

A - literature review- references

Literature about iCount as a Solution:

Elgharably AN, Desai K, Nevill AM, et al. BMJ Innovation 2024; doi:10.1136/bmjinnov-2024-001248

WHAT ARE THE NEW FINDINGS

- ⇒ Despite established policies and procedures when swab counting, issues such as distraction, confirmation bias, competing task priorities and changes in swab appearance contribute to swab miscounts and therefore swab retention.
- ⇒ Cases of count discrepancies/miscounts are under-reported, and their impact extends to patient's health, clinician's time and trust's reputation and finances.
- ⇒ iCount is a low-cost device designed and developed with human factors-ergonomics principles. It is a docking system that behaves as a physical checklist when swab counting and facilitates conscious engagement using visual and tactile cues when counting.
- ⇒ Users believe iCount to be a viable alternative to manual two-person swab counting with greater time efficiency and perceived safety. This could be valuable in emergency maternity situations.

HOW MIGHT IT IMPACT ON HEALTHCARE IN THE FUTURE

- ⇒ iCount has the potential to reduce or prevent retained swabs after vaginal deliveries along with appropriate policies, training and teamwork.
- ⇒ Additional clinical research and widespread adoption would be needed to validate this effectively.

Contemporary Ergonomics and Human Factors 2024. Chartered Institute Ergonomics Human Factors. Prize winning abstract presented at CIEHF World Congress held in UK

A vision to 'Design out' accidentally retained surgical items in vaginal childbirth

Ahmed ElGharably¹, Kiran Desai², Aaron Vance³, Jon Lester⁴, Emma Bonfiglio⁵, Colin Rigby⁶, Andrew Forrester⁷, Prof Peter Ogrodnik⁸, Jeffrey Faint⁹, Prof Tom Clutton-Brock¹⁰, Aditi Desai¹¹

¹The Royal Wolverhampton NHS Trust, ²Eureka Inventions Ltd, ³University of Wolverhampton, ⁴University of Wolverhampton, ⁵Keele University, ⁶Keele University, ⁷Manufacturing Technology Centre, ⁸Keele University, ⁹NHRR Trauma Management MedTech Co-operative MD-Tec (Medical Devices Testing and Evaluation Centre), ¹⁰NHRR Trauma Management MedTech Co-operative MD-Tec (Medical Devices Testing and Evaluation Centre), ¹¹The Royal Wolverhampton NHS Trust

Retained vaginal swabs are a well-recognised and recurrent patient safety 'never event' with the potential to cause significant morbidity. Surgical swabs and surgical tampons, which are considered a type of surgical swab, are the single largest retained item. There have been 340 incidents of retained vaginal swabs reported in England (2012-2022) and underreporting of these incidents is known. The current practice of manual counting is prone to human error and demonstrates a lack of efficacy in dealing with this issue. A simple, cost-effective device was developed collaboratively based on human factors/ergonomics principles. This is designed to help users focus on the largest problem space, functioning as a physical checklist and memory aid for accurate counting. The team adopted a systems thinking approach to develop the innovation, progressing through steps such as hierarchical task analysis and human factors systems analysis through the SEIPS framework. AcciMap, barrier analysis and user-centred iterative design. The near-manufacture prototype was user-tested in simulation, and results indicate that the device has the potential to facilitate accurate counts in a time-efficient manner. We acknowledge that there will be a need for training, and culture change for the adoption of design solutions in the current workflow. It is known that around

Discussion

The overarching aim of the human factors and ergonomics discipline is to enable us to adopt a design-driven systems approach to achieve performance and well-being. Retained vaginal swabs are a recurrent 'never event' that leaves women at risk of harm after childbirth. The team has applied these principles to redesign the task and tools to address this. The simulation testing and user testing of the near-final version show staff time saved and encouraging results regarding user confidence.

We acknowledge that there will be a need for training, and culture change for the adoption of design solutions in the current workflow. Initially, it may be practical to introduce only the device, which acts as a physical checklist and increases system resilience. We will be working with electronic medical records providers to move towards a strong systemic barrier with the aim of preventing this problem. This will need some additional resources if we wish to move towards safer care. The introduction of design solutions to work procedures will hopefully encourage other clinicians to work collaboratively on other problems, which are pressing needs within maternity and wider healthcare.

