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Supplementary Appendix

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Supplementary Tables

eTable 1. Number of Ineligible Patients by Reason(s)

	Number of Patients
Did not meet inclusion criteria (Multiple reasons for exclusion are possible)	2043
Injury not eligible	1079
Study injury already infected prior to definitive fixation surgery	32
Prior definitive fixation	188
Language (patient speaks neither English nor Spanish)	58
Already intubated at the time of definitive fixation surgery	76
History of COPD/chronic respiratory disease (patient oxygen dependent)	161
Follow-up problems	430
Other	99

(Protocol adapted, with permission, from: O'Toole RV, Joshi M, Carlini AR, Sikorski RA, Dagal A, Murray CK, Weaver MJ, Paryavi E, Stall AC, Scharfstein DO, Agel J, Zadnik M, Bosse MJ, Castillo RC; METRC. Supplemental Perioperative Oxygen to Reduce Surgical Site Infection After High-Energy Fracture Surgery [OXYGEN Study]. J Orthop Trauma. 2017 Apr;31 Suppl 1:S25-S31.)

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eTable 1a. Patient Characteristics and Pre-injury Health Status at Baseline

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Age		
18–34	158 (27%)	146 (26%)
35–65	371 (65%)	376 (67%)
66–80	46 (8%)	39 (7%)
Education		
Less than high school	16 (3%)	12 (2%)
High school or GED	244 (42%)	252 (45%)
Some college	312 (54%)	287 (51%)
Refused/unknown/missing	3 (1%)	10 (2%)
Insurance		
Yes	499 (87%)	478 (85%)
No	66 (11%)	68 (12%)
Unknown	10 (2%)	15 (3%)
Chronic Alcohol Abuse	16 (3%)	13 (2%)
Chronic Drug Abuse	16 (3%)	21 (4%)
Diabetes, by types (one or more)		
Diet Controlled	9 (2%)	10 (2%)
Insulin Controlled	16 (3%)	21 (4%)
Oral Medication Controlled	25 (4%)	21 (4%)
Poverty Status		
Poor	67 (12%)	58 (10%)
Near poor/not poor	278 (48%)	269 (48%)
Refused/unknown/missing	230 (40%)	234 (42%)
Preinjury Infection		
Yes	14 (2%)	14 (2%)
Treated with a surgery for the infection and antibiotics	0 (0%)	0 (0%)
Treated with antibiotics only	11 (2%)	12 (2%)
Unknown / missing	3 (1%)	2 (0%)
Previous Injury to Study Leg		
Yes	75 (13%)	79 (14%)
No	495 (86%)	477 (85%)
Refused / unknown / missing	5 (1%)	5 (1%)
Preinjury Infection		
No	556 (97%)	539 (96%)
Yes, by types	14 (2%)	14 (2%)
Pneumonia	0 (0%)	1 (0%)
Urinary tract infection	7 (1%)	9 (2%)
Surgical site infection for a surgery other than this injury	0 (0%)	0 (0%)
Other infection	7 (1%)	5 (1%)
Refused	0 (0%)	0 (0%)
Unknown	4 (1%)	5 (1%)
Missing	1 (0%)	3 (1%)
VR-12: General Health		
Excellent	159 (28%)	152 (27%)
Very good	227 (39%)	199 (35%)
Good	160 (28%)	162 (29%)

Fair	21 (4%)	40 (7%)
Poor	5 (1%)	3 (1%)
Missing	3 (1%)	5 (1%)
VR-12: PCS, Mean (SD)	52.7 (7.2)	52.2 (7.6)
Missing	4 (1%)	9 (2%)
VR-12: MCS, Mean (SD)	55.1 (10.6)	55.5 (9.6)
Missing	4 (1%)	9 (2%)

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eTable 1b. Injury Characteristics at Baseline (*continued)*

