



## ORIGINAL ARTICLE

# Contemporary results from the PelvEx collaborative: improvements in surgical outcomes for locally advanced and recurrent rectal cancer

## The PelvEx Collaborative

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### Abstract

**Aim:** The PelvEx Collaborative collates global data on outcomes following exenterative surgery for locally advanced and locally recurrent rectal cancer (LARC and LRRC, respectively). The aim of this study is to report contemporary data from within the collaborative and benchmark it against previous PelvEx publications.

**Method:** Anonymized data from 45 units that performed pelvic exenteration for LARC or LRRC between 2017 and 2021 were reviewed. The primary endpoints were surgical outcomes, including resection margin status, radicality of surgery, rates of reconstruction and associated morbidity and/or mortality.

**Results:** Of 2186 patients who underwent an exenteration for either LARC or LRRC, 1386 (63.4%) had LARC and 800 (36.6%) had LRRC. The proportion of males to females was 1232:954. Median age was 62 years (interquartile range 52–71 years) compared with a median age of 63 in both historical LARC and LRRC cohorts. Compared with the original reported PelvEx data (2004–2014), there has been an increase in negative margin (R0) rates from 79.8% to 84.8% and from 55.4% to 71.7% in the LARC and LRRC cohorts, respectively. Bone resection and flap reconstruction rates have increased accordingly in both cohorts (8.2%–19.6% and 22.6%–32% for LARC and 20.3%–41.9% and 17.4%–32.1% in LRRC, respectively). Despite this, major morbidity has not increased.

**Conclusion:** In the modern era, patients undergoing pelvic exenteration for advanced rectal cancer are undergoing more radical surgery and are more likely to achieve a negative resection margin (R0) with no increase in major morbidity.

### KEYWORDS

international collaboration, locally advanced, rectal cancer, surgical outcomes, survival outcomes

## INTRODUCTION

Radical surgery remains the mainstay of curative treatment for locally advanced and locally recurrent rectal cancer (LARC and LRRC, respectively) [1]. Improved techniques, protocolized perioperative care and advances in adjuvant therapies have led to an increase

in the number of patients being considered for surgery [2, 3]. Proportionately, there has been an increase in research relating to pelvic exenterative surgery.

Numerous studies and regionalized groups have highlighted the importance of achieving a negative margin (R0) [4–6]. This is well established to be the 'holy grail' of exenterative surgery, as it is the

See [Appendix 1](#) for members of The PelvEx Collaborative.

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greatest predictor of long-term survival [4–7]. Challenges arise in the setting of locally advanced and recurrent malignancy, where anatomical distortion of tissue planes occurs due to a combination of infiltrative disease, prior surgical intervention and the effect of other treatment modalities (e.g. irradiation). As a result, the traditional principles of total mesorectal excision surgery do not apply. The exenterative resection margin is in the disrupted extramesorectal plane and often requires *en bloc* resection of adjacent soft tissue, bone, ligaments and/or neurovascular structures to ensure tumour clearance [7–9].

Increased operative experience and collaboration has resulted in previous absolute contraindications being challenged, with ‘higher and wider’ resections being pursued in highly selected patients [10–13]. Ultimately, the boundaries of surgery are less clear, and tailoring surgery to the individual patient is increasingly important [14].

The PelvEx Collaborative was established to produce large-volume data from specialist centres around the globe regarding a relatively uncommon procedure. Since it was established, it has grown to include 150 units from across six continents, including centres that are early in their exenterative experience and long-established high-volume units. The collaborative has generated several key publications reporting on surgical and survival outcomes, guidance and consensus documents, and is currently recruiting for its first randomized controlled trial. The role of the group has been to collectively share experiences and to disseminate clinical and research ideas to improve the outcomes of patients. By analysing contemporary data, we hoped to determine whether surgical outcomes have improved during this time, and to benchmark the data against previous PelvEx publications.

## METHOD

An updated review of PelvEx data (2017–2021) was undertaken to assess surgical outcomes of patients undergoing pelvic exenteration for LARC and LRRC. Forty-four international institutions participated, representing 26 countries. Each centre has a specialist interest in the treatment of advanced pelvic cancer. All patients are routinely discussed at a dedicated colorectal cancer multidisciplinary team conference. A principal investigator from each participating centre collated their data and submitted them centrally for analysis. Ethical approval was sought at an individual institutional level.

The diagnosis of LARC was based on histological assessment and/or radiological imaging. An agreed data set was predetermined and completed by all participating institutions. Data were then audited centrally. Any discrepancies were highlighted and reviewed by the relevant submitting institution for clarification.

