IDEAL Collaboration

Conference 2016
Evaluating innovation in surgery and therapeutic technology: the IDEAL approach

7 April
St Catherine’s College, Oxford

www.ideal-collaboration.net
# IDEAL 2016 Conference Programme

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<td>9.00-9.10AM</td>
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<td>10.10-10.30AM</td>
<td><strong>Commissioning of innovation in the UK</strong></td>
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<td>- Is more evidence always better? The value of adding decision analytical modelling to the IDEAL framework. (C Tax, 0027).</td>
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<td>- Evaluation of innovation in radiation oncology: R-IDEAL. (H Verkooijen, 0013)</td>
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<td>- Small Simple Trials: A Strategy to Study Rare Surgical Conditions. (J Wright, 0014)</td>
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<td>12.50-1.50PM</td>
<td><strong>OXFORD INNOVATION SHOWCASE</strong></td>
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<td>11.10-11.30AM</td>
<td><strong>Long-term evaluation of the electronic retina – the last step of the IDEAL framework</strong></td>
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<td><strong>Clinical HIFU in Oxford: Thermal and Chemo-Ablation of Tumours</strong></td>
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<td>12.50-1.50PM</td>
<td><strong>LUNCH</strong> (Dining Hall)</td>
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### 1.50-3.35PM PARALLEL SESSION C
Bernard Sunley Lecture Theatre

**IDEAL: EVALUATING SURGICAL INNOVATION INTERNATIONAL EXAMPLES**  
Session Chair: Prof Peter McCulloch and Marion Campbell

1.50 - 2.10PM An innovative view on surgical research  
(Netherlands)  
Prof Maroeska Rovers

2.10-2.30PM Is Buxton’s Law still true? Evaluating evolving surgical techniques within pilot and full RCTs. IDEAL in practice (UK)  
Prof Jane Blazeby

2.30-2.50PM A multicenter IDEAL 2b study: Evaluation of HIFU ablation for uterine fibroids (China)  
Assoc Prof Joey Kwon

2:50-3:35PM SUBMITTED PAPERS (15 min presentations)

- Short-term cost-effectiveness of colonic stenting is lost at 90-day follow-up in patients with malignant large bowel obstruction. (S Sharma, 0015)
- Stereotactic body radiotherapy followed by surgery for unstable spinal metastases: Technical feasibility and safety study according to the IDEAL stages 1 and 2a. (H Verkooijen, 0017)
- Reconstruction of bladder defects with amniotic membrane - Step 1-2 of IDEAL recommendations of surgical innovation (D Barski, 0025)

### 3.50-5.30PM COFFEE & TEA (poster viewing in Room A)

### 3.50-3.50PM PARALLEL SESSION E
(Bernard Sunley Lecture Theatre)

**ROBOTICS + OTHER SURGICAL TECHNOLOGY**  
Session Chair: Dr Rick Kuntz and Prof Philipp Dahm

3.50 – 4.10PM Robotic Kidney Transplantation  
Prof Craig Rogers

4.10-4.30PM System Robotics in Urology: An IDEAL Perspective  
Prof Philipp Dahm

4.30-4.50PM Clinical integration and evolution of Transanal Total Mesorectal Excision: The IDEAL framework in practice  
Marta Penna

4:50-5:35PM SUBMITTED PAPERS (15 min presentations)

- Perioperative Outcomes, Health Care Costs and Survival After Robotic-assisted Versus Open Radical Cystectomy: A National Comparative Effectiveness Study (J Hu, 0019)
- Comparative Effectiveness of Cancer Control and Survival After Robotic Assisted versus Open Radical Prostatectomy (B Chughtai, 0020)
- Advancing the cause of Research Registration: The First 500 Registrations of the ResearchRegistry.com (R Agha, 0009)

### 3.50-5.30PM PARALLEL SESSION F
(Seminar Room C)

**REGULATION/COMMISSIONING/HTA AND POLICY(1)**  
Session chair: Prof Art Sedrakyan

1.50 – 2.10PM IDEAL and Devices  
Christopher Pennell

2.10 – 2.30PM IDEAL and the FDA  
Dr Danica Marinac-Dabic

2:35-3:35PM SUBMITTED PAPERS (15 min presentations)

- 3-Year Outcomes and Cost-Savings of Combined Endoscopic Laparoscopic Surgery (CELS) for Benign Colon Polyps (J. Milsom, 0016)
- Access to innovative treatments and device support during IDEAL stages 2b-4. (K Hutchison, 0003)
- MiCollar - A novel iPhone application to analyse cervical spine motion restriction with different size and type of cervical orthoses (R Ingleton 0029)
- Applying IDEAL: Early stage surgical innovation of a novel bio-wrap-assisted vasectomy reversal technique. (A Gudeloglu, 0036)

3.35-3.50PM COFFEE & TEA (poster viewing in Room A)

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### 3.50-5.30PM PARALLEL SESSION F
(Seminar Room C)

**REGULATION/COMMISSIONING/HTA AND POLICY(2)**  
Session Chair: Profs Art Sedrakyan and Bruce Campbell

3.50 - 4.15 IDEAL/specialist commissioning (UK)  
Dr Daphne Austin

4.15 – 4.35PM Using IDEAL in practical public health work (Canada)  
Dr Janet Martin

4.35 – 4.55PM Mind the (uncertainty) gap: A comparative analysis of HTA of robotic surgery (Canada)  
Dr Tammy Clifford

4:55-5:40PM SUBMITTED PAPERS (15 min presentations)

- The merits of decision modelling in the earliest stages of the IDEAL framework - the case of innovative bilateral DIEP flap surgery (J Grutters, 0012)
- Radical cystectomy with epidural anaesthesia – feasibility analysis using the IDEAL recommendations (H Gerullis,0032)
- Surgical trainee research collaboratives in the United Kingdom (A Kolias, 0010)
### PLENARY SESSION 2
Bernard Sunley Lecture Theatre

**POSTER PRIZE PRESENTED BY:** Riaz Agha *(Balliol College, Oxford and SpR Plastic Surgery)* and Natalie Blencowe *(NIHR Clinical Lecturer in Surgery, University of Bristol)*

**CLOSING REMARKS** – **Prof Peter McCulloch** *(Chair, IDEAL Collaboration & NDS, University of Oxford)*

### 7.30PM WINE RECEPTION FOLLOWED BY BANQUET IN DINING HALL
Dinner speaker: Dr Trish Groves, Head of Research, BMJ & Editor-in-chief, BMJ Open
“Gazing into the future of clinical research”

### LIST OF SPEAKERS IDEAL CONFERENCE 2016

#### SPEAKERS SESSION 2 (A/B):
- **Prof Guy Maddern** *(R.P. Jepson Professor of Surgery, University of Adelaide Discipline of Surgery, The Queen Elizabeth Hospital)*
- **Dr Gillian Lancaster** *(Senior Lecturer in Medical Statistics, University of Lancaster, UK)*
- **Prof Jenny Donovan** *(Professor of Social Medicine, University of Bristol, UK)*
- **Prof Freddie Hamdy** *(Nuffield Professor of Surgery and HoD NDS, Oxford, Professor of Urology and SITU Co-Director)*
- **Prof Peter Friend** *(Professor of Transplantation, NDS and Consultant Transplant and HPB Surgeon, Director Oxford Transplant Centre)*
- **Prof Robert MacLaren** *(Prof of Ophthalmology, University of Oxford)*
- **Mr Paul Lyon** *(Nuffield Department of Surgical Sciences, University of Oxford)*

#### SPEAKERS SESSION 3 (C/D):
- **Prof Maroeska Rovers** *(Professor of Evidence-based surgery, Radboudumc, The Netherlands)*
- **Prof Jane M Blazby** *(Director Bristol Centre for Surgical Research, University of Bristol, UK)*
- **Assoc Prof Joey Kwon** *(Associate Professor, Executive Associate Director of Chinese Cochrane Center, Chinese Evidence-Based Medicine Center)*
- **Christopher Pennell** *(MD, Maimonides Medical Center, Brooklyn, NY)*
- **Dr Danica Marinac-Dabic** *(Director of the Division of Epidemiology (FDA), Center for Devices and Radiological Health (CDRH))*

#### SPEAKERS SESSION 4 (E/F):
- **Prof Craig Rogers** *(Director of Renal Surgery, Henry Ford Hospital, Director of Urologic Oncology, Henry Ford West Bloomfield, Co-Director, VUI Center for Outcomes Research Analytics and Evaluation, Clinical Associate Professor of Urology, Wayne State University School of Medicine, Vattikuti Urology Institute, Henry Ford Health System, US)*
- **Prof Philipp Dahm** *(Professor of Urology, University of Minnesota and Minneapolis VAMC/Coordinating Editor, Cochrane Urology)*
- **Marta Penna** *(Colorectal research fellow, NDS, University of Oxford and Oxford University Hospitals)*
- **Dr Daphne Austin** *(Right Care, UK)*
- **Dr Janet Martin** *(MD, Director, High Impact Technology Evaluation Centre (HiTEC) London Health Sciences Centre, University of Western Ontario, Canada)*
- **Dr Tammy Clifford** *(Vice President, Medical Device and Rapid Response Programs, Canadian Agency for Drugs and Technologies in Health)*

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IDEAL Conference Vision

The IDEAL conference 2016 will examine how to create a pathway for the effective scientific evaluation of modern surgical treatments, with a focus on the potential of the IDEAL Framework and Recommendations as an evaluation template.

