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# Rate of and risk factors for intermediate-term reoperation after ankle fracture fixation: a population based, cohort study

**Authors:**

Daniel Pincus[1,2,3] MD
Andrea Veljkovic[4] MD, FRCS(C)
Thomas Zochowski[1] MD, MSc, FRCS(C)
Nizar Mahomed[1,2,5] MD, MPH, ScD, FRCS(C)
Darrell Ogilivie-Harris[1,5] MBBS, FRCS(C)
David Wasserstein[1,6] MD, MSc, MPH, FRCS(C)

**Affiliations:**

[1]Department of Surgery, University of Toronto, Toronto, Canada
[2]Institute for Clinical Evaluative Sciences, Toronto, Canada
[3]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Canada
[4]Department of Surgery, University of British Columbia, Vancouver, Canada
[5]Arthritis Program, University Health Network, Toronto Western Hospital, Toronto, ON
[6]Sunnybrook Health Sciences Centre & Sunnybrook Research Institute, Toronto, ON

**Correspondence:**

Daniel Pincus MD
Department of Surgery, Division of Orthopaedic Surgery, University of Toronto
149 College Street, Room 508-A
Toronto, ON M5T 1P5
Phone: 416-946-7957 (w), 647-244-3324 (c)
Fax: 416-978-3928
d.pincus@utoronto.ca

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**STRUCTURED ABSTRACT**

*Objective:* Establish baseline rates of and risk factors for reoperation within 1 or 2 years of ankle open reduction internal fixation (ORIF).

*Design:* Retrospective, population based, cohort study.

*Setting:* 202 hospitals in Ontario, Canada (approximate population 13.6 million in 2014).

*Patients/Participants:* 45,444 patients that underwent ankle ORIF performed by 710 different surgeons between January 1, 1994 and December 31, 2011.

*Main outcome measurements:* Intermediate-term reoperation due to isolated implant removal, repeat ORIF, irrigation and debridement (I&D) due to infection, or amputation. Multivariable logistic regression related potential prognostic factors (patient, provider, and injury) to reoperation.

*Results:* There were 8,936 patients who underwent at least one subsequent operation (19.7%). The most common procedure was isolated implant removal (18.7%); odds of removal being higher for females (odds ratio [OR], 1.53; 95% confidence interval [CI], 1.45 – 1.62 p<0.001). N=674 patients (1.5%) underwent reoperation for another reason. The odds of repeat ORIF and I&D infection were greater for open fractures (OR 2.17; 95% CI, 1.22 – 3.86; p = 0.008 and OR 3.12; 95% CI 1.94 – 5.03; p < 0.001). Odds of amputation was highest for diabetics (OR 7.42; 95% CI 3.73 – 14.86; p < 0.001).

*Conclusion:* Isolated implant removal accounts for the vast majority of intermediate-term reoperations after ankle ORIF. Reoperation for other reasons (repeat ORIF, I&D, or amputation) was extremely rare, even among the highest risk patients. Concerns regarding reoperation for these reasons should not preclude operative treatment in any patient, provider or injury group we considered.

**Key Words:** Ankle Fractures; Fracture Fixation, Internal; Osteosynthesis; Complications; Epidemiology; Retrospective studies; Canada

**Level of Evidence:** Prognostic Level II. See Instructions for Authors for a complete description of levels of evidence.

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**INTRODUCTION**

Unstable rotational ankle fractures are considered the most common cause of post-traumatic ankle arthritis.(1-5) Standard of care for these fractures includes open reduction internal fixation (ORIF), which reduces tibio-talar joint reactive forces(6, 7) and has been shown to improve clinical and radiographic outcomes compared to cast treatment.(8) Indeed, ankle ORIF is the second most common fracture fixation procedure in our Province.(9)

Recently published Level I evidence, however, suggests a certain subset of unstable rotational ankle fractures among older adults may be adequately treated by non-surgical methods.(10) Conclusions were drawn based on early, non-inferior patient reported outcomes among older patients undergoing close-contact casting, compared to those who received ORIF. Accurate data regarding reoperation rates, however, may also guide clinical decision-making between treatment alternatives. In particular, identifying less suitable candidates for operative treatment, such as patients at increased risk for reoperation, is critical. Unfortunately, prior large, prognostic studies after ankle ORIF are limited by short-term follow-up (90 days),(11) restricted cohort definitions (geriatric patients),(12) and the range of potential prognostic factors investigated.(11, 12) As a result, rates of reoperation, and factors that predict reoperation, are not clear in existing literature.

Given recent evidence in support of alternative ankle fracture treatment and limitations in prior prognostic studies, we investigated intermediate-term (1-2 year) reoperation rates following ankle ORIF in a large, population based cohort. Specific aims of our study were to (A) establish reoperation rates following ankle ORIF in the general population and (B) identify patient, provider, and surgical factors that may influence theses rates.

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## MATERIALS and METHODS

Data sources and Setting

Data were obtained from several health administrative databases, at 202 different hospitals, in Ontario, Canada (population 13.6 million in 2014). These databases are held securely in linked, encoded form and were analyzed at the Institute for Clinical Evaluative Sciences (ICES; www.ices.on.ca). This data has been used successfully in prior prognostic studies of orthopaedic trauma patients.(13, 14)

The supplementary appendix contains a detailed description of the data sources used in this study as well as the specific diagnostic and billing codes utilized for cohort identification and outcome assessment. The study protocol was approved by the Research Ethics Board at Sunnybrook Health Sciences Centre.

Cohort inclusion (Figure 1)

All adult patients aged > 16 undergoing isolated ankle ORIF in Ontario between January 1, 1994 and December 1, 2011 were eligible for inclusion. Non-Ontario residents, patients less than 16 years old, and those with bilateral or tibial plafond fractures were excluded (Figure 2). The beginning of the study period was selected to allow up to 2 years look-back for patient comorbidity score calculation, and identification of tibial plafond fractures in administrative databases that began data capture in 1992. Figure 1 displays the study design.