RCOG World Congress 2021 - Prevention of retention of vaginal swabs and tampons with novel device system. Desai A, Ogrodnik, Desai K, Mapunde V
Top scoring abstract and Sir William Gilliatt prize

Literature about the problem and implications

The references have been broadly classified into categories depending on the issues they highlight

References to overall importance of the problem to health and wellbeing of the public and patients and health and care services

National reports

HSIB-Detection of retained vaginal swabs and tampons following childbirth.

Healthcare Safety Investigation I2018/025 December 2019 Edition. Healthcare Safety Investigation Branch

CQC-Opening the door to change. NHS Safety Culture and the need for transformation Dec 2018. Care Quality Commission.

Surgical Never Events (2018). NHS Improvement. Learning from 38 cases occurring in English hospitals between 2016 and 2017 .

US Joint Commission report: Preventing unintended retained foreign objects

https://www.jointcommission.org/assets/1/18/retained_foreign_objects_faqs.pdf (Accessed on May 29, 2019)

UK NHS National Patient Safety Agency. Rapid response report NPSA/2020/RRR012.Reducing the risk of retained swabs after childbirth and perineal suturing.

The Australian Commission on Safety and Quality in Health Care (the Commission)- Sentinel events list- retained swabs

The New Zealand Health Quality and Safety Commission, New Zealand. Retained vaginal swabs following childbirths- problem and prevention strategies. Dec 2015.

US Institute for Clinical Systems Improvement. Health care protocol: prevention of unintentionally retained foreign objects during vaginal deliveries . 3rd ed.Bloomington (MN): ICSI; 2009. Available at:. Retrieved April 30, 2010.

Spotlight on patient safety. Minnesota department of Health. Focus on retained foreign objects- vaginal sponges which contributes significantly to.... www.health.state.mn.us/patientsafety and similar reports from each US state.

NHS Long term plan - NHS Improvement Jan 2019.

Link related to maternity as one of the priorities and patient safety within the report

US Navy Navmed Policy 09-007. Call for robust policy to prevent cases of sponge retention after vaginal delivery. May 2009.

Review Articles and case reports

The recurring problem of retained swabs and instruments. Best practice and research clinical Obstetrics and Gynaecology. 2013. Montasser A.Mahran, Eman Toeima, E.P.Morris

Never Events – the ongoing problem of the retained vaginal sponge/swab. BJOG perspectives. British Journal of Obstetrics and Gynaecology. 2016.Helen Bolton. <https://doi.org/10.1111/1471-0528.14041>

Retained Surgical Foreign Bodies: A Comprehensive Review of Risks and Preventive Strategies.2009. S. P. Stawicki, D. C. Evans, J. Cipolla et al. Scandinavian Journal of Surgery. <https://doi.org/10.1177/145749690909800103>

Improving safety in the operating room: a systematic literature review of retained surgical sponges. 2009. Wan, Wenshuaia; Le, Thuanb; Riskin, Lorenc; Macario,

Current Opinion in Anaesthesiology: 2009 doi: 10.1097/ACO.0b013e328324f82d. Copeland A, Cochran A, Collins K. Retained surgical sponge (gossypiboma) and other retained surgical items: Prevention and management.

Up To Date- Evidence based Clinical Decision Support.

[https://www.uptodate.com/content/Retained-surgical-sponge-\(gossypiboma\)-and-other-retained-surgical-items:-Prevention-and-management](https://www.uptodate.com/content/Retained-surgical-sponge-(gossypiboma)-and-other-retained-surgical-items:-Prevention-and-management)

Bell R. Hide and seek, the search for a missing swab: a critical analysis. J Perioper Pract. 2012 May;22(5):151-6. doi: 10.1177/175045891202200503. PMID: 22720504.

Patial T, Thakur V, Vijhay Ganesun N, Sharma M. Gossypibomas in India - A systematic literature review. J Postgrad Med. 2017 Jan-Mar;63(1):36-41. doi: 10.4103/0022-3859.198153. PMID: 28079043; PMCID: PMC5394815.

Feldman DL. Prevention of retained surgical items. Mt Sinai J Med. 2011 Nov-Dec;78(6):865-71. doi: 10.1002/msj.20299. PMID: 22069210.

