Российский национальный исследовательский медицинский университет имени Н.И. Пирогова

Доклинические хирургические исследования: проблемы и перспективы

Ануров Михаил Владимирович
Ведущий научный сотрудник отдела экспериментальной хирургии НИИ клинической хирургии, д.м.н.

CLINICS 2011;66(1):159-161 DOI:10.1590/S1807-59322011000100027

REVIEW

Limits to clinical trials in surgical areas

Marco Kawamura Demange,[I] Felipe Fregni[II]

[I]Orthopaedics and Traumatology, Faculdade de Medicina da Universidade de Sao Paulo, São Paulo, São Paulo, Brasil. [II]Harvard Medical School -

Randomized clinical trials are considered to be the gold standard of evidence-based medicine nowadays. However, it is important that we point out some limitations of randomized clinical trials relating to surgical interventions.

BMJ VOLUME 324 15 JUNE 2002 bmj.com

Randomised trials in surgery: problems and possible solutions

Peter McCulloch, Irving Taylor, Mitsuru Sasako, Bryony Lovett, Damian Griffin

Some aspects of surgery present special difficulties for randomised trials

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

Ethical Issues of Participant Recruitment in Surgical Clinical Trials

The nature of clinical trials in surgery raises ethical issues that are different from those outside of surgery.

Peter Angelos, MD, PhD, FACS

ANNALS OF SURGERY
A MONTHLY REVIEW OF SURGICAL SCIENCE SINCE 1885

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Modulating Portal Hemodynamics With Vascular Ring Allows Efficient Regeneration After Partial Hepatectomy in a Porcine Model

Bucur, Petru O.; Bekheit, Mohamed; Audebert, Chloe; More

Annals of Surgery. 268(1):134-142, July 2018.

To investigate safety and efficacy of temporary portal hemodynamics modulation with a novel percutaneously adjustable vascular ring (MID-AVR) onto a porcine ***model*** of 75% hepatectomy.

Abstract | Favorites | PDF | Get Content & Permissions

BUY SDC

Stem Cell Mobilization Is Lifesaving in a Large Animal Preclinical Model of Acute Liver Failure

Ahmadi, Ali R.; Chicco, Maria; Wesson, Russell N.; More

Annals of Surgery. 268(4):620-631, October 2018.

Acute liver failure (ALF) affects 2000 Americans each year with no treatment options other than liver transplantation. We showed previously that mobilization of endogenous stem cells is protective against ALF in rodents. The objective of this study was to assess whether stem cell mobilizing drugs are lifesaving in a large ...

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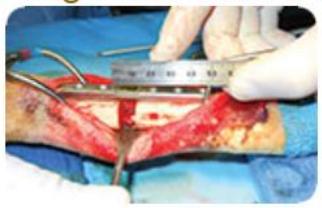
BUY SDC

A Novel Large Animal Model of Acute Respiratory Distress Syndrome Induced by Mitochondrial Products

PRECLINICAL SURGICAL RESEARCH LABORATORY

Colorado State University

Large and Small Animal Models

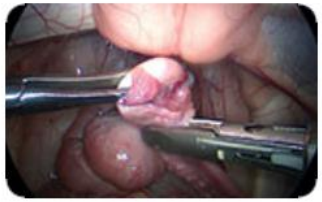


Orthopaedic

- Bone healing studies
- Internal fixation implant testing
- External fixation implant testing
- Allograft, autograft and xenograft testing
- Osteochondral defect/cartilage regeneration

Spine

- Lumbar interbody fusion
- Posterolateral intervertebral fusion - PLIF
- Cervical fusion
- Vertebroplasty
- Laminectomy