The effective scientific evaluation of modern surgery and other invasive therapeutic interventions based on technology has become an increasingly important issue because of the lack of a clear pathway and the rate at which new technological innovation has increased. Surgical treatments can often be complex and are challenging to evaluate in a way which provides valid evidence of safety, efficacy and cost-effectiveness. This imposes problems on regulators and purchasers of treatment who need to make evidence-based decisions about them.

The IDEAL Scientific Committee

Peter McCulloch, Allison Hirst, Art Sedrakyan, Philipp Dahm, David Beard, Bruce Campbell, Jonathan Cook, Sean Kehoe, Sally Hopewell, Guy Maddern, Bill Summerskill

Sponsors & Supporters

Many thanks to the following organisations for sponsoring/supporting this years conference:
Abstracts

This year's abstraction submissions.

Oral Presentations

0003

Access to innovative treatments and device support during IDEAL stages 2b-4.

Katrina Hutchison
Monash University, Melbourne, Australia

A strength of the IDEAL framework is the commitment to long-term studies and the use of registries. This helps address problems that arise during diffusion (IDEAL phases 2b - 4) when promising procedures move beyond the initial pioneers and carefully selected patients. It is widely recognised that uptake by a broader surgeon base for wider indications can be associated with higher complication rates, but two other sorts of issues, arising most notably for new devices, have received less attention:

(1) Justice and access-to-care issues associated with rolling out new interventions.
(2) The need for scalable models of technical support for innovative devices.

This paper explains how and why diffusion processes can influence patterns of access to new procedures and lead to inequities; and provides an account of why technical support protocols must be carefully developed for broad-scale deployment. Notably, once the clinicians and engineers who pioneered the technology can no longer provide follow-up support to increasing numbers of recipients, industry may step in to provide technical support, with implications for outcomes and cost and potential for conflicts of interest. As it stands, the IDEAL framework does not explicitly recognise issues of fair access to care and models for technical support. These issues may appear to be beyond the remit of IDEAL, but this shouldn't be the case: given their implications for both the clinical effectiveness and cost-effectiveness of interventions, these issues should be regarded as critical to robust evaluation. The discussion is informed by experiences with robotic surgery and vascular devices.

0009

Advancing the cause of Research Registration: The First 500 Registrations of the ResearchRegistry.com

Riaz Agha1, Alexander J. Fowler1, Christopher Limb2, Yasser Al Omran3, Harkiran Sagoo4, Kiron Koshy5, Daniyal Jafree5, Mohammed Omer Anwar5, Peter McCulloch6, Dennis P. Orgill7

1Guys and St Thomas' NHS Foundation Trust, London, UK, 2Royal Sussex County Hospital, Brighton, UK, 3Barts and The London School of Medicine and Dentistry, London, UK, 4GKT School of Medical Education, London, UK, 5University College London, London, UK, 6Nuffield Department of Surgery, University of Oxford, Oxford, UK, 7Harvard Medical School, Boston, MA, USA

Introduction: Previously, registries have focused on the registration of trials. However, many study types are under registered, despite a mandate from the Declaration of Helsinki 2013 to register all studies involving human participants. We developed a registry to increase registration of studies, including those not possible to register on existing registries.

Methods: A new global research registry was launched in February 2015. This allows registration of any research involving human participants and enables retrospective registration. We monitored number and type of registrations, country of origin and a quality score, which was developed based on Austin Bradford-Hill's earlier work, and retrospectively assessed. Registrations identified as inappropriate by data curation were removed from the database or modified. All registrations from
launch of the registry (February 2015) to October 2015, when 500 studies were registered, are
included in this analysis.

**Results:** 500 studies were registered and these included a wide range of article types: from first-in-
man case reports to observational and interventional studies. The commonest study type was
retrospective cohort and Turkey was the top source of submissions. 1.7 million patients were
registered in included studies. Retrospective data curation found 90 studies to be inappropriate, of
which 80 required correction. Median quality scores increased over the period analysed (44% to
100%, R=0.77).

**Conclusion:** The Research Registry has established itself as a new registry with a clear focus on
areas not well represented in existing registries. Going forward, our plan is to continue developing the
platform in line with user feedback and usability studies.

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### Surgical trainee research collaboratives in the United Kingdom

**Angelos G Kolias**, Aimun AB Jamjoom, Pho NH Phan, Peter JA Hutchinson

**Division of Neurosurgery, Addenbrooke’s Hospital & University of Cambridge, Cambridge, UK,**
**Centre for Clinical Brain Sciences, University of Edinburgh, Edinburgh, UK,**
**Medical School, University of Warwick, Coventry, UK**

**Objectives:** Over the last seven years, surgical trainee research collaboratives have sprung up all
over the United Kingdom. In this study, we aimed to analyse their research activity and publication
output.

**Design:** An observational bibliometric study.

**Methods:** Primary datapoints were identified for each collaborative including surgical sub-specialty,
numbers and types of projects. For published articles, additional data-points including study
population size, journal impact factor, number of citations and evidence level (Oxford CEBM “Levels
of Evidence” hierarchy) to applicable articles were collected.

**Results:** A total of 24 collaboratives met our inclusion criteria with a portfolio of 80 projects. The
project types included audit (46%), randomized clinical trial (16%), surveys (16%), cohort studies
(10%), systematic reviews (2.5%) and other or unidentifiable (9.5%). A total of 35 publications were
identified of which just over half (54%) were original research articles. The median size of studied
population was 540 patients with a range from 108-3138. The published works provided a varied
compilation of evidence levels ranging from 1b-5 with a median level of 2b. The West Midlands
Research Collaborative had the highest number of publications (13), citations (130) and h-index (5).

**Conclusion:** The experience of UK-based trainee research collaboratives provides useful insights for
surgeons and policy makers in global healthcare systems on the value and feasibility of trainee-driven
high quality surgical research.

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### The merits of decision modeling in the earliest stages of the IDEAL framework - the
  case of innovative bilateral DIEP flap surgery

**Janneke Grutters**, Jeroen Gerrits, Leo Schultze Kool, Dietmar Ulrich, Maroeska Rovers,
Stefan Hummelink

**Radboudumc, Nijmegen, The Netherlands**

**Background:** IDEAL improves the evidence base of available surgical innovations. However, the
development of such innovations and collection of evidence is costly. Surgical innovation can provide
more value for money if innovations are evaluated in an early stage, where it can inform the decision
whether to develop the innovation. We illustrate how decision modeling can be readily adopted at the
earliest stages (0-1) of the IDEAL framework, using innovative bilateral breast reconstruction as an example.

**Methods:** Using decision modeling, we quantified expected costs and quality-adjusted life years (QALYs) of the current standard of deep inferior epigastric perforator (DIEP) flap breast reconstruction surgery, compared with an innovation aimed at reducing complications and surgery time. We first explored the maximum impact of eliminating all complications. Second, we modeled three scenarios with varying complication and surgery time reduction. Third, in a threshold analysis we estimated the maximum price of the innovation.

**Results:** If the innovation prevents all complications, it adds 0.0079 QALYs and saves €600 per patient. Scenario analysis showed cost savings between €256 and €828 per patient, with QALY gains up to 0.002. If the innovation reduces 50% of complications and 45 minutes of surgery time, it may cost up to €1122 per surgery.

**Discussion:** In a field struggling with cost containment, decision modeling can prove key to separating promising innovations from costly failures in an early stage. In this example, decision modeling showed that it seems worthwhile to develop the innovation because it potentially saves money, with a small quality of life gain.

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**Evaluation of innovation in radiation oncology: R-IDEAL**

Helena Verkooijen¹, Linda Kerkmeijer¹, Dave Fuller², Robbert Huddart³, Corinne Faivre-Finn⁴, Marcel Verheij⁵, Arjun Sahgal⁶, Emma Hall⁶, Marco van Vulpen¹,²

¹UMC Utrecht, Utrecht, The Netherlands, ²MD Anderson Cancer Center, Houston, USA, ³The Institute of Cancer Research, London, UK, ⁴The Christie NHS Foundation Trust, Manchester, UK, ⁵Netherlands Cancer Institute, Amsterdam, The Netherlands, ⁶Sunnybrook Health Sciences Center, Toronto, Canada

The pace of innovation in radiation oncology is high, and the window of opportunity for evaluation narrow. Financial incentives, industry pressure and patients’ demand for ‘high-tech’ treatments have led to widespread implementation of innovations without robust evidence of improved outcomes. Examples include proton therapy and intensity modulated radiotherapy.

Like surgery, evaluation of innovations in radiation oncology is complicated by continuous technical development, team and operator dependence, and differences in quality control. Contrary to surgery, radiotherapy innovations may be used in various ways, eg. at different tumor sites and with different aims, including margin reduction, treatment adaptation, and dose escalation. Also, the effect of radiation treatment can be modeled, allowing better prediction of potential benefits and improved patient selection. We adapted the IDEAL framework to fit the radiation oncology setting. Key distinctive features of ‘R-IDEAL’ include the important role of predicate and modeling studies (stage 0), randomization at an early stage in the development of the technology, and long-term follow up for late toxicity.

R-IDEAL is applied in the evaluation of a recent innovation in radiation oncology, the MRI guided linear accelerator (MR-Linac). MR-Linac combines a radiotherapy accelerator with 1.5 Tesla MRI, allowing accurate targeting, dose escalation, and margin reduction, and is expected to lead to an increase in hypofractionated radiation treatments, improved tumor control, higher cure rates and less toxicity. An international consortium, with participants from nine large cancer institutes from Europe and the US, has adopted the R-IDEAL framework to work towards coordinated, evidence-based introduction of the MR-Linac.
Small Simple Trials: A Strategy to Study Rare Surgical Condition.

