

# **Pre-surgery Osteoarthritis Severity Over 10 Years in Two Ontario Prospective Total Knee Replacement Cohorts**

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This work was funded by operating grants from the Canadian Institute of Health Research  
number 77518 and The Arthritis Society.

None of the authors have any conflicts or competing interests related to this work.

## Abstract

**Background:** It has been suggested that total knee replacement (TKR) is being performed on those with less severe osteoarthritis (OA). We aimed to determine if there were differences in the pre-surgery profile, symptoms and disability of two cohorts with TKR spanning a 10-year period.

**Methods:** This double cohort study recruited **during** 2006-2008 (Cohort 1 (n=494)) and 2012-2015 (Cohort 2 (n=251)). Eligibility criteria: primary TKR, age 18-85 years, English fluency and consent. Exclusion criteria: unicompartimental or revision TKR. Demographic, health (body mass index (BMI), comorbidity) and OA severity (Western Ontario McMaster Universities' Osteoarthritis Index (WOMAC) and the Late Life Disability Instrument (LLDI)) were collected pre-surgery. Proportions, means and standard deviations with 95% confidence intervals (CIs) were calculated for all data in each cohort. Density plots by tertile score were constructed for each of WOMAC pain and function and LLDI limitations subscales.

**Results:** There were no differences in age, sex, education, living status, BMI, comorbidity, pain severity or disability in the two cohorts based on overlapping 95% CIs and the density plots. More people in Cohort 1 were single, 36.7% (95% CI: 32.5, 41.1) vs. 25.3% (95% CI: 20.3, 31.0) in Cohort 2. Cohort 2 reported less limitations in higher demand activities (LLDI): mean scores 62 (95% CI: 60.7, 63.9) vs. 59 (95% CI: 58.2, 60.2).

**Interpretation:** The patient profile and reported OA severity were similar in those having TKR over a 10-year period. This suggests that increasing TKR volumes over this period likely are not driven by these factors.

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**Introduction**

Osteoarthritis (OA) is a common, disabling, and costly disease. (1-4) When medical management of knee OA fails, total knee replacement (TKR) is recommended with the intent of improving pain, function and quality of life. (5-7) TKR is one of the fastest growing surgical interventions in the developed world. (8-10) A decade ago, Canada reported a 139% 10-year increase in TKR (11) with the United States reporting a 100% increase over a similar period, (8) and with a 143% projected increase by 2050. (12) Demand for TKR is expected to continue, with resultant ongoing challenges managing wait-times for surgery (13) and resources in health care systems with increasing cost constraints.

Demand for TKR is increasing due to the rising prevalence of knee OA from aging of the population, obesity and knee injury. (14) However, research shows that aging of the population and obesity only account for about 20% of the increased number of TKRs in the United States. (8, 14) TKR is being performed in younger people and this is in part supported by data from the Canadian Joint Replacement Registry indicating the greatest increase in TKR volume in those 45 to 54 years of age. (11) Still others have suggested that TKR is, perhaps inappropriately, being offered to those with less severe disease and symptoms. (15) We aimed to determine if there were differences in the demographic profile and OA severity, defined by symptoms and disability, of two cohorts of patients who had TKR in Ontario over a 10 year period.

**Methods**

**Cohort Samples**

Cohort 1 was recruited between March 2006 and March 2008 and all had their TKR surgery from April 2006 to April 2008. Cohort 2 was recruited between November 2012 and March 2015 and had their TKR surgery between December 2012 and April 2015. Cohort 1 was

recruited from four tertiary care centres in Toronto: University Health Network, Mount Sinai Hospital, St. Michael's Hospital and Sunnybrook Health Science Centre. Recruitment sites for Cohort Two included three sites, two of the four centres in Cohort 1 (University Health Network and St. Michael's Hospital), with the third site, Strathroy Middlesex Hospital, a community-based hospital approximately 250 kilometres from Toronto.

Eligibility criteria for both cohorts were the same. All patients were deemed surgical candidates based on the surgeon's usual criteria of radiographic severity, clinical findings and patient symptoms and functional difficulties and had agreed to surgery, primary TKR for OA. Additional eligibility criteria included: age 18-85 years and sufficient fluency in English to complete questionnaires and consent. Exclusion criteria included TKR for other than OA (e.g. trauma or malignancy) and unicompartmental or revision arthroplasty.

