disagreements.

Clinical records will also be checked for antibiotic prescriptions within 30 days of surgery with manual checking to see if the antibiotic prescription was related to the surgical wound. Any cases where antibiotics have been prescribed for a wound infection within 30 days of surgery, but the patient was coded as 'no complication' will be moved to the 'complication' group for the primary outcome.

For determining the severity of complications, animals will be assigned to one of three categories based on their wound codes and clinical notes:

1. Minor complication – topical treatment given (e.g. chlorhexidine).
2. Moderate complication – systemic treatment given (e.g. analgesia, antibiotics).
3. Major complication – surgical treatment required.

Due to the pragmatic nature of the trial, we expect a significant loss to follow up for the following reasons:

- Not all practices routinely schedule post-operative checks for all patients.
- Not all owners will bring their animals to scheduled post-operative checks.
- Not all post-operative checks will result in a post-operative code being assigned in the PMS.

We will attempt to reduce loss to follow-up through training participating practices on post-operative checks and coding, reminders within practice buildings throughout the trial and regular feedback to participating practices. Numbers lost to follow-up will be presented clearly for each group and the sample size calculation has allowed for a 40% loss to follow up.

Sample size calculation

Sample size has been calculated for the primary outcome using the following parameters:

Significance (a) = 5%.
Power (1-b) = 80%.
Expected prevalence of complications = 7.5%.
Threshold = 10.5% (i.e. a difference of 3%).
Sample size per group = 1425.
Total calculated sample size = 2850.

Due to an estimated attrition rate (due to withdrawal of consent or failure to present for post-operative checks) of 40%, a sample size of 2850 requires recruitment of at least 4750 patients.

The expected prevalence of complications has been derived from internal clinical audit data from routine neuters across 55 VetPartners practices.

Data processing and cleaning

Peri-operative data will be collected at the time of surgery using a survey monkey form and downloaded as Excel spreadsheets. Data will be cleaned and cross-checked, before export to SPSS. Post-operative outcomes will be collected by data mining from the PMS, using a database and queries written in SMSS (SQL Server Management Studio) using a process designed and previously used by the authors. All clinical notes and sales entries for participating animals for the 30 days following the date of surgery will also be extracted from the PMS and transferred to Excel spreadsheets.

Data analysis

Background patient data

Background data will be analysed descriptively, with frequencies/percentages (with 95% confidence intervals) presented for categorical variables. For numerical variables, histograms will be examined and measures of symmetry (kurtosis/skewness) used to determine whether the data are normally distributed. Mean, standard deviation and range will be calculated for normally distributed variables, and median, interquartile range and range for non-parametric variables. Statistical comparisons will be carried out to ensure randomisation has been effective and groups are similar in terms of background data. Chi-square analysis will be used to compare categorical variables between patients in the disposable and reusable drapes groups and also to compare loss to follow up between groups. T-tests will be used to compare normally distributed numerical variables and Mann Whitney U will be used to compare non-parametrically distributed numerical variables between the disposable and reusable drapes groups.

Primary outcome

Period prevalence of wound complications (i.e. any wound considered to have a complication as a proportion of all wounds receiving a post-op code) during the 30 day time period will be calculated, along with a 95% confidence level. The distribution of time to wound complication will be examined for normality, and descriptive statistics calculated as appropriate.

Analysis will be conducted on an intention-to-treat basis and checked against per-protocol basis to ensure consistency. Logistic regression will be conducted, with a binary outcome of wound complication (yes/no). The variables to be considered as fixed effects below will be tested via univariable analysis, and also assessed for collinearity and interaction:

- Drape type (assigned (intention to treat), used (per protocol)).
- Species (cat, dog).
- Age (in years/months).
- Sex (male/female).
- ASA status (1, 2).
- Sterile gloves worn by surgeon (y/n).
- Surgical time (in minutes).
- Any surgical complications (y/n).
- Any known break in aseptic technique (y/n).
- Deviations from study protocol e.g. drape changed/more drapes added (y/n).
- Presence of surgical site dressings (y/n).
- Post-operative pain relief given (y/n).
- Provision of collar or shirt for patient (y/n).

Variables with $p < 0.2$ and biological plausibility will be nominated for inclusion as fixed effects in the multivariable model, which will be built using the backwards method and tested for goodness-of-fit. Significance in the multivariable model will be set at $p < 0.05$, with point estimates and 95% confidence intervals reported.

Secondary outcomes

Types of wound complications (minor/moderate/major as defined above) will be compiled descriptively, with prevalence (point estimate and 95% confidence intervals) of each type reported. Chi-square analysis will be used to examine the data for any difference in the severity of complications, and in the prescribing of post-operative antibiotics for wound related reasons, between patients in the disposable and reusable drapes groups.