James Wright  
*University of Oxford, Oxford, UK*

Many surgical conditions are relatively rare making surgical trials logistically difficult. Furthermore many surgeons and surgical centres are relatively inexperienced in the procedures of clinical trials. Large simple trials have enormous sample sizes, broad entry criteria, minimal data collection, and objective end points. Modifying that concept, small simple trials are a strategy to address rare surgical disease. The choice of a small simple trial influences both the study question, as well as trial administration. Study questions for small simple trials must have straightforward and non-controversial diagnosable conditions, treatments that are easy to proficiently deliver, short-term straightforward and ideally objective outcomes. In addition to minimal data collection, as many aspects of trial management as possible are centralised to address the issue of site trial (in)experience including ethical review, contract management, and arrangements for patient follow up. Small simple trials enrol few patients in many centres (rather than many patients in a few centres) to achieve sample size, but also reduce the burden on centres. This model was used to enrol 90 children with simple bone cysts in 23 centres in less than 2 years to address an important clinical question comparing two intra-lesional treatments. While still prone to baseline prognostic differences and not amenable to all study questions, small simple trials are one strategy to study relatively rare surgical diseases.

Short-term cost-effectiveness of colonic stenting is lost at 90-day follow-up in patients with malignant large bowel obstruction

Heather Yeo, Jonathan Abelson, Jeffrey Milsom, Sam Sharma, Art Sedrakyan  
*New York Presbyterian Hospital - Weill Cornell Medicine, New York, NY, USA*

Introduction: Stenting in patients with malignant large bowel obstruction (MLBO) is an established device-based practice (IDEAL Stage 4). The cost-effectiveness is known at 30-day follow-up; real-world 90-day outcomes, however, are unknown. We report 90-day outcomes using a large database serving as a registry.

Methods: A comprehensive all-age, all-payer, statewide database was used to group patients treated emergently for MLBO into 4 management groups: Group1 (stenting); Group2 (stenting and resection within 14 days); Group3 (resection with primary anastomosis); and Group4 (stoma creation with/without resection).

Results: 2,435 patients were treated for MLBO from 2009-2013: (Group1=235; Group2=57; Group3=1,388; Group4=755). Given the small number in Group2, this group was removed from analysis. There were no differences between age, gender, or comorbidity. High-volume centers were more likely to perform stenting compared to low-volume centers (19.4% vs 3.5%;p<0.01). There were no differences in major complication rates during the index hospitalization and 90-days post-procedure. Group1 had the highest rate of 90-day readmissions (42.6% vs 26.9% and 30.3%;p<0.01) and reoperations (17.0% vs. 2.7%, and 4.0%;p<0.01) compared to Group3 and 4. While total median charges were significantly lower for Group1 during the index hospitalization(p<0.01), there was no difference at 90-days(p=0.11).

Conclusion: In this IDEAL Stage 4 study we found that stenting remains an uncommon intervention for patients treated emergently for MLBO. 30-day benefits of stenting are eclipsed at 90-days owing to higher readmission and reoperations rates. New technology development is needed to improve longer-term outcomes of stenting. Testing should be performed using trials nested within registries with longer-term follow-up.
3-Year Outcomes and Cost-Savings of Combined Endoscopic Laparoscopic Surgery (CELS) for Benign Colon Polyps

Maria Kiely¹, Sam Sharma², Art Sedrakyan², James Yoo¹, Heather Yeo², Jonathan Abelson², Jeffrey Milsom²
¹Tufts Medical Center, Boston, MA, USA, ²New York Presbyterian Hospital - Weill Cornell Medicine, New York, NY, USA

Introduction: CELS is an alternative approach to bowel resection for the management of benign colon polyps that fail endoscopic removal. The technology was developed by Cornell surgeons (JM) and has been used by a larger group of investigators. We report a comprehensive analysis of long-term outcomes and costs comparing CELS to traditional surgical options.

Methods: We performed an IDEAL Stage 2a-2b study to evaluate 3-year outcomes in 102 patients with colon polyps that underwent CELS at a major academic center from 2003-2014. Analysis of outcomes utilized two-sample independent t-test and Fisher’s exact test. Preoperative factors that predict risk of conversion to partial bowel resection were determined through multivariate linear/logistic regression modeling. A non-recursive decision tree was designed and interrogated to determine intention to treat (ITT) costing estimates for CELS versus laparoscopic/open resection approaches.

Results: 62% of cases underwent CELS. Complication rates were significantly higher in the conversion to resection group versus the CELS group (28% vs. 2%, p<0.0005). Median LOS for successful CELS was significantly shorter compared to ITT CELS, laparoscopic and open resection (1day vs. 2days vs. 5days vs. 6days, p<0.00005). The perioperative cost savings for ITT CELS compared to laparoscopic and open resection was $4,636 and $10,530, respectively. There was no difference between groups in postoperative colonoscopy requirement.

Conclusions: CELS is at IDEAL Stage 2a-2b and is less morbid and costly than bowel resection for colon polyps that fail endoscopic removal. Widespread use of CELS could result in large cost savings across the population while maintaining clinically equivalent outcomes.

Stereotactic body radiotherapy followed by surgery for unstable spinal metastases: Technical feasibility and safety study according to the IDEAL stages 1 and 2a.

Anne Versteeg¹, Joanne van der Velden², Helena Verkooijen², Wietse Eppinga², Nicolien Kasperts², Sophie Gerlich², Cumhur Oner¹, Marco van Vulpen², Jorrit-Jan Verlaan¹
¹University Medical Center Utrecht, dept. of Orthopedic Surgery, Utrecht, The Netherlands, ²University Medical Center Utrecht, dept. of Radiation Oncology, Utrecht, The Netherlands

Objective: Standard treatment of unstable vertebral metastases includes stabilizing surgery followed by radiotherapy after an interval of at least two-weeks. This interval is required for adequate wound healing, but delays time to radiotherapy-induced pain relief and local tumor control. Most radiotherapy schemes require multiple hospital visits, and induce inadequate pain relief in 60-70% of patients. Alternative treatment strategies with faster and better pain relief and less hospital visits are needed. Stereotactic body radiotherapy (SBRT) can avoid irradiation of the surgical area to prevent impaired wound healing. This study aims to assess safety and feasibility of single fraction SBRT followed by surgical stabilization within 48-hours for unstable spinal metastases.

Methods: Thirteen patients will be included in this IDEAL stage I/IIa study feasibility and safety study. SBRT is used to deliver 18Gy on the metastasis and 8Gy on the vertebra. Surgical stabilization follows within 48-hours according to routine practice. Information on demographic and clinical characteristics, treatment, toxicity (grade 3-4), complications and survival is systematically collected
**Results:** So far, six consecutive patients have successfully been treated, none of whom experienced wound complications or toxicity. Patients experienced no discomfort during SBRT. No technical modifications were made.

**Conclusion:** SBRT followed by immediate surgical stabilization is safe and feasible in patients with unstable vertebral metastases. A randomized stage IIb study is being planned, based on the current results, to evaluate early effectiveness of the new intervention compared to standard treatment.

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**Perioperative Outcomes, Health Care Costs and Survival After Robotic-assisted Versus Open Radical Cystectomy: A National Comparative Effectiveness Study**

Jim Hu¹, Bilal Chughtai¹, Padraic O'Malley¹, Joshua Halpern¹, Jialin Mao², Douglas Scherr¹, Dawn Hershman³, Jason Wright³, Art Sedrakyan²

¹Department of Urology, Weill Cornell Medical College-New York Presbyterian Hospital, New York, NY, USA, ²Department of Healthcare Policy and Research, Weill Cornell Medical College-New York Presbyterian Hospital, New York, NY, USA, ³Herbert Irving Comprehensive Cancer Center, Columbia University College of Physicians and Surgeons, New York, NY, USA

Background: Radical cystectomy is the gold-standard management for muscle-invasive bladder cancer. There is debate concerning the comparative effectiveness of robotic-assisted (RARC) versus open radical cystectomy (ORC).

**Objective:** IDEALS Phase 3 study (“Assessment”): Compare utilization, perioperative, cost and survival outcomes of RARC versus ORC in nationally representative database.

**Design:** Bladder urothelial carcinoma treated with RARC (n=439) or ORC (n=7308) during 2002-2012 using the Surveillance, Epidemiology, and End Results Program (SEER)-Medicare linked data.

**Outcomes and Analysis:** Propensity score matching used to compare perioperative and survival outcomes, including lymph node yield (LNY), perioperative complications and healthcare costs.

**Results:** RARC (n=385) increased from 0.7% of radical cystectomies in 2002 to 18.5% in 2012 (p<0.001). RARC was associated with greater LNY with 41.5% vs. 34.9% having ≥10 lymph nodes removed (RR 1.1, 95% CI 1.01-1.22, p=0.03) and shorter mean length of hospitalization at 10.1 (± SD 7.1) days vs. 11.2 (±8.6) days (p=0.004). Inpatient costs were similar, RARC was associated with increased home healthcare utilization (RR 1.14, 95% CI 1.04-1.26, p=0.009) and higher 30 (p<0.01) and 90-day (p<0.01) costs. Median follow-up of 21 months (IQR 6-52), overall survival (HR 0.88, 95% CI 0.74-1.05) and cancer-specific survival (HR 0.91, 95% CI 0.66-1.26) were similar.