Basic patient demographics, use of neoadjuvant (regimen) and type of exenteration including bone resection or flap reconstruction (where applicable) were documented. Histopathological assessment including margin status (R status) was recorded. Length of hospital

### What does this paper add to the literature?

This study reports contemporary PelvEx Collaborative data on outcomes following surgical management of locally advanced and locally recurrent rectal cancer. Overall, there has been a considerable improvement in negative margins rates, with higher rates of bone resection and flap reconstruction, without a major difference in morbidity.

stay, 30-day overall and major complication rate and 90-day mortality rate were also noted.

## Definitions

The terminology for exenterative surgery has evolved significantly in the last two decades. Total pelvic exenteration was defined as complete *en bloc* resection of the rectum, genitourinary viscera, internal reproductive organs, regional lymph nodes and peritoneum. Partial pelvic exenteration included those having an anterior, posterior and/or modified pelvic exenteration. Anterior pelvic exenteration included resection of the bladder with or without the internal reproductive organs (uterus, vagina, cervix, prostate, seminal vesicles). Posterior pelvic exenteration included resection of the rectum with or without the internal reproductive organs, while preserving the bladder. Modified pelvic exenteration was subdivided into those requiring lateral sidewall compartment resection with/without neurovascular resection or those requiring a bony resection. Histopathological evaluation considered an R0 resection if all margins were  $>1$  mm. R1 resection was the presence of microscopic residual disease defined as  $\leq 1$  mm, while R2 resection was the presence of macroscopic residual disease.

## Endpoints

The primary endpoint was surgical outcomes in terms of resection margin status. Secondary endpoints included the use of neoadjuvant treatment, type of resection, volume of bony resection, use of flap reconstruction, postoperative length of stay, overall complication (morbidity) rates and 90-day mortality.

## Statistical analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 22. Descriptive analysis was undertaken to report variable frequencies. Differences between patient groups were evaluated using the chi-square ( $\chi^2$ ) test (for categorical variables), Student's *t*-test and the Mann–Whitney *U*-test as appropriate. Reported intergroup comparisons were significant at the 5% level ( $p < 0.05$ ).

## RESULTS

A total of 2186 patients with advanced rectal cancer who underwent pelvic exenteration between 2017 and 2021 were included in the study; of these 1386 patients (63%) had LARC and 800 patients (37%) had LRRC. Male gender was more common ( $n=1232$ , 56%), and the median age was 62 years [interquartile range (IQR) 52–71 years]. The median body mass index for the study cohort was 25 kg/m<sup>2</sup> (IQR 22.8–28.9 kg/m<sup>2</sup>).

Overall, 608 patients (28%) and 701 patients (32%) had a bone resection and flap reconstruction, respectively. The median length of hospital stay was 17 days (IQR 11–26 days), 1385 (63%) experienced a postoperative complication and 90-day mortality was 2.6% ( $n=57$ ).

### Locally advanced primary rectal cancer

There were 1386 patients with LARC (63.4%). Male gender was more common ( $n=759$ , 54.8%) and the median age was 61 years (IQR 51–70 years). The majority of patients ( $n=1130$ , 81.5%) underwent neoadjuvant treatment prior to pelvic exenteration. [Table 1](#) gives a breakdown of the exenterative procedures and a comparison with previously reported PelvEx data [4, 15].

In recent years (2017–2022) there has been an increase in bone resection rates to 19.6% ( $n=273$ ) of all LARC cases; the corresponding figure in the original PelvEx paper was 8% [4]. Use of flap reconstruction has also increased to 32% ( $n=444$ ) from 23%. The median length of surgery was 420 min (IQR 315–561 min) and median blood loss was 1100 mL (IQR 550–1800 mL). Importantly, negative margins (R0) were achieved in 84.8% of cases ( $n=1176$ ). Overall, a complication of any type was observed in 816 patients (58.8%); of these, 320 patients (20.4%) had a major complication (Clavien–Dindo 2+). Having a bone resection was associated with a higher rate of major complications (hazard ratio 1.65, 95% CI 1.14–2.25,  $*p \leq 0.001$ ). The median length of hospital stay was 17 days (IQR 15–24 days) and 90-day mortality was 2.6% ( $n=37$ ). [Table 1](#) outlines the benchmarking against previous reported PelvEx data and [Table 2](#) outlines outcome details for those having a bone resection.

### Locally recurrent rectal cancer

There were 800 patients with LRRC (36.6%). Male gender was more common ( $n=473$ , 59.2%), and the median age was 63 years (IQR 53–70 years). The majority of patients ( $n=488$ , 61%) had neoadjuvant treatment prior to pelvic exenteration. [Table 3](#) gives a breakdown of exenterative procedures and a comparison with previously reported PelvEx data [7, 15].

