

TITLE- A study into the controversial aspects interlocking nail of femur

INTRODUCTION

Interlocking nails of femur have evolved to be the gold standard of fixation of these fractures. The advantages being a closed reduction and closed internal fixation in most of the cases thus not disturbing the fracture hematoma and the reamed material acting as an autogenous bone graft. Further the intramedullary nail acts as a load sharing device and the locked screws provide rotational stability. The expected union rate in the various recently published series have been reported from 95-99% with occasional complications of non union and malunion in at least the closed and the type 1 and 2 open fractures.

However controversies exist about several aspects of the interlocking nail for example, the role of reaming in the compound fractures, the entry point, the role of static or dynamic locking, the suitability of the antegrade or the retrograde nailing, etc.

My study is an endeavour to analyse the difference in results of the nailing due to these variables.

MATERIALS AND METHODS

All the details of the patients operated in our hospital are maintained in the computerized medical records department of our hospital since 1996. The source of my data is the same records. These records have incorporated every point noted at the follow up clinic by the respective surgeons who in turn recorded every detail as per the performa for follow up in this institute.

The study involves the prospective cohorts in past which were followed up for one year. All the findings and the data were recorded as per the Performa described here subsequently. The population selected were in the age group 20-40; non smoker.

EXCLUSION CRITERIA

- 1) Any fracture of the femur which was significantly comminuted (WINQUIST-HANSENS grade 3 or 4) was excluded from the study.
- 2) Any pathological fracture and pre existing non unions were excluded from the study.

The cases were grouped in the following prospective cohorts in past.

Cohort 1-all closed fractures

Cohort 1p(n=47) subset of cohort 1 in which the entry point was through pyriformis

Cohort 1 t(n=89) subset of cohort 1 in which the entry point was through the greater trochanter.

Cohort 1 d subset of cohort 1 fractures of femur which were in the distal 40% of the femoral shaft.

Cohort 1da(n=33) fractures in the distal 40% for which ante grade nail was done.

Cohort 1dr(n=16) subset of cohort 1 in which the femoral shaft fracture was in the distal 40% and retrograde nail was done.

Any comminuted fracture WINQUIST-HANSEN grade 3 or 4 was excluded.

Cohort 2-comp type 1 or 2 fractures

Cohort 2 p r were those compound fractures in which reaming was done (N=18)

Cohort 2 p u were those in which reaming was not done.(N=14)

Cohort 2 s- in which nailing was done after conversion from external fixator.

THE TOTAL SCORES FOR ALL THE INDIVIDUAL CASES IN EACH OF THESE COHORTS WERE CALCULATED AS PER THE SCORING SYSTEM ALREADY GIVEN IN APPENDIX 2.

ANALYTICAL METHODS USED:

The total score calculated as per the scoring system is a **quantitative estimation of the outcome of the interlocking nail** and this quantitative estimation allows us to analyze the outcome statistically and to understand the significance of these results.

Along with total scores, there were specific scores of several particular aspects under consideration for example the knee ROM scores in the antegrade and retrograde nail after 3 and 6 months or callus scores in the unreamed and reamed nails after 3 and 6 months..

STATISTICS APPLIED:

Null hypothesis or hypothesis of no difference was assumed for each of the set of the classes under consideration and the **p** value was calculated using SPSS soft ware to find the significance of the difference by calculating **unpaired t test**

OUTCOME

Union time:

Union was considered to have occurred when there was,Callus in three or four cortices radiological, with presence of bridging callus and No tenderness on direct pressure at fracture site.

In the closed fractures group, taken as a whole, we found that maximum number (77.6%) of fractures uniting between 12-16 weeks.(mode= 12-16 weeks.) By **16 weeks** or before, **136(89.4%)** of the fractures had united In the retrograde nail group, **17 (99.44%)** of the fractures had united before **16 weeks**, whilst in the antegrade nail group (antegrade nail in the distal 3rd fractures) only **81%** of the fractures united by 16 weeks. (**p=.07**)

In the primary reamed nails after the type 2 compound fractures, **15(88.23%)** of the fractures united by 16 weeks. Whilst in the primary unreamed group, only **7(50%)** of the fractures united by 16 weeks. (**p=.001**).

PAIN AT FRACTURE SITE (number denote the number of cases)

COHORTS									
PAIN AT FRACTURE	1	1t	1p	1da	1dr	2p	2pr	2pu	2s
1.nil	134	79	42	35	17	29	17	10	31
2.occasional,	9	5	3	1	1	0	0	2	7
3.with fatigue	3	2	1	0	0	2	1	1	2

4.constant	4	3	1	1	0	1	0	1	3
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ENTRY POINT

We got 33% eccentric nails if a solid straight nail was entered through the trochanter as compared to <4% in hollow nails entered through either entry point (**p=.002**)

In the hollow nails entered through the pyriformis fossa we found trochanteric pain in 16% as compared to 4% in those entered through the trochanter (**p=.002**). In the solid nails entered through the trochanter there was trochanter pain in 37.5%(**p<.001**)

In our series 91% of the closed nail group as a whole regained their full range of movement by 5-6 months as recorded in their case sheets.

