

# A Simple Clinical Grading of Complexity Based on Local and Systemic Factors Demonstrates Pre-Operative Differences, Longer Operative Times, and Length of Stay in a Total Knee Replacement Patient Cohort

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## Abstract

**Background:** A 4-part grading system was developed and used to better stratify knee arthroplasty patients, based on presence or absence of systemic and local (site of surgery) factors with defined parameters. The 4 groups are: 1) C0 (Complexity Nil) patients having no local or systemic complexity. 2) C1 (Complex Local) patients having local site of surgery complexity but no systemic complexity. 3) C2 (Complex Systemic) patients having systemic complexity but no local complexity. 4) C3 (Complex Local & Systemic) patients having both local and systemic complexity. **Methods:** A cohort of consecutive primary knee arthroplasty patients were graded pre-operatively. Operative time, length of stay in hospital, 42-day readmission and 90-day mortality were key measured outcomes. **Results:** Of 1943 patients, group proportions were: C0 44%, C1 25%, C2 20%, C3 11%. There were statistically significant differences in demographics, operative times, length of hospital stays and 90-day mortality between groups. Combined local and systemic complexity (C3) patients demonstrated the poorest outcomes of all groups with statistical significance. **Conclusions:** This grading methodology shows differences in demography, total operating time and lengths of stay between groups. It shows summative interaction between local and systemic factors impacting operative performance, currently overlooked by many health systems and registries. The results have implications for patient information, resource allocation, case-mix assessment and economics. It establishes the case for further investigation

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of patient outcomes and application to other procedures and formal validation.

### **Keywords**

Total Knee Arthroplasty, Knee Replacement, Case Complexity, Clinical Complexity, Early Outcomes

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## **1. Introduction**

Knee replacement surgery is an established major surgical procedure, with excellent results based on implant survival and quality of life improvements [1]-[9]. Risks of complications and poor outcomes are also well documented [10]-[15].

Systemic factors such as the presence of comorbidities, extremes of age and body mass index (BMI) are cited as key risk factors for increasing length of stay and negative outcomes [8]-[17]. The principle focus of joint replacement literature, joint registries and coding systems is predicated on measure of comorbidities not on the severity of arthritis or other local complexity factors. In the UK for example case complexity is based on the presence of comorbidities and complications. Less attention has been given to the role of local surgical site-related complexities and its impact on outcomes [18]-[31]. Local site-of-surgery factors are poorly defined, have been reported only in small scale studies and are not currently fully captured in registry or coding data [32]-[34]. A small scale, single-surgeon evaluation of local and systemic factors has been undertaken [35]. This study highlighted the potential impact of local site of surgery factors in determining short term outcomes such as length of stay and heightened complication risk, particularly when combined with systemic comorbidities.

The study hypothesis based on clinical empirical observation was that local site factors would impact early surgical outcomes, defined by operative times, length of stay, 42-day readmission and 90-day mortality. If the effect was significant, the inference is that there is a system-wide neglect of the impact of local complexities in this patient population.

The primary research question was, “does pre-operatively determined local site of surgery complexity affect short-term surgical outcomes, in isolation or in combination with systemic complexity.” Secondary questions were the quantification of these differences and whether there were demographic differences between these complexity groups.

The potential utility of such a grading would be to provide a simple, accurate stratification of patients better reflecting the true spectrum of current primary knee arthroplasty complexity. This would provide patients, clinicians and clinical teams with a better understanding of the risks and recovery times. It would also provide healthcare commissioners a “real world” understanding of the complexity of workload being undertaken.

## 2. Patients and Methods

The Clinical Complexity Grading (CCG) is comprised of local and systemic complexity criteria, detailed in Box 1, which were defined and agreed by the Institution's specialist knee arthroplasty surgeons prior to the project start. Compilation and refinement of the criteria was undertaken in a staged process. A long-list of potential factors was established by discussion and literature reviews [8]-[10] [22]-[30] [36]-[41]. From this a short-list of factors was created and limits defined, such as degrees of deformity. Weekly knee group meetings over 15 months were used to discuss cases to establish cut-off criteria.