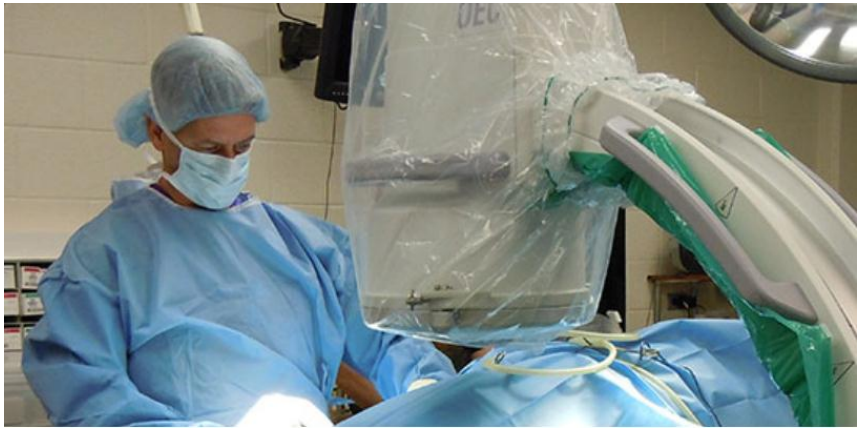
Soft Tissue

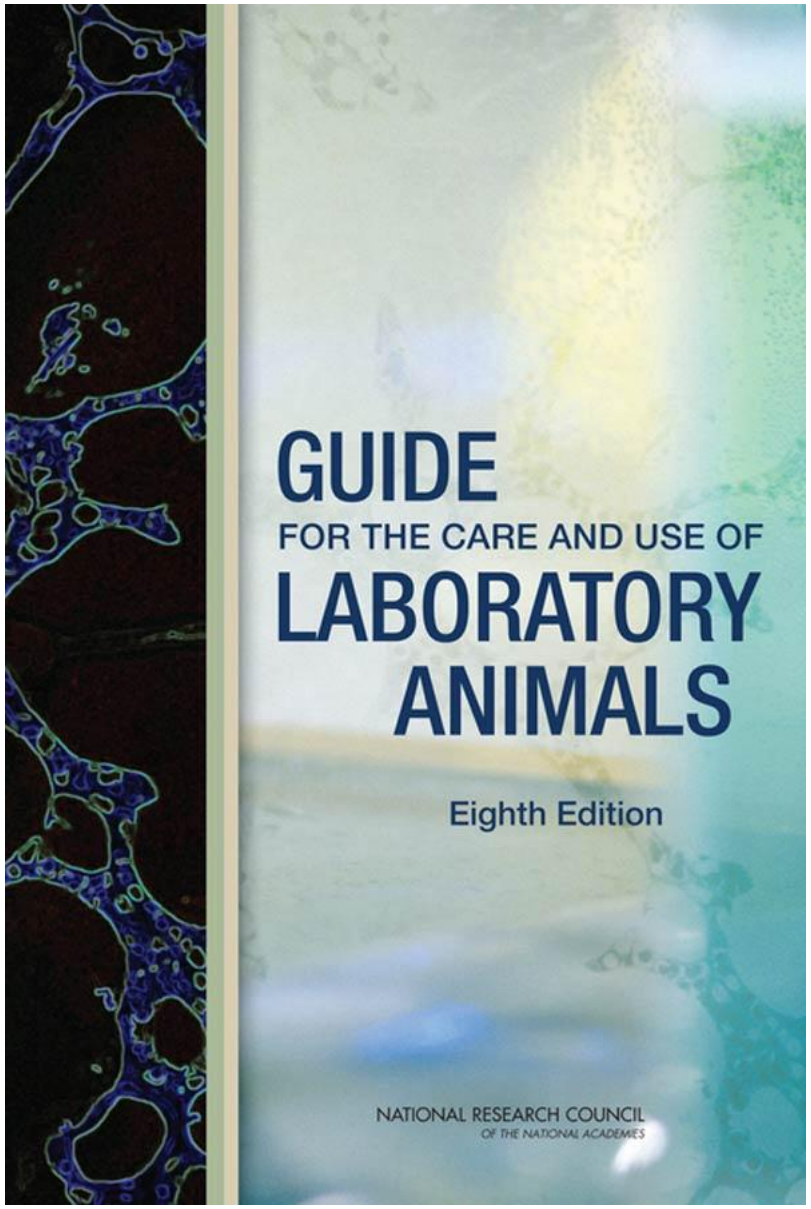
- Wound reconstruction/healing
- Urogenital implants
- Laparoscopic surgery

Osteoporosis

- Nutritional studies
- Hormonal studies
- Laparoscopic ovariectomy

The SRL provides the university, private and corporate researchers with a state-of-the-art laboratory dedicated to professional service, research efficiency and cutting edge technologies.