### **Data Collected**

Consenting participants completed questionnaires within one month of surgery at their pre-admission clinic visit. The questionnaire included demographic (age, sex, education level, marital status, living alone or with others) and health information (body mass index (BMI), comorbidity) and patient-reported outcomes of symptom and functional limitations. Comorbidity was evaluated using the disease listing (no/yes) of the reliable and valid American Academy of Orthopedic Surgeons questionnaire. (16, 17) Pain severity and functional limitations (e.g. walking, getting up from a chair, climbing up and down stairs, dressing etc.) were recorded using the reliable and valid Western Ontario McMaster Universities' Osteoarthritis Index (WOMAC). (18, 19) Higher demand functional activities (i.e. participation in instrumental activities of daily living, personal roles (e.g. managing personal health, errands, household business) and social roles (e.g. visiting friends/family, social activities, active recreation and exercise)) were

evaluated with the reliable and valid limitations subscale of the Late Life Disability Instrument (LLDI). (20, 21) The WOMAC and LLDI subscales were scored 0-100, with higher scores representing less pain and functional limitations.

**Analysis**

Proportions, means and standard deviations with 95% confidence intervals (CIs) were calculated for all data in Cohort 1 and Cohort 2. Density plots were constructed for each of WOMAC pain, WOMAC function and the LLDI limitations subscale scores for both cohorts, by tertile.

Written informed consent was obtained for each cohort participant in accordance with the ethics review board that approved the study at each participating site.

**Results**

**Description of the Cohorts**

Figure 1 provides a flow diagram showing how the analytic sample was derived from those initially enrolled or approached about the study. The analytic sample size of Cohorts 1 and 2 were 494 and 251 respectively. As shown in table 1, both samples were on average 65 years of age and each included more females than males. The majority had high school or greater education and only 20% lived alone. The proportion of people who were single in Cohort 1 was 37% as compared to 25% in Cohort 2. This was the only demographic variable for which the 95% CIs did not overlap, although the CIs for sex overlap by only 0.3 percentage points.

There were no differences between the health variables for the two cohorts. Eighty-three percent of the individuals in Cohort 1 were overweight or obese and 80% of those in Cohort 2 also had a BMI >25. Eighty percent in both cohorts reported at least one comorbid condition.

## Severity of the Cohorts

There was no difference in severity between the cohorts based on the pain and function subscale scores of the WOMAC. The mean LLDI limitations score for Cohort 1 was 59 whereas it was 62 for Cohort 2 and the CIs did not overlap. The density plots for each subscale are shown in Figures 2-4. The plots for each of WOMAC pain and function across tertiles of scores show similar distributions for the two cohorts. While the lower and upper tertile of the LLDI show similar distributions between the cohorts, the middle tertile in Cohort 1 has a more restricted score range and higher density than that of Cohort 2. Specifically, the middle tertile scores for Cohort 1 range from 50 to 65 with peak density of 17 whereas scores for Cohort 2 range from 50 to 70 with peak density of 12 at score 60.

## Interpretation

We evaluated two cohorts of patients who had TKR for OA in Ontario, Canada and found that, while there were minor differences in marital status and higher demand activities, patient demographics, health based on obesity and comorbidity, and OA symptom and disability severity were consistent between the cohorts although they were recruited at different time in a 10-year period. It is, however, important to note that the CI for sex overlapped by less than 1% and for both marital status and high demand activities missed overlapping by only 1%. The reasons for this trend to a larger proportion of males in the cohort recruited in the later time period is not clear but some research has suggested that males are more likely to access orthopaedic surgeons in Ontario. (22) Marital status is unlikely to influence whether a patient has TKR or not and, while the mean score for high demand activities as measured by the LLDI was 3 points lower in the earlier cohort, this difference is not clinically meaningful. (21) There were no differences in

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the WOMAC pain and function subscale scores between the cohorts. Our findings from these samples, therefore, do not support that increased TKR volumes are in part due to those with less OA severity having this surgery.

There was a four year gap in recruitment of the two cohorts in this study and two sites were included in both cohorts. The sample characteristics of our cohorts are very similar to those of other TKR cohorts, including an Ontario cohort of 1578 TKR patients published in 2008. (23) Patients generally are average age in the 60s, overweight or obese, and have comorbidities.