Systemic complexity was derived from the Charlson Major Comorbidity groups and the American Society of Anaesthesiology (ASA) grading for systemic complexity, due to their previous documented use and utility in surgical patients [8]-[10] [36]-[43].

Local complexity factors were: previous bony surgery such as osteotomies, bone loss > 20 mm, severe deformity: fixed flexion  $\geq 30^\circ$ , fixed varus  $\geq 20^\circ$ , valgus  $\geq 10^\circ$  from physiologic, deformed bone, multi-ligament instability (Grade 2+) in 2 planes and previous non-midline large (>20 cm) scars or reconstructive surgery.

Combining these factors produces the  $2 \times 2$  matrix shown in **Figure 1**, Box 2, which defined patients' clinical complexity grade (CCG) into the 4 groups, C0-C3. Example cases of 3 of the 4 complexity groups are shown in **Figure 2** & **Figure 3**.

All patients having an elective primary total knee replacement (TKR) surgery at our Institution were assessed and consented by a specialist knee surgeon at a pre-operative assessment consultation. The clinician assessed patients' CCG which was entered this prospectively onto the secure departmental database (Microsoft Access 2010, Microsoft Corporation, WA USA). Complexity grading wasn't a mandatory database field.

INDEX CONDITION ie knee OA	SIMPLE: straightforward OA pattern, NO local complexity criteria	COMPLEX: 1 or more local complexity criteria (as in Box 1)
GENERAL patient status		
SIMPLE Generally well ASA 1-2, NO systemic complexity criteria	<b>C0</b>	<b>C1</b>
COMPLEX With 1 or more systemic complexity criteria (as in Box 1)	<b>C2</b>	<b>C3</b>

**Figure 1.** Box 2: C0 to C3 stratification matrix for the clinical complexity grades.



**Figure 2.** Case example AP & lateral radiographs of the knee of a healthy 62 year old man, ASA1, with post-traumatic OA (ICD17.31) with marked fixed flexion, bone loss >1 cm medially and fixed varus deformities and multiple scars around the knee. Classified as C1.



**Figure 3.** Case example AP radiograph of the knee of a multi-morbid patient with cardiac, urologic and peripheral vascular comorbidities, ASA 3 with severe knee osteoarthritis (ICD-10, M17.1). Classified as C3.

Inclusion criteria for this study were primary unilateral total knee replacement procedures, with a pre-operatively entered clinical complexity grading. The joint replacement system utilised was the Triathlon total knee replacement system (Stryker, Newbury UK).

Exclusions were: unicompartmental joint replacement, bilateral simultaneous primary replacement surgery, any revision replacement operation including revision of unicompartmental to total replacement, any non-arthroplasty procedure. Patients with incomplete linkage to other hospital datasets were also excluded.

Operative time in this study is from the start of anaesthetic (needle to skin) to the end of operation (application of dressing). Information on theatre time, length of stay, 42-day readmission and time of death were obtained by cross-referencing

2 other hospital patient datasets.

Demographics, operative time and length of stay for the four clinical complexity groups were examined using ANOVA (analysis of variance) with application of Scheffe post-hoc testing (IBM SPSS Statistics Version 28.0, Armonk, USA). Categorical data differences were assessed using the Chi-square calculation. Mortality numbers were analysed using a Fisher's t-test. Statistical significance was  $p \leq 0.05$  for all analyses.

The study was submitted to the Institution's Research & Innovation Department and validated as a Service Evaluation Project, with the aims of optimising resource allocation and improving awareness of case-mix complexity. No external funding was applied for or received.

