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Safety and efficacy of prophylactic onlay resorbable synthetic mesh with a comprehensive wound bundle at laparotomy closure in high-risk emergency abdominal surgery: an observational study

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Abstract

Background There has been a slow uptake of wound bundles and prophylactic mesh augmentation (PMA) strategies despite evidence supporting their role in reducing burst abdomens and incisional hernias (IH). This study evaluates outcomes of resorbable synthetic prophylactic mesh augmentation in reducing these rates and assesses the complication profile in emergency abdominal surgery.

Methods A retrospective ethically approved observational study of all patients who underwent emergency open abdominal surgery using supplemental prophylactic onlay TIGR® Mesh at Letterkenny University Hospital between September 2017 and April 2024 was undertaken to assess safety, complication profiles and outcomes. Comprehensive wound bundles and subcutaneous space closure were used.

Results Of the 49 patients included, the mean age was 64 years (± 16.4 , 31–86), 33/49 (67%) were female, and the mean body mass index (BMI) was 27 (± 7.4 , 17.3–45). 20% of patients had previous abdominal surgery. 19/49 (38%) patients experienced postoperative complications, of these 8 (42%) were Clavien-Dindo Grade I-II, and 11 (58%) were Grade III-IV. There were 7 in-hospital post-operative deaths (Grade V). 8 patients had open abdomens. Thirteen surgical site occurrences (SSO) were identified in 9 (18%) patients. There were no burst abdomens. Four of the superficial SSOs responded to antibiotics while one required opening and wound NPWT. Three patients (6%) developed an incisional hernia, which was detected at a mean follow-up of 353 days.

Conclusion A comprehensive, evidence-based wound bundle using onlay PMA with a synthetic resorbable mesh, achieves efficacious, safe abdominal wall closure in high-risk, emergency laparotomy patients, including those who require delayed abdominal wall closure.

Keywords Emergency laparotomy, Incisional hernia, Prophylactic mesh, TIGR, Wound dehiscence, Surgical site infection, Seroma, Onlay mesh, Wound bundle

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Background

Emergency general surgery (EGS) accounts for up to 50% of the modern general surgeon's workload. Emergency laparotomy is the highest-risk procedure we perform, with mortality rates approaching 15% internationally [1]. As outcomes improve through initiatives such as EGS registries [2], we need to focus not only on mortality but also on morbidity.

Paradigm shifts in fascial and wound closure [3] have been facilitated by randomised control trials (RCTs) of fascial closure techniques, such as small bite [4] and prophylactic mesh placement [5], which have shown significant reductions in IH rates. Similarly, reductions in burst abdomen [6], seroma formation [7] and surgical site infections (SSI) are possible through the implementation of wound bundles [8]. The uptake of these new approaches has been slow in clinical practice. Prophylactic mesh fascial augmentation has failed to gain wide acceptance with only 3% of surgeons in the UK currently using PMA [9]. This is due in part to a fear of adverse effects [10], perceived increased infection risk [11], potential chronic pain [12], mesh extrusion [13] and risk of enterocutaneous fistula [14]. In addition to potentially preventing IHs, which can develop in about 22% of emergency laparotomies [12], fascial dehiscence (burst abdomen), which occurs in 0.2–5% of elective and 3.8–45% of emergency abdominal surgery [6, 15], is also reduced with mesh-reinforced fascial closure [16]. With greater experience in mesh placement and novel forms of synthetic long-acting resorbable meshes, new opportunities have arisen [11]. The merits of using prophylactic mesh are highlighted in many scientific papers; however, there is limited data looking at their application in the emergency setting [12]. Resorbable mesh has the theoretical advantage of facilitating subsequent abdominal surgery as it has resorbed by 18 months. The European and American Hernia Societies as well as the World Society of Emergency Surgery guidelines for laparotomy closure highlight the evidence for PMA and recommend considering it at elective abdominal closure, however, they recognise that a knowledge gap exists in its use in emergency settings and fail to reach a consensus recommendation here [17, 18]. Emergency surgery can carry an increased risk of post-operative complications when compared with elective surgery, in part due to the inability to optimise patient risk factors before surgery, such as through weight reduction or achieving properly controlled comorbidities, as well as the presence of systemic inflammatory response syndrome and sepsis in 30–50% of those who undergo emergency laparotomies [19]. Meta-analyses, though limited, have similarly demonstrated a reduction in IH and fascial dehiscence, although with increased SSI rates in emergency surgery [20, 21].