Porteous J. Surgical counts can be risky business! Can Oper Room Nurs J. 2004 Dec;22(4):6-8, 10, 12. PMID: 15709630.

Tumer AR, Yasti AC. Medical and legal evaluations of the retained foreign bodies in Turkey. Leg Med (Tokyo). 2005 Oct;7(5):311-3. doi: 10.1016/j.legalmed.2005.04.004. PMID: 16043376.

Schelhaas E, Mastboom WJ. Een achtergebleven gaas als oorzaak voor onbegrepen buikklachten [A retained gauze as a cause of unexplained abdominal complaints]. Ned Tijdschr Geneesk. 2002 Feb 9;146(6):241-5. Dutch. PMID: 11865650.

Lacombe C, d'alincourt A, Lerat F, Goura à Mougnot E. Quid? [What is it? Abdominal foreign body and small intestine fistula]. J Radiol. 2000 Jun;81(6):641-2. French. PMID: 10844344.

Haleem S, Mahmoud MH, Kainth GS, Botchu R, Hassan MF, Rehousek P. A perioperative overview of a retained surgical swab in spinal surgery: Case report and prevention protocol. Journal of Perioperative Practice. 2024;34(4):101-105. doi:10.1177/17504589231163685

References to surgical swabs/sponges are commonest items left behind

Gawande AA, Studdert DM, Orav EJ et al. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003; 348: 229–235.

Cima RR, Kollengode A, Garnatz J et al. Incidence and characteristics of potential and actual retained foreign object events in surgical patients. *J Am Coll Surg* 2008; 207: 80–87.

Lincourt AE, Harrell A, Cristiano J et al. Retained foreign bodies after surgery. *J Surg Res* 2007; 138: 170–174.

Gibbs VC, Coakley FD, Reines HD. Preventable errors in the operating room: retained foreign bodies after surgery – Part I. *Curr Probl Surg* 2007; 44: 281–337.

D Hariharan and DN Lobo. Retained surgical sponges, needles and instruments. *Ann R College of Surgery England*.2015;95(2) 87-92.

Implications of retained swabs

Retained surgical items have 70% re-interventions, reaching 80% morbidity and 35% mortality.

90% of retained items were textiles (swabs/sponges)

Birolini DV, Rasslan S, Utiyama EM. Unintentionally retained foreign bodies after surgical procedures. Analysis of 4547 cases. *Rev Col Bras Cir* 2016; 43: 12–17. 2016/04/21. DOI: 10.1590/0100-69912016001004.

References to total number of surgeries in UK

T. E. F. Abbott, A. J. Fowler, T. D. Dobbs, E. M. Harrison, M. A. Gillies, R. M. Pearse, Frequency of surgical treatment and related hospital procedures in the UK: a national ecological study using hospital episode statistics, *BJA: British Journal of Anaesthesia*, Volume 119, Issue 2, August 2017, Pages 249–257,

References to Litigation burden and costs

Links to copy paste in browser:

https://e1cf0d39-bf70-4edc-8252-971a0e7482f8.filesusr.com/ugd/d0e9ff_8fb55c2f8378423aaef11e5db0efbb5f.pdf

https://e1cf0d39-bf70-4edc-8252-971a0e7482f8.filesusr.com/ugd/d0e9ff_422b566e3d3645e598e8b83049e84d2b.pdf

In the US the average cost incurred from litigation in these cases is estimated to be more than \$50,000

Ref

Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med*. 2003 Jan 16;348(3):229-35. doi: 10.1056/NEJMsa021721. PMID: 12529464.

Kaiser CW, Friedman S, Spurling KP, Slowick T, Kaiser HA. The retained surgical sponge. *Ann Surg*. 1996 Jul;224(1):79-84. doi: 10.1097/0000658-199607000-00012. PMID: 8678622; PMCID: PMC1235250.

Increased length of stay and mortality (AHRQ- association of healthcare research and quality data)

According to the report issued by association of healthcare research and quality, the discovery of a retained foreign body added four days to the average hospital stay and 57 patients died because of this type of error.

Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA*. 2003 Oct 8;290(14):1868-74. doi: 10.1001/jama.290.14.1868. PMID: 14532315.