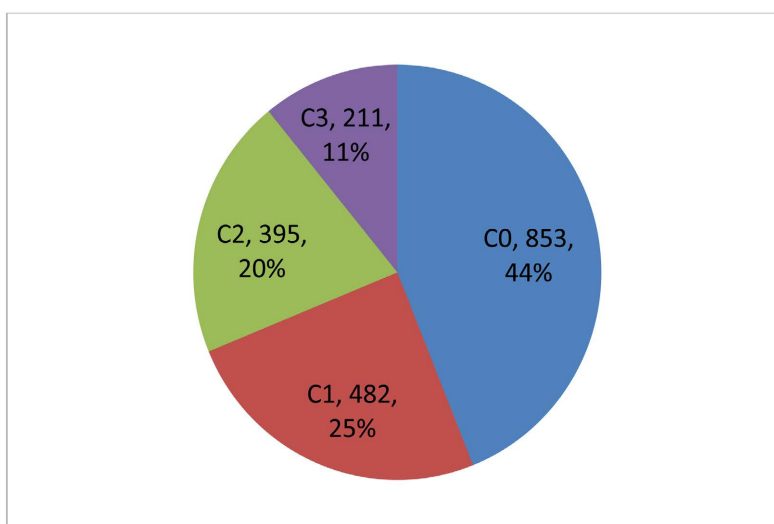
### 3. Results

There were 1,943 patients that met all the inclusion criteria. The mean age was 69.4 years (standard deviation [SD] 10.1 years) with a range from 27 to 95 years. A total of 1,174 (60.4%) of the patients were female. The mean BMI for the cohort was 32.6 (SD 6.8). During the study period 3,210 primary total knee arthroplasties were entered from our institution onto the National Joint Registry [25]; the study cohort represents 60.5% of this total.

The size and proportions of CCG groups C0 to C3 is shown in **Figure 4**, with the largest group of patients being the C0 "straightforward, no complexity" patient group. Baseline demographics by complexity groups are summarised in **Table 1**.

Age differences were highly significant ( $p < 0.0001$ ) between the CCG's. The C0 group patients were oldest at time of surgery, mean age 70.4 (95%CI 69.8 to 71.0) years; C3 were youngest, mean age 66.6 (95%CI 65.1 to 68.2) years.

The proportion of females and males between the complexity groups, shows more females represented in the complexity groups C1 and C3. The difference was statistically significant, when comparing C0 & C2 with C1 & C3 groups ( $p < 0.001$ ).



**Figure 4.** Overall distribution of C0-3 clinical complexity groups.

**Table 1.** Differences in baseline demographics between CCG.

	Complexity group			
	C0	C1	C2	C2
Age Mean (95%CI)	70 (69.6 - 70.8)	68 (67.0 - 68.9)	70 (68.8 - 70.7)	66 (64.8 - 68.0)
Female Gender	506 (60%)	299 (62%)	214 (45%)	154 (73%)
Male Gender	347 (40%)	183 (38%)	181 (55%)	57 (27%)
BMI Mean (95%CI)	30 (30.5 - 31.1)	31 (31.0 - 32.0)	35 (33.9 - 35.5)	38 (336.9 - 39.7)

Mean BMI increased progressively from C0 through to C3 groups, which is expected from the systemic complexity definitions included elevated BMI. Overall differences in BMI were highly significant ( $p < 0.0001$ ) across the CCGs, except C0 and C1, where the mean BMI for the C0 group was 30.9 (SERR 0.2, 95%CI 30.5 to 31.2) and the mean BMI for the C1 group, 31.5 (SERR 0.3, 95%CI 31.0 to 32), which was not statistically significant. However, there were significantly ( $p < 0.0001$ ) higher mean BMI values, relative to C0, for the C2, mean BMI 34.7 (SERR 0.4, 95%CI 3.9 to 35.4) and C3, mean BMI 38.3 (SERR 0.7, 95%CI 36.9 to 39.7) groups. The mean BMI for C3 was also significantly ( $p < 0.0001$ ) greater than that for C2.