We previously reported early favourable outcomes with onlay mesh and, in view of the reported slow uptake of wound bundles and prophylactic mesh prevention strategies [9, 10], we have expanded our review. This study evaluates the outcomes of using a wound bundle and resorbable synthetic prophylactic mesh augmentation in reducing early fascial dehiscence and incisional hernia rates and assesses the complication profile in emergency abdominal surgery.

Methods

Inclusion criteria

A retrospective ethically approved observational study of all patients who had emergency open abdominal surgery in a single surgical unit using supplemental prophylactic onlay TIGR[®] Matrix Surgical Mesh (Novus Scientific, Uppsala, Sweden) at Letterkenny University Hospital, Ireland between September 2017 and April 2024 was undertaken. TIGR[®] Matrix Surgical Mesh is a macroporous multifilament long-term resorbable synthetic surgical mesh, consisting of a fast-resorbing component (a copolymer of glycolide, lactide, and trimethylene carbonate), and a slow-resorbing component (a copolymer of lactide and trimethylene carbonate) [22]. The TIGR[®] mesh was placed at abdominal wall closure. Patients who underwent laparotomy during this time but did not have a TIGR[®] placed were not included. This included two patients who had an onlay prolene mesh, and three patients with perforated cancers to avoid a theoretical risk of cancer cells seeding into the mesh.

Peri-operative management and surgical technique

All surgeries were carried out by a single consultant (MS) and his team. In all cases, the consultant was scrubbed for the entire operation, including skin closure, dressing application, and patient sign-out. A standardised wound bundle was used. This incorporated pre-, intra-, and post-operative elements [23], including early antibiotic administration within one hour of emergency room presentation, control of blood glucose, prevention of hypothermia, pre-incision removal of patient hair, chlorhexidine and alcohol skin preparation, rectal wash-out with betadine for lower GI cases, double gloving, and wound and abdominal irrigation preceded by peritoneal swab/fluid sampling for gram stain and cultures [8]. Wound protectors were universally used. In the setting of peritonitis, the abdominal cavity was irrigated with one litre of warm antibiotic wash, co-amoxiclav in mild cases or gentamycin and clindamycin for severe purulent cases.

Prior to fascial closure, the subcutaneous fat was cleared from the fascia for 4 cm to facilitate “white on white” fascial anastomosis and the application of onlay mesh. A small bite fascia-only closure of 5 mm intervals and 10 mm lateral depth was performed with a 2/0

polydioxanone (PDS) suture (Stratafix, Ethicon Inc. NJ, US) on a 26 mm round-bodied needle. Two sutures were used, with one starting at either end of the incision. Self-locking fascial knots were not used. A 4:1 suture-to-wound ratio was used, and length documented.

Before placement, the mesh was soaked in an antibiotic solution and contact with skin was avoided. An onlay strip of TIGR® was fixed to the fascia with a running continuous locking 3/0 PDS suture. Before January 2023, two 4 cm mesh strips were incorporated into the fascia before closure [24] but subsequently, unless there was fascial shredding, the fascia was closed first and then a classic 6 cm wide onlay mesh was used. The subcutaneous space was obliterated with an interrupted 3/0 PDS and, in addition, the subcutaneous tissue was plicated to the mesh. Multiple layers of subcutaneous sutures were used in high BMI patients. Drains were used in the case of suspected bile leaks and in one case of a perforated duodenal ulcer.

The skin was closed using 3/0 spiral Monocryl (Stratafix, Ethicon Inc. NJ, US) with triclosan. The peritoneum was not closed in any of the patients. All wounds received incisional negative pressure wound therapy (NPWT), except for one patient enrolled in the PROPEL-2 study [25]. NPWT was not changed until the fifth postoperative day unless contaminated.

Management by open abdomen (OA) with planned delayed closure was reserved for patients on large doses of inotropes or vasopressors, or those requiring a second look for mesenteric ischaemia. The hospital was a registered site in the Closed Or Open after Laparotomy (COOL) study [26] and enrolled one patient who was randomized to OA.