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Outcomes

We considered four reasons for reoperation after ankle ORIF: (1) implant removal in isolation, (2) repeat ORIF, (3) irrigation and debridement (I&D) due to infection, and (4) lower extremity amputation. Implant removal was assessed up to 2-years and had to occur without repeat ORIF, I&D, or amputation (in other words, 'in isolation') to be considered. Other reasons for reoperation were assessed up to 1-year. We defined "intermediate-term" differently in this way based on our clinical experience as to when these complications most commonly occur.

Exposures (potential prognostic factors)

Several patient, provider and surgical factors previously suggested to influence reoperation rates after ankle ORIF were considered.(11, 12) Age and sex were analyzed as continuous and categorical variables, respectively. Comorbidities listed on hospital discharge abstracts in the three years before the index fixation procedure were categorized according to both the Charlson Comorbidity Index(15) and Collapsed Aggregate Diagnosis Groups (CADGs).(16) In addition, previously validated algorithms identified patients with diabetes,(17) hypertension,(18) and "frailty"(16) at the time of their index procedure. Median neighbourhood household income quintile was used as a surrogate for socioeconomic status and living conditions. (19-21)

Index surgeon-related factors were assigned at patient entry into the cohort. These included (a) years since their Canadian orthopaedic certification ('surgeon experience') and (b) the number of ankle ORIF procedures performed in the year preceding the index event ('surgeon volume'). Surgeon volume was categorized by quintile. Index hospitals were

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categorized as either ''academic'' or ''non-academic'' on the basis of their membership in the Council of Academic Hospitals of Ontario (www.cahohospitals.com). Surgical covariates identified by ICD-10 diagnosis codes and OHIP billing codes included the presence of an open fracture, fracture-dislocation, and single malleolus versus bi-/tri- malleolus fractures. Lastly, length of stay (LOS) was categorized as (a) day surgery, (b) 1 night-stay or (c) >1 night-stay.

Statistical Analysis

Descriptive statistics of baseline characteristics were calculated for the entire cohort and stratified by the presence of reoperation (isolated implant removal, repeat ORIF, I&D for infection, and amputation are presented separately; Table 1). These include means (and standard deviations) and proportions as appropriate. Multivariable logistic regression was used to assess the influence of potential prognostic factors (patient, provider, and surgical factors) on intermediate-term re-operation rates. Predictors included in each multivariable model were: age, sex, Charlson index, frailty, diabetes, income quintile, LOS, surgeon experience and volume, hospital academic status, fracture-dislocation, and open fracture. Since overparameterization was a concern in modeling 'lower extremity amputation' (N=48), we developed a parsimonious model for this outcome that included only the following predictors: age, sex, Charlson index, frailty, and diabetes (Figure 3). All analyses were performed using SAS software (version 9.3 and SAS EG 6.1, SAS Institute, Cary, NC) and the type I error probability was set to 0.05.

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## RESULTS

Baseline characteristics (Figure 2, Table 1)

After exclusions, we identified 45,444 patients during the study period who underwent isolated ankle ORIF in Ontario (Figure 2). Their mean age was forty-eight years (SD ± 19 years) and 41.2% were male. Most fractures (70.8%) were bi- or tri-malleolar and most procedures (83.9%) took place in community hospitals (Table 1).

Outcomes (Figure 3, Table 1)

*Reoperation (overall)*

We identified 8,936 patients (19.7%) who underwent intermediate-term reoperation after ankle ORIF. The vast majority of reoperations were isolated implant removal (8,232 cases or 92.1% of all reoperations).

*Repeat ORIF*

Analyses of repeat ankle ORIF were performed separately for single malleolus and bi-/tri malleolus fractures. Two hundred (0.4%) single malleolus fracture patients underwent repeat ORIF within one year. Older age, hypertension, increasing LOS, and initial fracture-dislocation were associated with repeat ORIF among this group. Median time to repeat ORIF was 34 days (interquartile range (IQR) = 15, 87).

There were 216 multiple malleolus fracture patients (0.4%) underwent repeat ankle ORIF. Risk of repeat ORIF was higher among those who initially presented with an open fracture (OR 2.17; 95% CI, 1.22 – 3.86; p = 0.008). It was also more common in male patients, those with

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higher medical comorbidity (including diabetes) and those with initial fracture-dislocation (Table 1 and Figure 3). Median time to repeat ORIF among this group was 20 days (IQR = 10, 63).

*Isolated Implant Removal*

Isolated implant removal occurred in 8,232 cases (18.7%). Female patients more commonly underwent implant removal in comparison to males (OR 1.53; 95% CI 1.45 – 1.62; p<0.001). Implant removal was also more common in patients with higher socioeconomic status, when index procedures were performed at community hospitals, and those with initial fracture-dislocations or open fractures. Patients with medical comorbidity were less likely to receive implant removal (Table 1 and Figure 3). Median time to implant removal was 346 days (IQR = 185, 469).

*Irrigation and Debridement (I&D) for Infection*

I&D for infection occurred in 207 patients (0.4%). Infection risk was highest amongst patients with open fractures (OR 3.12; 95% CI 1.94 – 5.03, p < 0.001) or diabetes (OR 2.0; 95% CI 1.38 – 2.87, p < 0.001). It was also more common among males, those with medical comorbidity, at academic hospitals, and after fracture-dislocations (Table 1 and Figure 3). Median time to I&D was 100 days (IQR = 48, 194)

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*Amputation*

Amputation was performed in 48 cases (0.1%). Risk of amputation was not surprisingly highest among patients with diabetes (OR 7.4; 95% CI 3.7 – 14.8, $p < 0.001$) and males (OR 2.46; 95% CI 1.36 – 4.45, $p < 0.001$) (Table 1 and Figure 3). Median time to amputation was 135.5 days (IQR = 79, 239)

## DISCUSSION

*Principal findings*

Intermediate-term reoperation after ankle ORIF was common, occurring in 8,936 cases (19.7%). The vast majority of reoperations comprised implant removal in isolation (8,232 cases or 92.1% of all reoperations). Reoperation for other reasons (repeat ORIF, I&D, or amputation) was rare, even among the highest risk patients.  Risk factors for more severe complications were associated with patient factors for poor healing (e.g., diabetes) and injury factors suggestive of higher degrees of soft-tissue compromise (e.g., open fracture or initial fracture-dislocation).