Other Review Articles, case reports, Systematic reviews

Tabibzadeh, M., & Kumari, N. (2024). Retained surgical sponges: Systematic root cause analysis of 652 reported cases using data analytics. *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care*, 13(1), 123–129. <https://doi.org/10.1177/2327857924131077>

Sirihorachai R, Saylor KM, Manojlovich M. Interventions for the Prevention of Retained Surgical Items: A Systematic Review. *World J Surg*. 2022 Feb;46(2):370-381. doi: 10.1007/s00268-021-06370-3. Epub 2021 Nov 12. PMID: 34773133; PMCID: PMC10186264.

Retained surgical sponges, needles and instruments. D Hariharan et al. 2013. <https://doi.org/10.1308/003588413X13511609957218>-- A surgical sponge is the most commonly reported retained item following surgery, while reports of retained needles and instruments are extremely rare.

Wrong-Site Surgery, Retained Surgical Items, and Surgical Fires. A Systematic Review of Surgical Never Events. Susanne Hempel, PhD; Melinda Maggard-Gibbons, MD; David K. Nguyen, MD; Aaron J. Dawes, MD; Isomi Miake-Lye, BA; Jessica M. Beroes, BS; Marika J. Booth, MS; Jeremy N. V. Miles, PhD; Roberta Shanman, MLS; Paul G. Shekelle, MD, PhD. *JAMA Surg*. 2015;150(8):796-805. doi:10.1001/jamasurg.2015.0301

Global state of patient safety report by the Institute of Healthcare Improvement and Imperial College 2023. Retained surgical items are one of the important metrics featured in International patient safety reports

Siddharth S Adyanthaya, Vishal Patil, Never events: an anaesthetic perspective, *Continuing Education in Anaesthesia Critical Care & Pain*, Volume 14, Issue 5, October 2014, Pages 197–201, The transfusion of ABO incompatible blood groups has become a rarity particularly since the introduction of the Portable Blood Audit Release System. The barcode scanning system for patient identification and blood transfusion is a good example of the use of technology to prevent never events.

Investigation report: Retained swabs following invasive procedures. Health Services Safety investigation body, UK. 2024. <https://www.hssib.org.uk/patient-safety-investigations/retained-surgical-swabs/investigation-report/> --Describes the problem and value of adjunct technology to risk mitigate human error

Current practices for counting medical sponges have a 10% to 15% error rate

Joint Commission. Preventing unintended retained foreign objects. . Published October 17, 2013.

Research grant funded by the Health Research Board of Ireland Research Collaborative in Quality and Patient Safety

Value of technological adjunct solutions in preventing never events - limitations of manual counting and value of technological adjuncts

Manual counting alone has been shown to be inherently unreliable, with multiple studies demonstrating that retained surgical items frequently occur despite apparently correct counts.

Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med.* 2003;348(3):229–235.

Egorova NN, Moskowitz A, Gelijns A et al. Managing the prevention of retained surgical instruments: what is the value of counting? *Ann Surg.* 2008;247(1):13–18.

Greenberg CC, Regenbogen SE, Lipsitz SR et al. The frequency and significance of discrepancies in the surgical count. *Ann Surg.* 2008;248(2):337–341.

Christian CK, Gustafson ML, Roth EM et al. A prospective study of patient safety in the operating room. *Surgery.* 2006;139(2):159–173.

Edel EM. Surgical count practice variability and the potential for retained surgical items. *AORN J.* 2012;95(2):228–238.

Joint Commission. Preventing unintended retained foreign objects. Published October 17, 2013.

Technological adjuncts have been developed to address the limitations of manual counting by providing independent verification, improving detection reliability, and reducing reliance on human memory and workflow variability.

Regenbogen SE, Greenberg CC, Resch SC et al. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effectiveness. *Surgery.* 2009;145(5):527–535.

Sirihorachai R, Saylor KM, Manojlovich M. Interventions for the prevention of retained surgical items: a systematic review. *World J Surg.* 2022;46(2):370–381.

Corrigan S, Kay A, O'Byrne K et al. A socio-technical exploration for reducing and mitigating the risk of retained foreign objects. *Int J Environ Res Public Health.* 2018;15(4):714.