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GUIDANCE DOCUMENT

General Considerations for Animal Studies for Cardiovascular Devices - Guidance for Industry and FDA Staff

JULY 2010

B. Study Assurances

FDA recognizes that, for various reasons, use of a GLP facility may not be possible, such as when a highly specialized skill set of investigators is only available at a particular non-GLP facility. In these situations, FDA recommends that you provide a complete rationale for the selection of the test site, and that you follow the highest levels of oversight, record-keeping, and reporting. FDA also recommends that you hire an independent auditor so that impartial quality assurance is provided.

Доклинические хирургические исследования

1. Имплантация новых медицинских устройств для хирургии:

   - предрегистрационные исследования (реакция организма на имплантируемое устройство)

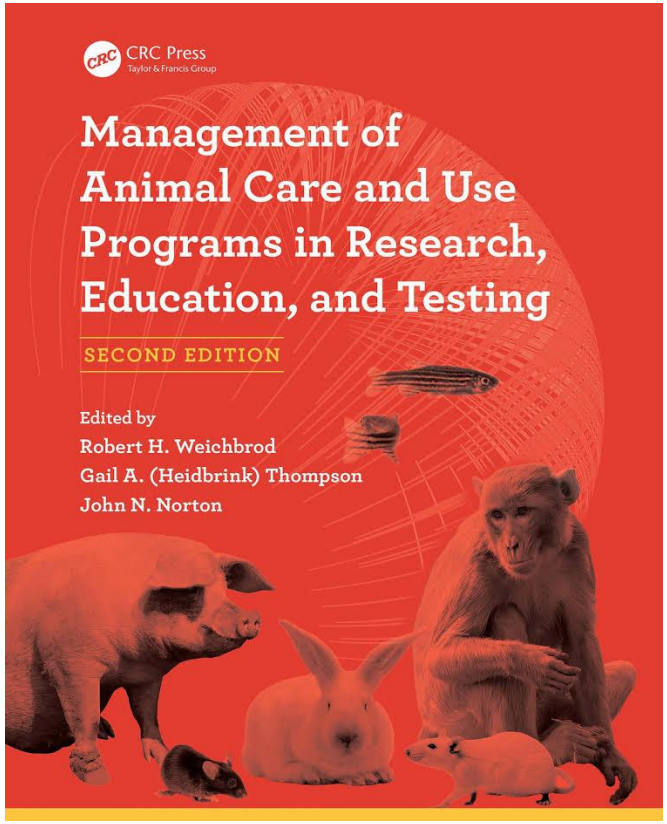
   - пострегистрационные исследования (функционирование имплантированного устройства)

2. Моделирование патологических процессов с целью разработки новых способов диагностики и хирургического лечения

   - исследование эффективности новых устройств в условиях модели патологического процесса

3. Создание моделей различных заболеваний для других медицинских специалистов и исследователей

4. Исследования, связанные с трансплантацией органов, замещением их функций и протезированием тканей



Chapter 34 Surgery

Authors

Randall R. Clevenger, Jan Bernal, Michael Talcott, Teresa R. Gleason, Tracie Rindfield, and Robert F. Hoyt, Jr.

The role of a surgical facility manager (SFM) within a laboratory animal surgical facility, or surgery department, has changed significantly over the past 15–20 years. Historically, because of their advanced training and experience, veterinarians were usually involved in managing surgical facilities in a research environment. However, in recent years, because of increased veterinary animal care and use responsibilities, in some instances this has resulted in nonveterinarians assuming that role. In either case, a

Персонал

У сотрудников должно быть понимание выполняемых хирургических процедур и их клинического значения, знание современного хирургического оборудования и анестезиологической аппаратуры

Сотрудники должны уметь творчески моделировать, а не копировать клиническую ситуацию

