Locking Intramedullary Nails Compared with Locking Plates for Displaced Three- and Four-Part Proximal Humerus Fractures: A Double-Blinded Randomized Controlled Trial with Two-Year Follow Up of 76 Patients

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INTRODUCTION:

To help orthopaedic surgeons choose the optimal implant, this study addresses the following questions:Does intramedullary nailing or locked plating yield the best patient-reported outcomes after open reduction and internal fixation of displaced 3- and 4-part proximal humerus fractures (PHF)s? Which implant has less complications and reoperations?

METHODS:

This prospective, single-center randomized controlled trial included 76 adult patients with displaced three or four-part PHFs who were randomized to receive a locking intramedullary nail or a locking plate. Displacement was defined as >45° valgus or >30° varus in a true anteroposterior projection, 45° angulation in a scapular Y projection, or >50% displacement of the humeral head against the shaft. The degree of tubercle displacement was not critical for inclusion.

Primary outcome measure was difference in two-year DASH score. Secondary outcome included Constant score (CS), Oxford shoulder score (OSS), Eq5D, reoperations, and complications. Patients were seen at 6 and 12 weeks, 6 months, 1 and 2 years. Assessors at six months and two years were blinded to treatment.

RESULTS:

There was no statistical significant difference in any functional endpoints at two years; mean Dash score: nails 12.7 and plates 10.0, $p = 0.4$. Patients treated with nails scored significantly worse in CS at six months; mean CS (nails 48.8 and plates 58.4, $p= 0.004$), but there were no difference in DASH and OSS at this point. There were significantly more complications and reoperations in the nail group:

Nails: 15 reoperations (4 patients reoperated twice); 3 infections and 6 avascular necrosis (AVN)

Plates: 2 reoperations. No infections and 3 AVNs

Reoperations were either removal of metal, arthrolysis, debridement antibiotics and implant retention (DAIR), or renailing after nail-removal (patient fell). One patient had fallen and had slight osteosynthesis failure where a AVN developed gradually after metal removal.

DISCUSSION AND CONCLUSION:

There is to our knowledge only one other level 1 RCT of 3 and 4 part fractures with two years follow up comparing modern nails and plates (Boyer et al 21). They found significant higher Constant scores in the nails, complications and revision rates higher in the locking plate group. Generally they had very satisfactory clinical outcomes. Surgery of complicated PHFs has a steep learning curve and can generate high rates of complications. The reason for the diverging results between these two RCTs may just be that the two centers use different implants in their daily work and what you use most is what you do best. Probably the best solution is to keep the treatment on few hands and choose the patients wisely.

Fixation of complex PHFs with locking plates or locking intramedullar nails yielded similar clinical outcomes after two years, but patients treated with nails exhibited inferior results at six months in regard to CS and had higher rates of reoperations and complications.

TABLE 2 Demographic and baseline characteristics and operative data of the patients		
	Nail (n=38)	Plate (n=38)
Baseline DASH ± SD	1,5 ± 3,6	1.0 ± 2,3
Gender/ Men	5 (13 %)	7 (18 %)
Mean age at surgery, years ± SD	66 ± 9	67 ± 10
Smokers	3 (8%)	5 (13 %)
Diabetes mellitus	2 (5%)	2 (5%)
Body Mass Index ± SD	27 ± 4	29 ± 5
Time from trauma to surgery, days ± SD	6 ± 3	8 ± 5
Fracture of dominant side	20 (52%)	14 (36%)
Duration surgery, minutes ± SD	101 ± 23	93 ± 22
Mean HSA* of healthy shoulder ± SD	141° ± 5°	141° ± 6°
Range HSA	Range 127°-155°	Range 131°-160°
*HSA= Head Shaft Angle		

	Plate (n=38)	Nail (n=38)	p-value
6 months			
DASH	15.1 ± 12.7	20.1 ± 12.4	0.1
OSS	40.4 ± 8,1	37.8 ± 6.6	0.1
CS	58,4 ± 13.9	48.8 ± 13.9	0.004
2 years			
DASH	10.0 ± 15.6	12.7 ± 13.5	0.4
OSS	43.6 ± 7.8	42.0 ± 7.2	0.3
CS	69.9 ± 14.9	65.7 ± 15.0	0.2
Continuous data presented as means ± standard deviations			