Data monitoring

There are no anticipated harms to animals resulting from this study; using both disposable and reusable drapes is common and recognised veterinary practice and for these reasons there will not be an independent data monitoring committee for this trial. However, interim complication rates will be monitored by the study team every 3 months/500 animals. Should an increase in post-operative complication rates (>50% increase, informed again by the variability observed in VetPartners clinical audit data) be noted, this would constitute a stop point until any reasons for this change had been identified. Should this occur, and any increase be deemed outside the influence of the study (e.g. a batch of faulty suture material), the study would be allowed to resume.

Practitioners will also be regularly invited to feedback on any practical impacts of drape use, and these data will be collated to ensure considerations around making changes to drapes are documented.

Discussion

This study is being conducted as a pragmatic, multi-centre field-based randomised controlled trial. Pragmatic trials test interventions in the full spectrum of everyday clinical settings to maximise applicability and generalisability [7]. Across veterinary practices there is wide variability in approaches to routine procedures and therefore a pragmatic trial will improve the external validity of the results and their relevance to general practice.

Impact of the study

Waste from single-use items is a significant contributor to the environmental impact of veterinary care. Providing evidence on the impact of drape type on post-operative wound complication rates will allow practitioners to make evidence-based choices. If the rate of complications is comparable between drape types, this will enable practitioners to select the more sustainable option, confident that their patients will not be impacted by this choice.

Equally, if a relationship between drape type and risk of wound complication was identified this would facilitate better patient care in future by providing evidence for the use of one type of drape over the other. This would lead to a reduction in morbidity for patients undergoing routine neutering surgery and may also reduce the use of antibiotics post-operatively, which benefits both humans and animals by slowing the development of antibiotic-resistant bacteria.

The results from this study will be published in a peer-reviewed journal as well as being presented at relevant conferences and disseminated widely within VetPartners network of practices.

Limitations of the study

Blinding of clinical colleagues within this study, including those who will be assessing the wounds post-operatively, would be too restrictive and time-consuming within this pragmatic trial which will be conducted in busy practices with a high routine neutering caseload. It is possible that a clinician assessing a wound post-operatively could remember the drape type used for the surgery and be biased in their assessment of wound appearances based on existing preconceived ideas about which drape type is preferable.

For similar reasons we will not be recording the numbers of animals excluded from the study and the reasons for this, including a lack of consent. This means we will not be fully aware of any potential differences between the population of included and excluded animals. The inclusion criteria on ASA status having to be 1 or 2 means we will be excluding most brachycephalic patients from the study.

The use of opaque sealed envelopes being held by the practice site means there is a risk of the intervention allocation for the patient being known by the local practice team and therefore altered.

The large potential losses to follow-up are being minimised as much as possible as described in the methods above, however it is still expected there will be significant loss to follow up throughout the trial. If needed, the duration of recruitment will be extended and additional practices from within the VetPartners network recruited so the required sample size is still achieved.

Abbreviations

ASA	American society of Anesthesiologists
BVA	British Veterinary Association
PMS	Practice Management System
RCVS	Royal College of Veterinary Surgeons
SOP	Standard Operating Procedure

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12917-024-04276-5.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Acknowledgements
Not applicable.

Author contributions
ND/HJ responsible for the original idea and concept. ND/HJ/HD/JS/NR/RD/KW all contributed to protocol design. KW drafted the first version of this manuscript. ND/HJ/HD/JS/NR/RD/KW contributed to the editing of this publication and have read and approved the final manuscript.

Funding
This study is being partially funded by a BSAVA PetSavers' Clinical Research Grant. This funding body has no involvement in the design of the study, collection, analysis or interpretation of data or manuscript preparation. Any additional costs incurred beyond this grant will be covered by VetPartners Ltd.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study is conducted under the regulatory framework of the Veterinary Surgeons Act, and therefore a Home Office (Experimental) License is not required for this work, as it does not fall under A(SP)A. Ethics consent has been granted by the Royal College of Veterinary Surgeons (RCVS) Ethics Review Panel (Reference: 2022-012-Stavisky). Owner consent: All owners will be informed that participation is voluntary, and that refusal to participate will in no way prejudice or influence the care of their pets. Owners will be guided through the consent form, invited to ask questions and, where owners agree to participate, will be asked to sign to indicate this. Owners will be provided with material (printed and/or online) which will supply further details about the study, and a point of contact for queries or if they would like to withdraw. The consent form was supplied to the RCVS Ethics Review Panel as part of the ethical review process.

Consent for publication
Not applicable.

Protocol amendments
Any necessary amendments to the protocol will be clearly communicated in the final manuscript produced from the study.

Competing interests
The authors declare no competing interests.

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Received: 15 November 2023 / Accepted: 10 September 2024
Published online: 28 September 2024

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