

TABLE E-1 Inclusion and Exclusion Criteria

Inclusion Criteria:

- An unstable and/or displaced distal radial fracture resulting from a low-energy impact
- An extra-articular fracture (AO type A2.1, A2.2, A3.1, A3.2, and A3.3) or simple articular fracture (AO type C1.1, C1.2, C1.3, C2.1, and C2.2) (see text)
- Male or female, 45 years of age or older
- Living independently and able to walk at the time of injury
- Treatment administered within 5 days of injury
- Agreement to return for the specified follow-up evaluations
- Signed written informed consent
- Anatomic reduction within 2 mm of radial length, a volar angle of 0° to 28°, volar cortical alignment, and normal joint congruity

Exclusion criteria:

- A multifragmentary intra-articular fracture extending into the diaphysis
- Major ligamentous disruption (i.e., scapholunate instability)
- A Smith fracture (i.e., volar displacement) or Barton fracture (i.e., shearing)
- Open surgical reduction or bone-grafting required
- A nondisplaced or stable fracture
- A previous wrist fracture in the injured limb within the last 12 months
- A concomitant limb fracture, ipsilateral ulnar fracture (excluding ulnar styloid), an open fracture, nerve or blood vessel injury, or infection at the operative site
- Receiving radiation therapy or chemotherapy
- Receiving anticoagulation therapy
- Medications known to affect skeletal metabolism, or a metabolic disorder known to affect the skeleton (excluding osteoporosis)
- Physically or mentally compromised and unable to perform functional examinations
- Social problems that would potentially affect follow-up (drug-abuser, prisoner, transient)

TABLE E-2 Results, Clinical Parameters

	6-8 Weeks		3 Months		6 Months		12 Months	
Outcome	SRS	Control	SRS	Control	SRS	Control	SRS	Control
Grip strength (%)								
Mean	37.2	21.5	58.6	57.3	76.7	74.3	88.8	89.4
Standard deviation	36.2	14.8	24.5	35.1	22.3	23.8	24.3	23
Significance	0.0001							
Flexion (%)								
Mean	52.9	45.9	66.8	69.2	75.8	76.5	79.2	84.1
Standard deviation	22.4	23.4	23.3	26.6	27	23.8	28.8	25.7
Significance	0.0091							
Extension (%)								
Mean	66.5	44.8	81.0	79.9	88.2	89.6	93.4	95.7
Standard deviation	24.7	30.2	25.2	28.3	25.7	28.2	26.7	28.5
Significance	0.0001							
Pronation (%)								
Mean	90.6	76.0	96.7	92.7	98.3	94.2	99.9	95.0
Standard deviation	30.5	25.6	28.8	13.9	30.6	12.4	31.1	12.7
Significance	0.0001							
Supination (%)								
Mean	68.8	55.0	80.4	84.1	87.3	88.3	89.7	92.3
Standard deviation	27.3	31.4	21.3	24.7	17.3	21.4	18.1	17.9
Significance	0.0001							
Radial deviation (%)								
Mean	73.1	44.6	94.1	88.3	97.6	101.8	106.5	111.5
Standard deviation	36.9	52.3	46.8	61.7	40.8	58.3	45.3	64.3
Significance	0.0001							
Ulnar deviation (%)								
Mean	61.1	53.5	74.4	75.9	79.7	83.7	85.2	90.1
Standard deviation	29.4	29.2	34.0	33.9	33.8	39.1	34.5	41.9
Significance	0.027							