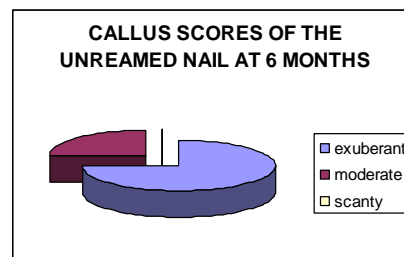
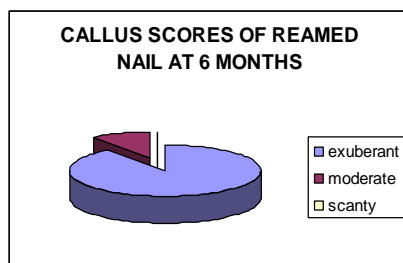
Only 72.2% of the retrograde nail groups gained their full range of movement by 5-6 months. We observed that although the retro nail group was late to regain the knee movement but there was no significant difference at the end of 6 months.

KNEE FLEXION ACHIVED IN THE ANTEGRADE AND THE RETROGRDE NAIL AT 3 MTHS AND 6 MTHS

KNEE FLEXION	RETROGRADE NAIL		ANTEGRADE NAIL	
	3MTH	6MTH	3MTH	6MTH
>125	0	13	10	33
110-125	6	1	17	3
100-109	8	2	7	0
<100	4	2	3	1

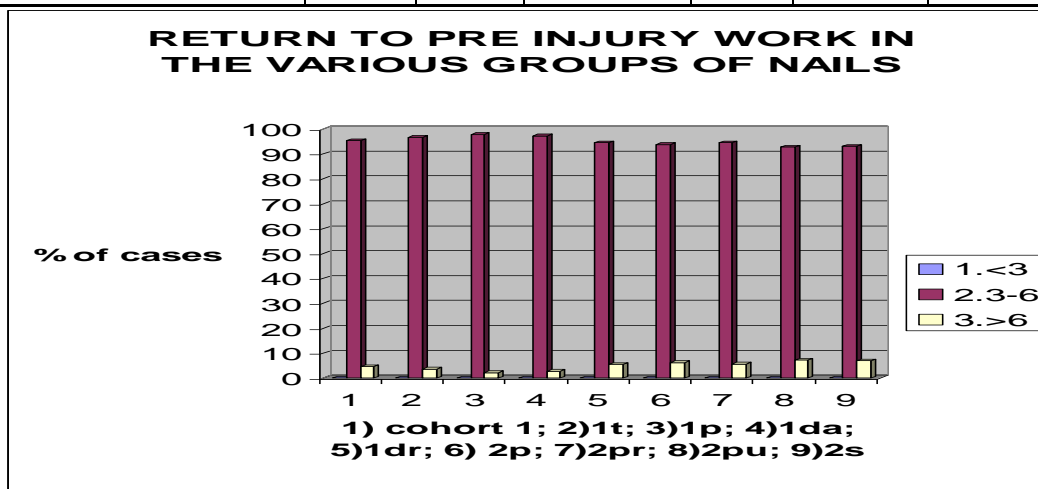
TROCHANTERIC PAIN:

8 (16%) of the nails entered through the pyriformis fossa developed trochanteric pain. There were two cases in which the nail head was proud and there were some evidence of calcific bursitis. 9 (10%) of the patients with nail through the trochanter developed trochanteric pain.



THE OUTCOME IN THE VARIOUS GROUPS

FINAL OUTCOME As per the scoring system appndx 2	cohorts							
	1	1p	1t	1da	1dr	2pr	2pu	2s
Excellent	118	34	68	31	12	12	8	18
Good	31	12	19	15	4	6	5	22
Fair	0	0	0	0	0	0	0	0
Poor	3	1	2	1	0	0	1	2



The bar diagram shows the return to work after nailing in months

THE INFECTION CHART

results considered	cohorts									
	1	1p	1t	1da	1dr	2p	2pr	2pu	2s	
no infection	144	44	84	37	16	30	17	13	31	
superficial infection	7	2	4	0	1	2	1	1	6	
deep infection	3	1	1	0	1	1	0	1	2	

THE RESULTS OF THE STATISTICAL ANALYSIS:

1. The unpaired t test for the final total scores of the ante-grade and the retrograde nail ; $p=0.838$; thus it is not significant.
2. The distal 3rd femoral fractures treated with retrograde nail appear to unite faster than those treated with the antegrade nail but with p value of 0.7, no statistical significance could be made.
3. The comparison between the scores of the knee flexion of the ante-grade and the retrograde nail **at 6 months**; $p=0.702$; thus it is not significant.
4. The undreamed nail group was slower to unite than the reamed nail group as evidenced by analysis at 16 weeks ($p=0.1$).
5. The unpaired t test for the callus score of the reamed and the unreamed nails at **6 months**; **$p=0.645$** ; thus it shows there is no significant difference at the callus in both the groups at 6 months.
6. The incidence of trochanteric pain was less in those nails entered through the trochanter than those entered through the piriformis fossa.