Symptom and disability severity and the timing of TKR for people with OA are subject to debate. As with other cohorts, our data (Table 1) show that pre-operative pain and disability scores pre-TKR largely reflect the available score range of the WOMAC and LLDI. Some have suggested that such data indicate that patients with too little pain and disability are having TKR. (15) However, OA pain is known to fluctuate; there is a constant, less intense pain accompanied by more severe intermittent pain (24) suggesting that a single pain rating based on the prior week may not reflect the pain experience for a patient. Additionally, others have shown that those with less severe OA symptoms and disability benefit from and are just as satisfied with their outcome as those with more severe symptoms and disability. (25) Research also shows that those with severe symptoms and disability, while they benefit, do not achieve the gains from TKR of those who report less pain and functional limitations. (23) These data with the low quality evidence for appropriateness criteria, (26) in sum, may contribute to the less than satisfactory application of appropriateness criteria for TKR to date. (15, 27) Decisions to offer and proceed with TKR are much more complex. (28) There is increasing recognition of the need to consider the individual's response (or lack thereof) to adequate conservative management, including weight management,



exercise and pharmacotherapy (29-32) as well as pain and disability and their impact on quality of life.

Our study has several limitations. Thirty percent of Cohort 2 had incomplete or did not complete one of the outcome measures which precluded their inclusion in the study. The reasons for this are not clear but we cannot discount that these excluded individuals in cohort 2 limit generalizability. Our sample included only those fluent in English due to the need to complete the questionnaires and the results, therefore, need to be interpreted in the context of this patient group. A high proportion of people in both cohorts were highly educated and this may not reflect other cohorts. However, the Organisation for Economic Co-operation and Development reports that Canada ranks first in the proportion of people with higher education (i.e. more than high school) with Canadian women representing the highest proportion (33) such that generalizability to the Canadian population is likely less problematic. Additionally, while the age distribution of our cohorts would not support a shift to increased numbers of younger people having TKR, younger people may have declined to participate in the study. Finally, our data are based on two cohorts, while with overlapping sites, largely represented recruitment in tertiary centres in Toronto. While the outcomes of patients in community and academic centres are similar, (34) the pre-surgery profile of patients having surgery in community versus academic centres may differ.

In conclusion, our data indicate that the demographic profile and symptom and disability severity of people having TKR for OA was unchanged over a 10-year period such that it is unlikely that these factors are related to the increased volumes of TKR. While this work needs to be replicated in other regions and with larger sample sizes, tackling the rising volumes and associated costs of TKR likely needs a multi-faceted strategy that addresses prevention of knee

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OA and access to and delivery of evidence-based conservative management that may limit or delay the progression of knee OA symptoms and disability.