In recent years (2017–2022), there has been an increase in bone resection rates to 41.9% ( $n=335$ ) of all LRRC cases, compared with 20% reported in the original PelvEx LRRC paper. Use of flap reconstruction has also increased to 32.1% ( $n=257$ ). The median length of surgery was 480 min (IQR 340–600 min) and median blood loss

**TABLE 1** Comparison of previous PelvEx data with contemporary data for locally advanced rectal cancer.

Benchmark variable	Previous PelvEx data (2004–2014)	Contemporary PelvEx data (2017–2021)
Sample size (N)	1291	1386
Median age (years)	63	61
Gender, $n$ (%)		
Male	778 (60.3%)	759 (54.8%)
Female	513 (39.7%)	627 (45.2%)
Neoadjuvant therapy, $n$ (%)	1008 (78.1%)	1130 (81.5%)
Type of PE, $n$ (%)		
Total PE	551 (42.7%)	501 (36.1%)
Modified PE	740 (57.3%)	885 (63.9%)
Bone resection, $n$ (%)	106 (8.2%)	273 (19.6%)
Flap reconstruction, $n$ (%)	292 (22.6%)	444 (32%)
Median length of surgery (min)	433	420
Median blood loss (mL)	NR	1100
Margin status, $n$ (%)		
R0	1030 (79.8%)	1176 (84.8%)
R1	172 (13.3%)	190 (13.7%)
R2	29 (2.2%)	14 (1%)
Unknown	60 (4.6%)	6 (0.5%)
Median length of hospital stay (days)	16	16
Postoperative complication rate, $n$ (%)	NR	816 (58.8%)
Major complication rate, $n$ (%)	488 (37.8%)	320 (23.1%)
90-day mortality, $n$ (%)	NR	37 (2.6%)

Abbreviations: NR, not recorded; PE, pelvic exenteration.

was 1685 mL (IQR 950–3100 mL). Importantly, negative margins (R0) were achieved in 71.7% of cases ( $n=574$ ). Overall, complications were observed in 569 patients (71.1%), with 191 of these (23.9%) having a major complication. Having a bone resection was associated with higher rate of major complications (hazard ratio 2.81, 95% CI 1.19–3.75,  $*p=0.02$ ). The median length of hospital stay was 19 days (IQR 13–28 days) and the 90-day mortality was 2.5% ( $n=20$ ). [Table 3](#) outlines the benchmarking against previously reported PelvEx data and [Table 4](#) outlines outcome details for those undergoing bone resection.

## DISCUSSION

This study highlights improved surgical outcomes for those undergoing pelvic exenteration for rectal cancer across the PelvEx Collaborative [4, 7, 15]. R0 resection rates in particular have improved in both LARC and LRRC cohorts when compared with our historical data [4, 7]. This may be attributed to the increased rates of bone resection, from 8% to 20% and from 20% to 42% in the context

**TABLE 2** Outcome data for those having bone resection in management of locally advanced rectal cancer.

Sample size (N)	273
Median length of surgery (min)	528 (IQR 390–648)
Median blood loss (mL)	1600 (IQR 900–2450)
Negative margin status, n (%)	230 (84.2%)
Median length of hospital stay (days)	22 (IQR 16–36)
Postoperative complication rate, n (%)	187 (68.5%)
Major complication rate, n (%)	66 (24.2%)
90-day mortality, n (%)	8 (2.9%)

Abbreviation: IQR, interquartile range.

**TABLE 3** Comparison of prior PelvEx dataset with contemporary data for locally recurrent rectal cancer.

Benchmark variable	Previous PelvEx data (2004–2014)	Contemporary PelvEx data (2017–2021)
Sample size (N)	1184	800
Median age (years)	63	63
Gender, n (%)		
Male	752 (63.5%)	473 (59.2%)
Female	432 (36.5%)	327 (40.8%)
Neoadjuvant therapy, n (%)	614 (51.9%)	488 (61%)
Type of PE, n (%)		
Total PE	418 (35.3%)	202 (25.3%)
Modified PE	766 (64.7%)	598 (74.7%)
Bone resection, n (%)	240 (20.3%)	335 (41.9%)
Flap reconstruction, n (%)	206 (17.4%)	257 (32.1%)
Median length of surgery, n (min)	509	480
Median blood loss, n (mL)	NR	1685
Margin status, n (%)		
R0	656 (55.4%)	574 (71.7%)
R1	363 (30.8%)	206 (25.8%)
R2	87 (7.3%)	19 (2.4%)
Unknown	76 (6.4%)	1 (0.1%)
Median length of hospital stay (days)	15	19
Postoperative complication rate, n (%)	NR	569 (71.1%)
Major complication rate, n (%)	380 (32.1%)	191 (23.9%)
90-day mortality, n (%)	NR	20 (2.5%)

Abbreviations: NR, not recorded; PE, pelvic exenteration.

of LARC and LRRC, respectively. These rates function as a surrogate of radicality, and have not been associated with an increase in major morbidity in either cohort.