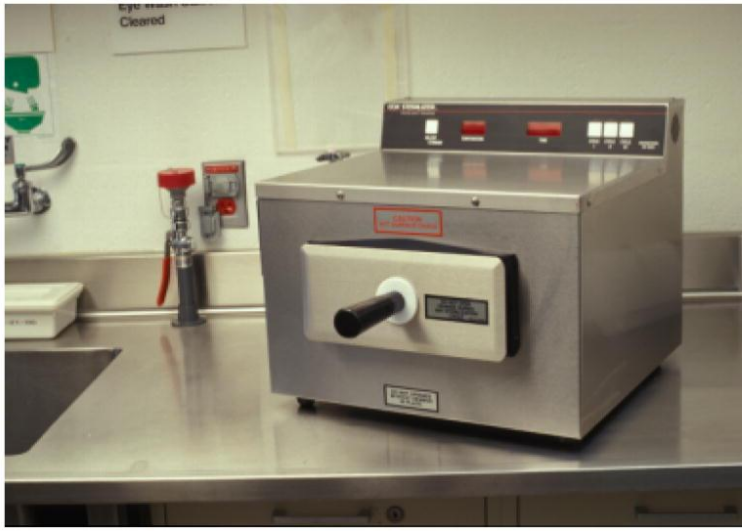
Организация и планирование.

1. Участие сотрудников хирургического подразделения в планировании экспериментального исследования еще на этапе формирования заявки в IACUC
2. Выполнение пилотного проекта, которое облегчает создание протокола, подаваемого в IACUC, и проведение эксперимента с соблюдением принципа 3 R

