Title:

Effect of Lateralization and Distalization on Tuberosity Healing and Functional Outcomes After Reverse Shoulder Arthroplasty for Proximal Humerus Fractures: A Randomized Controlled Trial Comparing 135° and 155° Uncemented Stems

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Abstract

Introduction: Controversy remains regarding whether neck shaft angle influences tuberosity healing in reverse shoulder arthroplasty (RSA) for proximal humerus fracture (PHF). This study aimed to compare the tuberosity healing rates between RSA using a lateralized and a distalized configuration for PHFs. The secondary objective was to evaluate functional outcomes based on stem inclination and tuberosity healing status.

Methods: This randomized controlled trial enrolled patients ≥65 years with Neer 3- or 4-part PHF or a displaced Neer 2-part PHF with osteoporosis and/or a rotator cuff tear. Patients were randomized into two groups: 135º stem with 4 mm of lateralization or 155º stem with 2.5 mm of distalization. A priori power analysis determined a sample size of 78 patients to detect a 15% difference in tuberosity healing between groups with statistical significance. Healing of the tuberosities was assessed by two independent shoulder surgeons on radiographs. Range of motion and patient-reported outcomes (PROs) were compared. PROs included Visual Analogue Scale for pain (VAS), Constant-Murley score (CMS), and Quick-DASH (Disabilities of the Arm, Shoulder and Hand). Post-hoc analyses compared outcomes by greater tuberosity healing and implant configuration.

Results: A total of 79 patients were enrolled, and 38 in each group completed at least a 2-year follow-up. Non-healing of the greater tuberosity occurred in 3 patients in the 155º-distalized group and 12 in the 135º-lateralized group (P=.009). The relative risk of greater tuberosity non-healing in the 135º-lateralized group compared to the 155º-distalized group was 4.0 (95% CI: 1.23–13.05, P=.022) at 24 months. Postoperative outcomes were similar between groups (P>.050). In non-healed greater tuberosity cases, the 155°-distalized configuration showed significantly lower ER than the 135°-lateralized (–17° ± 6 vs. 15° ± 19, P=.006). No significant differences were found between implant types in healed cases (P>.050). Within the 155°-distalized group, non-healed GT was linked to reduced ER compared to healed GT (–17° ± 6 vs. 20° ± 18, P=.006), while outcomes were comparable in the 135° group regardless of healing status (P>.050).

Discussion: This is the first RCT comparing tuberosity healing rates and functional outcomes between RSA with a 135º and 155º humeral uncemented stem in the treatment of PHFs. Our findings demonstrated that while the 155º-distalized configuration exhibited a significantly higher tuberosity healing rate, functional outcomes were comparable to the 135º-lateralized configuration. In addition, ER was better in the 135º-lateralized group compared to the 155º-distalized group when tuberosity healing failed, while outcomes were similar between designs when healing occurred. In the 155º-distalized group, tuberosity healing significantly improved ER, whereas in the 135º-lateralized group, healing had minimal impact functional outcomes. This suggest that the 135º-lateralized configuration provides more consistent shoulder external rotation, as it appears less dependent on tuberosity healing than the 155º-distalized design.