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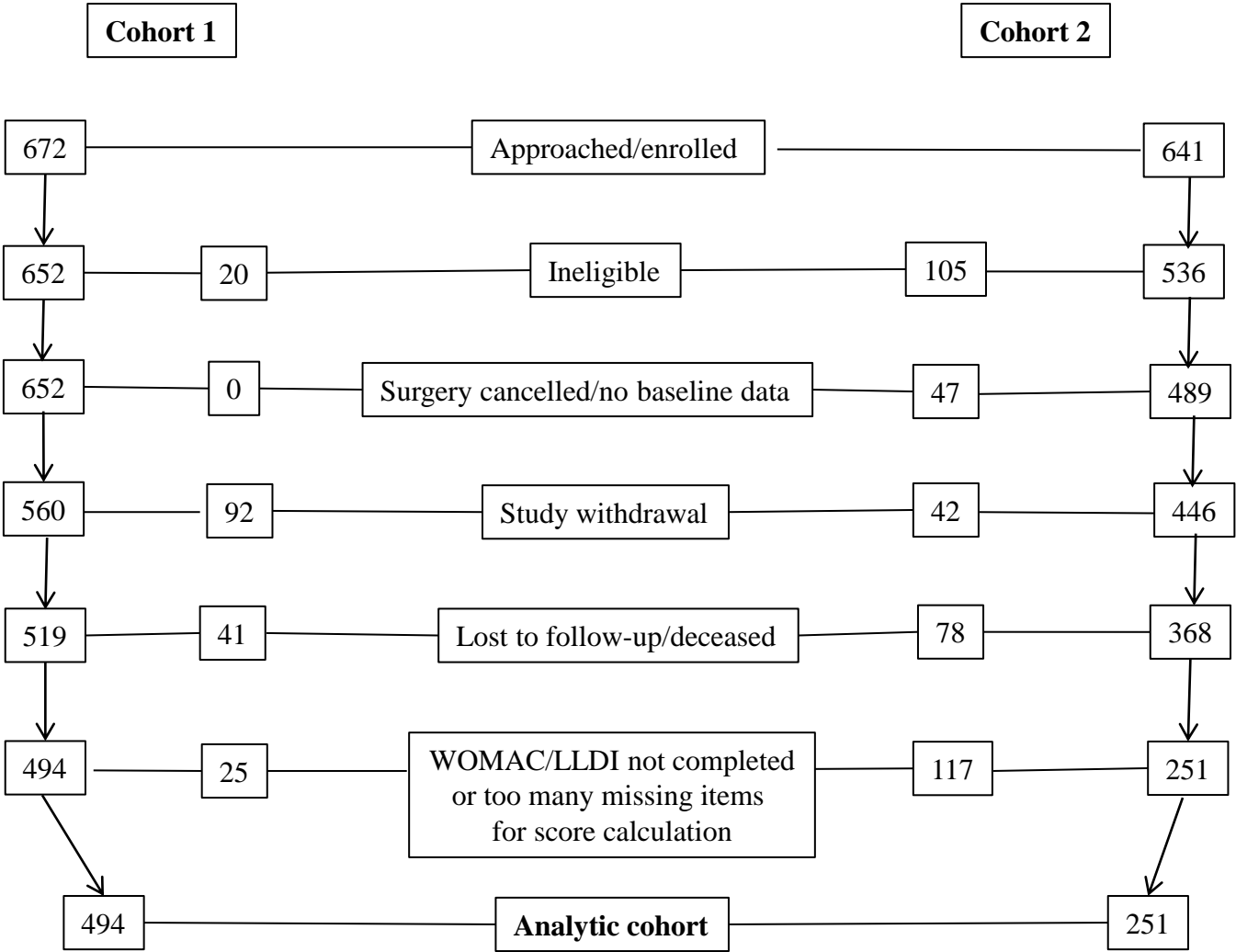
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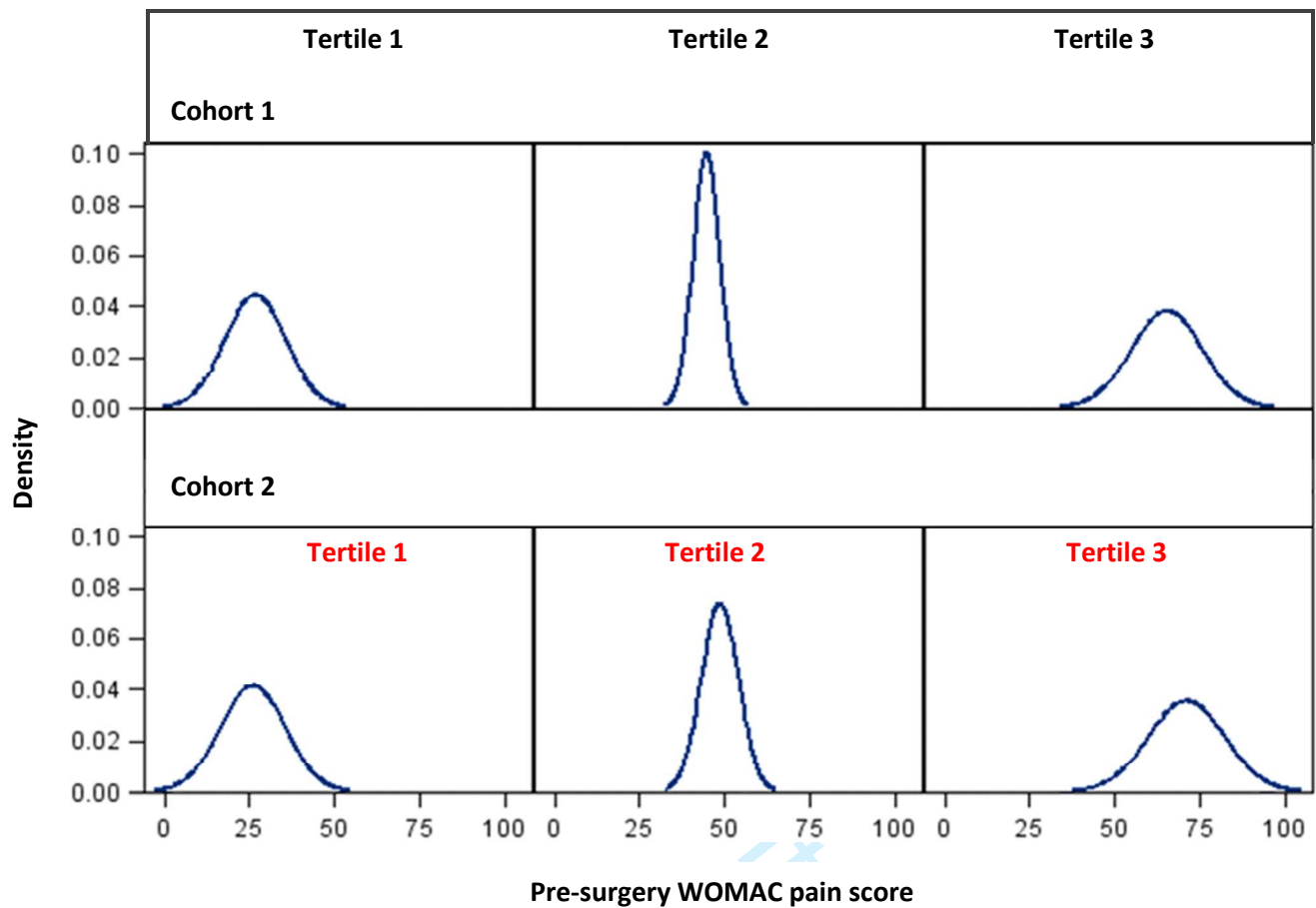
Figure 1: Flow diagram depicting derivation of the analytic cohorts