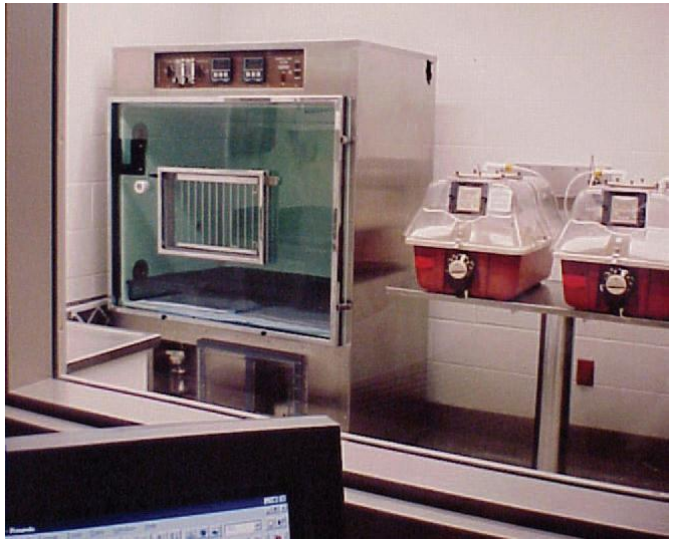
Организация помещений

Помещение для подготовки хирургов

Комната подготовки животных

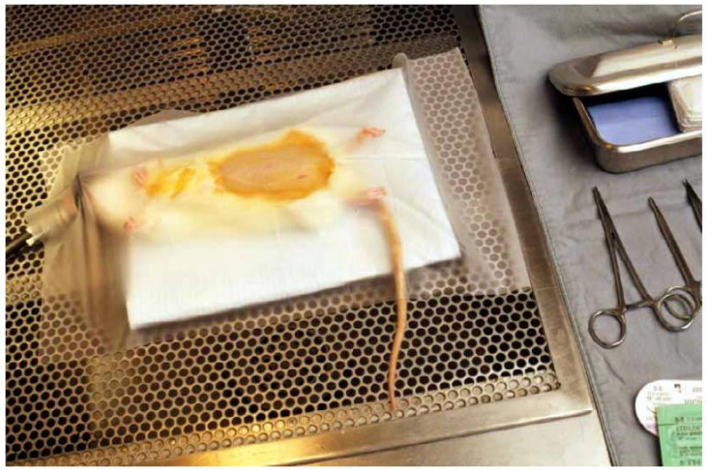


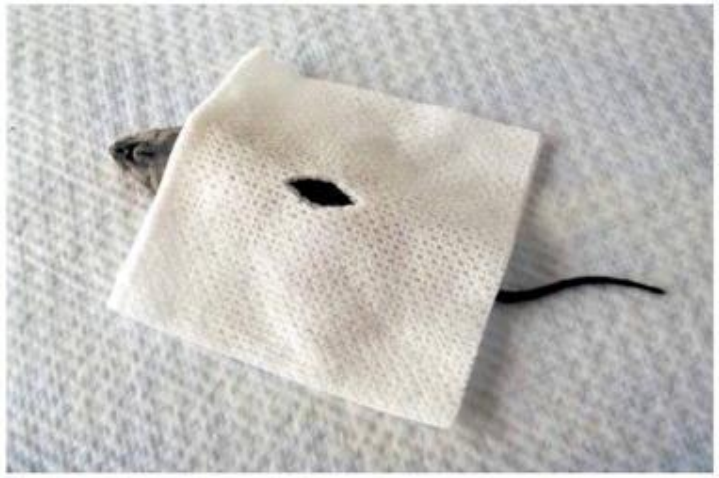
Стерилизационная



Комната восстановления

Операции у грызунов с соблюдением правил асептики





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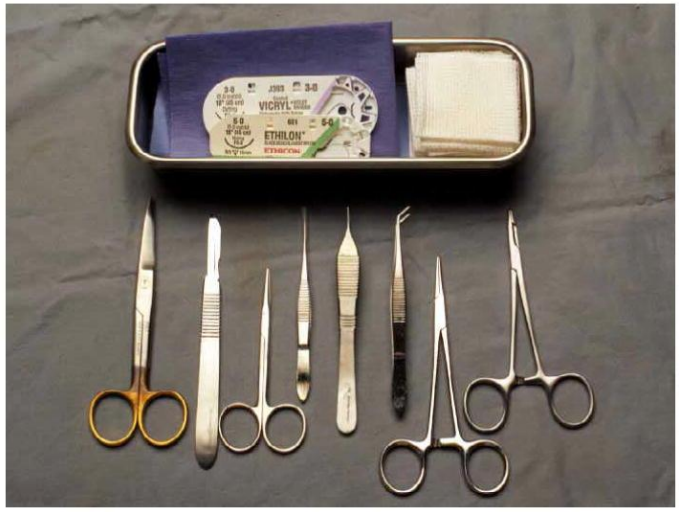
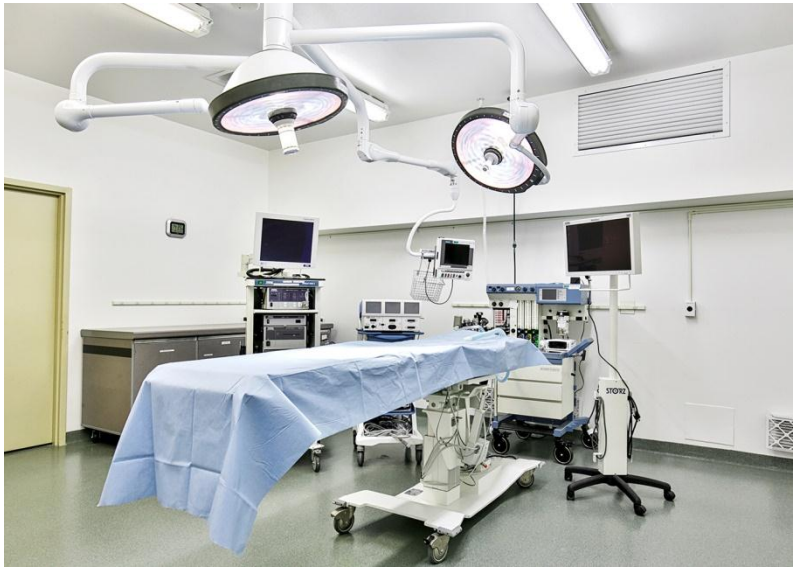