Hempel S, Maggard-Gibbons M, Nguyen DK et al. Wrong-site surgery, retained surgical items, and surgical fires: a systematic review of surgical never events. *JAMA Surg.* 2015;150(8):796–805.

Health Services Safety Investigation Body (HSSIB). Investigation report: Retained swabs following invasive procedures. UK, 2024.

These studies collectively demonstrate that while manual counting remains an important component of surgical safety, system-based approaches incorporating technological adjuncts provide additional safeguards, particularly in complex, high-pressure clinical environments where human error, distraction, and workflow interruptions are common

Competitive costs to other technological adjunct solutions

Explains the costs of available adjunct technologies such as barcoded swabs and RFID enabled swabs.

Representative costs of these technologies are:

Bar-coded - \$10.60/ patient in 2009, now \$32.10 (company info)

RFID enabled - \$75.39/patient in 2009, now \$112 (company info). Hence these have only adopted in a total of 18% hospitals in the US and have not been adopted anywhere else in the world despite being on the market since 2007.

These technologies cost far higher than iCount, which will only cost a maximum of £9/patient

USA

Gossypiboma: an asymptomatic presentation ten years post gynecologic surgery. Neil Patel MD,² Sibel Dikmen, MS,² Sandeep Sirsi MD FACS,¹ Armand Asarian MD FACS,¹ Dmitry Youskho MD, FACOG² Department of General Surgery, The Brooklyn Hospital Center, USA

²Department of Obstetrics and Gynecology, The Brooklyn Hospital Center, USA Correspondence: Dmitry Youskho, MD, FACOG. The Brooklyn Hospital Center. 121 Dekalb Ave, Brooklyn, NY, 11201, USA, Tel 718-250-7494 Received: July 05, 2022 | Published: July 19, 2022

-Journal of Cardiothoracic Surgery, volume 14, issue 1, publication number 69 Intrapericardial gossypiboma found 14 years after coronary artery bypass grafting. Fatmir Caushi¹ Lindita Coku² Ilir Skenduli¹ Daniela Xhemalaj¹, Department of Cardio-Thoracic Surgery, Mount Sinai Hospital, New York, USA |

Gossypiboma manifesting as urachal mass. Department of Urology, University of Texas Southwestern Medical Center, Dallas, TX

Unintended retention of foreign bodies remain the most frequently reported sentinel events. Surgical sponges account for the majority of these retained items. The purpose of this study was to describe reports. Authors: Victoria M. Steelman, Clarissa Shaw, Laurel Shine and Abbey J. Hardy-Fairbanks. Citation: Patient Safety in Surgery 2018 12:20

Gossypiboma Resection after Eight Years in a Patient with Rheumatoid Arthritis and Diabetes Unruh, Kenley; Hsieh, Hsien Sing Sam. Case Reports in Surgery; New York Vol. 2017, (2017). DOI:10.1155/2017/3239093

Routine Blood loss measurement is important to treat PPH adequately. article which presents good evidence that measurement of blood loss during birth is recommended:

Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized trial of early detection and treatment of postpartum hemorrhage. N Engl J Med. 2023; 389(1): 11–21.

Ingela Wiklund, Soledad Alarcón Fernández, Markus Jonsson, Midwives' ability during third stage of childbirth to estimate postpartum haemorrhage, European Journal of Obstetrics & Gynecology and Reproductive Biology: X, Volume 15, 2022, 100158, ISSN 2590-1613

References to overall incidence and in emergency operations and surgery in children, reports from different countries and different surgeries

Teixeira PG, Inaba K, Salim A, Brown C, Rhee P, Browder T, Belzberg H, Demetriades D

Retained foreign bodies after emergent trauma surgery: incidence after 2526 cavitary explorations. *Am Surg.* 2007;73(10):1031.

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Biolini DV, Rasslan S, Utiyama EM. Unintentionally retained foreign bodies after surgical procedures. Analysis of 4547 cases. *Rev Col Bras Cir.* 2016 Feb;43(1):12-7. English, Portuguese. doi: 10.1590/0100-69912016001004. PMID: 27096851.

Yildirim T, Parlakgumus A, Yildirim S. Diagnosis and management of retained foreign objects. *Journal College Physicians Surgeons Pak.* 2015 May;25(5):367-71. PMID: 26008665.