Data collection and analysis

Patient demographics, pre-operative observations, bloods, operative indications, American Society of Anaesthesiologists (ASA) grade, Charlson Comorbidity Index (CCI) [27], operation duration, intraoperative findings, postoperative outcomes, number of surgeries, bacterial culture results, intensive care unit (ICU) and high dependency unit (HDU) admission, length of stay, and length of follow-up were extracted from patient medical records and captured in a standardised proforma. Wounds were classified according to The Centers for Disease Control and Prevention (CDC) Wound Classification: clean (class I), clean-contaminated (class II), contaminated (class III), and dirty (class IV) [28] and complications were graded using the Clavien-Dindo classification [29]. The patients' pre-operative risk of mortality was predicted using The National Emergency Laparotomy Audit (NELA) score [30]. The primary outcome was the development of an SSO as per the Ventral Hernia Working Group guidelines as any of the following:

SSI, seroma, wound dehiscence, enterocutaneous fistula, wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischaemia or necrosis, serous or purulent drainage, stitch abscess, haematoma, or infected or exposed mesh [31]. All patients were followed up for at least 30 days. Twenty-four patients included in this study were previously reported [32]. Data is reported as mean (\pm -standard deviation, range) unless otherwise specified. Multivariable logistic regression was performed using Stata/SE 18 [33].

Results

Patient demographics, operative characteristics, and hospital stay

This study identified 49 patients who underwent emergency open abdominal surgery between September 2017 and April 2024 with an onlay TIGR® mesh placed at fascial closure. The mean age was 64 years (\pm 16.4, 31–86), and 33/49 (67%) patients were female. The mean BMI was 27 (\pm 7.4, 17.3–45). A fifth (10/49) of patients had previous abdominal surgery.

Over half (51%) of patients were unstable pre-operatively in the emergency department with tachycardia (pulse > 100), hypotension, or significant acidosis (pH < 7.3). The mean ASA grade was 3. The CCI was 0–2 in 45/49 (92%) patients and 3–5 in 4/49 (8%) patients. The mean NELA predicted mortality was 10% (\pm 16%).

Surgery began laparoscopically in 9 cases, prior to conversion. The site of pathology, as outlined in Table 1, was lower gastrointestinal (GI) in 33/49 (67.3%), gallbladder in 5/49 (10.2%), upper GI in 4/49 (8.2%), abdominal wall in 3/49 (6.1%), appendicular in 2/49 (4.1%), and pelvic in 2/49 (4.1%). The mean duration of surgery was 160 (85–305) minutes. A midline approach was most commonly used at 43/49 (88%) and transverse, Kocher, and Lanz incisions were used equally frequently (4%). The position of the initial midline incision was guided by the site of anticipated pathology and was extended as required.

According to the CDC Wound Classification, 0/49 (0%) incisions were class I, 29/49 (59.2%) were class II, 10/49 (20.4%) class III, and 10/49 (20.4%) class IV. Peritonitis was present in the majority (57%) of operations. Peritoneal cultures were obtained from 23/49 (47%) patients and were positive in 12/23 (52%). A single pathogen was identified in 3/12 (25%) of the cultures, and 9/12 (75%) contained multiple pathogens. Candida was present in 5/23 (22%).

Anastomosis was performed in 21 cases, all hand-sewn, including 7 patients with large bowel obstruction who had primary anastomosis without stoma. There was one leak (4.8%) in a patient who underwent multiple segmental small bowel resections. Hartmann's patients had a stapled rectal stump and routine decompression with an indwelling Foley catheter post-operatively.

Table 1 Cause for surgery, Surgical Site occurrence, 30-day mortality, Follow-up

Cause for surgery		
<i>Site of Pathology</i>		
Large bowel	22	44.9%
Small bowel	11	22.4%
Gallbladder	5	10.2%
Upper gastrointestinal	4	8.2%
Strangulated hernia	3	6.1%
Grade 5 appendicitis	2	4.1%
Pelvic surgery	2	4.1%
Surgical Site Occurrence Complications	13 in 9 patients	
Superficial SSI	5	10%
Deep SSI	1	2%
Organ/Space SSI	3	6%
Incisional hernia	3	6%
Superficial wound dehiscence	1	2%
30-day mortality	7	14%
<i>Cause of death</i>		
Multiorgan failure due to sepsis	4	8%
Covid pneumonitis	1	2%
Central line infection	1	2%
Fungal septicaemia	1	2%
Follow-up		
Outpatient Clinic	41	98%
Transferred to another country	1	2%

Multiple visits to the operating theatre were required for 8/49 (16%) patients. Of these, 7 were OAs at index laparotomy with planned relooks (14%) and one was an unplanned return (2%). In the OA group, the average number of laparotomies was 4.5 (range 2–8). Direct peritoneal resuscitation was used post-operatively until abdominal closure was achieved [34]. An AbThera™ Advance Open Abdomen Dressing system (3 M Company, MN, USA) was used in all these cases. An inlay prolene mesh was used to prevent abdominal wall lateralisation [35], which was removed at OA closure and replaced with a TIGR® onlay mesh at final surgery. The single unplanned return to theatre related to a small bowel anastomotic leak – the initial TIGR® onlay mesh was removed at the first redo surgery to facilitate an OA. The mesh was not infected and did not contribute to the patient's anastomotic leak.