*Limitations*

Administrative data used in this study do not include several potential predictors of reoperation. These relate to the initial injury and surgical technique and include: (a) fracture pattern (other than single malleolus vs. bi-/tri- malleolus), (b) fracture displacement or comminution, (c) fixation device and orientation, and (d) soft tissue dissection and stripping.

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Bloodwork, radiographs, body mass index, and compliance with post-operative weight-bearing instructions were also unknown. Although we could not determine laterality of the index event and potential outcomes, we argue attributing reoperations to the index ankle ORIF is reasonable given that we only considered (a) isolated ankle fractures and (b) intermediate-term reoperations within 1 or 2 years. Furthermore, the large sample size and event rate of this study allowed us to adjust the multivariable analyses for a broader range of potential prognostic factors (patient, provider and injury) compared to those examined in prior literature.(11, 12) Another significant strength of this investigation is the ability of our universal system to track every patient up to 2-years postoperatively, even if lost to follow-up from their original surgeon, as long as they continued to be treated in Ontario.

It is also important to emphasize that our study focused on intermediate-term reoperation following ankle ORIF. We did not consider other adverse outcomes that may be clinically important in this population, such as wound complications treated with non-procedural means. Outcomes occurring over longer follow-up periods, such as ankle arthrodesis or arthroplasty, were also not assessed.(22) Future work at the population level is also required to examine failure of treatment and reoperation after non-operatively treated ankle fractures.

*Implications*

Ankle fracture incidence is increasing,(23) particularly amongst the elderly.(23, 24) Although open reduction internal fixation (ORIF) reduces tibio-talar joint reactive forces(6, 7) and has been shown to improve clinical and radiographic outcomes compared to cast treatment,(8) recently published Level I evidence suggests some unstable rotational ankle

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fractures among older adults may be adequately treated by non-surgical methods (provided there is no unacceptable displacement or predictive features of syndesmosis widening).(10) In light of this evidence and limitations in prior prognostic studies following patients after ankle ORIF, we investigated reoperation rates after ankle ORIF in a large, population based cohort.

Similar to large prognostic studies that followed patients after undergoing ORIF for clavicle or tibial plateau fractures,(13, 14) we found isolated implant removal accounted for the vast majority of intermediate-term reoperations (92.1%). Implant removal following ankle ORIF can range from removing prominent hardware, syndesmosis screw removal upon healing of the syndesmosis, or due to surgeon standard of care. Among orthopaedic surgeons, routine implant removal is controversial. The procedure may pose a burden on the health-care system and cause patient morbidity itself.(25-27) Surveys of patients, however, identify their surgeon's recommendation (68%), as the most common reason why they underwent the procedure.(28) The true value of implant removal remains unknown as there is a paucity of reported clinical outcomes on the efficacy of the procedure. In addition to practice variation between surgeons, we detected important differences in the provision of implant removal at the patient level. For example, disparities in implant removal may be addressed among females and those with high socioeconomic status.

Also similar to prior literature examining the epidemiology of ankle fractures, we found that women were more likely to suffer ankle fractures and that operative injuries are more likely to be bimalleolar.(24) The majority of ankle ORIF procedures in our Province occur in community practice (83.7%). Interestingly, surgeon volume and experience did not appreciably influence the rate of reoperation. Since we were unable to judge the technical difficulty of each

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operation, however, high volume / experienced ankle fracture surgeons who are referred challenging cases may be predisposed having complications occur. Instead, risk factors for more severe complications were associated with patient factors for poor healing (e.g., diabetes) and injury factors suggestive of higher degrees of soft-tissue compromise (e.g., open fracture or initial fracture-dislocation). Since diabetes is a potentially modifiable risk factor, further research is warranted to understand whether improved glucose control and/or non-operative treatment strategies would be beneficial when these patients suffer ankle fractures.

Nonetheless, reoperation for reasons other than isolated implant removal (repeat ORIF, I&D for infection, or amputation) was extremely rare, even among the highest risk patients. For example, though diabetes was a risk factor for amputation (OR 7.4; 95% CI 3.7 – 14.8) and I&D (OR 2.0; 95% CI 1.4 – 2.9, $p < 0.001$), the absolute risk of these complications was still extremely low (amputation = 0.67% and I&D=1.1% after ankle ORIF among patients with diabetes). For this reason, we conclude concerns regarding repeat ORIF, I&D, or amputation should not preclude operative treatment in any patient, provider or injury group we considered. Instead, operative intervention in each case should be evaluated in the context of this reoperation data, as well as individual patient preferences, perioperative medical risk, and the long-term risk of developing post-traumatic arthritis (>50,000 cases reported each year in the United States).(4, 29) This study was conducted among a diverse population of more than 13.6 million Ontarians, treated at 202 different academic and community hospitals, by 710 different surgeons. As such, we argue our conclusions apply to patients undergoing ankle ORIF throughout the developed world. The population based reoperation rates described in this study may also inform power calculations for future prospective research.