Camp M, Chang DC, Zhang Y, Chrouser K, Colombani PM, Abdullah F. Risk factors and outcomes for foreign body left during a procedure: analysis of 413 incidents after 1 946 831 operations in children. *Arch Surg.* 2010;145(11):1085.

Corrigan S, Kay A, O'Byrne K, Slattery D, Sheehan S, McDonald N, Smyth D, Mealy K, Cromie S. A Socio-Technical Exploration for Reducing & Mitigating the Risk of Retained Foreign Objects. *Int J Environ Res Public Health.* 2018 Apr 10;15(4):714. doi: 10.3390/ijerph15040714. PMID: 29642646; PMCID: PMC5923756. Research grant funded by the Health Research Board of Ireland Research Collaborative in never events

Murdock D. Trauma: when there's no time to count. *AORN J.* 2008 Feb;87(2):322-8. doi: 10.1016/j.aorn.2007.07.008. PMID: 18323023.

Reference about underreporting –

Terkimbi UB, Joseph IT, Barnabas E. Retained Post-Operative Foreign Body of Gynaecologic Origin at Ascending Colon, *Gynecol Obstet Case Rep.* 2016, 2:2. doi:10.21767/2471-8165.1000028

Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review Su Golder^{1*}, Yoon K. Loke², Kath Wright³, Gill Norman⁴

Reference about underreporting in developing world

Biolini DV, Rasslan S, Utiyama EM. Unintentionally retained foreign bodies after surgical procedures. Analysis of 4547 cases. *Rev Col Bras Cir.* 2016 Feb;43(1):12-7. English, Portuguese. doi: 10.1590/0100-69912016001004. PMID: 27096851

Iftikhar, T., Sultana, N., Shah, S.A. Gossypiboma: An underreported surgical mishap 2017/10/01. *Rawal Medical Journal*

References to human error in counting, count discrepancies and risk of retained object when there is a count discrepancy

Greenberg et al study- At least one count discrepancy occurred in 12.8% of 148 operations (approximately one in eight operations); 41% of the discrepancies were due to process errors, including miscounts mathematical errors or documentation problems and 59% due to a misplaced surgical item.

Greenberg CC, Regenbogen SE, Lipsitz SR, Diaz-Flores R, Gawande AA. The frequency and significance of discrepancies in the surgical count. *Ann Surg.* 2008 Aug;248(2):337-41. doi: 10.1097/SLA.0b013e318181c9a3. PMID: 18650646.

Christian CK et al study-In a study that detailed activities doing ten complex general surgery cases and academic hospital accounting was that was in direct competition with the primary patient centred activities and average of 35 minutes per case was dedicated to counting representing 14.5% of nursing time during the operation. In spite of the time involved 17 count discrepancies were observed, 11 which disrupted activities of the surgical team. The observational team identified two events labelled as 'safety compromising' that occurred when attempt will be made to reconcile an inconsistent count.

Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM. A prospective study of patient safety in the operating room. *Surgery.* 2006 Feb;139(2):159-73. doi: 10.1016/j.surg.2005.07.037. PMID: 16455323.

Gawande AA, Studdert DM study and Greenberg CC, Gawande AA. The odds of a retained foreign body are increased 100-fold if there is a discrepancy between the initial and final count.

Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med.* 2003;348(3):229.

Greenberg CC, Gawande AA. Beyond counting: current evidence on the problem of retaining foreign bodies in surgery? *Ann Surg.* 2008 Jan;247(1):19-20. doi: 10.1097/SLA.0b013e318160c194. PMID: 18156917.

Steelman, Schaapveld et al study- The cost of reconciling incorrect- unresolved swab counts is considerable. Peri-operative personnel required from one to 90 minutes of additional time to reconcile each of 212 incorrect/unresolved counts. Using an estimate of \$62 per minute of operating room time, one study estimated that the total annualised cost of operating room time spent searching for sponges and ruling out the presence of potentially retained sponges at a busy level 1 trauma centre hospital at \$219,056

Steelman VM, Schaapveld AG, Perkhounkova Y, Storm HE, Mathias M. The Hidden Costs of Reconciling Surgical Sponge Counts. *AORN J.* 2015 Nov;102(5):498-506. doi: 10.1016/j.aorn.2015.09.002. PMID: 26514707.