Post-surgery, all 49 patients were managed in ICU (47%) or HDU (53%). The median hospital stay was 11 days (3–220 days). Of those who survived and left hospital, 41/42 (98%) were reviewed within 30 days (Table 1). The mean extended follow-up was 353 days. All had at least one outpatient review, and 54% had two or more.

Surgical site occurrences

19/49 (38%) patients had a complication, of which 8 (42%) were Clavien-Dindo Grade I-II, and 11 (58%) were Grade III-IV. There were 7 in-hospital post-operative

deaths (Grade V) (Table 1). Thirteen SSOs were identified in nine (18%) patients, nine of which were infective in origin. There were no burst abdomens. Four of the superficial SSIs responded to antibiotics while one required wound opening and NPWT. The wound classifications in those with superficial or deep SSIs were dirty in two, contaminated in two, and clean-contaminated in two. A midline approach was used in 8/9 (88.9%) of those that developed a surgical site occurrence, and a Kocher incision in 1/9 (11.1%) patients. Organ space SSIs were drained radiologically (Table 1).

Three patients (6%) developed an incisional hernia during long-term follow-up, detected with combined clinical and radiological follow-up. Two were small incisional hernias in the upper part of the wound, with a 4 cm neck and asymptomatic – one was repaired during the patient's stoma reversal. One patient has a 10 cm incisional hernia and is awaiting surgery. No patient was referred to a pain specialist or required long-term synthetic opioids. There was no statistically significant relationship between hernia formation and BMI ($p=0.379$), diabetes ($p=0.700$), hypertension ($p=0.418$), ICU admission ($p=0.786$), or use of OA ($p=0.150$) on multivariable logistic regression analysis.

Discussion

This consecutive cohort of 49 patients undergoing emergency laparotomy reflects the real-world, pragmatic implementation of wound bundles and routine PMA at fascial closure with very low rates of IHs (6%) at short-term follow-up, no abdominal wall dehiscence, seromas, or mesh-related complications and without increased rates of SSO (18%) or postoperative complications (38%) compared to the international literature [36].

EGS patients account for over 10% of all hospital admissions, resulting in over 4 million admissions in the US alone in 2023 with 15% readmitted within 30 days of surgery [37]. Our cohort is a typical EGS sample of high-risk patients, with high-risk patients being classified as those with a NELA predicted 30-day mortality of greater than 5% [38]. The patients had diverse pathologies as demonstrated by the high rates of pre-operative physiological derangement and NELA predicted mortality. A GI origin accounted for 33/49 (67.3%) with the expected higher rates of Class III and IV wounds which are by definition high risk for SSIs. Despite half the patients having secondary peritonitis, and 25% of patients having positive peritoneal cultures, the rates of SSIs were not significantly increased by the insertion of a mesh compared to international studies for EGS laparotomy [36, 39]. When combined with mesh-mediated traction and NPWT, the abdominal wall was successfully closed in all OAs without any burst abdomens, abdominal wall fistulas, or mesh infections. In these delayed closure cases, a small

bite technique was still used without retention sutures or other adjuncts in all but one case, in which a Fasciotens® vertical traction device [40] was utilised with abdominal wall botox injection to facilitate eventual small bite closure with PMA.

Patients that require management by OA have a high associated mortality rate, with an international OA register reporting postoperative mortality rates of 31.9–56.9% internationally [41]. In our series, 4/8 OA patients died in hospital, limiting long-term follow-up in these patients. OA survivors carry a significant risk of IH estimated at 35–66% at 4–5 years, with those that develop IHs demonstrating a significant reduction in quality-of-life measures [42]. These IHs are some of the most technically challenging to repair requiring complex surgery, and one of four surviving OA patients developed an IH.