TABLE E-3 Results, Radiographic Parameters

	6-8 Weeks		3 Months		12 Months	
Outcome	SRS	Control	SRS	Control	SRS	Control
Loss of radial length (<i>mm</i>)						
Mean	4.7	3.9	4.7	4.0	4.5	3.7
Standard deviation	4.3	4.1	4.3	4.3	4.0	4.0
Significance						
Loss of radial angle (<i>deg</i>)						
Mean	4.5	4.8	4.8	4.9	4.5	4.6
Standard deviation	6.2	6.2	6.1	6.4	5.9	5.8
Significance						
Change in volar/dorsal angle (<i>deg</i>)						
Mean	10.6	12.0	10.6	11.7	10.3	10.5
Standard deviation	10.6	13.4	16.6	14.3	16.9	13.5
Significance						
Change in ulnar variance (<i>mm</i>)						
Mean	2.2	1.5	2.2	1.5	2.0	1.4
Standard deviation	1.9	2.0	2.1	2.1	2.1	2.0
Significance	0.002		0.0052		0.018	
Radial shift (<i>mm</i>)						
Mean	2.5	2.3	2.4	2.2	2.7	2.4
Standard deviation	2.6	2.4	2.2	2.4	2.5	2.3
Significance						
Articular step-off						
No. of fractures with step-off	9	11	8	11	5	9
Size of step-off (<i>mm</i>)						
Mean	0.9	0.9	1.1	1.1	0.8	1.0
Standard deviation	0.3	0.4	0.6	0.5	0.3	0.3

TABLE E-4 Data on Complications*

Type of Complication	Group Treated with Norian SRS (n = 161)				Control Group (n = 162)			
	Patients Per Event	Percentage of Patients	Event Frequency	Percentage of Events	Patients Per Event	Percentage of Patients	Event Frequency	Percentage of Events
Loss of reduction	46	28.6	46	45.5	40	24.7	41	33.9
Infection								
Ext. fix. pin-tract infection	0	0.0	0	N/A	18	11.1	18	14.9
Kirschner-wire pin-tract infection	3	1.9	3	3.0	7	4.3	7	5.8
Osteomyelitis	1	0.6	1	1.0	0	0.0	0	0.0
Cellulitis	0	0.0	0	0.0	2	1.2	2	1.7
Tendinopathies								
Tendon weakness	1	0.6	1	1.0	0	0.0	0	0.0
Tendinitis	1	0.6	1	1.0	1	0.6	2	1.7
Stenosing tenosynovitis	4	2.5	4	4.0	3	1.9	3	2.5
Tendon adhesion	0	0.0	0	0.0	2	1.2	2	1.7
Tendon rupture	6	3.7	7	6.9	2	1.2	2	1.7
Neuropathies								
Dysesthesia	2	1.2	2	2.0	1	0.6	1	0.8
Paresthesia	3	1.9	3	3.0	1	0.6	1	0.8
Radial nerve symptoms	1	0.6	1	1.0	1	0.6	1	0.8
Ulnar nerve symptoms	0	0.0	0	0.0	1	0.6	1	0.8
Median nerve symptoms	2	1.2	2	2.0	2	1.2	2	1.7
Carpal tunnel syndrome	4	2.5	4	4.0	8	4.9	8	6.6
Reflex sympathetic dystrophy/Sudeck atrophy	7	4.3	7	6.9	8	4.9	8	6.6
Pain	4	2.5	4	4.0	10	6.2	10	8.3
SRS-specific								
Intra-articular SRS	4	2.5	4	4.0	N/A	N/A	N/A	N/A
Shoulder events								
Shoulder bursitis	1	0.6	1	1.0	0	0.0	0	0.0
Shoulder impingement	0	0.0	0	0.0	2	1.2	2	1.7
Shoulder pain	1	0.6	1	1.0	0	0.0	0	0.0
Other								
Swelling	2	1.2	2	2.0	1	0.6	1	0.8
Pin problems	2	1.2	2	2.0	2	1.2	2	1.7
Ulnar fracture	1	0.6	1	1.0	2	1.2	2	1.7
Thumb fracture	1	0.6	1	1.0	0	0.0	0	0.0
Ulnar styloid nonunion	0	0.0	0	0.0	1	0.6	1	0.8
Fall onto treated wrist	3	1.9	3	3.0	3	1.9	3	2.5
Minor trauma to wrist	0	0.0	0	0.0	1	0.6	1	0.8
Total	-	46.0	101	100.0	-	50.6	121	100.0
Total no. of patients	74				82			

*Some patients had more than one complication. N/A = not applicable.