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Study Injury		
Fracture Type		
Tibial Plateau B	46 (8%)	39 (7%)
Tibial Plateau C	196 (34%)	195 (35%)
Tibial Plateau, unknown AO classification	1 (0%)	0 (0%)
Tibial Pilon B	44 (8%)	37 (7%)
Tibial Pilon C	149 (26%)	159 (28%)
Tibial Pilon, unknown AO classification	0 (0%)	1 (0%)
Calcaneus B	4 (1%)	4 (1%)
Calcaneus C	131 (23%)	122 (22%)
Calcaneus, unknown AO classification	4 (1%)	4 (1%)
Open Fracture		
Open	88 (15%)	81 (14%)
Gustilo Type		
I	13 (2%)	5 (1%)
II	23 (4%)	29 (5%)
IIIA	52 (9%)	47 (8%)
Closed	487 (85%)	480 (86%)
Tscherne Classification		
Grade 0	44 (8%)	39 (7%)
Grade 1	126 (22%)	131 (23%)
Grade 2	269 (47%)	264 (47%)
Grade 3	46 (8%)	45 (8%)
Missing	2 (0%)	1 (0%)
Open Fracture Classification		
Contamination		
None or minimal contamination	41 (7%)	46 (8%)
Surface contamination	36 (6%)	29 (5%)
Imbedded in bone or deep soft tissues OR high risk environmental conditions (barnyard, fecal, dirty water, etc.)	11 (2%)	6 (1%)
Missing	0 (0%)	0 (0%)
Bone Loss		
None	41 (7%)	41 (7%)
Bone missing or devascularized but still some contact between proximal and distal fragments	39 (7%)	37 (7%)
Segmental bone loss ≤ 2 cm	3 (1%)	1 (0%)
Segmental bone loss > 2 cm	5 (1%)	2 (0%)
Missing	0 (0%)	0 (0%)
Muscle		
No muscle in area, no appreciable muscle necrosis or some muscle injury with intact muscle function	57 (10%)	54 (10%)
Loss of muscle but the muscle remains functional, some localized necrosis in the zone of injury that requires excision, intact muscle-tendon unit	29 (5%)	27 (5%)

eTable 1b. Injury Characteristics at Baseline (*continued)*

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Dead muscle, loss of muscle function, partial or complete compartment excision, complete disruption of a muscle-tendon unit, muscle defect does not approximate	1 (0%)	0 (0%)
Missing	1 (0%)	0 (0%)
Skin		
Can be approximated	81 (14%)	74 (13%)
Cannot be approximated	4 (1%)	6 (1%)
Extensive degloving	3 (1%)	1 (0%)
Missing	0 (0%)	0 (0%)
Arterial		
No injury	83 (14%)	78 (14%)
Artery injury without ischemia	5 (1%)	2 (0%)
Artery injury with distal ischemia	0 (0%)	1 (0%)
Missing	0 (0%)	0 (0%)
Injury severity score, ISS (include study injury)		
< 13	420 (73%)	426 (76%)
13 – 17	41 (7%)	48 (9%)
18 – 24	32 (6%)	29 (5%)
25 – 34	18 (3%)	12 (2%)
≥ 35	7 (1%)	4 (1%)
Missing	57 (10%)	42 (7%)
Other Injuries (except for study injury)		
Injuries (AIS ≥ 2), count		
0	166 (29%)	153 (27%)
1	81 (14%)	84 (15%)
2 or more	271 (47%)	282 (50%)
Missing	57 (10%)	42 (7%)
Injuries (AIS ≥ 2), by type		
Head	42 (7%)	44 (8%)
Face	22 (4%)	20 (4%)
Neck	5 (1%)	3 (1%)
Thorax	73 (13%)	67 (12%)
Abdomen	29 (5%)	21 (4%)
Spine	66 (11%)	75 (13%)
Upper Extremity	85 (15%)	73 (13%)
Lower Extremity	328 (57%)	334 (60%)
Unspecified	0 (0%)	0 (0%)
Missing	57 (10%)	42 (7%)

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eTable 1c. Pre-, Intra-, and Post-Operative Care Characteristics (part 1) *(continued)*