While wound bundles are increasingly used, compliance can be difficult to maintain [43]. Meta-analysis of wound bundles suggests that they can reduce SSIs, but that their success is relative to the number of components [44]. We know from the NELA study that consultant input is a vital element in improving laparotomy outcomes [38], and our wound bundle program is driven by consultant oversight of iteration, implementation, and practice. At this hospital, the wound care package is continually improved on as new evidence becomes available [8].

Multiple RCTs have investigated elements of abdominal closure over the last decade. The STITCH (21% vs. 13%) [3] and ESTOIH (10.5% vs. 7.6%) [4] RCTs showed reduced rates of incisional hernias with small bite closure compared to large bite closure after laparotomy, which have since been supported by a meta-analysis demonstrating reduced rates of incisional hernia (relative risk (RR) 0.54) and SSI (RR 0.68), with a modest increase in closure times (mean difference 4.78 min) with small bite closure [45]. Implementation into practice is affected by surgeon's perceptions of the study limitations and applicability of findings and their anecdotal experiences, patient factors, and healthcare environments. Peer influence and a lack of training further influence adaptation [46]. Uptake has varied internationally – a survey from 2022 of 561 general and colorectal surgeons suggested 74.5% used small bite in clean-contaminated cases, and 59.5% in cases of faeculent peritonitis [47] however, a more recent UK study suggested as few as 19.9% of consultant surgeons were using it routinely [9].

Anti-septic subcutaneous wound irrigation has been extensively investigated by RCTs, looking at multiple anti-septic solutions including polyhexanide, chlorhexidine gluconate, and povidone-iodine with most, though not all, suggesting that they significantly reduce SSI rates compared to no irrigation (10.6–21.5% vs. 12.8–34.7%, 9.4% vs. 19.2%, and 16% vs. 13% respectively) [48–51].

Prior meta-analysis suggested that SSI rates were reduced by wound irrigation with any solution when compared to no irrigation (odds ratio (OR) 0.54) [52]. Similarly, the use of prophylactic wound NPWT in closed laparotomy wounds has been investigated by multiple RCTs, observational studies and meta-analyses, with most showing reduced SSI rates compared to standard dressings (RD 0.65, OR 0.25) [53,54], though in some cases the effect did not reach significance due to wide confidence intervals (RR 0.56, CI 0.3–1.03, $p=0.064$) [55]. In a pragmatic cluster RCT, routine change of gloves and instruments prior to abdominal closure reduced SSIs by 2.9% [56].

Use of PMA remains very low in the surgical community, even in the elective setting, as demonstrated by the CLAMSS survey with only 3% of respondents routinely performing it at laparotomy closure [9]. Lack of research evidence and a perception of low personal IH rates were cited as reasons for low uptake [9]. The PRIMAAT study provides the most dramatic evidence in favour of PMA at midline closure with 5-year outcomes showing a 49.2% IH rate with suture closure alone, and 0% with mesh reinforcement [57]. This is supported by meta-analyses of PMA at elective and emergency laparotomy which have consistently demonstrated reduced rates of IH (OR 0.38) but with variable outcomes regarding risks of wound complications such as seromas [20, 21]. The benefit of PMA specifically in emergency laparotomy is seen in a long-term follow-up series from Bravo-Salva et al., showing a 36.6% IH rate for suture closure alone compared to 14.3% for onlay PMA beyond 2-year follow-up, with just 2 mesh infections occurring in 131 patients without the need for mesh explantation [58]. Hernández et al. recently introduced the concept of the number needed to treat suggesting that 5 patients needed to undergo PMA to exceed any potential harm [59].

Concerns regarding mesh infection and the need for explantation are often raised. Mesh infection after groin and abdominal surgery is rare at 1.9%, though when it occurs these meshes often need to be explanted (21.2%) [60, 61]. However, this appears to be more common in patients that undergo intraperitoneal onlay mesh (IPOM) repair with 5.6% of patients in a series of 1,072 requiring complete or partial explant [62]. This rose to 34.9% when looking at patients who had experienced SSIs [62].

Synthetic meshes are considerably cheaper than biologic meshes, for a similar outcome [63]. Biosynthetic meshes have potential in contaminated fields as they are resorbed. Meta-analysis suggests an SSI rate of 17.3% and SSO of 32.4% with these meshes, but also a promising rate of hernia recurrence of 11.5% during a mean follow-up of 23.0 months [11]. We chose to use a synthetic fully resorbable mesh (TIGR®) due to its two-stage resorption profile. An optimum mesh for PMA has not been determined to date, but biosynthetic and synthetic meshes

appear to have preferable outcomes and cost compared to biological meshes. The optimal position, either onlay, in-lay, retrorectus, sublay, or intra-peritoneal, for PMA has not been established. While PRIMAAT used retrorectus mesh, this is technically complex compared to onlay and less suitable in the emergency setting [57]. An onlay mesh preserves the retrorectus space, which allows it to be used for subsequent definitive repair in the event of an incisional hernia.