In terms of outcomes, the mean theatre time for the cohort was 101.1 (standard error [SERR] 0.5, 95%CI 100.1 to 102.2) minutes, with 84% of patients having an operation time within 120 minutes. The mean length of stay was 5.5 days (SD 3.8), with 50% of patients discharged by day 5 and 86% by day 7 post-operatively. The short-term outcomes for each complexity group are shown in **Table 2**.

**Table 2.** Short term outcomes of operative time and length of stay by CCG.

	Complexity group			
	C0	C1	C2	C3
Theatre time (mins) Mean (95%CI)	95 (94 - 96)	109 (107 - 111)	100 (98 - 102)	114 (111 - 117)
Length of hospital stay (days) Mean (95%CI)	4.8 (4.6 - 5.0)	5.2 (4.9 - 5.5)	6.3 (5.8 - 6.8)	7.2 (6.5 - 8.0)
Re-admission within 42-day of operation	7%	8%	11%	10%
90-day mortality rate	0.1%	0	0.5%	1.6%

Overall, there was a highly significant ( $p < 0.0001$ ) difference in theatre time between complexity groups. The C0 group had the shortest theatre time, mean 94.5 (SERR 0.7, 95%CI 93.2 to 95.8) minutes. Systemic complexity alone, the C2

group, significantly ( $p = 0.002$ ) increased theatre time to 99.8 (SERR 1.1, 95%CI 97.7 to 101.9) minutes compared to C0. Isolated local complexity, C1, further increased theatre time, mean value was 108.6 (SERR 1.2, 95%CI 106.1 to 111.0) minutes, this was highly significantly different ( $p < 0.0001$ ) to both C0 and C2. The combination of local and systemic complexity, C3, had the longest mean theatre time, 113.3 (SERR 1.7, 95%CI 109.9 to 116.6) minutes, this was significantly ( $p < 0.0001$ ) greater than that for C0 and C2 groups. The only non-statistically significant difference in operating time was between the C1 and C3 groups.

Length of hospital stay was impacted by the presence of complexity. Local complexity (C1) alone did not significantly increase length of stay, where a mean difference of 0.4 days more was noted compared to C0, which was not statistically significant. However, systemic complexity (C2) added a mean of 1.7 days (95% CI 1.3 - 2.1) on to hospital stay ( $p < 0.0001$ ), and the presence of both local and systemic complexity (C3) resulted in a length of stay by 2.4 days (95% CI 1.9-3) longer compared to C0 patients i.e. patients without complexities ( $p < 0.0001$ ). There was statistically significant ( $p = 0.021$ ) between the mean difference between the C2 and C3 groups, with a difference between the C2 and C3 group of 0.9 days.

The 42-day readmission rates showed no statistically significant differences, but there were differences between the groups, with the lowest rate of 6.5% being in the C0 group, and higher rates in the other groups, suggesting a trend towards significance with increasing complexity.

The 90-day mortality did confirm statistically differences with the highest mortality noted in the C3 group of 1.6%, compared with none in C1, 0.1% in the C0 group and 0.3% in the entire cohort. There were no statistically significant differences between 90-day mortality between C2 and C3 groups.

#### 4. Discussion

Currently the strong emphasis on clinical risks and adverse outcomes of total joint arthroplasty surgery is centred on systemic factors, and this is the principle focus of data collection by national organisations including joint registries and hospital episode statistics [8]-[10] [12]-[18] [32]-[34]. This has been validated by a number of studies using very large patient numbers confirming the effects of systemic comorbidities on total knee replacement surgery outcomes. The patients in these databases can be characterised either as C0 or C2 groupings, with no, or very limited, recognition of the C1 and C3 patient sub-groups.