Использование стерильных хирургических инструментов и перчаток

Оснащение операционных

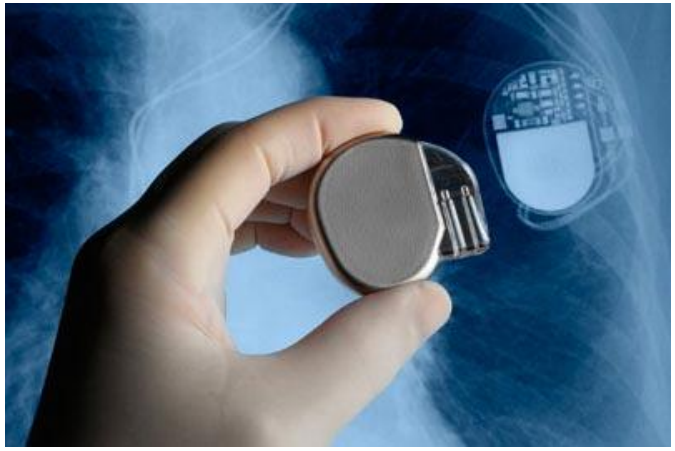


Экспериментальная операционная

Экспериментальная рентгенооперационная

Лапароскопическая стойка

Имплантируемые медицинские устройства



Водитель ритма

Сердечный клапан

Сетчатый протез для герниопластики

Внутрисосудистый стент

SCIENTIFIC REPORTS

OPEN

Conventional and Specific-Pathogen Free Rats Respond Differently to Anesthesia and Surgical Trauma

Received: 7 January 2019
Accepted: 12 June 2019
Published online: 28 June 2019

Hayley L. Letson, Jodie Morris, Erik Biros & Geoffrey P. Dobson

using rotational thromboelastometry. Health screening was outsourced to Cerberus Sciences. SPF rats had significantly lower pulse pressure (38% decrease), arrhythmias and prolonged QTc (27% increase) compared to conventional rats. No arrhythmias were found in conventional rats. SPF rats had significantly higher white cell, monocyte, neutrophil and lymphocyte counts, and were hyperfibrinolytic, indicated by EXTEM maximum lysis >15%. Independent assessment revealed similar pathogen exclusion between colonies, with the exception of *Proteus* in SPF animals. Returning to a conventional facility restored normal host physiology. We conclude that SPF animals displayed an abnormal hemodynamic, hematological and hemostatic phenotype in response to anesthesia and surgery, and provide a number of recommendations to help standardize research outcomes and translation.

Surgical and Anesthetic Record

(Large Animal)

Protocol Information		Personnel Information	
Protocol #::		LR:	
Species		Surgeon:	
Animal ID #:		Assistant Surgeon:	
Animal Name:		Anesthetist:	
Procedure Date:		Assistant:	

Surgical Procedures:

Preoperative Exam, Preparation, & Physical Condition of Animal:
(i.e., describe any abnormalities and signs of injury, illness, lack of appetite, diarrhea, etc.)

Baseline Values		Preoperative Items		Times	
Wt (kg):		IV catheter:		Surgery Start Time:	
HR:		Endotracheal tube size:		Surgery End Time:	
RR:		Ointment placed in eyes:		Time Returned to Cage:	
Temp:		Supplemental heat supplied:			

PERIOPERATIVE TREATMENTS

Time	Drug	Dose (mg/kg)	Dose (ml or other)	Route

MONITORING PARAMETERS & TREATMENTS DURING SURGERY

The following parameters, at a minimum (or as described in the approved IACUC protocol) must be recorded every 15 minutes starting from administration of the pre-anesthetic, throughout surgery, and continued until animal is recovered from the anesthesia.

Time	% Anesthetic Gas	End Tidal CO_2	HR	RR	O_2 Sat	Mucous Membranes (e.g., pink, pale, cyanotic)	Anesthetic Level	Fluids (running total of volume administered)	Temp	Comments

Surgical and Anesthetic Record

(Rodent)

Protocol Information		Personnel Information	
Protocol #:		Lead Researcher:	
Species:		Surgeon:	
Procedure Date:			

Surgical Procedure(s):

MONITORING PARAMETERS & TREATMENTS DURING SURGERY

The following parameters, at a minimum (or as described in the approved IACUC protocol) must be recorded. (Note: if Isoflurane is only drug that is used, animal weight does not need to be recorded. Please make note of any re-dosing of drug.)

Animal ID	Weight	Anesthetic Name	Dosage (mg/kg) (For gas - use %)	Dosage (mg/animal)	Analgesic Name	Dosage (mg/kg)	Comments

NC 3Rs ARRIVE

The ARRIVE Guidelines Checklist

Animal Research: Reporting In Vivo Experiments

Carol Kilkenny[1], William J Browne[2], Innes C Cuthill[3], Michael Emerson[4] and Douglas G Altman[5]

[1]The National Centre for the Replacement, Refinement and Reduction of Animals in Research, London, UK, [2]School of Veterinary Science, University of Bristol, Bristol, UK, [3]School of Biological Sciences, University of Bristol, Bristol, UK, [4]National Heart and Lung Institute, Imperial College London, UK, [5]Centre for Statistics in Medicine, University of Oxford, Oxford, UK.