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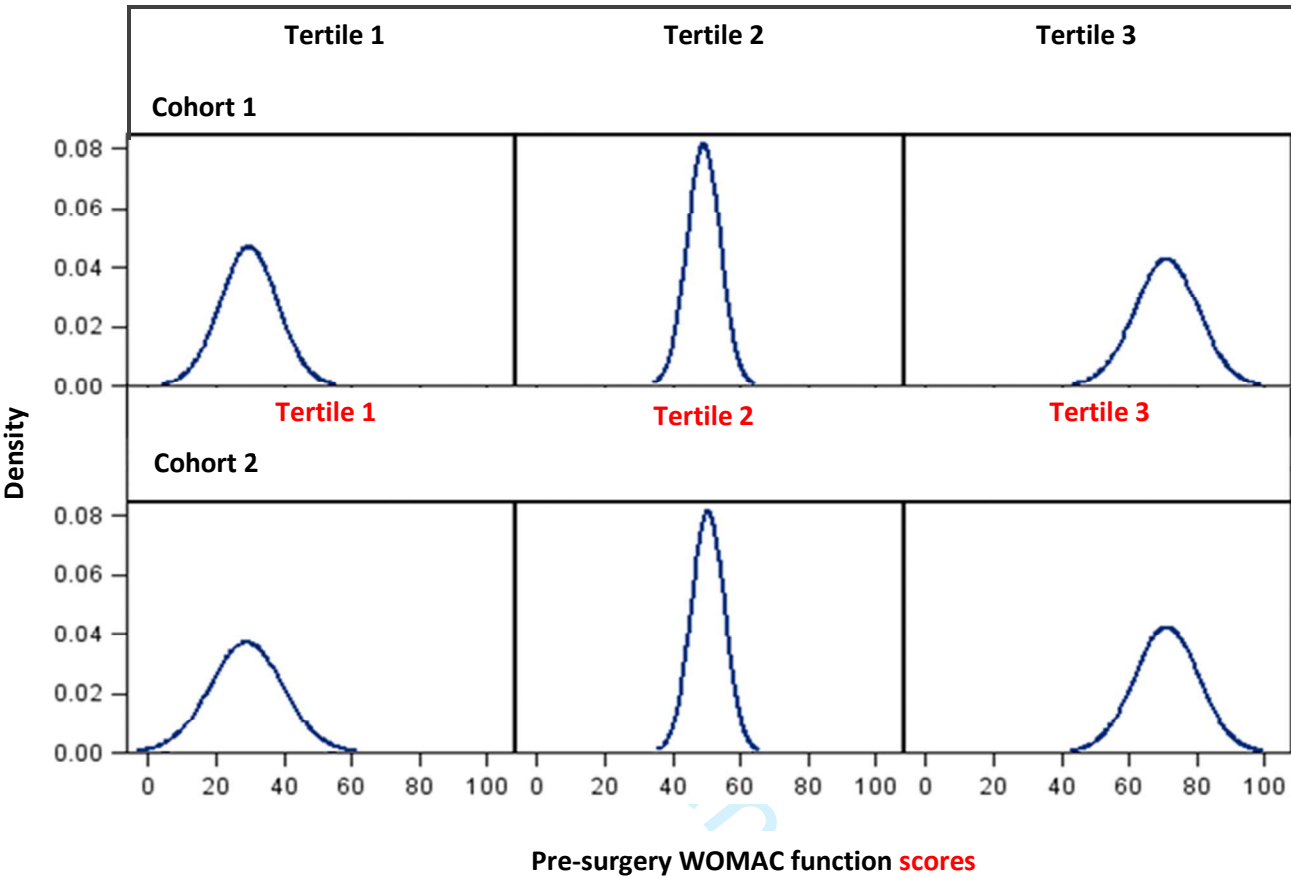
WOMAC=Western Ontario McMaster Universities' Osteoarthritis Index; LLDI=Late Life Disability Index  
For Peer Review Only