**Conclusions:** RARC provides equivalent perioperative and middle-term outcomes to ORC. As an IDEALS Phase 3 study, this study demonstrates the early and middle-term clinical outcomes and cost effectiveness of the robotic approach. It furthermore highlights the need for additional long-term and randomized studies for continued comparative effectiveness assessment of RARC vs. ORC.

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**Comparative Effectiveness of Cancer Control and Survival After Robotic Assisted versus Open Radical Prostatectomy**

Jim Hu¹, Bilal Chughtai¹, Padraic O'Malley¹, Abby Isaacs², Jason Wright³,⁴, Dawn Hershman⁵,⁴, Art Sedrakyan²

¹Department of Urology, Weill Cornell Medical College-New York Presbyterian Hospital, New
Importance: Robotic-assisted surgery has been rapidly adopted in the U.S. for treatment of prostate cancer (PCa), largely driven by market forces and patient preference. Debate exists whether it offers significantly improved outcomes to justify higher costs.

Objective: IDEALS Phase 3-4 study ("Assessment" & "Long-term study"): Examine comparative effectiveness of robotic assisted (RARP) versus open radical prostatectomy (ORP) in cancer control and survival in nationally representative population.

Design: Population based observational cohort study of PCa patients undergoing RARP and ORP during 2003 to 2012 captured in Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database.

Outcomes and Analysis: Propensity score matching and time to event analysis used to compare all-cause mortality, PCa-specific mortality and use of additional treatment following RARP and ORP.

Results: 6,430 RARP and 9,161 ORP were performed during 2003 to 2012. RARP increased in use from 13.6% in 2003 to 72.6% in 2011. Median follow-up 6.5 years (IQR 5.2-7.9). RARP associated with lower risk of all-cause mortality (HR 0.79 [0.67-0.93]) but similar cancer specific mortality (HR 0.73, [0.46-1.15]) versus ORP. RARP associated with less use of post-operative androgen deprivation and radiation therapy (HR 0.74 95% CI 0.67-0.81).

Conclusions: RARP associated with better intermediate cancer control, evidenced by less use of additional therapies and better overall survival. An IDEALS Phase 3-4 study, this highlights need for longer-term follow-up to assess differences in cancer specific survival, which was similar during our follow-up. This study provides reassurance regarding the adoption of a more expensive technology in the absence of randomized controlled trials.
postoperative complications were assessed. Histological and immunohistological analyses were performed to look for the degradation of AM, graft rejection and the ingrowth of surrounding tissue 7, 21 and 42 days after the implantation.

Results: In the case of VVF-repair a recurrent fistula was detected 8 month after the surgery. In the animal experiment two rats died due to sepsis. All other rats survived, had no severe complications and showed no signs of leakage. The bladder capacity did not change over time. First signs of AM degradation were found 7 days postoperatively and this process was completed between 21 and 42 days. No severe signs of inflammation were detected.

Conclusions: For the first time we applied AM-assisted bladder repair. Further allogenic human cohort and randomised studies are necessary to proof the possible indications.

Is more evidence always better? The value of adding decision analytical modeling to the IDEAL framework

Casper Tax¹, Paulien Govaert², Janneke Grutters¹,³, Maroeska Rovers¹,³
¹Radboudumc Institute for Health Sciences, department of Operating Rooms, Nijmegen, Gelderland, The Netherlands, ²Master student Biomedical Science Radboud University, Nijmegen, Gelderland, The Netherlands, ³Radboudumc Institute for Health Sciences, department of Health Evidence, Nijmegen, Gelderland, The Netherlands

Background: Randomized clinical trials (RCT) are the golden standard to evaluate the effectiveness of surgical interventions. But how much evidence is needed to assess (cost-)effectiveness and is further research warranted? Decision modeling can provide valuable insight in these answers.

To study the merits of decision analytical modeling as compared to another RCT, we analyzed the (cost-)effectiveness of laparoscopic (LDP) versus open distal pancreatectomy (ODP).

Methods: We modeled the clinical pathway for LPD and ODP in a decision-tree. Estimates and confidence intervals regarding both the effectiveness and costs were based on current literature and expert opinion.

We studied whether LPD or ODP appears to be most (cost-)effective, and analyzed at which parameter value the (cost-)effectiveness changes. Furthermore, we performed sensitivity analyses to study the robustness of the results.

Results: Our model shows that LDP appears to be cost-effective over ODP under almost all circumstances. Only if the 30day mortality rate is 2.6 times higher in LDP compared to ODP, pneumonia occurs in 41% of LDP cases, incisional hernias occur in 24% which all need surgical repair, 78% needs a conversion, or if LDP patients would have a 5.8 days longer in hospital stay than ODP patients then LDP would be less (cost-)effective. Taking all confidence intervals into account, LDP has a probability of 100% on being (cost-) effective.

Conclusion: LDP is more cost-effective than ODP and a new trial will probably not change this view. This example shows that decision analytical modeling can further inform the IDEAL framework, and precludes further research waste.

Pogressing through IDEAL: When is the right time to move from observational to randomised studies? A case study of REBOA

Jan Jansen¹,², Marion Campbell¹, (on behalf of the UK-REBOA Study Investigators). ¹
¹Health Services Research Unit, University of Aberdeen, Aberdeen, UK, ²Departments of Surgery and Intensive Care Medicine, Aberdeen Royal Infirmary, Aberdeen, UK
The IDEAL framework recommends that the evaluation of novel interventions should progress through defined stages, but there is limited guidance on when to progress from observational studies to randomised trials.

This abstract describes our experience of designing a study to evaluate REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta), a complex interventional procedure for exsanguinating haemorrhage caused by traumatic injury.

To date, REBOA has undergone evaluation at IDEAL stages 1, 2a, and 2b, although the 2b evaluation comprised a single, retrospective, propensity score matched study. These studies reported conflicting results, raising some concerns about the safety of the procedure.

Feedback from potential funders, in response to an outline proposal for a prospective observational study (to undertake a more robust 2b evaluation), questioned whether such a design would provide convincing evidence of safety or efficacy, even with case mix adjustment.

A randomised study is the optimal method to provide a truly fair comparison but identifying when there is enough observational data to inform the design of a conventional randomised trial is challenging.

We now propose a combined IDEAL stage 2b/3 study. The design incorporates a feasibility phase, in keeping with a stage 2b study, to gather empirical data prior to progression to a full trial, with a Bayesian group sequential design, in keeping with a stage 3 study.

Our experiences highlight the difficulties of knowing when to progress from observational to randomised evaluations, and that such decisions can be influenced by a number of factors, including the recommendations of potential funders.

MiCollar - A novel iPhone application to analyse cervical spine motion restriction with different size and type of cervical orthoses

Rose Ingleton\textsuperscript{2}, Claudia Ashton\textsuperscript{3}, Jonathan Bull\textsuperscript{1}, Vejay Vakharia\textsuperscript{1}

\textsuperscript{1}Department of Neurosurgery, Royal London Hospitals, London, UK, \textsuperscript{2}King George Hospital, London, UK, \textsuperscript{3}Milton Keynes Hospital, Milton Keynes, UK

Orthotic collars are used to manage cervical spine injuries in the acute pre-hospital setting and as a definitive treatment strategy. Patients must be fitted with an appropriately sized orthosis to ensure adequate cervical immobilisation.

This study aims to validate a new iPhone application to objectively quantify range of cervical motion and detect inadequately sized collars.

By using the iPhone's inbuilt gyroscope, we can measure motion of the cervical spine in three planes - flexion/extension (FE), lateral flexion (LF) and axial rotation (AR). These parameters were measured at baseline movement and with two different cervical collars: 1) Laerdal Stifneck (sizes short, regular, tall) and 2) Aspen Vista (sizes 1, 4, 6).

The results of this study show statistically significant variation in cervical spine range of motion between optimally and poorly sized collars. The mean degrees of cervical motion without an orthotic device was 112\textdegree (FE), 103\textdegree (LF) and 148\textdegree (AR). Optimum Laerdal collar selection allowed mean degrees of cervical motion of 42.9\textdegree (FE), 45.2\textdegree (LF) and 60.2\textdegree (AR). Optimum Vista collar selection allowed 48.9\textdegree (FE), 65.8\textdegree (LF) and 77.4\textdegree (AR). An incorrectly sized Laerdal collar allowed 58.0\textdegree (FE), 59.1\textdegree (LF) and 89.1\textdegree (AR) compared to an incorrectly sized Vista collar of 68.9\textdegree (FE), 79.4\textdegree (LF) and 107.8\textdegree (AR).

We demonstrate that the iCollar application can objectively quantify cervical motion between different collar types/sizes. This can ensure optimal collar selection so that adequate motion restriction is achieved. This application can also be used to identify poorly fitting and inadequately sized cervical collars.
The X-Bolt Dynamic Hip Plating System: evaluating a novel surgical device for hip fracture surgery

Miguel Fernandez¹, Juul Acten², Nick Parsons¹, Matthew Costa², Xavier Griffin²
¹Warwick Medical School, Warwick, UK, ²Oxford University, Oxford, UK

We describe the challenges faced in the assessment of a novel surgical device, the X-Bolt, for the treatment of hip fractures from IDEAL stage 2a to 3. The X-Bolt represents an innovation compared with the current standard of care device, the Sliding Hip Screw.