Figure 1. Study flowchart (CONSORT diagram). *PHF: Proximal humerus fracture.*

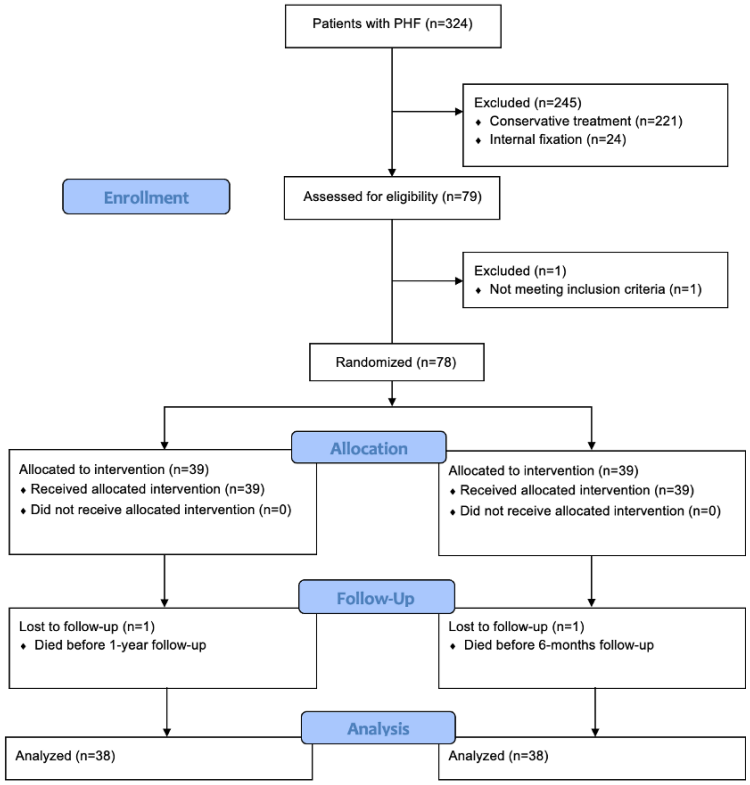

Table 1. Comparison of postoperative outcomes of 155º-distalized and 135º-lateralized groups.

		155º-Distalized N = 38	135º-Lateralized N = 38	P value	HB correction
Greater tuberosity healing					
	6 months	36 (95%)	27 (71%)	**.006**	
	12 months	36 (95%)	26 (68%)	**.003**	
	24 months	35 (92%)	26 (68%)	**.009**	
CMS					
	6 months	61.7 ± 15.2	56.8 ± 17.7	.235	1
	12 months	62.3 ± 17.4	65.4 ± 14.7	.440	1
	24 months	65.9 ± 13.9	66.2 ± 13	.948	1
Adjusted CMS					
	6 months	85.1 ± 18.7	76.6 ± 22.5	.102	1
	12 months	90.6 ± 15.3	90.2 ± 14.5	.914	1
	24 months	92.3 ± 14.2	91.4 ± 13.3	.785	1
Quick DASH					
	6 months	27.4 ± 19	31.8 ± 19.3	.355	1
	12 months	18.1 ± 14.5	23.7 ± 19	.177	1
	24 months	18.4 ± 16.3	21.9 ± 22.5	.464	1
VAS					
	6 months	2.9 ± 2.3	3.6 ± 2.6	.268	1
	12 months	2.4 ± 2.3	2.7 ± 2.4	.625	1
	24 months	1.5 ± 2.3	2.4 ± 2.8	.180	1
Active FF°					
	6 months	113 ± 23	101 ± 18	.548	1
	12 months	122 ± 18	120 ± 14	.744	1
	24 months	121 ± 15	119 ± 14	.560	1
Active ER°					
	6 months	8 ± 18	20 ± 17	**.008**	.408
	12 months	14 ± 20	24 ± 19	**.043**	1
	24 months	19 ± 20	27 ± 18	.110	1
Active IR: months	6/12/24			.207 / **.035** / **.031**	1/1/1
	Dorsal	6 (16%) / 10 (26%) / 21 (55%)	12 (32%) / 22 (58%) / 29 (76%)		
	Lumbar	27 (71%) / 21 (55%) / 14 (37%)	24 (63%) / 14 (37%) / 7 (18%)		
	Sacral	4 (11%) / 6 (16%) / 1 (3%)	1 (3%) / 1 (3%) / 1 (3%)		
	Hip	1 (3%) / 1 (3%) / 2 (5%)	1 (3%) / 1 (3%) / 1 (3%)		

Categorical variables are represented as counts and percentages (%) and continuous variables as mean ± standard deviation, Bold numbers denote statistical significance, ° Degrees, CMS: Constant-Murley score, DASH: Disabilities of the Arm, HB: Holm-Bonferroni, Shoulder and Hand, ER: external rotation at side, FF: forward flexion, IR: internal rotation, VAS: Visual Analog Scale