Figure 2: Density plots comparing distribution of pre-surgical WOMAC pain for cohort 1 (03/2006-03/2008) and cohort 2 (11/2012-03/2015) by tertile scores



WOMAC pain score: 0=no pain, 100=extreme pain

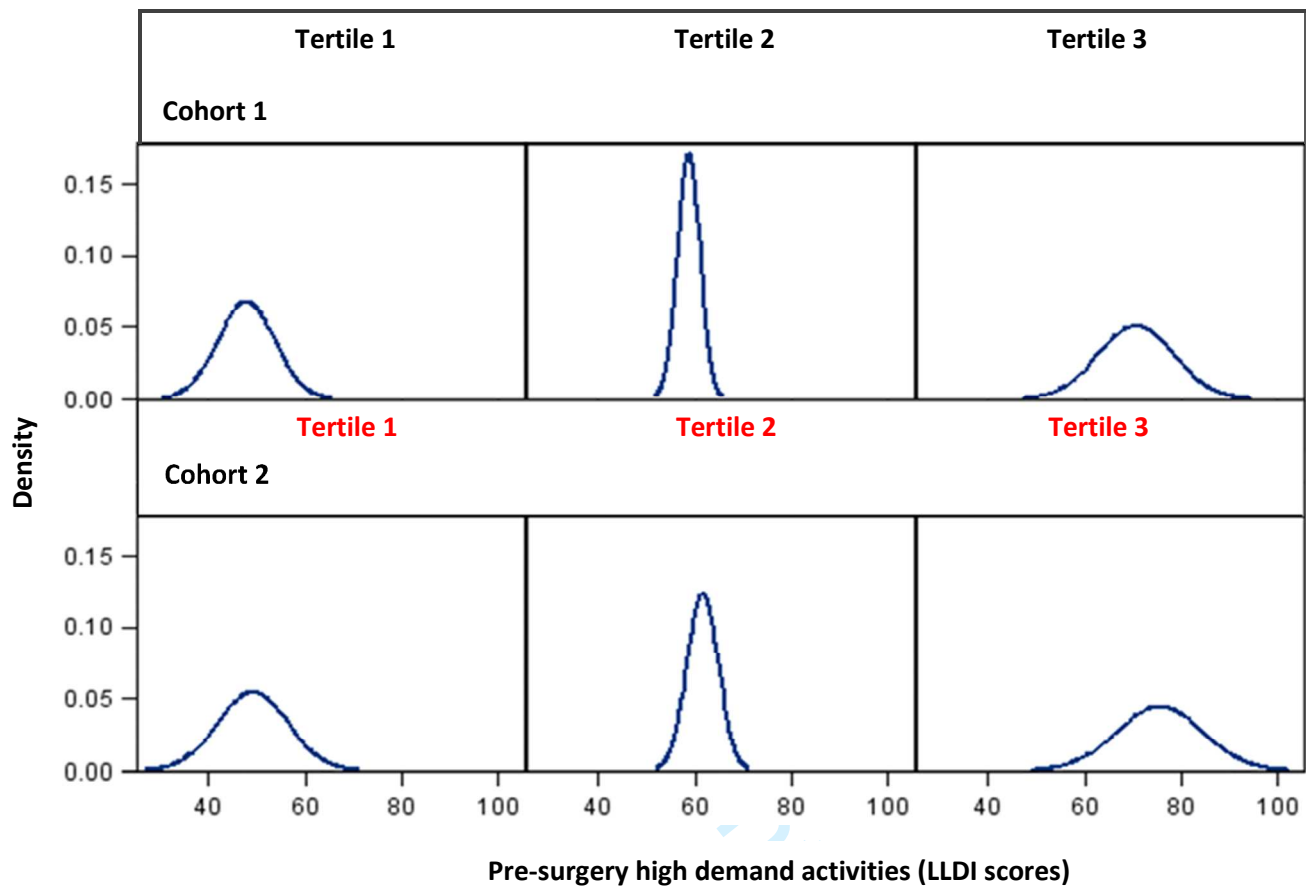
Figure 3: Density plots comparing distribution of pre-surgical WOMAC functional limitations for cohort 1 (03/2006-03/2008) and cohort 2 (11/2012-03/2015) by tertile scores