On closer observation we found that out of these. Thus 37.5% of those solid nail which were inserted through the trochanter had trochanteric pain.

7. The comparison between the scores of primary and the secondary nails give a **p value of 0.004**. Thus it's highly significant and it establishes the inferior results with the nails done after external fixator.

In my study almost all the fractures were mechanically stable and wherever the callus formation was not adequate by 8-10 weeks, dynamization was done. This did enhance the callus in next few weeks on a subjective assessment. From my study we inferred that routine conversion of static to dynamic nailing was not necessary for enhancing healing but in cases of delayed union dynamization did help in promoting.

DISCUSSION

This study was designed to understand the results of the various variables of interlocking nail and its correlation with the final outcome in the set up of a developing country.

Merits of the study

The study had a uniform follow up of 1 year in all cases. The confounding factors were removed inside the groups to have a meaningful study. For example all the cases were in the age group 20-40; non smokers, compound type 3 fracture and comminuted type 3 and 4 were excluded.

The cases of locked nails were grouped into various cohorts to have a meaningful comparison and analysis. This is unlike the earlier studies in which they were studied together and the groups had several confounding factors.

Demerits of the study

The study was conducted based on the case records, and the pictures and the x rays which were meticulously maintained in the soft ware of the medical records division. The information during the follow up was recorded based on already existing Performa. Thus although the surgeons recording the follow up were extremely capable, I had to depend on others recording of the information. This can put some amount of bias.

This study was based on the work of various surgeons and their skills, learning curves can vary.

Although I tried to establish statistical significance in some cases but for some of the variables likely to influence the results, the statistical significance could not be established.

No correlation between certain specific results like infection or delayed union/non union and their causative factors could be established because these complications were so rare in this series that statistical correlation cannot be established.

Comparative study

Kempf et al (6) in their study found an average union rate of 98% and an average union time of 14 months. The union time is similar to our series but we had no nonunions. More over the study mentioned does not have as comprehensive grouping as ours.

Clatworthy et al (2) in their study found superiority of the solid unreamed nails in the compound fractures by finding lower infection rates but we have recommended the reamed nail s even in the compound fractures.

Dora et al (3) in their study found found the more incidence of soft tissue damage with the pyriformis entry than the trochanteric entry and we agree with that.

Anup k et al (1) recommended retrograde nailing in the distal femoral fractures and we agree to that.

CONCLUSIONS AND RECOMMENDATIONS

My study draws following conclusions-

1. Interlocking nail is an excellent modality of treatment of the fractures shaft femur.
2. Interlocking nail can be done even up to one week delay in the type 2 compound fractures instead of an external fixator. Hence i recommend a reamed interlocking nail in type 2 compound fractures insted of external fixator. Reamed hollow steel nails are superior to the solid undreamed titanium nails which are also much costlier.
3. In the retrograde nails, the knee movement is slower to return but the final knee scores after 6 months are comparable to antegrade nails.
4. There may be a cancellous collapse in the distal femur making the nail tip proud in the distal entry nails, so they should be well buried deep in the bone at the time of surgery.
5. Trochanteric entry is easier and superior to the pyriformis entry and hence should be practised. Only exception to this rule is the solid straight nail with the locking screws in the head which is designed for pyriformis entry. In this case a trochanteric entry may put the screws out of the head.
6. A distal entry nail gives superior overall result in the distal 3rd femoral fractures all though the knee movement is slower to pick up. Hence in shaft fractures of the distal 3rd the distal entry or the retrograde nails are recommended.