Assessment began at Stage with a consecutive series of 25 participants in a single centre with 'enthusiast' surgeons in 2008. Challenges here were around appropriate surgeon training and support, developer and distributor inexperience in the NHS market place and institutional resistance to change.

We conducted a single centre randomised, standard of care controlled feasibility trial. This was a pragmatic study to test feasibility - inclusion criteria were wide, multiple operating surgeons were involved and follow-up mirrored clinical practice. Ethical approval was granted by NRES, who strongly supported the stepwise progression of the research effort. Once institutional friction had dissipated collaboration with the developer led to successful accrual. Stakeholders’ concerns were allayed through a demonstrably strong governance framework that supports randomised trials and trials units.

The feasibility study informed Stage 3 - a multicentre randomised trial to assess clinical and cost effectiveness - recruitment is planned to begin in April 2016. The main threat to the delivery of the trial is assessed to be surgeon compliance with recruitment. That same institutional friction is now expected across multiple sites. Strategies to counter this risk include early procurement of the device at centres, the recruitment of centres with a track record in trauma trials and the fostering of PIs.

Radical cystectomy in epidural anaesthesia – feasibility analysis using the IDEAL recommendations

Holger Gerullis¹, Thorsten Ecke², Carsten Bantel¹, Andreas Weyland¹, Dimitri Barski³, Jens Uphoff¹, Friedhelm Wawroschek¹, Alexander Winter¹
¹University of Oldenburg, Oldenburg, Germany, ²HELIOS Hospital Bad Saarow, Bad Saarow, Germany, ³Lukas Hospital Neuss, Neuss, Germany

Objective: To describe our experience with radical cystectomy under epidural anaesthesia and to classify this method for the first time according to the IDEAL recommendations for surgical innovations. Material and Methods: Medical records of 3 patients who underwent the procedure were retrospectively evaluated with focus on clinical data, intraoperative and perioperative parameters and postoperative complications. A literature review of recent reports of this technique has been performed and the method has been evaluated using the IDEAL criteria in order to define its current status of evidence. Results: The procedure was performed under epidural anaesthesia in three male patients with a mean age of 73 years (range: 66–79) and ASA Score of II (n=1) and III (n=2). Surgical time ranged from 159 to 261 min. Mean intraoperative blood loss was 1000 ml (700-1300 ml) requiring no perioperative transfusions. All patients stayed one day at Intensive Care Unit, mean overall hospital stay was 19 days. Only minor complications were documented. The current report according to IDEAL corresponds to stage 1 whereas the entire method provides a case series ranking the procedure at stage 2a. Conclusions: In this study we confirm functional results of the previously described technique as a feasible and applicable method for selected indications. The highest level for the method reaches 2a (D) according to IDEAL.
Applying ideal: early stage surgical innovation of a novel bio-wrap-assisted vasectomy reversal technique

Ahmet Gudeloglu¹, Jamin Brahmbhatt², Sijo Parekattil²
¹Memorial Ankara Hospital, Ankara, Turkey, ²The PUR CLINIC, Clermont, USA

Objectives: Microsurgical vasovasostomy (VV) failures have been attributed to granuloma/scar formation at the anastomosis site. A previous rodent study has shown that using a bio-wrap to cover the VV site reduces granuloma/scar formation. We report the early stage investigation of a novel bio-wrap assisted modified single layer robotic microsurgical vasovasostomy (RMV) technique.

Materials & Methods: We obtained IRB approval for four RMV patient cases and performed a modified single layer vasal anastomosis utilizing five double arm 10-0 nylon sutures in all cases. The bio-inert matrix material (Axogen Inc., Alachua, FL) was placed around the anastomosis site and anchored using two 9-0 nylon sutures to the muscularis of the vas deferens. Preoperative and postoperative pain was assessed using an externally validated pain QOL impact score (PIQ-6). Semen analyses were obtained at the second and fifth months postop.

Results: Three bilateral RMV and 1 crossover unilateral RMV procedures were performed (12/2012-3/2013). Median duration from vasectomy was 4.5 years (1 – 9). Median follow up was 8 months. Patency (> 1 million motile sperm per ejaculate) was achieved in all 3 bilateral RMV patients. All four patients had a significant reduction in pain (78, 78, 69, 68 to 57, 52, 44, 54, respectively at 6 month follow up).

Conclusion: Based on an IDEAL Stage 1 study, bio-wrap assisted modified single layer robotic microsurgical vasovasostomy is safe, feasible and has promising preliminary outcomes with regards to semen parameters meritng further investigation.

Posters

Matching trial design decisions to the needs of those you hope will use the results: the PRECIS-2 tool

Kirsty Loudon¹, Merrick Zwarenstein², Frank Sullivan³, Peter Donnan⁴, Shaun Treweek⁵
¹University of Stirling, Stirling, UK, ²Western University, London, Ontario, Canada, ³University of Toronto, Toronto, Ontario, Canada, ⁴University of Dundee, Dundee, Tayside, UK, ⁵University of Aberdeen, Aberdeen, Grampian, UK

Randomised trials are difficult and costly. Like most things that are hard, the effort expended is only worth it because we hope to make a difference. Sadly, the benefit to potential users such as patients, healthcare professionals and policy makers is often smaller than it should be because trial design decisions reduced the relevance of the trial to users.

PRECIS-2 is a tool designed to help trialists match their design decisions to the information needs of those they hope will use the trial results. PRECIS-2 was developed in collaboration with over 80 international trialists, methodologists and others to produce a tool that supports improved design insight for trialists.

PRECIS-2 has a wheel format with nine design domains including Eligibility, Recruitment, Setting and Primary outcome. One domain - Organisation - is explicitly aimed at making trialists consider the resource requirements their intervention will place on health care systems if it were to be rolled out into routine care, the intention being to think about implementation at the design stage. The highly visual presentation makes inconsistent decision-making immediately obvious; it also highlights differences of opinion between trial team members.
The IDEAL framework was created to improve the quality of research in surgery. It is proposed that PRECIS-2 could be part of this framework to design these complex intervention trials. We will present the tool, explain how to use it and show examples of how it has been used already. This work is part of the Trial Forge initiative to improve trial efficiency.

The GASTROS Study: Standardising Outcome Reporting in Gastric Cancer Surgery Research

Bilal Alkhaffaf¹ 2, Iain Bruce¹ 2, Anne-Marie Glenny², Paula Williamson³ 2, Jane Blazeby⁴

¹Central Manchester University Hospitals NHS Foundation Trust, Manchester, UK, ²University of Manchester, Manchester, UK, ³University of Liverpool, Liverpool, UK, ⁴University of Bristol, Bristol, UK

Aims: Gastrectomy, the mainstay of curative treatment for gastric cancer, is associated with significant complications. The process of identifying surgical approaches which minimise these risks and improve overall survival includes the ability to synthesise evidence from trials. This is presently difficult as outcome reporting in surgical trials is heterogeneous.

The GASTROS study (GAstric cancer Surgery Trials Reported Outcome Standardisation) is an international initiative which aims to develop a core outcome set (COS) - a minimum standardised group of outcomes - which should be reported by all future gastric cancer surgery trials. This will enable more accurate comparison of outcomes from different surgical approaches. GASTROS is fully funded by the National Institute for Health Research and supported by the Medical Research Council’s Hubs for Trials Methodology Research. Here we present our study protocol.

Methods: GASTROS has 3 stages. Stage 1 involves undertaking a systematic review of studies to identify a 'long-list' of possible outcomes to include in the COS. Qualitative interviews with gastric cancer patients will be undertaken to identify any further outcomes which patients deem important. Stage 2 involves 3 rounds of a Delphi survey of key stakeholders (surgeons, cancer nurse specialists and patients) to determine which outcomes to include in the COS. Stage 3 will focus on identifying the most appropriate methods of measuring these outcomes.

Anticipated Benefit: This study will enable more reliable comparison of surgical interventions for gastric cancer. It will inform future gastric cancer surgical trials by identifying standardised outcomes relevant to both patients and clinicians.

Support for reporting guidelines in surgical journal needs improvement: a systematic review

Riaz Agha¹, Ishani Barai², Shivanchan Rajmohan², Seon Lee³, Mohammed Anwar⁴, Alex Fowler⁵, Dennis Orgill⁶, Douglas Altman⁷

¹Department of Plastic Surgery, Guy’s and St. Thomas’ NHS Foundation Trust, London, UK, ²Imperial College School of Medicine, London, UK, ³University of Southampton Medical School, Southampton, UK, ⁴Bart’s and The London School of Medicine and Dentistry, Queen Mary and Westfield University, London, UK, ⁵Department of Medicine, Guy’s and St. Thomas’ NHS Foundation Trust, London, UK, ⁶Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, USA, ⁷Centre for Statistics in Medicine, University of Oxford, Oxford, UK

Introduction: In the era of evidence-based medicine, the underlying quality of research is critical. Previous studies have shown reporting quality to be lacking in the field of surgery. Reporting guidelines are an important tool for authors to optimize the reporting of their research. Therefore, the study aim was to analyse the frequency and strength of recommendation for available reporting guidelines within surgical journals.
**Methods:** A systematic review of the 198 journals within the Journal Citation Report 2014 (surgery category) published by Thomson Reuters was undertaken. The online guide for authors for each journal was screened by two independent groups and results compared. Data regarding the presence and strength of recommendation to use reporting guidelines was extracted.