	ITEM	RECOMMENDATION	Section/ Paragraph
Title	1	Provide as accurate and concise a description of the content of the article as possible.	
Abstract	2	Provide an accurate summary of the background, research objectives, including details of the species or strain of animal used, key methods, principal findings and conclusions of the study.	
INTRODUCTION			
Background	3	a. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale. b. Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.	
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.	
METHODS			
Ethical statement	5	Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), and national or institutional guidelines for the care and use of animals, that cover the research.	
Study design	6	For each experiment, give brief details of the study design including: a. The number of experimental and control groups. b. Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g. randomisation procedure) and when assessing results (e.g. if done, describe who was blinded and when). c. The experimental unit (e.g. a single animal, group or cage of animals). A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.	
Experimental procedures	7	For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: a. How (e.g. drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s). b. When (e.g. time of day). c. Where (e.g. home cage, laboratory, water maze). d. Why (e.g. rationale for choice of specific anaesthetic, route of administration, drug dose used).	
Experimental animals	8	a. Provide details of the animals used, including species, strain, sex, developmental stage (e.g. mean or median age plus age range) and weight (e.g. mean or median weight plus weight range). b. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naïve, previous procedures, etc.	
Housing and husbandry	9	Provide details of: a. Housing (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions; tank shape and material etc. for fish). b. Husbandry conditions (e.g. breeding programme, light/dark cycle, temperature, quality of water etc for fish, type of food, access to food and water, environmental enrichment). c. Welfare-related assessments and interventions that were carried out prior to, during, or after the experiment.	
Sample size	10	a. Specify the total number of animals used in each experiment, and the number of animals in each experimental group. b. Explain how the number of animals was arrived at. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.	
Allocating animals to experimental groups	11	a. Give full details of how animals were allocated to experimental groups, including randomisation or matching if done. b. Describe the order in which the animals in the different experimental groups were treated and assessed.	
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).	
Statistical methods	13	a. Provide details of the statistical methods used for each analysis. b. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single neuron). c. Describe any methods used to assess whether the data met the assumptions of the statistical approach.	
RESULTS			
Baseline data	14	For each experimental group, report relevant characteristics and health status of animals (e.g. weight, microbiological status, and drug or test naïve) prior to treatment or testing. (This information can often be tabulated).	
Numbers analysed	15	a. Report the number of animals in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[2]). b. If any animals or data were not included in the analysis, explain why.	
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).	
Adverse events	17	a. Give details of all important adverse events in each experimental group. b. Describe any modifications to the experimental protocols made to reduce adverse events.	
DISCUSSION			
Interpretation/ scientific implications	18	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including any potential sources of bias, any limitations of the animal model, and the imprecision associated with the results[2]. c. Describe any implications of your experimental methods or findings for the replacement, refinement or reduction (the 3Rs) of the use of animals in research.	
Generalisability/ translation	19	Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.	
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.	

Резюме

На сегодняшний день, несмотря на высокую потребность, в большинстве конвенциональных виварием возможно проведение очень ограниченного числа хирургических исследований. К ним можно отнести, и то условно, только острые эксперименты с использованием грызунов.

Сопутствующие проблемы

Отсутствие экспериментальных лабораторий для проведения хирургических исследований надлежащего уровня порождает проблемы, выходящие за рамки собственно исследований. Создаются альтернативные площадки не контролируемых исследований и тренингов.

Перспективы

Согласно последнему анализу Evaluate Ltd, мировая отрасль медицинских устройств будет расти в совокупном годовом темпе на 5,6%, достигнет 595 миллиардов долларов к 2024 г.

Общие расходы на исследования и разработки в области медтехники будут расти ежегодно на 4,5% и к 2024 году составят 39 млрд. долларов.