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*Final Conclusions*

Isolated implant removal accounts for the vast majority of intermediate-term reoperations after ankle ORIF. Disparities we found in the provision of implant removal may be addressed at the patient level, among females and those with high socioeconomic status, in particular. In contrast, reoperation for other reasons (repeat ORIF, I&D, or amputation) was extremely rare, even among the highest risk patients. Concerns regarding reoperation for these reasons should not preclude operative treatment in any patient, provider or injury group we considered.

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## Table and Figure Legends

**Figure 1: Description of the study design.** We conducted a population-based, cohort study among Ontarians that received ankle ORIF between January 1, 1994 and December 31, 2011. Reoperation after ankle ORIF was the primary outcome: (a) isolated implant removal at 2-years or (b) repeat ORIF, I&D, or lower extremity amputation at 1-year. Multivariable logistic regression was used to assess the influence of potential prognostic factors (patient, provider, and surgical factors) on reoperation rates.

**Figure 2. Patients included and excluded in the study cohort.**

**Figure 3. Multivariable logistic regression analyses relating potential prognostic factors to re-operation.** Predictors included in each multivariable model were: age, sex, Charlson index, frailty, diabetes, income quintile, LOS, surgeon experience and volume, hospital academic status, fracture-dislocation, and open fracture. A parsimonious model was used for lower extremity amputation. Adjusted odds ratios [95% confidence intervals] are reported.

**Table 1: Baseline characteristics amongst 45,444 ankle fracture patients in Ontario between 1994-2011, overall and by outcome.**

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**Table 1:** Baseline characteristics amongst 45,444 ankle fracture patients in Ontario between 1994-2011, by outcome

| Variable | Value | Overall cohort N=45,444 | Implant removal N=8,232 | Repeat ORIF (1 mal) N=200 | Repeat ORIF (2 mal) N=219 | I+D for infection N=207 | Amputation N=48 |
|---|---|---|---|---|---|---|---|
| **Age** | Years | 48.66 ± 18.15 | 44.15 ± 16.18 | 44.57 ± 16.29 | 53.29 ± 17.82 | 54.33 ± 17.68 | 63.83 ± 13.80 |
| **Sex** | Female | 26,731 (58.8%) | 5,256 (63.8%) | 111 (55.5%) | 116 (53.0%) | 116 (56.0%) | 22 (45.8%) |
| | Male | 18,713 (41.2%) | 2,976 (36.2%) | 89 (44.5%) | 103 (47.0%) | 91 (44.0%) | 26 (54.2%) |
| **Charlson score** | | 0.17 ± 0.67 | 0.09 ± 0.48 | 0.19 ± 0.73 | 0.48 ± 1.11 | 0.44 ± 1.02 | 1.77 ± 1.73 |
| **CADG score** | 0--4 | 25,737 (56.6%) | 4,627 (56.2%) | 107 (53.5%) | 86 (39.3%) | 76 (36.7%) | NR |
| | 5--8 | 19,203 (42.3%) | 3,512 (42.7%) | 93 (46.5%) | 127 (58.0%) | 125 (60.4%) | NR |
| | 9--12 | 504 (1.1%) | 93 (1.1%) | 0 (0.0%) | 6 (2.7%) | 6 (2.9%) | NR |
| **Frailty** | Yes | 8,814 (19.4%) | 1,262 (15.3%) | 33 (16.5%) | 72 (32.9%) | 54 (26.1%) | 12 (25.0%) |
| **Hypertension** | Yes | 12,515 (27.5%) | 1,652 (20.1%) | 58 (29.0%) | 87 (39.7%) | 95 (45.9%) | 31 (64.6%) |
| **Diabetes** | Yes | 4,755 (10.5%) | 607 (7.4%) | 24 (12.0%) | 60 (27.4%) | 54 (26.1%) | 32 (66.7%) |
| **Income quintile** | 1 | 9,092 (20.0%) | 1,492 (18.1%) | 36 (18.0%) | 63 (28.8%) | NR | NR |
| | 2 | 9,191 (20.2%) | 1,579 (19.2%) | 49 (24.5%) | 40 (18.3%) | NR | NR |
| | 3 | 8,862 (19.5%) | 1,685 (20.5%) | 43 (21.5%) | 42 (19.2%) | NR | NR |
| | 4 | 9,018 (19.8%) | 1,717 (20.9%) | 37 (18.5%) | 30 (13.7%) | NR | NR |
| | 5 | 9,043 (19.9%) | 1,732 (21.0%) | 35 (17.5%) | 44 (20.1%) | NR | NR |
| | Missing | 238 (0.5%) | 27 (0.3%) | 0 (0.0%) | 0 (0.0%) | NR | NR |
| **Length of Stay** | Day surgery | 6,558 (14.4%) | 964 (11.7%) | 22 (11.0%) | 34 (15.5%) | 25 (12.1%) | NR |
| | 1 night | 8,326 (18.3%) | 1,364 (16.6%) | 29 (14.5%) | 35 (16.0%) | 28 (13.5%) | NR |
| | >1 night | 30,559 (67.2%) | 5,904 (71.7%) | 149 (74.5%) | 150 (68.5%) | 154 (74.4%) | NR |
| **Surgeon volume*** | Zero | 1,323 (2.9%) | 214 (2.6%) | 8 (4.0%) | NR | NR | NR |
| | 1-10 | 11,682 (25.7%) | 2,255 (27.4%) | 50 (25.0%) | NR | NR | NR |
| | 11-15 | 11,459 (25.2%) | 2,158 (26.2%) | 52 (26.0%) | NR | NR | NR |
| | 16-21 | 9,953 (21.9%) | 1,770 (21.5%) | 38 (19.0%) | NR | NR | NR |
| | >21 | 11,027 (24.3%) | 1,835 (22.3%) | 52 (26.0%) | NR | NR | NR |
| **Surgeon experience** | Years | 13.44 ± 9.52 | 14.68 ± 9.78 | 13.21 ± 9.91 | 14.67 ± 9.96 | 11.12 ± 8.92 | 13.85 ± 9.73 |
| **Hospital Status** | Teaching | 7,399 (16.3%) | 1,075 (13.1%) | 24 (12.0%) | 39 (17.8%) | 54 (26.1%) | NR |
| | Community | 38,045 (83.7%) | 7,157 (86.9%) | 176 (88.0%) | 180 (82.2%) | 153 (73.9%) | NR |
| **Dislocation** | Yes | 4,116 (9.1%) | 827 (10.0%) | 26 (13.0%) | 35 (16.0%) | 33 (15.9%) | 6 (12.5%) |
| **Open fracture** | Yes | 1,217 (2.7%) | 300 (3.6%) | 6 (3.0%) | 13 (5.9%) | 20 (9.7%) | 8 (16.7%) |
| **Time to event**** | Days | - | 346 (185, 469) | 34 (15, 87) | 20 (10, 63) | 100 (48, 194) | 135.5 (79, 239) |