The wealth of information centred on comorbidities [9] [10] [12]-[18] affecting the likelihood of a good outcome and complication risk, does not exclude other factors involved in determining outcomes. This may be due to the difficulties in having consistent, reproducible methods of measuring local, site of surgery, factors such as bone loss, limb alignment deformities or ligament laxities. At the time of publication, there are still no clear definitions for what constitutes a locally complex primary replacement in general orthopaedic practice, joint registries or

literature. There are some obvious examples in day-to-day practice such as the presence of a severe deformity due to bone loss, requiring revision implants or metaphyseal augmentation. Based on the current study result, defining local complexity by the use of additional implants or implant types alone is a poor surrogate of local complexity as only about 15% of patients had constrained implants or revision augments. An additional factor causing this potential bias is that historically patients with complex arthritis patterns may have made up only a small proportion of total caseload, making them too small a sub-group to acknowledge. In contemporary knee arthroplasty practice, these cases are becoming increasingly common [44]. The authors have sought a pragmatic solution to this by selecting simple, reasonably measurable criteria for local complexity, as noted in **Figure 5**, Box 1.

Complexity types	Complexity criteria*
<p>LOCAL FACTORS</p> <p>Local complexity if following noted</p>	<ul style="list-style-type: none"> <li>- previous bony surgery (osteotomies etc)</li> <li>- Bone loss &gt; 20mm</li> <li>- Severe deformity: fixed flexion <math>\geq 30^\circ</math>, fixed varus <math>\geq 20^\circ</math>, valgus <math>\geq 10^\circ</math> from physiologic</li> <li>- previous bony surgery with deformed bone</li> <li>- multi-ligament instability (Grade 2+) in 2 planes.</li> <li>- previous non-midline large (&gt;20cm) scars or reconstructive surgery</li> </ul> <p>* rationale detailed in text</p>
<p>SYSTEMIC FACTORS</p> <p>Systemic complexity if following noted:</p>	<ul style="list-style-type: none"> <li>- ASA <math>\geq 3</math></li> <li>- BMI <math>\geq 50</math></li> <li>- more than 3 Major Charlson comorbidities</li> <li>- long-term immunosuppression</li> </ul>

**Figure 5.** Box 1: Definitions of local and systemic complexity.

The difficulty in defining local complexity has potentially led to confirmation and inattention biases against the contribution of local factors and its impact in individual patients, particularly those with multiple comorbidities [45]-[47]. Similar issues and solutions have occurred in other specialties, such as Cardiothoracic surgery with the creation of the Euroscore and ESOS [48] [49] for assessing risk in adult heart and thoracic surgery patients, which also combines site of surgery and systemic factors in determining operative risk. There are no other equivalent gradings in other medical fields, in particular Orthopaedics.

Defining cut-off points to create the 4 groups is the principal element in the creation of the CCG. We chose the use of major Charlson comorbidities and the American Society of Anaesthesiologists Scale [36]-[43] as they had been well documented in the past in surgical patient groups and local site of surgery factors as

described in the methods, but the principle is that the CCG criteria for both systemic and local factors can be updated, such that new information can be added over time, for example the use of the recent papers based on large national joint registry data highlighting mortality risks in knee replacement surgery [12] [14] [16]. Similarly, the criteria for local complexity could also be altered based on additional research, observation, and consensus. The advent of machine learning will provide a system by which multiple datapoints inputted in real-time could produce changes to CCG sub-group inclusion criteria.

The results show demonstrable differences between the four sub-groups, many of which are highly statistically significant, demonstrating the impact and summative effects of local site of surgery complexity alone and with systemic complexity. The finding of operating times being in the presence of local and systemic complexity (C3) as a cohort sub-group, even with the use of standard implants, has not previously highlighted in other studies.

The data relating to lengths of stay are slightly dated with the rapid shift towards daycase or 1 day admission surgery, however the themes are likely to remain even in contemporary practice, such that a small proportion of the most complex patients will have a potentially longer in-patient stay.