Быстрорастущие области производства медицинских изделий - кардиология, диагностическая визуализация, ортопедия, офтальмология, общая и пластическая хирургия, эндоскопия, доставка лекарств, неврология и нейрохирургия, лечение диабета

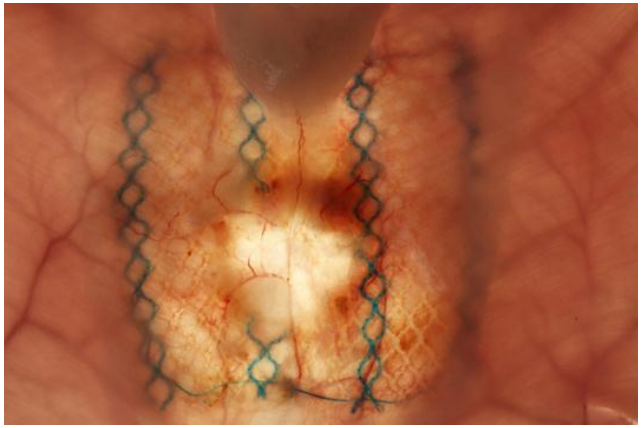
UNIKLINIK RWTH AACHEN

Klinik für Allgemein-, Viszeral- und Transplantationschirurgie

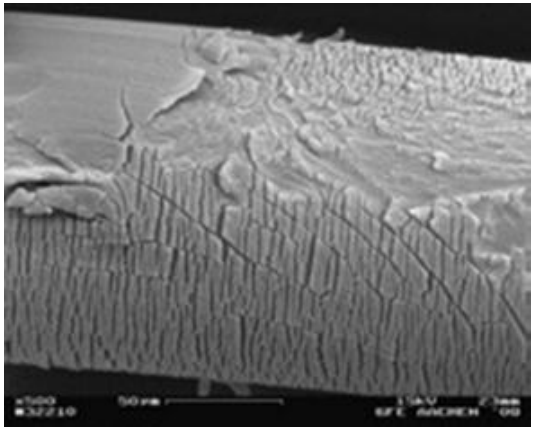
Результаты сотрудничества

- **80 совместных экспериментальных проектов**
- **17 диссертаций**
- **67 публикаций**
- **38 исследовательских грантов (DFG, INTAS, медицинские и фармакологические компании)**

Исследование имплантируемых биоматериалов



Центральный разрыв протеза



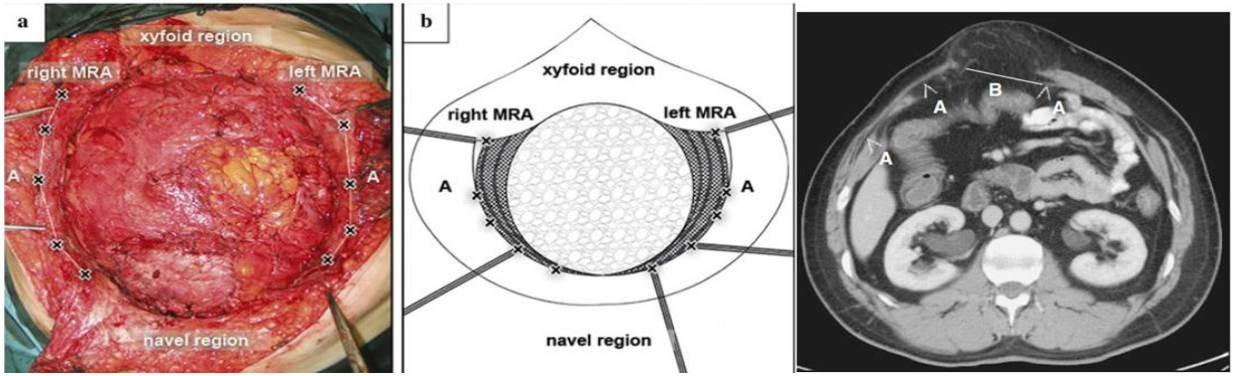
Оксидативное повреждение волокна

Hernia
DOI 10.1007/s10029-013-1197-1

CASE REPORT

Central rupture and bulging of low-weight polypropylene mesh following recurrent incisional sublay hernioplasty

M. Žuvela · D. Galun · A. Djurić-Stefanović · I. Palibrk · M. Petrović · M. Milićević



Изучение ранних биомаркеров ишемического повреждения кишки при странгуляционной непроходимости