± values indicate mean values ±standard deviation.
NR – 'not reportable', small cells have been suppressed in accordance with guidelines at ICES.
*Number of ankle fracture procedures performed by the index surgeon in the year prior, by quintile (Zero, 1-10, 11-15, 16-21, >21).
**Median (IQR) time to reoperation event reported in days.

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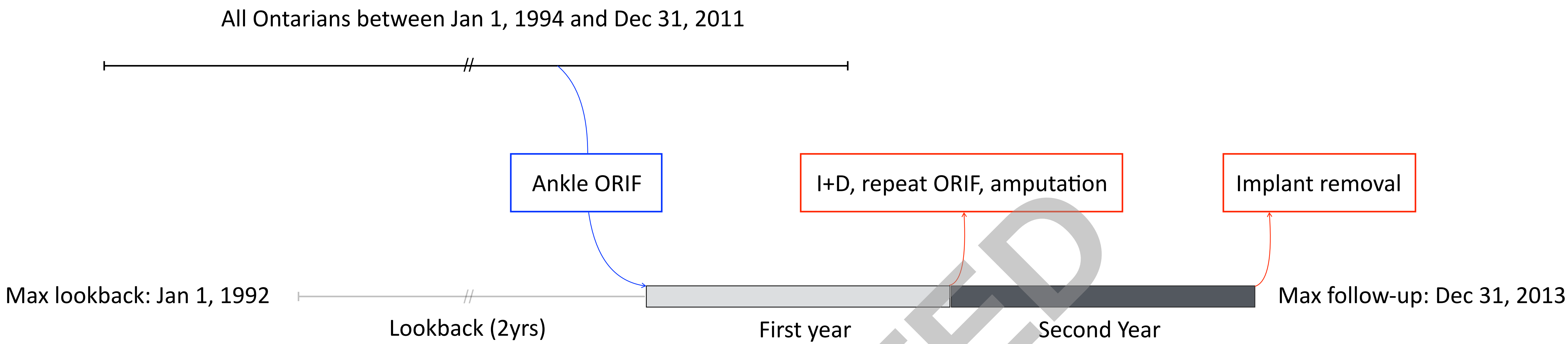


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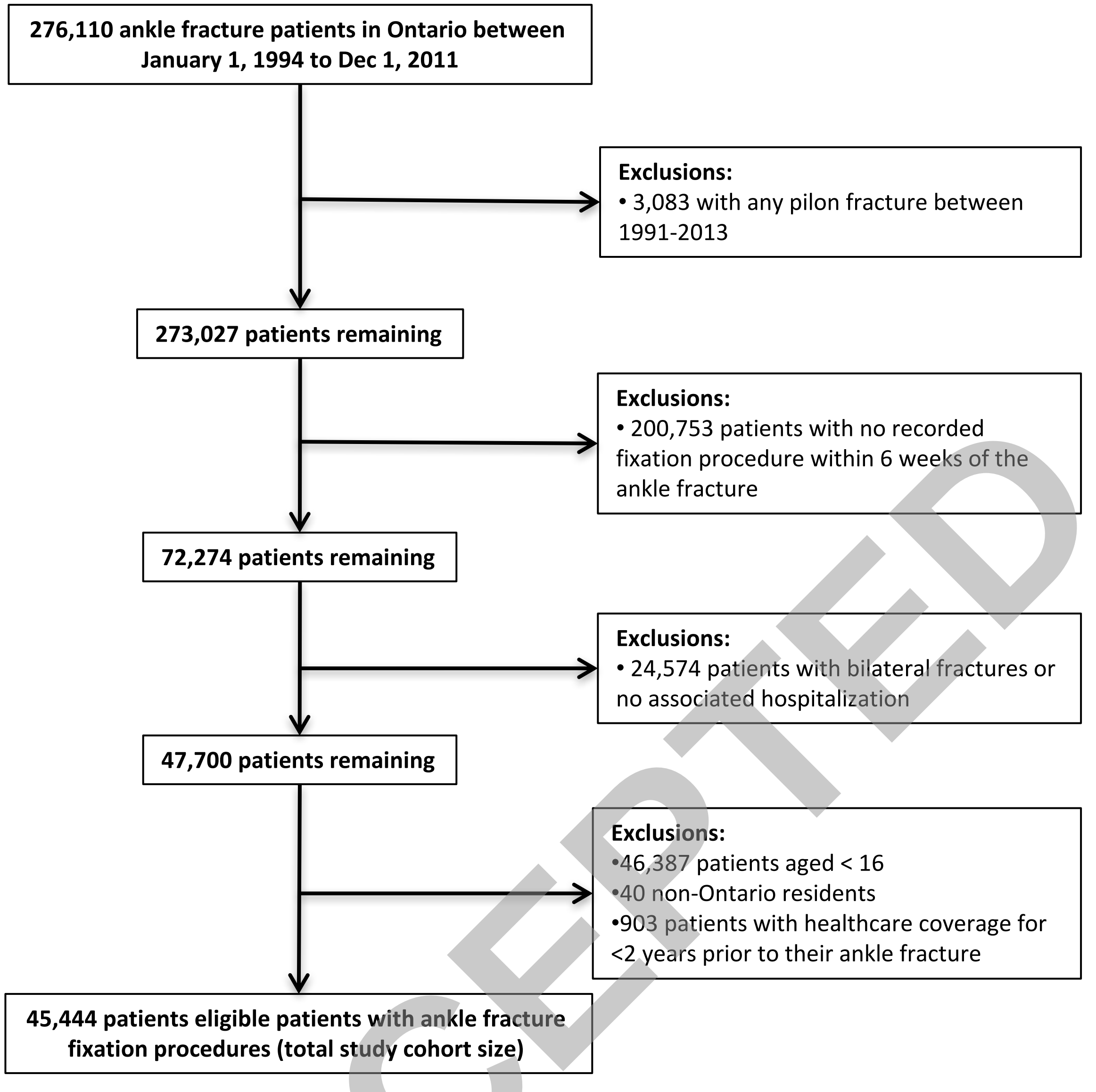