Sensitivity, specificity, positive predictive value of counting

Egorova NN, Moskowitz et al. Managing the prevention of routine surgical instruments; what is the value in counting? *Ann Surg* 2008; 247:13 -18. Sensitivity of counts process is 77% and the positive predictive value is 1.6%. 88% of retained foreign bodies were associated with a correct count.

According to the Gawande et al report a positive likelihood ratio of 113, meaning that's the odds of retained for are increased 100 times if there is a persistent discrepancy

Count practice variability and unreliability of manual count

Edel EM. Surgical count practice variability and the potential for retained surgical items. *AORN J.* 2012 Feb;95(2):228-38. doi: 10.1016/j.aorn.2011.02.014. PMID: 22283914. Assessment of the policies and practices indicated that clinical practice requirements in the policies varied greatly, and there was a high degree of count practice variability among staff members.

The Frequency and Significance of Discrepancies in the Surgical Count. Greenberg, Caprice C. MD, MPH*†; Regenbogen, Scott E. MD‡§; Lipsitz, Stuart R. ScD*; Diaz-Flores, Rafael MD, MPH*†; Gawande, Atul A. MD, MPH*† Swab Count discrepancies can happen in upto 12 % procedures

Moffatt-Bruce SD, Cook CH, Steinberg SM, Stawicki SP. Risk factors for retained surgical items: a meta-analysis and proposed risk stratification system. *J Surg Res.* 2014 Aug;190(2):429-36. doi: 10.1016/j.jss.2014.05.044. Epub 2014 May 23. PMID: 24953990.

D Hariharan and DN Lobo. Retained surgical sponges, needles and instruments. Counting is time intensive occupying up to 14% of operative time. *Ann R College of Surgery England.* 2015;95(2) 87-92.

Regenbogen SE, Greenberg CC, Resch SC, Kollengode A, Cima RR, Zinner MJ, Gawande AA. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effectiveness. *Surgery.* 2009 May;145(5):527-35. doi: 10.1016/j.surg.2009.01.011. Epub 2009 Mar 21. PMID: 19375612; PMCID: PMC2725304.

Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM. A prospective study of patient safety in the operating room. *Surgery.* 2006 Feb;139(2):159-73. doi: 10.1016/j.surg.2005.07.037. PMID: 16455323.

References to imaging done in cases of retained items

Mathew RP, Thomas B, Basti RS, Suresh HB. Gossypibomas, a surgeon's nightmare-patient demographics, risk factors, imaging and how we can prevent it. *Br J Radiol.* 2017 Feb;90(1070):20160761. doi: 10.1259/bjr.20160761. Epub 2017 Jan 3. PMID: 27885854; PMCID: PMC5685123.

Radiology challenges in diagnosis:

Imoto, S., Shinjo, E., Aoyama, K., & Takenaka, I. (2018). A case of failure to detect lost surgical sponges with intraoperative radiography: A pitfalls in detecting retained sponges. *Japanese Journal of Anesthesiology*, 67(8), 844–846.

Cases where retained swab led to misdiagnosis

Boghration AH, Al-Tae AM. Gossypiboma Masquerading as Small Bowel Malignancy. *Middle East J Dig Dis.* 2020 Apr;12(2):123-125. doi: 10.34172/mejdd.2020.172. PMID: 32626566; PMCID: PMC7320991.

Atay M, Ahmad IC, Bilgin M, Kocakoc E. Gossypiboma/textiloma mimicking as tumour recurrence. *J Pak Med Assoc.* 2014 Jun;64(6):708-10. PMID: 25252498.

Maynard J, Shah N, Groom K, Khan S. Gossypiboma: a hidden passenger. *BMJ Case Rep.* 2015 Aug 25;2015:bcr2015212229. doi: 10.1136/bcr-2015-212229. PMID: 26307651; PMCID: PMC4550857.

Kim TH, Lee HH. Gossypiboma misdiagnosed as uterine subserosal myoma. *J Minim Invasive Gynecol.* 2015 May-Jun;22(4):534. doi: 10.1016/j.jmig.2014.11.004. Epub 2014 Nov 11. PMID: 25460523.