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Number of Fixation Stages		
1	564 (98%)	542 (97%)
2	11 (2%)	18 (3%)
3	0 (0%)	1 (0%)
Total Fixation Stages	586	581
Systemic Antibiotic Use at Definitive Fixations (all stages)		
Number of systemic antibiotics used		
Mean (SD)	1.4 (0.9)	1.4 (0.9)
0	2 (0%)	2 (0%)
1	427 (74%)	420 (75%)
2	109 (19%)	100 (18%)
3 or more	37 (6%)	39 (7%)
Antibiotics used (one or more types)		
Cefazolin	503 (87%)	507 (90%)
Vancomycin	107 (19%)	94 (17%)
Clindamycin	31 (5%)	30 (5%)
Levofloxacin	15 (3%)	4 (1%)
Trimethoprim Sulfamethoxazole	8 (1%)	9 (2%)
Tobramycin	4 (1%)	5 (1%)
Piperacillin/Tazobactam	5 (1%)	4 (1%)
Gentamicin	4 (1%)	4 (1%)
Ceftriaxone	4 (1%)	2 (0%)
Cefepime	2 (0%)	3 (1%)
Daptomycin	1 (0%)	4 (1%)
Other	26 (5%)	15 (3%)
Percutaneous Insertion		
Yes	255 (44%)	260 (45%)
No	331 (56%)	321 (55%)
Nasal Swabs		
Yes	120 (20%)	131 (23%)
No	466 (80%)	450 (77%)
Antibiotic Use		
Prophylactic Antibiotics Used	577 (98%)	572 (98%)
Infusion Duration (min)		
Median	10	10
Missing	8 (1%)	10 (2%)
Any Other Antibiotics (24 hr prior)		
Yes, for infection at another site	10 (2%)	3 (1%)
Yes, for some other reason	37 (6%)	39 (7%)
No antibiotics were given	539 (92%)	539 (93%)
Surgical Site Prepared for Fixation (one or more)		
Isopropyl Alcohol	301 (51%)	308 (53%)
Duraprep	32 (5%)	23 (4%)
Chlorhexidine (Chloroprep, Hibiclens, etc.)	398 (68%)	399 (69%)
Povidone-Iodine (Betadine)	219 (37%)	222 (38%)
Other	31 (5%)	40 (7%)

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eTable 1c. Pre-, Intra-, and Post-Operative Care Characteristics (part 1) *(continued)*

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Nasal Application of Bactroban for MRSA		
Yes	11 (2%)	7 (1%)
No	574 (98%)	574 (99%)
Missing	1 (0%)	0 (0%)
Plate Characteristics (by fracture type)		
Tibial Plateau: Surgical Incision (one or more)	247 (42%)	240 (41%)
Lateral	142 (24%)	143 (25%)
Medial	76 (13%)	90 (15%)
Anterior	22 (4%)	26 (4%)
Posterior medial	77 (13%)	66 (11%)
Posterior	5 (1%)	4 (1%)
Transfibular	0 (0%)	1 (0%)
Other	54 (9%)	54 (9%)
Tibial Pilon: Surgical Incision (one or more)	199 (34%)	210 (36%)
Anterior	18 (3%)	18 (3%)
Anterior medial	63 (11%)	59 (10%)
Anterior lateral	88 (15%)	82 (14%)
Medial	46 (8%)	31 (5%)
Posterior medial	18 (3%)	14 (2%)
Posterior lateral	26 (4%)	44 (8%)
Lateral	28 (5%)	24 (4%)
Other	8 (1%)	7 (1%)
Calcaneus: Surgical Incision (one or more)	140 (24%)	131 (23%)
L type lateral	72 (12%)	53 (9%)
Sinus Tarsi	49 (8%)	50 (9%)
Medial	5 (1%)	11 (2%)
Other	16 (3%)	22 (4%)
Skin Preparation (Prior to Surgery)		
Yes	37 (6%)	37 (6%)
No	549 (94%)	544 (94%)
Skin Preparation (Day of Surgery)		
Yes	215 (37%)	214 (37%)
No	371 (63%)	367 (63%)
External Fixator (At Surgery)		
No	179 (31%)	159 (27%)
Yes	407 (69%)	422 (73%)
Left in Place and Prepped into Surgical Field		
Yes	230 (39%)	245 (42%)
No	176 (30%)	177 (30%)
Missing	1 (0%)	0 (0%)
Any Other Procedures, by count	133 (23%)	132 (23%)
Number of other procedures, mean (SD)	1.4 (1.0)	1.4 (1.0)
1	105 (18%)	102 (18%)
2	17 (3%)	18 (3%)
3	4 (1%)	8 (1%)
4 or more	7 (1%)	4 (1%)
Operative Environment		
Is the operating room a laminar flow room		

eTable 1c. Pre-, Intra-, and Post-Operative Care Characteristics (part 1) *(continued)*