**Results:** 193 journals were included (following exclusion of duplicate journal names). These had a median impact factor of 1.526 (range 0.047 to 8.327), with 34,036 articles published in total over the two-year window 2012-2013. 62% of surgical journals made no mention of reporting guidelines within their guidance for authors. Of the 38% that did mention them, only 14% required the use of all relevant reporting guidelines. The most frequently mentioned reporting guideline was CONSORT (46 journals).

**Conclusion:** The mention of reporting guidelines within the guide for authors of surgical journals needs improvement. Journals should uniformly endorse relevant reporting guidelines and update their instruction to authors to reflect this. This will likely improve methodology and quality of reporting, raising the level of scholarly discourse between authors and the scientific community and reducing frustration amongst readers.

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**Compliance of Systematic Reviews in Plastic Surgery with the PRISMA Statement: A Systematic Review**

Seon-Young Lee¹, Harkiran Sagoo², Katharine Whitehurst³, Georgina Wellstead⁴, Alexander Fowler⁵, Riaz Agha⁶, Dennis Orgill⁷

¹Southampton Medical School, Southampton, UK, ²GKT School of Medical Education, King's College London, London, UK, ³University College London, London, UK, ⁴Barts and the London School of Medicine and Dentistry, QMUL, London, UK, ⁵Guys and St Thomas' NHS Foundation Trust, London, UK, ⁶Guy's and St. Thomas' NHS Foundation Trust and Balliol College, University of Oxford, London & Oxford, UK, ⁷Division of Plastic Surgery, Brigham and Women's Hospital, Boston, USA

**Introduction:** Systematic reviews are an important tool in evidence based medicine. We aim to determine the reporting quality of recent systematic reviews and meta-analyses in plastic surgery with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.

**Methods:** This systematic review was conducted following the Cochrane Handbook, reported in line with the PRISMA Statement, and registered with the Research Registry (unique identifying number: reviewregistry18). MEDLINE and EMBASE were searched for systematic reviews published between January 1, 2013, and December 31, 2014, in five major plastic surgery journals. Screening, identification and data extraction were performed independently by two teams. Analysis was conducted from January 1 to July 30, 2015.

**Results:** From an initial set of 163 articles, 79 met the inclusion criteria. The median PRISMA score was 16 of 27 items (59%) (range, 6-26; 95% CI, 14-17). Compliance varied highly between individual PRISMA items. It was poorest for items related to the use of review protocol (item 5; 4 articles [5%]) and presentation of data on the risk of bias of each study (item 19; 14 articles [18%]). Compliance was the highest for description of rationale (item 3; 78 articles [99%]), sources of funding and other support (item 27; 75 articles [95%]), and inclusion of a structured summary in the abstract (item 2; 75 articles [95%]).

**Conclusion:** The reporting quality of systematic reviews in plastic surgery requires improvement. Enforcement of compliance through journal submission systems, with improved education, awareness and a cohesive strategy among all stakeholders, is required.
A Systematic Review of the Methodological and Reporting Quality of Case Series in Surgery

Riaz Agha1, Alexander Fowler2, Seon-Young Lee3, Buket Gundogan4, Katharine Whitehurst4, Harkiran Sagoo5, Kyung Jin Lee Jeong6, Douglas Altman7, Dennis Orgill8
1Guy’s and St. Thomas’ NHS Foundation Trust and Balliol College, University of Oxford, London & Oxford, UK, 2Guys and St Thomas’ NHS Foundation Trust, London, UK, 3Southampton Medical School, Southampton, UK, 4University College London, London, UK, 5GKT School of Medical Education, King’s College London, London, UK, 6Norfolk and Norwich University Hospital, Norfolk, UK, 7Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, Oxford, UK, 8Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, USA

Introduction: Reporting guidelines have been shown to improve reporting quality. No guidelines currently exist for reporting case series. There is evidence of key data being missed from such reports. We propose to develop a reporting guideline for case series using a methodologically robust technique. The first step in this process is to systematically review literature relevant to the reporting deficiencies of case series.

Methods: A systematic review of methodological and reporting quality in surgical case series was conducted in line with the Cochrane Handbook and reported in line with the PRISMA statement. The electronic search strategy included electronic searches of MEDLINE, EMBASE, Cochrane Methods Register, Science Citation Index and Conference Proceedings Citation index, from the start of indexing until 5th November 2014. Independent screening, eligibility assessments and data extraction was performed. Included articles were analysed for five areas of deficiency: failure to use standardised definitions, missing or selective data, transparency or incomplete reporting, consideration of alternate study designs and other issues.

Results: The database search identified 2,205 records, of which 92 met inclusion criteria. The following methodological and reporting issues were identified: failure to use standardised definitions (57%), missing or selective data (66%), transparency or incomplete reporting (70%), consideration of alternate study designs (11%) and other issues (52%).

Conclusion: Our data shows that methodological and reporting quality of surgical case series needs improvement. Clear evidence-based guidelines for the conduct and reporting of case series may aid those planning or conducting them. Future research should focus on developing such guidelines.

An assessment of the compliance of systematic review articles published in craniofacial surgery with the PRISMA statement guidelines: A systematic review

Thomas Edward Pidgeon1,2, Georgina Wellstead1,3, Harkiran Sagoo1,4, Daniyal Jafil Jafree1,5, Alexander Fowler1,6, Riaz Agha1,6
1The Academic Surgical Collaborative, National, UK, 2St. Andrews Centre for Plastic Surgery and Burns, Essex, UK, 3Barts and the London School of Medicine and Dentistry, London, UK, 4Guy’s, King’s and St. Thomas’ School of Medical Education, London, UK, 5University College London Medical School, London, UK, 6Guy’s and St. Thomas’ NHS Foundation Trust, London, UK

Introduction: The PRISMA checklist aids authors in reporting important features of systematic review evidence. The compliance of systematic review articles in craniofacial surgery with the PRISMA checklist was formally reviewed.

Methods: The Thomson-Reuters impact factor identified three top craniofacial journals. A search for all systematic review articles published within the Journal of Cranio-Maxillo-Facial Surgery,
Orthodontics and Craniofacial Research, and the Cleft Palate Craniofacial Journal from 1st May 2010 to 30th April 2015 was performed. Two independent researchers extracted data on: author; year; journal; the pathology and interventions examined; and compliance of each review article with the PRISMA checklist.

**Results:** 62 systematic review articles proceeded to data extraction. The mean percentage of applicable PRISMA items that were met across all studies was 72.5% (range 28.6-96.2%). The areas of poorest compliance were with the declaration of a study protocol (19.4% of studies) and with the declaration of funding (37.1% of studies). All studies (100.0%) described the rationale for the review, declared the results of any additional analyses, and provided a summary.

**Conclusions:** Compliance of secondary research within craniofacial surgery with areas of the PRISMA checklist could be improved. Knowledge of these areas could inform future authors and improve the specialty's evidence base.

**The Use of Study Registration and Protocols in Plastic Surgery Research: A systematic review**

**Thomas Edward Pidgeon**¹,²,⁷, **Christopher Limb**²,⁷, **Riaz Agha**³,⁷, **Katharine Whitehurst**⁴,⁷, **Charmilie Chandrakumar**³,⁷, **Georgina Wellstead**⁵,⁷, **Alexander Fowler**³,⁷, **Dennis Orgill**⁶,⁷ ¹St. Andrew’s Centre for Plastic Surgery and Burns, Essex, UK, ²Royal Sussex County Hospital, Brighton and Sussex NHS Trust, Brighton, UK, ³Guy’s and St. Thomas’ NHS Foundation Trust, London, UK, ⁴University College London Medical School, London, UK, ⁵Barts and the London School of Medicine and Dentistry, London, UK, ⁶Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, USA, ⁷The Academic Surgical Collaborative, National, UK

**Background:** In 2013, the Declaration of Helsinki mandated that every research study involving human subjects must have its protocol registered in a publicly accessible database prior to the enrolment of the first patient. This systematic review assessed the number of studies published in leading journals of plastic surgery that had either published or registered a protocol with a publicly accessible database.

**Methods:** All research articles involving human participants published in Plastic and Reconstructive Surgery, The Journal of Plastic Reconstructive and Aesthetic Surgery and The Annals of Plastic Surgery from 1st April 2014 - 31st March 2015 were examined. The primary outcome measure was whether each study had registered or published a protocol with any mainstream registry database. ClinicalTrials.gov, International Standard Randomised Control Trial Number (ISRCTN), WHO (World Health Organisation) International Clinical Trials Registry Platform, The Cochrane Collaboration, the Research Registry, PROSPERO and PubMed were all reviewed.

**Results:** Of 595 included articles, the most common study designs were case series (n=185, 31.1%). There were 24 randomised controlled trials (RCTs, 4.0%). A total of 24 studies had a protocol registered (4.0%), although no studies had published a protocol in a journal. The most common database to register a protocol was ClinicalTrials.gov (n=17). The study design that most commonly had a registered protocol was the RCT (n=8 of 24, 33.3% of RCTs).