The low rates of IH (6%) and absence of burst abdomen, seroma, and mesh explanation in our cohort suggest that our choice of TIGR® PMA in association with a comprehensive wound bundle is safe and effective. However, this study is not without its limitations. The duration of follow-up was on average less than a year and it is likely that more IHs will develop over time. A further limitation of this study is that patients were not routinely sent for a computed tomography (CT) scan after their emergency laparotomy – those who had a CT scan post-laparotomy were done for post-operative oncological surveillance. The most accurate way in which to detect incisional hernias is by CT, trumping both physical examination and ultrasound [64]. The sample size, while large enough to capture the generality of EGS, is small relative to the rarity of outcomes such as mesh explantation. All surgeries were performed by the same surgeon, which exhibits a potential selection bias. However, the same technique was used in all cases and without the variability of surgical technique, and so it was applied in an unbiased approach across a very heterogeneous patient group.

With a median follow-up of 27 months in the PRIMA trial, where lightweight prolene mesh was used, 3.1% of patients underwent reoperation to have their mesh explanted due to infection, seroma or hematoma [5]. TIGR® mesh appears to be well tolerated and has the advantage in those who may need unrelated later relaparotomy of being absorbed. The number of re-operations in the PRIMA follow-up series for abdominal wall or mesh-related complications was 15 (6.2%) [5], which was higher than our unplanned relaparotomy figures, despite our series' significant load of class 3 and 4 wounds. This highlights the importance of a wound bundle.

Conclusion

In conclusion, this cohort demonstrates that a comprehensive, evidence-based wound bundle using small bite closure and onlay PMA with a synthetic resorbable mesh achieves efficacious, safe abdominal wall closure in high-risk, emergency laparotomy patients, including those that require delayed abdominal wall closure. Sub-optimal results remain with traditional abdominal closure techniques, with unacceptable rates of surgical site occurrence and incisional hernias. This study provides proof of concept that findings from RCTs preliminarily carried

out in elective abdominal procedures can be transferred to the EGS patient population with promising short and long-term outcomes, and without significantly increased risk of abdominal wall complications.

Abbreviations

PMA	Prophylactic Mesh Augmentation
IH	Incisional Hernia
BMI	Body Mass Index
SSO	Surgical Site Occurrence
EGS	Emergency General Surgery
RCT	Randomized Controlled Trial
SSI	Surgical Site Infection
NPWT	Negative Pressure Wound Therapy
OA	Open Abdomen
ASA	American Society of Anaesthesiologists
CCI	Charlson Comorbidity Index
ICU	Intensive Care Unit
HDU	High Dependency Unit
CDC	The Centers for Disease Control and Prevention
NELA	The National Emergency Laparotomy Audit
GI	Gastrointestinal
CT	Computed Tomography

Acknowledgements

The authors would like to thank Professor William Campbell for his generosity in funding this research.

Author contributions

According to the CRediT Contributor Roles: EK was involved in investigation, formal analysis, visualisation, writing the original draft and reviewing & editing the draft. AL was involved in investigation and reviewing & editing the draft. DA was involved in investigation and reviewing & editing the draft. IS was involved in conceptualization, visualisation, writing the original draft and reviewing & editing the draft. MS was involved in conceptualization, funding acquisition, project administration, resources, supervision, writing the original draft and reviewing & editing the draft. All authors have approved the submitted version of the manuscript and have agreed to both be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Funding

Professor William Campbell Scholarship.

Data availability

All data generated or analysed during this study is included in this article.

Declarations

Ethics approval and consent to participate

This research was ethically approved by the Clinical Research Ethics Committee at Letterkenny University Hospital.

Consent for publication

Not applicable.

Competing interests

Michael Sugrue used to be a consultant with 3 M, Smith & Nephew, and Novus Scientific – he has not received payment from any medical company in the last 2 years. The other authors declare that they have no conflict of interest.

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Received: 29 September 2024 / Accepted: 11 January 2025

Published online: 06 March 2025

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