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Yes	248 (42%)	260 (45%)
No	338 (58%)	321 (55%)
Is the operating room an ultraviolet room		
Yes	0 (0%)	0 (0%)
No	586 (100%)	581 (100%)
Total number of people scrubbed for surgery		
Mean (SD)	3.7 (1.8)	3.6 (1.9)
1	7 (1%)	8 (1%)
2	131 (22%)	152 (26%)
3	231 (39%)	206 (35%)
4	80 (14%)	87 (15%)
5	60 (10%)	49 (8%)
6	77 (13%)	79 (14%)
Were body exhaust system or space suits used		
Yes	1 (0%)	1 (0%)
No	585 (100%)	580 (100%)
Was a hair net used on any part of the patient at any time during the surgery		
Yes	486 (83%)	495 (85%)
No	100 (17%)	86 (15%)
Percent of the surgical time was the attending surgeon scrubbed in the operating room		
Mean (SD)	94.5 (11.6)	94.5 (11.8)
100	353 (60%)	352 (61%)
95 – 99	85 (15%)	84 (14%)
90 – 94	72 (12%)	73 (13%)
85 – 89	18 (3%)	16 (3%)
84 or less	58 (10%)	56 (10%)
Type of anesthesia (one or more)		
General	585 (100%)	578 (99%)
Regional	112 (19%)	122 (21%)
Spinal	0 (0%)	5 (1%)
Block-Sciatic	22 (4%)	20 (3%)
Block-Femoral	28 (5%)	19 (3%)
Block-Popliteal	80 (14%)	94 (16%)
Block-Other	45 (8%)	55 (9%)

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eTable 1d. Pre-, Intra-, and Post- Operative Care Characteristics (part 2)

	Treatment Group (N* = 586) no. (%)	Control Group (N* = 581) no. (%)
Number of Days Between Injury and Definitive Fixation		
Mean (SD)	13.9 (8.9)	15.0 (9.0)
1 or less	19 (3%)	15 (3%)
2 - 7	109 (19%)	98 (17%)
8 - 14	207 (35%)	193 (33%)
15 - 21	160 (27%)	162 (28%)
22 - 28	65 (11%)	77 (13%)
29 or more	26 (4%)	35 (6%)
Missing	0 (0%)	1 (0%)
Duration of Operation		
Mean (SD)	3.4 (1.5)	3.3 (1.4)
< 1 hr	7 (1%)	9 (2%)
1 – 1.9 hr	90 (15%)	75 (13%)
2 – 2.9 hr	184 (31%)	191 (33%)
3 – 3.9 hr	138 (24%)	152 (26%)
4 – 4.9 hr	84 (14%)	88 (15%)
5 hr or more	83 (14%)	66 (11%)
Missing	0 (0%)	0 (0%)
Tourniquet use at each stage		
Not Used	138 (24%)	150 (26%)
Used	448 (76%)	431 (74%)
Duration, mean (SD)	113.5 (32.8)	115.0 (30.4)
< 60 min	24 (4%)	23 (4%)
60 – <120 min	148 (25%)	134 (23%)
120 – <180 min	264 (45%)	263 (45%)
180 min or more	9 (2%)	10 (2%)
Missing	3 (1%)	1 (0%)
Were any local antibiotics used in the wound at the time of definitive fixation		
Yes, by type(s) of local antibiotics used (one or more)	102 (17%)	76 (13%)
Antibiotic without carrier	66 (11%)	44 (8%)
Antibiotic with dissolvable carrier	4 (1%)	2 (0%)
Antibiotic beads/cement	8 (1%)	7 (1%)
Antibiotic irrigation	29 (5%)	27 (5%)
No	484 (83%)	504 (87%)
Missing	0 (0%)	1 (0%)

* Number of fixation stages

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eTable 2. Use of Oxygen Across Stages of Definitive Fixation

	Treatment Group (N* = 586) no. (%)	Control Group (N* = 581) no. (%)
Oxygen data available	585 (100%)	581 (100%)
Measures of Adherence		
Adherence Measure 1: *Proportion of surgery time that falls at or below 40% (control group) or at or above 70% (treatment group)*		
Mean (SD)	0.9 (0.2)	0.9 (0.3)
10th percentile	0.8	0.4
25th percentile	1	0.9
Median	1	1
75th percentile	1	1
90th percentile	1	1
Measure 1b: *Proportion of surgeries ≥ 80% adherence using Measure 1*	530 (90%)	482 (83%)
Adherence Measure 2: *Average Absolute Distance from assigned FiO_2 range using same boundaries as in Measure 1*		
Mean (SD)	2.5 (8.6)	4.8 (11.5)
10th percentile	0	0
25th percentile	0	0
Median	0	0
75th percentile	0	3.4
90th percentile	4.2	17.9
Adherence Measure 3: *Proportion of surgery time that falls within either 20% - 40% (control group) or 70% - 90% (treatment group)*		
Mean (SD)	0.9 (0.3)	0.9 (0.3)
10^{th} percentile	0.5	0.4
25^{th} percentile	0.9	0.9
Median	1	1
75^{th} percentile	1	1
90^{th} percentile	1	1
Measure 3a: *Proportion of surgeries ≥ 80% adherence using Measure 3*	504 (86%)	479 (82%)