These findings indicate significant developments across the entire spectrum of care; from diagnosis, input from specialist multidisciplinary teams, use of neoadjuvant treatment, preassessment

**TABLE 4** Outcome data for those having bone resection in management of locally recurrent rectal cancer.

Sample size (N)	335
Median length of surgery (min)	525 (IQR 385–636)
Median blood loss (mL) (IQR)	2100 (1100–4000)
Negative margin status, n (%)	258 (77%)
Median length of hospital stay (days)	22 (IQR 15–34)
Post-operative complication rate, n (%)	260 (77.6%)
Major complication rate, n (%)	93 (27.8%)
90-day mortality, n (%)	7 (2.1%)

Abbreviation: IQR, interquartile range.

and medical optimization, to refinements in surgical techniques and anaesthetic care in the perioperative phase. The development of the PelvEx Collaborative, with its subsequent research, meetings and guideline documents, has enabled the dissemination of new ideas and streamlining of expert opinion and has provided benchmarking of standards. It has cultivated supra-regional partnerships in advanced training, which have furthered the development of exenterative surgery at a global level and benefitted patient care. Classical contraindications to exenterative surgery have been abandoned and an individualized, patient-centred approach is encouraged. The selective upfront use of chemotherapy, immunotherapy and/or radiotherapy affords clinicians a period of time to identify those with adverse biology. In the future, machine learning and artificial intelligence may help clinicians to discern which patients may benefit from radical surgery. Importantly, there is a shift towards using quality of life measures as a more appropriate measure of treatment success, rather than focusing on survival outcomes alone.

The learning curve for surgery correlates with the complexity of the operation and the experience of the surgeon [16]. Formative analysis across the group is difficult, given that each centre is at a different individual and institutional stage in this process. Nonetheless, our findings indicate that, through collaboration, results for patients with complex rectal cancer have improved. It should be noted that surgical advances have been complemented by improvements in neoadjuvant treatments. Most recently, the use of total neoadjuvant therapy has become the standard of care in LARC [17–21], while early data on the use of immunotherapy has produced promising results [22]. However, the optimal management approach in LRRC remains unclear and varies substantially between regions [23, 24]. Strategies include a straight-to-surgery approach, chemotherapy alone, long-course chemoradiotherapy in those who are radiotherapy naïve or reirradiation with or without chemotherapy. The ongoing PelvEx II trial is the first randomized controlled trial instigated by the collaborative and is comparing induction chemotherapy plus chemoradiotherapy with chemoradiotherapy alone in LRRC [25].

Collaboration has allowed us to accrue a large volume of data for analysis of these relatively infrequently performed procedures. In the last two decades, increased proficiency with techniques of extended resection, in this series sacrectomy, have significantly improved patient outcomes [5, 26–28]. High-volume units have

developed exenterative services which provide a very high standard of care, and these centres have provided important technical insight from their evolving experience [11, 28–31]. As similar advances are replicated with techniques such as vascular resection, sidewall excision and the selective use of minimally invasive approaches, we anticipate that more patients globally will be considered for curative treatment [32–35]. Ultimately, we posit that collaboration has contributed to standardization and has improved global outcomes. This current paper offers updated ‘real world’ data vital for counselling patients undergoing an exenteration. In addition, it allows for continued benchmarking to ensure outcomes are reflective of the global status of exenterative surgery.

## AUTHOR CONTRIBUTIONS

**Michael E Kelly:** Conceptualization; methodology; investigation; writing – original draft; validation; writing – review and editing.

## FUNDING INFORMATION

No funding disclosure relevant.

## ACKNOWLEDGEMENT

Open access funding provided by IReL.

## CONFLICT OF INTEREST STATEMENT

All authors declare no conflict of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in PelvEx at <https://www.pelvex.org>. These data were derived from the following resources available in the public domain: PelvEx, <https://www.pelvex.org>.

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**How to cite this article:** Contemporary results from the PelvEx collaborative: improvements in surgical outcomes for locally advanced and recurrent rectal cancer. *Colorectal Dis*. 2024;00:1–6. <https://doi.org/10.1111/codi.16948>

## APPENDIX 1

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