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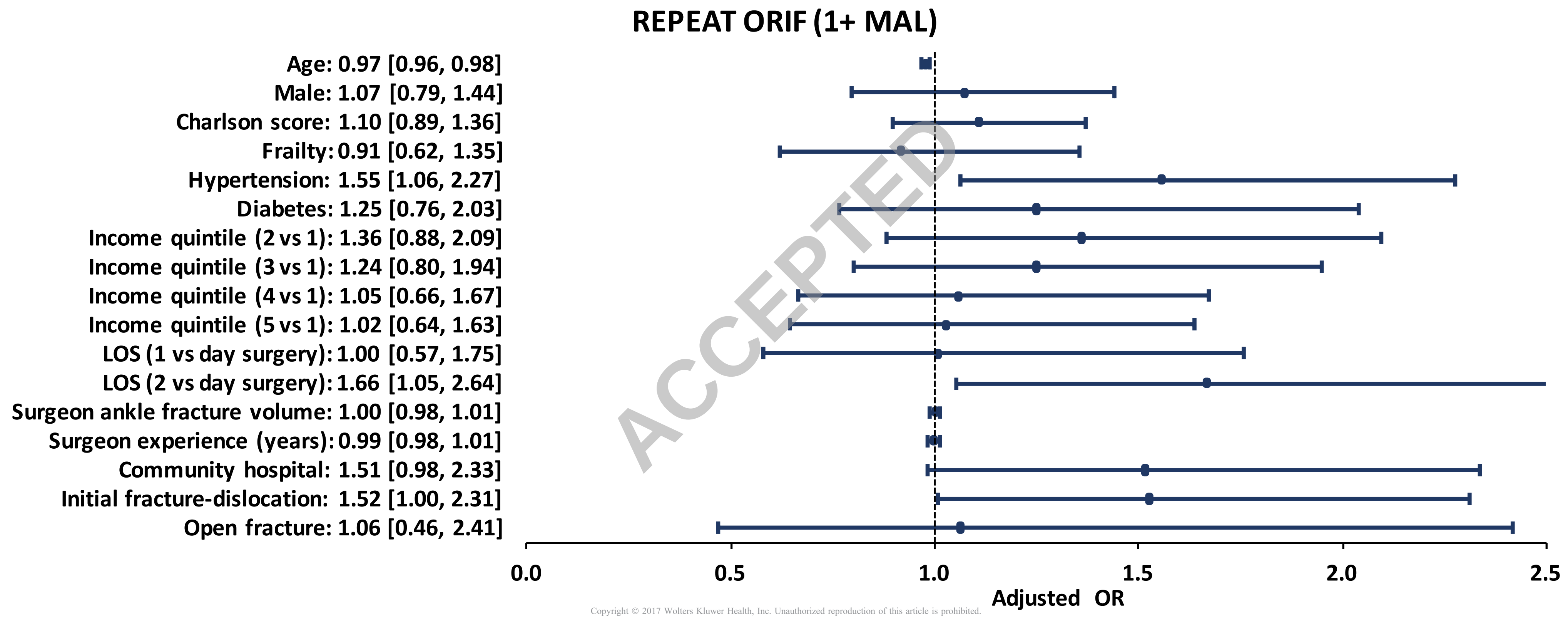