* Number of Fixations
** Oxygenation levels are administered oxygen, measured as % FiO_2

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eTable 3. Primary and Secondary Infection Outcomes

Kaplan-Meier Estimates	Treatment Group (N = 575)	Control Group (N = 561)	Treatment Effect		
			Risk Difference	Relative Risk	P Value
All SSI					
By 90 days	28 (4.9%)	46 (8.2%)			
Unweighted Estimates (95% CI)	5.0% (3.5%, 7.1%)	8.4% (6.4%, 11.1%)	-3.4% (-6.4%, -0.5%)	0.59 (0.38, 0.93)	0.024
Weighted Estimates (95% CI)	4.9% (3.4%, 7.1%)	8.4% (6.4%, 11.1%)	-3.5% (-6.4%, -0.5%)	0.59 (0.37, 0.93)	0.023
By 182 days	40 (7.0%)	60 (10.7%)			
Unweighted Estimates (95% CI)	7.3% (5.4%, 9.8%)	11.1% (8.7%, 14.1%)	-3.8% (-7.3%, -0.4%)	0.65 (0.45, 0.96)	0.030
Weighted Estimates (95% CI)	**7.2% (5.4%, 9.7%)**	**11.1% (8.7%, 14.0%)**	**-3.8% (-7.2%, -0.4%)**	**0.65 (0.45, 0.96)**	**0.030**
By 365 days	50 (8.7%)	78 (13.9%)			
Unweighted Estimates (95% CI)	9.3% (7.1%, 12.1%)	14.9% (12.1%, 18.2%)	-5.6% (-9.5%, -1.7%)	0.62 (0.45, 0.87)	0.006
Weighted Estimates (95% CI)	9.3% (7.1%, 12.1%)	15.0% (12.2%, 18.4%)	-5.7% (-9.6%, -1.8%)	0.62 (0.44, 0.87)	0.005
Deep SSI					
By 90 days	19 (3.3%)	28 (5.0%)			
Unweighted Estimates (95% CI)	3.4% (2.2%, 5.2%)	5.1% (3.6%, 7.4%)	-1.8% (-4.2%, 0.6%)	0.66 (0.37, 1.16)	0.147
Weighted Estimates (95% CI)	3.3% (2.1%, 5.2%)	5.1% (3.5%, 7.3%)	-1.7% (-4.1%, 0.6%)	0.66 (0.37, 1.16)	0.149
By 182 days	32 (5.6%)	37 (6.6%)			
Unweighted Estimates (95% CI)	5.9% (4.2%, 8.2%)	6.9% (5.0%, 9.4%)	-1.0% (-3.9%, 1.9%)	0.85 (0.54, 1.35)	0.493
Weighted Estimates (95% CI)	5.8% (4.2%, 8.2%)	6.8% (5.0%, 9.3%)	-1.0% (-3.9%, 1.9%)	0.86 (0.54, 1.35)	0.503
By 365 days	43 (7.5%)	55 (9.8%)			
Unadjusted Estimates (95% CI)	8.1% (6.1%, 10.8%)	10.6% (8.2%, 13.6%)	-2.5% (-6.0%, 1.0%)	0.76 (0.52, 1.12)	0.167
Weighted Estimates (95% CI)	8.1% (6.1%, 10.8%)	10.6% (8.3%, 13.6%)	-2.5% (-6.0%, 1.0%)	0.76 (0.52, 1.12)	0.167
Superficial SSI					
By 90 days	9 (1.6%)	19 (3.4%)			
Unweighted Estimates (95% CI)	1.6% (0.8%, 3.0%)	3.5% (2.2%, 5.4%)	-1.9% (-3.7%, 0.0%)	0.46 (0.21, 1.01)	0.054
Weighted Estimates (95% CI)	1.6% (0.8%, 3.1%)	3.5% (2.2%, 5.4%)	-1.9% (-3.8%, 0.0%)	0.46 (0.21, 1.01)	0.053
By 182 days	10 (1.7%)	24 (4.3%)			
Unweighted Estimates (95% CI)	1.8% (1.0%, 3.3%)	4.4% (3.0%, 6.5%)	-2.6% (-4.7%, -0.6%)	0.40 (0.19, 0.84)	0.015
Weighted Estimates (95% CI)	1.8% (1.0%, 3.3%)	4.4% (3.0%, 6.5%)	-2.6% (-4.7%, -0.6%)	0.41 (0.20, 0.85)	0.016
By 365 days	11 (1.9%)	27 (4.8%)			
Unweighted Estimates (95% CI)	2.0% (1.1%, 3.6%)	5.1% (3.5%, 7.4%)	-3.1% (-5.4%, -0.9%)	0.39 (0.19, 0.78)	0.008
Weighted Estimates (95% CI)	2.0% (1.1%, 3.6%)	5.1% (3.5%, 7.4%)	-3.1% (-5.3%, -0.9%)	0.39 (0.20, 0.78)	0.008