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APPENDIX 1 PROFORMA FOR DATA COLLECTION

1. Case serial number

Hospital indoor number

Name age sex

2. Date of admission 3. date of trauma

4. date and time of surgery

5. Mode of trauma 6. date of discharge

7. Side of fracture

8.Type of fracture - closed/open type 2, (open type 1 and type 3 fractures excluded from the study)

Fracture configuration- simple fracture/ wedge fracture(complex fractures excluded from the study)

9.Injury surgery interval

10.Any systemic disease /anaesthetic problem

11.Entry point – trochanteric/ pyriformis

12.Reamed / unreamed

13.Period of hospital stay

14.Post op rehab

Physiotherapy started on

a.quadriceps(static)

b. knee and hip mobilization

c.ambulation on crutches (non weight bearing)

15.partial weight bearing started on

16 dynamization done/ not done time of dynamization

follow up clinics

post operative months

3 months

6 months

1 year

Recording of scores as per the scoring system

1.tenderness at fracture site **score** 3 mths/6 mths

2.trochanteric tenderness **score** 3 mths/6mths

3.pain at screw site **score** 3 mths/6mths

4.knee flexion **score** 3mths/6mths

5.knee extension deficit

6.deformity of femur score

a)shortening/lengthening **score**

b)torsional deformity **score**

7. muscle atrophy score 3mths/6mths

8.radiological union

- a) callus **score** 3mths/6mths
 - b)visibility of fracture line (**score**) 3mth/ 6mth
 - c)timing of union (**score**) 3 mth/6mth
 - d)angular deformity (**score**) 3 mth/6mth
9. ability to sit cross legged (**score**)
 10. walking ability (**score**)
 - 11.return to pre injury score (**score**)

COMPLICATIONS

Definitions of the complications recorded during follow up

Deep infection – presence of collection/indurated skin/ discharging sinus/ radiological irregular bone formation/ periosteal reaction

Delayed union- callus score<2, visibility of fracture site score <2,

Knee stiffness – knee movement arch less than 100 degrees.

Intra op

- 1.nail impaction /bending
- 2.femoral neck fracture
- 3.respiratory distress

Immediate post op

- 1 Respiratory distress needing intervention
- 2.deep venous thrombosis/ thromboembolism

Complications recorded at follow up clinic

- 1 deep infection at any site in femur
2. Nail fracture at any time
3. Nail bending at any time
4. Non union
5. Delayed union
6. Pudendal nerve neuropraxia
7. knee stiffness (flexion arch less than 100 degrees)
8. Pain at fracture site/ at trochanter/at screw insertion
9. Deformity of femur-shortening/lengthening/torsional
10. Muscle atrophy
11. Difficulty in sitting cross legged/squatting

12. Difficulty in walking

Total outcome score - excellent/good/fair/poor
(as per the criteria laid down
 in the scoring system)

APPENDIX 2 –THE SCORING SYSTEM

THE SCORING SYSTEM AND THE GRADES USED FOR FOLLOW UP

PAIN

-	points
A Pain at fracture site	
1. nil	4
2. occasional un related to fatigue	3
3. with fatigue	2
4. constant	0
B Pain at trochanter	
1.absent	1
2.present	2
C pain at screw insertion site	
1.absent	1
2.present	0

RANGE OF MOTION OF HIP

1. same as contralateral hip	3
2. restriction of 5° of any movement	2

3. restriction of 5-10° of any movement	1
4. restriction of greater than 10° of any movement	0

RANGE OF MOTION OF KNEE (FLEXION)

1. greater than 125°	4
2. 110°-125°	3
3. 100°-109°	2
4. less than 100	1

DEFORMITY OF FEMUR

Shortening/lengthening

None	4
0-1.5 cm	3
1.5-2.5cm	2
Greater than 2.5cm	0

Torsional

Less than 5°	3
5°-10°	2
11°-15°	1
Greater than 15°	0

Muscle atrophy

Less than 1 cm	4
1-2 cm	3
2.1-3 cm	2
Greater than 3 cm	0

Radiological union

a) callus	
exuberant	4
moderate	3
scanty	2

b)visibility of fracture line

not visible		4
partially visible		3
fully visible		2

c)timing of union

less than 4 months		4
4-6 weeks	3	
greater than 6 months		1

d)angular deformity

valgus/varus or procurvatum/recurvatum 0°		3
less than 5°		2
5°-10°		1
Greater than 10°		0

Ability to sit cross legged/squat

Unrestricted		3
Minimal restriction with minimal pain	2	
Painfully restricted	1	
Not possible	0	

Walking ability	a)unimpaired		3
	b)unimpaired but slight limp		2
	c)walking distance restricted		1
	d)uses cane or crutch		0

return to preinjury work (same or equivalent work)	a)less than 3 months		2
	b)3-6 months		1
	c) more than 6 months		0

COMPLICATIONS

Subtract 5 points for any of the following complications

1. deep infection
2. implant failure
3. Delayed healing
4. neurovascular complications

Subtract 2 points for any of the following

1. superficial infection
2. nail too short distally
3. Screw outside the hole
4. calcific bursa over the proximal end

Outcome (in points)

Grade	1 excellent	45-50
	2 good	40-44
	3 fair	35-39
	4 poor	less than 39