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Denmark

Danish Patient Compensation (official English site): confirms the compensation authority and 2024 activity levels. Official compensation example – “Gazetamponer glemt efter operation” (“gauze tampons forgotten after operation”): this is a direct retained-gauze / retained-sponge-type case example from the Danish Patient Compensation archive.

https://patienterstatningen.dk/eksempler-paa-afgoerelser/arkiv-over-tidligere-afgoerelser/2009/jun/gazetamponer-glemt-efter-operation?utm_source=chatgpt.com

Gauze Tampons Forgotten After Surgery

08 June 2009

Treatment Injury – Specialist Rule (KEL §20)

A 34-year-old woman underwent surgery in February 1996 for removal of a **benign pituitary tumour measuring 13 × 18 × 18 mm**. The procedure was performed via a **transsphenoidal approach (through the nose)** and proceeded as planned without complications. Six days later, following removal of the nasal tampons, the patient was discharged. In the subsequent period, the patient experienced **recurrent sinus infections** and was treated repeatedly with antibiotics. At a consultation with her general practitioner one year later, the patient reported that since the operation she had experienced **persistent blockage on the right side of the nose** along with **purulent (pus-containing) discharge**. She also reported that she had herself **pulled a piece of gauze from the right side of her nose**, along with a somewhat longer thread. During examination, the doctor identified and removed **an additional gauze tampon**. Medical records further indicated that **approximately 2½ months later**, yet another piece of gauze was extracted from the nose.

DecisionThe Danish Patient Compensation Association (Patienterstatningen) **recognised the case under** Patient Insurance Act §2(1)(1). **This was based on the fact that, in accordance with** accepted specialist standards, **all inserted gauze tampons should have been** counted and accounted for prior to completion of the operation.

Reasoning

In reaching its decision, Patienterstatningen emphasised that:

- Multiple gauze tampons had been inserted during the procedure
- **At least two tampons were left behind** following removal

As a result, the patient experienced:

- **Persistent symptoms for approximately one year**, including:
 - Headaches
 - Recurrent sinus infections
- Development of a **nasal polyp**

Case Reference

97-0819 (1997 Annual Report)

Norway

In Norwegian clinical terminology, a “swab” is often referred to as a *compress* (Norwegian: “**kompress**”)

Norway – Norsk pasientskadeerstatning (NPE)

Forgotten compress – compensation granted

A woman experienced a prolonged post-operative course after breast surgery. A retained **compress** (best understood in this context as a retained surgical swab/gauze sponge) was later identified in the breast wound after persistent infection and delayed healing. NPE concluded that the retained item had caused the complication and awarded compensation.

Reference: Norsk pasientskadeerstatning (NPE). *Gjenglempt kompress – medhold*. Official case summary. Available at: NPE website.

Forgotten compress after childbirth

A woman was found to have a retained **compress** in the genital tract about one week after childbirth. She later claimed that this had caused subsequent cardiac inflammation. NPE reviewed the case but found no probable causal link between the retained item and the later cardiac condition, and compensation was therefore denied.

Reference: Norsk pasientskadeerstatning (NPE). *Ettergløymd kompress – avslag*. Official case summary. Available at: NPE website.

Forgotten equipment – case index

NPE also maintains an official case index of retained-equipment claims, including retained compress cases in surgical and obstetric settings.

Reference: Norsk pasientskadeerstatning (NPE). *Gjenglempt utstyr*. Official case index. Available at: NPE website.

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Recent Media validated reports (2025 onwards)

A Hearst Newspapers investigation identified thousands of cases of surgical items unintentionally left in patients in recent years. Four patients have died in New York from these cases since August 2019.

<https://www.timesunion.com/projects/2025/objects-left-behind/>

Mel Schilling

Hospitals leave items in patients during surgeries in hundreds of cases per year, sometimes resulting in injuries and death.

<https://www.mrt.com/projects/2025/hospitals-surgical-objects-patients/>

<https://www.lakemchenryscanner.com/2025/02/03/lawsuit-alleges-staff-left-surgical-sponge-inside-patient-following-surgery-at-northwestern-medicine-hospital-in-mchenry/>

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