* Highlighted row indicates primary outcome comparison
# Totals for “All SSI” rows are not necessarily the sum of “Deep SSI” and “Superficial SSI” totals. The treatment and control groups each had 4 patients who experienced separate superficial and deep infection events at different time points.

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eTable 4. Tertiary Outcomes

Unadjusted Estimates (95% CI)	Treatment Group (N = 575)	Control Group (N = 561)	Treatment Effect		
			Risk Difference	Relative Risk	P Value
Nonunion	24 (4%)	26 (5%)			
By 182 days	1.9% (1.1%, 3.2%)	2.4% (1.5%, 3.8%)	-0.5% (-2.0%, 1.0%)	0.79 (0.39, 1.59)	0.511
By 365 days	4.1% (2.8%, 6.0%)	4.5% (3.1%, 6.6%)	-0.5% (-2.8%, 1.9%)	0.90 (0.52, 1.55)	0.704
Malunion	5 (1%)	6 (1%)			
By 182 days	0.5%	0.6%	-0.1%	0.84	--
By 365 days	0.9%	1.0%	-0.2%	0.82	--
Flap failure	1 (0%)	3 (1%)			
By 182 days	0.1%	0.3%	-0.2%	0.49	--
By 365 days	0.2%	0.5%	-0.4%	0.33	--
Peri-implant fracture	0 (0%)	1 (0%)			
By 182 days	0.0%	0.0%	0.0%	0.00	--
By 365 days	0.0%	0.1%	-0.1%	0.00	--
Reaction to hardware	2 (0%)	1 (0%)			
By 182 days	0.0%	0.0%	0.0%	0.00	--
By 365 days	0.1%	0.2%	0.0%	0.77	--

(Protocol adapted, with permission, from: O'Toole RV, Joshi M, Carlini AR, Sikorski RA, Dagal A, Murray CK, Weaver MJ, Paryavi E, Stall AC, Scharfstein DO, Agel J, Zadnik M, Bosse MJ, Castillo RC; METRC. Supplemental Perioperative Oxygen to Reduce Surgical Site Infection After High-Energy Fracture Surgery [OXYGEN Study]. J Orthop Trauma. 2017 Apr;31 Suppl 1:S25-S31.)

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eTable 5. Serious Adverse Events and Complications Other than Outcomes

	Treatment Group (N = 575) no. (%)	Control Group (N = 561) no. (%)
Deaths, by cause (days post-fixation)	**4 (1%)**	**6 (1%)**
Underlying disease; pulmonary embolism (range: 6 – 35)	0 (0%)	2 (0%)
Underlying disease; other or not further specified (range: 111 – 185)	1 (0%)	3 (1%)
Injury following discharge (179)	0 (0%)	1 (0%)
Out of hospital death* (range: 74 – 415)	3 (1%)	0 (0%)
Life-threatening or disabling adverse events	**1 (0%)**	**4 (1%)**
Pulmonary embolism	0 (0%)	2 (0%)
Heart attack	1 (0%)	0 (0%)
Stroke	0 (0%)	1 (0%)
Suicide attempt	0 (0%)	1 (0%)

* One death was determined to have occurred beyond the 365-day study period and is presented here for completeness.

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