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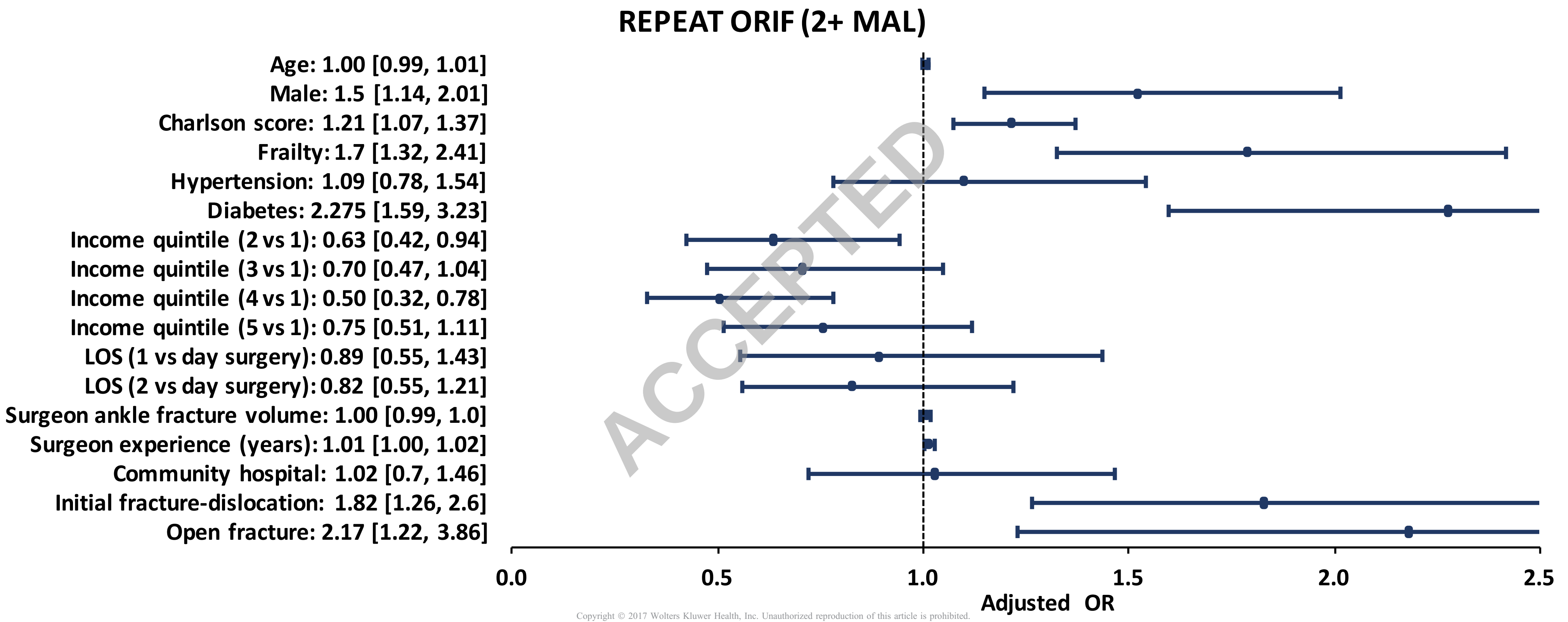


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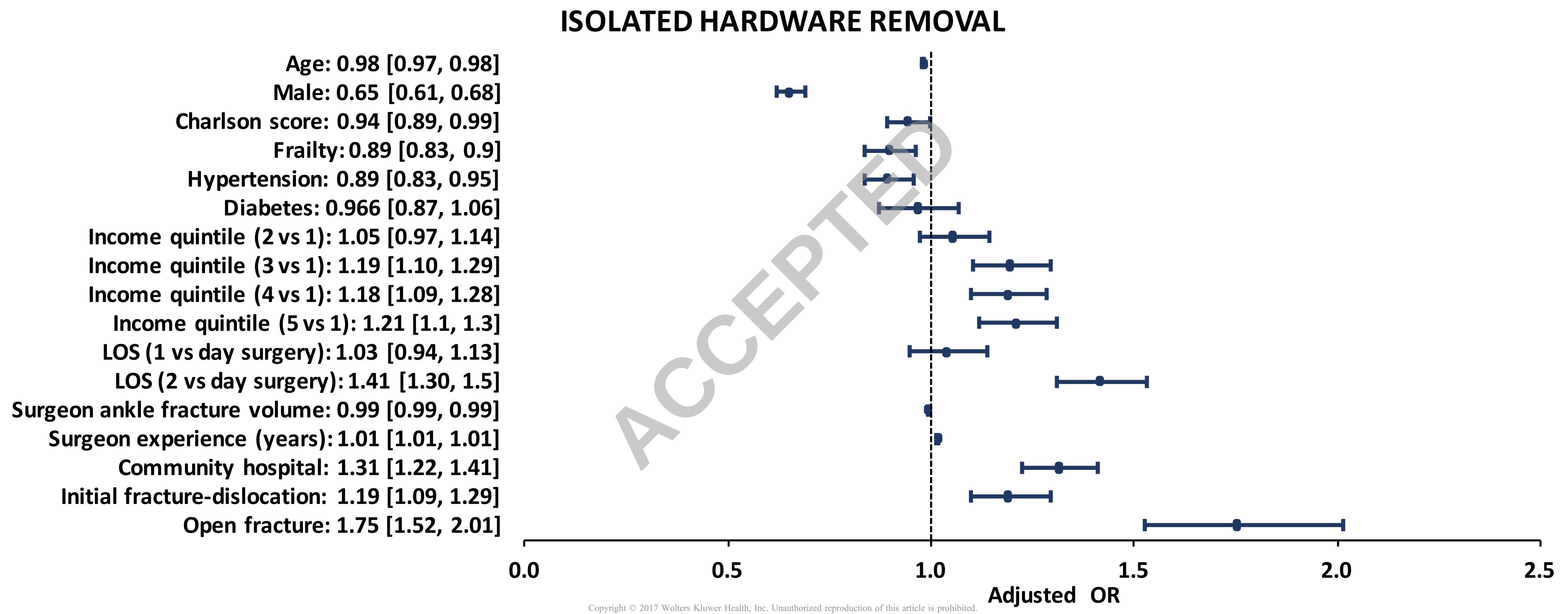