WOMAC function: 0=extreme difficulty, 100=no difficulty



Figure 4: Density plots comparing distribution of pre-surgical high demand activity limitations for cohort 1 (03/2006-03/2008) and cohort 2 (11/2012-03/2015) by **tertile scores**



LLDI=Late Life Disability Index; 0=no limitations, 100=extreme limitations

Table 1: Characteristics and OA severity pre-surgery of TKR cohorts

Variable	TKR cohort 1 (3/2006-3/2008) N=494	TKR cohort 2 (11/2012-3/2015) N=251
Age: mean (sd); range 95% CI	64.9 (10.2); 35-87 64.0-65.8	65.1 (9.2); 43-90 63.9-66.2
Sex: n (%) 95% CI Male	171 (34.6); 30.6-38.9	112 (44.6); 38.6-50.1
Education: n (%); 95% CI >high school Missing	326 (66.5); 62.2-70.6 4	180 (72.3); 66.4-77.5 2
*Marital status: n (%); 95% CI Single Missing	176 (36.7); 32.5-41.1 14	63 (25.3); 20.3-31.0 2
Living status: n (%);95% CI Lives alone Missing	121 (24.5); 20.9-28.5 0	49 (20.2); 15.7-25.8 9
BMI: n (%); 95% CI Underweight Normal Overweight Obese Missing	2 (0.4); 0.1-1.5 83 (16.8); 13.8-20.4 184 (37.2); 33.2-41.8 223 (46.1); 40.9-49.6 2	1 (0.4); 0.1-2.3 49 (20.1); 15.5-25.5 76 (31.1); 25.7-37.2 118 (48.4); 24.2-54.6 7
Comorbidity: n (%); 95% CI At least 1 condition	394 (80.0); 76.0-83.1	201 (80.1); 74.2-84.5
Hypertension: yes n (%); 95% CI	242 (49.0); 44.6-53.4	121 (48.2); 42.1-54.4
Cardiovascular: yes n (%); 95% CI	31 (6.3); 4.5-8.8	21 (8.4); 5.5-12.5
Diabetes: yes n (%); 95% CI	71 (14.4); 11.5-17.4	37 (14.7); 10.9-19.7
<b>*Pre-surgery Patient Reported Outcome Measures</b>		
WOMAC pain Mean (sd); minimum-maximum 95% CI Missing	47.8 (17.8) 0-100 46.2-49.4 11	49.3 (20.0); 0-100 46.8-51.8 3
WOMAC function Mean (sd); range 95% CI Missing	50.3 (18.5); 0-96 48.6-51.9 8	50.3 (19.4); 0-99 47.9-52.7 5
**Late Life Disability Limitations Mean (sd); range 95% CI Missing	59.2 (11.0); 23-100 58.2-60.2 47	62.3 (12.9); 19-100 60.7-63.9 5

WOMAC=Western Ontario McMaster Universities’ Osteoarthritis Index

\*all measures are scored 0-100 with higher scores indicating less pain and better function

\*\*95% confidence intervals (CI) do not overlap