The findings of escalating length of stay re-admission risk and 90-day mortality, by increasing CCG group, demonstrates that local complexity is a potent contributor to even larger increases in length of stay, operative times and 90-day mortality when combined with systemically complexity in the C3 group. A larger study may demonstrate statistically significant differences between C2 and C3 groups in terms of both readmission and 90-day mortality risk. If readmission and 90-day mortality are taken as surrogate markers for post-operative complications, this again has implications for the additional healthcare burden caused by the most complex patients. This could also be part of a future study.

The overall uptake of usage of the CCG in standard clinical practice, without additional prompts during the study period implies that this is a reasonably user-friendly system. Additional prompts produced higher uptake; this was instituted onto the database after 2018, the rate of CCG input went up to 94% from 61% The grading is easy to adopt using the methodology shown in Boxes 1 and 2.

To some extent this classification can be seen as a logical extrapolation of the Charnley hip/knee classification [50] [51], which has to a greater extent fallen out of favour, but which has merit in identifying and stratifying patients into post-operative sub-groups which may have different pace and extent of recovery and sets expectations for what constitutes a good recovery, such that comparison within sub-groups may be more appropriate, in a more tailored fashion to each patient group. We also note that elements of the methodology are being used in other complexity scores, such as the Revision Knee Clinical Complexity (RKCC) [52] [53]. The use of the CCG may explain why the results of some surgeons and units differ from others, and why some units are able to provide more training opportunities and undertake greater numbers of day-case arthroplasty surgery,

due to differing proportions of C0, C1 and C3 patients, which are currently not determined by UK Joint Registry or Hospital Coding data. This would be confirmed by larger studies.

This study has several weaknesses. The study was designed and undertaken in a single centre; there was incomplete data capture of complexity scores of all TKR patients. There was no additional follow up to monitor complications and longer-term outcomes. Incorporating patient-reported outcome measures (PROMs) such as pain scores, functional limitations, and quality of life assessments would be an important addition to further evaluation of the Clinical Complexity Grading (CCG) and its impact on patient recovery. Patients' pre-operative socio-economic status and levels of activity [54] [55] as additional factors with potential to impact on post-operative outcomes, were not noted. These deficiencies must be addressed in future studies.

The authors are aware that the definitions of both systemic and local complexity are not validated within the wider orthopaedic knee community but suggest that this is a pragmatic start point for further planning and discussion. The first step in any larger evaluation would be to assimilate an expert group with a structured literature review to define the criteria for Box 1, prior to re-deploying the methodology. Additionally, future studies would need to observe post-operative complications and recovery in the 1<sup>st</sup> 2 years of surgery.

Using the CCG results in our Institution, patients are better counselled as to their risk of a prolonged length of stay, theatre teams are aware of this and potential need for additional implants and patients are allocated to surgeons and anaesthetists with appropriate expertise.

Using the CCG may explain variances of results of some surgeons and units, and why some units are able to provide more training opportunities and undertake great numbers of day-case arthroplasty surgery, due to differing proportions of C0-3 patients.

From a UK perspective where private providers have taken a higher proportion of C0 patients away from established NHS centres, the potential impact of both C1 and C3 groups in pushing up operative times and length of stays as well as readmissions and mortality has not been taken into consideration. This may well be true for other countries.

It is evident that this methodology could be utilised in other areas of orthopaedic and surgical practice.

## 5. Conclusions

- Clinical Complexity Grading identifies four principal patient sub-groups by defining local and systemic factors.
- There are demographic and peri-operative differences noted between groups.
- Local complexity has measurable effects on surgical time duration especially in patients with combined local and systemic complexity (C3), who have the worst early peri-operative outcomes. This is currently not recognised by many

registries or coding schedules.

- The methodology is easily adopted into clinical practice and allows for enhanced patient information pre-operatively, improved surgical team skill-mix allocation and accurate case-mix assessment.
- The methodology provides a template for further validation and expansion.
- It is potentially applicable to other orthopaedic and surgical conditions.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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