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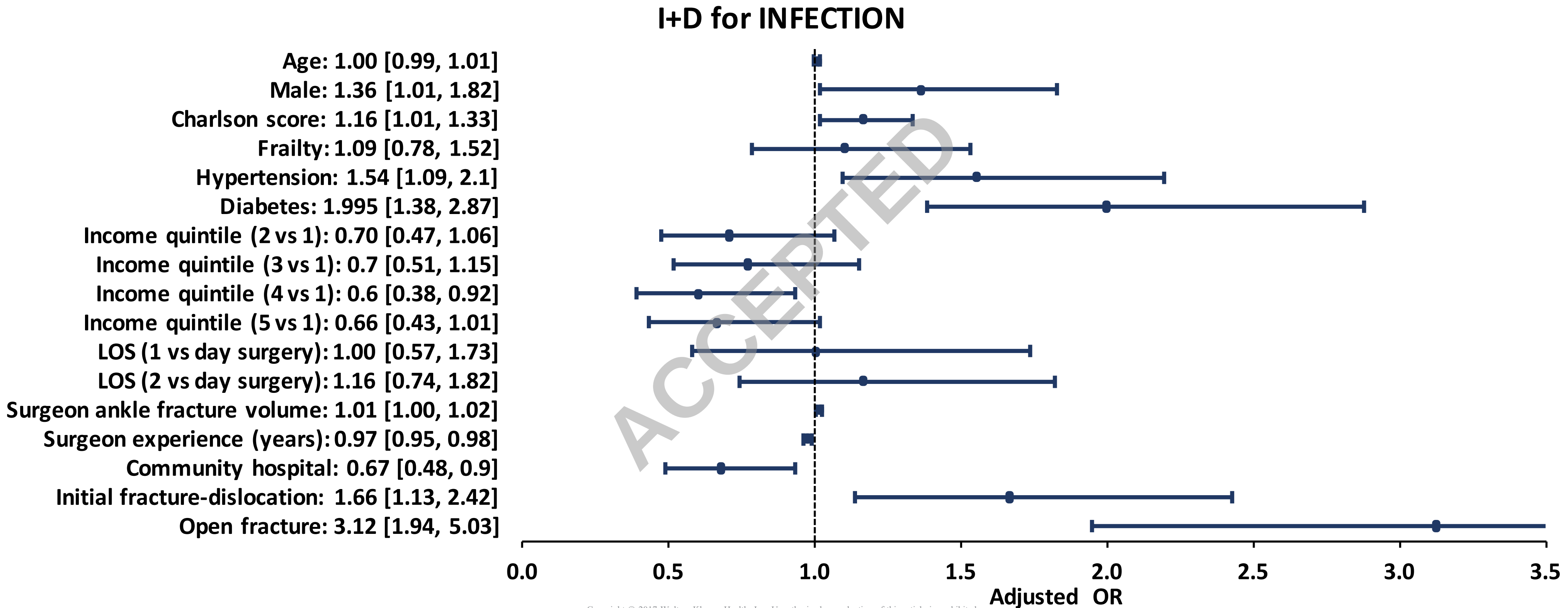


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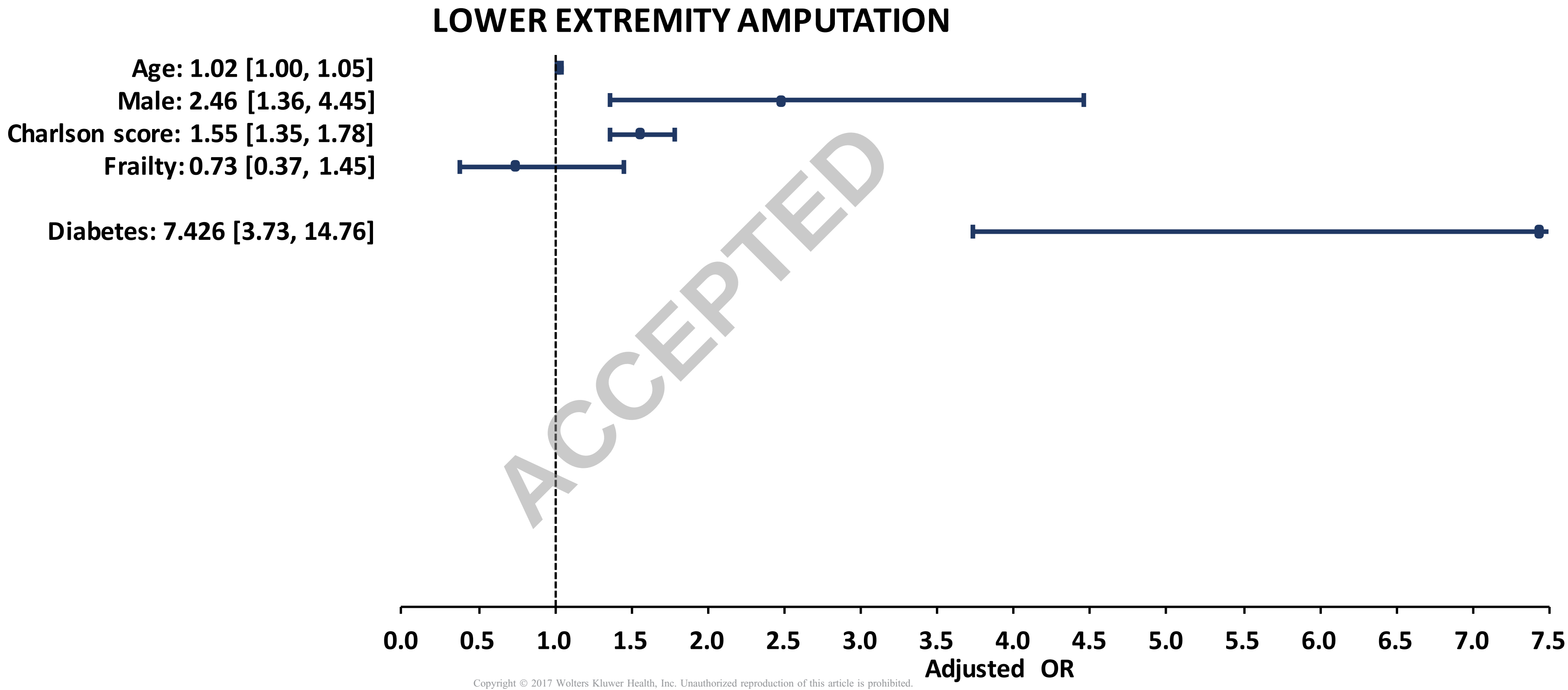

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