**Conclusions:** Publication or registration of protocols for recent studies involving human participants in major plastic surgery journals is low. There is considerable scope to improve this and relevant guidance is provided.
Twist-drill craniostomy with hollow screws for evacuation of chronic subdural haematoma

Angelos G Kolias1,2, Aswin Chari1, Simon J Bond2,3, Peter JA Hutchinson1,2
1Division of Neurosurgery, Addenbrooke’s Hospital & University of Cambridge, Cambridge, UK, 2Cambridge Clinical Trials Unit, Cambridge, UK, 3MRC Biostatistics Unit, Institute of Public Health, University of Cambridge, Cambridge, UK

Objectives: The incidence of chronic subdural haematoma (CSDH) is expected to increase substantially over the next 25 years. Continuing refinement of techniques for surgical evacuation is essential. A novel technique involving a hollow screw, which is threaded through a twist-drill hole in the cranium and then connected to a closed drainage system, has been increasing in popularity. The aim of this systematic review is to collate and analyse available published data.

Methods: MEDLINE, Web of Knowledge, EMBASE, and the Cochrane Database were searched for published series involving more than 10 patients.

Results: Nine eligible studies were found (6 case series and 3 case-control studies) comprising 796 patients. Seven used the SEPS system (commercially available and manufactured by Medtronic Inc) and 2 studies used the hollow screw (manufactured by Teleflex Medical). The procedures are similar, but the hollow screw procedure uses intra-operative and post-operative (once daily) irrigation routinely to promote brain re-expansion. The SEPS does not use irrigation but relies on a low negative pressure applied through a suction reservoir bulb to promote drainage of the collection and gradual brain re-expansion. Pooled analysis showed a ‘success rate’ of 77.6% (95% CI 74.6%–80.4%), recurrence rate of 22.4%, and in-hospital mortality of 1.4%.

Conclusions: On the basis of the available evidence, we believe that this new technique should be systematically assessed according to the IDEAL framework. As these techniques are not used in the UK, we propose that a prospective development study (IDEAL stage 2a) is necessary prior to a multicentre effectiveness trial.

Intra-operative hyperspectral imaging for brain tumour detection and delineation: current progress on the HELICoid project.

Silvester Kabwama1, Diederik Bulters1, Harry Bulstrode1, Himar Fabelo2, Samuel Ortega2, Gustavo M Callicco2, Bogdan Stanciulescu4, Ravi Kiran4, Daniele Ravi3, Adam Szolna5, Juan F Piñeiro0
1Wessex Neurological Centre, University Hospital Southampton, Southampton, UK, 2University of Las Palmas de Gran Canaria Institute for Applied Microelectronics, Las Palmas de Gran Canaria, Spain, 3Imperial College London, London, UK, 4ARMINES, Paris, France, 5University Hospital Doctor Negrin, Las Palmas de Gran Canaria, Spain

Background: Hyperspectral Imaging (HSI) captures spectral information that has been shown to characterise tissues. Since the surgeon’s naked eye is sometimes unable to differentiate between tumour and normal brain, HSI could be a solution.

Aims: We aim to develop an intra-operative HSI system capable of tumour detection and delineation.

Methods: Using a newly developed HSI system that captures images across the visible and near-infrared electromagnetic spectrum (from 400nm to 1700nm); we obtained hyperspectral images during tumour resection. Before imaging, markers were placed at the location of the tumour and normal brain. Images were then captured with the markers in-situ. Tissue samples were obtained from the location of the markers and sent for tissue diagnosis.
A pre-processing chain was then applied to the spectrum of each pixel within the hyperspectral images. The spectra and pixels within the areas marked areas were then labelled with their tissue diagnosis. This labelled data was then used to produce and test algorithms that automatically classified images from their spectral signatures.

**Results:** Using data from 22 resections, we have developed algorithms capable of automatically identifying tumour and normal brain from hyperspectral images. Furthermore, the algorithms were capable of producing a 2D colour map correlating to the location of the tumour and normal brain.

**Conclusion:** The HELICoid project has made excellent progress and current results are very promising. However, more images are needed in order for us to produce a validated HSI system capable of providing real time intra-operative information on tumour type, grade and location.

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**Developing a Patient and public Involvement intervention to enhance Recruitment and Retention In UK Surgical Trials (PIRRIST)**

Joanna Crocker¹,², Sian Rees¹, Louise Locock²,³, Sophie Petit-Zeman⁴, Alan Chant⁵, Shaun Treweek⁶, Jonathan Cook⁷,⁸, Nicola Farrar²,⁷, Kerry Woolfall⁹, Jennifer Bostock¹⁰, Louise Bowman¹¹, Richard Bulbulia¹¹,¹²


**Background and aims:** Poor recruitment and retention are common challenges to the successful delivery of surgical trials, possibly alleviated by greater patient and public involvement (PPI). We aim to develop a robust PPI intervention to improve recruitment and/or retention in surgical trials.

**Methods:** The study comprises four stages: (1) Mapping current PPI practice in UK surgical trials; (2) Focus groups with stakeholders (surgical trial investigators, administrators and patient or lay contributors) to explore their views on PPI, recruitment and retention; (3) Survey of stakeholders’ views about possible components of a PPI intervention; (4) Consensus workshop with selected stakeholders to design a PPI intervention for evaluation.

**Results:** Active, UK-led, adult surgical trials were eligible for the mapping survey; 129 were identified and 72 (59%) were included. Sixty-six (92%) reported PPI in designing the trial (79%), undertaking the trial (26%), analysing or interpreting results (31%) and/or disseminating findings (60%). Patients and/or lay people were usually involved as consultants (63%) and/or members of the trial steering committee (72%), and sometimes as grant co-applicants (36%) and/or members of the trial management group (35%). Developing participant information materials was the single most common PPI activity, reported in 71% of included trials.

**Conclusions:** UK surgical trials involve patients and members of the public in a variety of different ways, most commonly at the beginning and end of the trial lifecycle and in oversight or advisory roles. This knowledge will inform the development of a robust PPI intervention aimed at improving recruitment and retention in surgical trials.
Osseointegrated Joint Replacement Connected to a Lower Limb Prosthesis: An IDEAL Stage 1 Proof of Concept Study with 7 Cases

Aditya Khemka, Sarah Lord, Munjed Al Muderis

University of Notre Dame, Sydney, NSW, Australia

Background: One third of lower-limb-amputees experience socket-residuum interface problems, leading to reduced prosthetic use and quality-of-life. Bone-anchored-implants have been developed to eliminate this interface. Our findings from a prospective study suggest favorable benefit-harm trade-off with improved mobility and 100% 2-year implant survival with no major complications (including deep infection). However, this technique is contraindicated in amputees with short residuums due to small bone-implant-contact. We aim to report on feasibility and safety of combining total joint (hip/knee) replacement (THR/TKR) with osseointegrated implants for prosthetic attachment in this patient group.

Methods: We reviewed all patients who underwent this procedure in 2012-2014 at our centre. In a 2-stage procedure, a custom-made-implant was connected to THR/TKR and a stoma was created. Validated measures of health-related quality-of-life and ambulation were assessed at baseline and follow-up (24-44 months) including the Questionnaire-for-Transfemoral-Amputees (Q-TFA) and 6-minute-walk-test (6MWT). All adverse events were classified as major if they required surgical management.

Results: Seven (THR 3/TKR 4) patients aged 35-77 (46) years underwent the procedure. Two cases of superficial infection occurred but resolved with antibiotics without major complications. All patients showed improved Q-TFA and SF-36 scores (43 and 22 respectively). All 3 wheelchair-bound patients became community ambulators; the four other patients exhibited improved ambulation.

Interpretation: This proof-of-concept case-series presents the 1st report to combine osseointegration and THR/TKR. Meticulous planning, systematic recording of all outcomes indicate that this procedure is feasible for this challenging group. A prospective database has been developed by us to collect long-term data, better estimate safety and benefits, inform ongoing technical improvements and refine patient selection criteria.

Register of urogynecological implants: the development of an online platform for registration and outcome measurement according to the IDEAL long-term stage of surgical innovation

Dimitri Barski1,17, Holger Gerullis2, Thorsten Ecke3, Ralf Joukhadar4, Jennifer Kranz5,17, Rana Tahbaz6,17, Fabian Queissen7,17, Laila Schneidewind8,17, Sandra Mühlstädt9,17, Markus Grabbert10,17, Nadine Huppertz11,17, Alexandre Pelzer12,17, Uwe Klinge13, Mihaly Boros14, Werner Bader15, Frank Puppe16, Thomas Otto1

1Department of Urology, Lukas Hospital Neuss, Neuss, Germany, 2Department of Urology, School of Medicine and Health Sciences, Carl von Ossietzky University Oldenburg, Oldenburg, Germany, 3Department of Urology, HELIOS Hospital, Bad Saarow, Germany, 4Department of Gynecology, University Hospital Würzburg, Würzburg, Germany, 5Department of Urology, St.-Antonius Hospital Eschweiler, Eschweiler, Germany, 6Department of Urology, University Hospital Hamburg Eppendorf, Hamburg, Germany, 7Department of Urology, University Hospital Münster, Münster, Germany, 8Department of Urology, University Hospital Greifswald, Greifswald, Germany, 9Department of Urology, University Hospital Halle (Saale), Halle (Saale), Germany, 10Department of Urology, LMU University Hospital Munich, Munich, Germany, 11Department of Neuro-Urology, University Hospital Bonn, Bonn, Germany, 12Department of Urology, Klinikum Ingolstadt, Ingolstadt, Germany, 13Surgical Department, University Hospital of the RWTH Aachen, Aachen, Germany, 14Institute of Experimental Surgery, University of Szeged, Szeged, Hungary, 15Department of Gynecology, Klinikum Bielefeld, Bielefeld, Germany, 16Institute for
Introduction and hypothesis: Most aspects of implants for reconstruction of the pelvic floor are still under debate or poorly studied. Different tools and definitions of success make the comparability of studies and meta-analyses in this field of surgery difficult. The aim of the present study was to prove the feasibility of a register to analyse the outcome after implant application.

Methods: The available literature on the application of implants for pelvic organ prolapse (POP) and female and male stress urinary incontinence (SUI) repair was reviewed according to IDEAL stages of surgical innovation. A working group was formed to create an online platform for registration and outcome measurement of implant-assisted operations for POP and SUI repair. To date, 20 patients from a previous published study on modified mesh materials were evaluated over 23 months follow up in the register. For validation a previously published modified “satisfaction, anatomy, continence, safety – S.(A.)C.S score” was used.

Results: A review of the literature revealed missing data especially on male continence surgery and long-term trials. A register was established with consensus on clear definitions and classifications of patient variables, surgical procedures and mesh materials used, as well as outcome parameters. According to the S.(A.)C.S. scoring system, only 14 patients (70 %) reached the maximum score of cure.

Conclusion: An online platform for registration and outcome measurement of implant-assisted POP and SUI repair with clear definitions and classifications is offered to the surgical community.

Bringing laparoscopy to your own home

Martinique Vella-Baldacchino¹, Matthew Schembri², Mikhail Vella-Baldacchino³, Roberta Bugeja⁴
¹Dumfries and Galloway Royal Infirmary, DUMFRIES, UK, ²The Queen Elizabeth University Hospital, Glasgow, UK, ³Aberdeen Royal Infirmary, Aberdeen, UK, ⁴Mater Dei Hospital, Malta, Malta

Aim: The first recorded attempt of looking into the human body using a minimal intervention approach was in the year 1805. The technique began with a candle as the main source of light and radically improved with the development of a high resolution camera.

Method: Laparoscopic surgery requires training on costly simulators of which the ratio of availability to the number of surgical trainees may be limited thus reducing the time of exposure on these simulators. We designed an inexpensive laparoscopic training device composed of a webcam and LED lights mounted in a specifically designed box which allows medics to practice laparoscopic exercises at their own pace and at their own convenience..

Results: Current surgical practice is continuously changing due to rapid advancements in technology, we need to keep up with these changes and learn new skills quickly but appropriately. Our device is an inexpensive trainer of which anyone may build and use in their own home. The aim of the trainer is not to simulate real life operations in a live individual but to aid the individual to practice motor coordination prior to applying them in theatre.

Autologous plasma coating improves the biocompatibility of mesh implants. On the IDEAL way from bench to bedside.

Holger Gerullis¹,², Dimitri Barski¹, Christoph Eimer¹, Mihaly Boros³, Bernd Klosterhalfen⁴, Albert Ramon⁵, Thomas Otto¹
¹Lukas Hospital Neuss, Neuss, Germany, ²University of Oldenburg, Oldenburg, Germany,
Introduction: Since 2009, several FDA warnings relating to severe side-effects led to discussions concerning the biocompatibility requirements of surgical meshes. We aimed to develop a manufacturer-independent test system for the adherence performance of tissue clusters as a marker for mesh biocompatibility. In addition we investigated different coating strategies for meshes.

Material and methods: The entire experimental approach followed the recommendations of IDEAL. We developed an in vitro test systems investigating the tissue ingrowth score on meshes as predictive for their biocompatibility. Then, we investigated different coating strategies of the meshes accordingly. In order to explore the predictive value and validity of the test system and also newly tested coating strategies, we translated the preliminary in vitro results into in vivo circumstances and conducted a large-animal experiment in sheep. In a next step we applied our mesh modification strategy in a human setting.

Results: The in vitro test system could show a repeatable ranking of meshes with regard to their biocompatibility. The coating of meshes prior to cultivation, with blood plasma, increased their biocompatibility. In a long-term animal study, this in vitro test system predicted the in vivo performances of the meshes for native and coated meshes. In a first conducted observational study in human, the procedure of mesh coating with autologous plasma has been successfully applied and been shown to be a safe and feasible method. Conclusion As next steps a prospective randomized trial is planned and will be followed by the development of a long term registry to report clinical outcome features of this method.

Percutaneous Nephrolithotomy (PCNL) under local infiltrative Anesthesia with and without stand-by Anesthesia – Complication rates and clinical outcome for a method at the Exploration Stage according to IDEAL

Thorsten Ecke1, Guido Weingart4, Carsten Lange1, Steffen Hallmann1, Friedhelm Wawroschek3, Dimitri Barski2, Jürgen Ruttloff1, Holger Gerullis3
1HELIOS Hospital Bad Saarow, Bad Saarow, Germany, 2Lukas Hospital Neuss, Neuss, Germany, 3University of Oldenburg, Oldenburg, Germany, 4UroPraxis Hochmuth, Ulm, Germany

Introduction: This retrospective study aims to compare feasibility, safety and complication rates of percutaneous nephrolithotomy (PCNL) under local infiltration anesthesia alone (Group I) and additive intravenous analgetics and / or sedative medications (Group II).

Material and Methods: 439 patients have been included in the study, 226 in Group I, and 213 in Group II. The mean American Society of Anesthesiologists score (ASA) was 2.15 ±0.37 (range, 1-4). Demographic characteristics and stone characteristics have been evaluated to determine feasibility, complication rates for safety, and stone-free rates for effectiveness. The study has been retrospectively classified to the IDEAL stages of surgical innovation.

Results: All patients who accepted local infiltration anesthesia underwent PCNL successfully. Of the 439 patients, 138 had pelvic calculi, 173 renal calculi, 66 partial staghorn, 48 complete staghorn, and 16 upper ureteral stone. The total stone free rate in patients was 78.4% over all stone localizations. Compared to the possibility of using additive intravenous analgetics and / or sedative medications we could show differences in the median age, number of tracts, operation duration, hemoglobin drop, fever, transfusion rate, and stone free rate, but not for severe complications such as perirenal hematoma, colon perforation, pleura perforation, AV fistula, skin fistula, and mortality rate.

Conclusion: PCNL performed under local infiltration anesthesia is feasible and provides satisfactory positive clinical outcomes. In this retrospective analysis both kinds of treatment show similar in success and complication rates. The method can be assigned to the E level according to IDEAL.
The landscape of surgical innovation in robotic microsurgery

Ahmet Gudeoglu¹, Burhan Ozdemir², Sarah R. Fleischman³, Philipp Dahm⁴
¹Memorial Ankara Hospital, Ankara, Turkey, ²Dr. Sami Ulus Children’s Hospital, Ankara, Turkey, ³University of Florida, Gainesville, Turkey, ⁴University of Minnesota, Minneapolis, USA

Introduction: We systematically assessed the design of studies on robotic microsurgery in their relationship to the IDEAL stages of surgical innovation.

Methods: We conducted a protocol-driven PUBMED search (September 2015) for published on robotic-assisted microsurgery (RAM) in human subjects. Two independent reviewers screened studies in 2 stages (abstract and full-text) using Covidence online software, abstracted baseline characteristics of each study and mapped it to the relevant IDEAL stage of surgical innovation. We surveyed publication text and references for mention of the IDEAL recommendations.

Results: We identified 358 studies of which 35 unique clinical research studies ultimately met our inclusion criteria. We found 16, 5 and 13 studies that mapped to IDEAL stages 1, Stage 2a and Stage 2b, respectively as well as one studies that mapped to both stage 1 and 2a. There was no study addressing IDEAL stages 3 or 4 of surgical innovation. None of the identified publications of robotic microsurgery made reference to the IDEAL recommendations.

Conclusion: Uptake of the IDEAL recommendations appears limited, thereby emphasizing the importance of increased efforts and innovative approaches to the dissemination of IDEAL.

Awareness of the ideal recommendations among the members of the robotic-assisted microsurgery and endoscopic society (ramses)

Ahmet Gudeoglu¹, Sarah R. Fleischman², Philipp Dahm⁰
¹Memorial Ankara Hospital, Ankara, Turkey, ²University of Florida, Gainesville, USA, ³University of Minnesota, Minneapolis, USA

Introduction: Robotic assisted microsurgery (RAM) holds promise of improved surgical outcomes and decreased perioperative morbidity. We surveyed members of the Robotic-Assisted Microsurgery and Endoscopic Society (RAMSES) on their opinions of the IDEAL recommendations and perceived barriers for their adoption.

Methods: We conducted an IRB-approved online survey of RAMSES members (10/2014). The survey included 39 questions (multiple choice and open-ended) and was structured according to the IDEAL stages of surgical innovation. Prior to survey completion, we requested participants to view a streamed online presentation on the IDEAL framework.

Results: 21/28 RAMSES members (75%) completed the survey, ¾ of which were unaware of the IDEAL framework prior to this study. 43% of the respondents had performed at least one “first-in man” RAM procedure and 56% indicated that they had not sought IRB approval. Approximately 1/3 of respondents and 14% of participants declared that they had performed RAM procedures that mapped to IDEAL Stage 2a and 2b, respectively. A minority (5%) had performed an RCT (IDEAL Stage 3) and 24% of participants a long-term study (IDEAL Stage 4). Resource utilization (financial, time), concerns about delaying patient care and IRB approval were identified as barriers for IDEAL.

Conclusion: Awareness and uptake of the IDEAL recommendations among surgical sub-specialist at the forefront of surgical innovation remains limited, emphasizing the importance of increased efforts in promoting its rationale and importance.