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Case Series

Acute Correction of Distal femoral Deformities by a Monolateral Fixator: Lessons to Learn from Clinical Practice

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Abstract

Aim: We aim at investigating whether:

a) Acute correction of distal femoral deformities in adults can be performed safely and accurately.

b) The underlying pathology of each patient (specific indication for surgery) correlates with the final clinical outcome.

Materials & Methods: All adult patients (n=23) who were treated within five years were retrospectively reviewed. The device used for the corrections was a monolateral fixator, the Limb Reconstruction System (LRS Orthofix), guided by the Acute Correction Templates (ACT). Depending on the performance of additional surgery for lengthening of the femur, the patients were divided and studied separately in two groups, A(n=13) and B(n=10). The indications for surgery were grouped in four subgroups: congenital, trauma, infection, and degenerative (arthritis), and correlations between main indication and clinical outcome were studied statistically. Additionally, the following parameters were studied: Demographics, Healing Time (HT), Bone Healing Index (BHI), Maximum Angle Corrected (MAC), Maximum Length Corrected (MLC), and Grade of Complications. Non-parametric correlations were preferred because of the small amount of data.

Results: For the patients belonging to Group A, the mean MAC in any one plane was 15.9 degrees (range 10 to 26) and no statistically significant correlations were possible between HT and each of the following; the age and gender of the patient, the site of the osteotomy, the MAC values and the occurrence of translation following the osteotomy, by the use of non-parametric tests. The mean Healing Time (HT) for Group A was 24.3 weeks (range 14 to 42 weeks). For the patients belonging to Group B, the mean MAC was 15.3 degrees (range 5 to 30), and the mean MLC was 24mm (range 23.3-55mm). No significant correlation was found between HT and any of the following; age, gender, MAC, or MLC. The mean Healing Time (HT) for Group B was 38.3 weeks averaging from 14 to 60 weeks, and the mean BHI was 13.5 days/mm (range 7.6 to 42 days/mm). An osteotomy performed at the distal metaphyses demonstrated a higher healing potential. The accuracy for correction of procurvatum deformities reached 100%, whereas for varus, valgus and recurvatum deformities, the standard deviation was calculated SD=3, SD=7, and SD=7, respectively. All patients who suffered severe (Grade III-IV) complications had previously undergone lengthening procedures (three out of four) or multiple surgeries and grafting due to bone loss, at the level or below the osteotomy level. Translation occurred in seven out of 23 cases, five within Group A and two of Group B, and involved the cases where the level of osteotomy was performed elsewhere to the Center Of Rotation of Angulation (CORA). There was a weak correlation between HT and Indication for surgery only for Group A patients.

Conclusions: It is possible to correct acutely, safely, and accurately distal femoral deformities in adults using the LRS -ATC system when specific guidelines are followed. Post-traumatic cases seem to have a lengthier Healing Time (HT), and congenital cases seem to be doing better in that respect. Further cases are needed for a robust statistical significant result.

Keywords: Acute correction; Mono lateral fixator; Osteotomy

Introduction

The successful clinical application of an implant requires knowledge of the device's biomechanics, the biologic demands of the healing process, and, finally, the biocompatibility between host tissues and the implant materials [1]. Successful surgery depends on correct patient selection. Over five years, the Limb Reconstruction System (LRS Orthofix) guided by the Acute Correction Templates has been used in clinical practice for a range of distal femoral reconstruction in adult patients. Acute correction alone and acute correction followed by gradual lengthening have been applied with the same correction technique. To our knowledge, the method (acute correction employing Monolateral fixation in adults) has rarely been tried in adult patients before. The already existing literature, apart from being very limited it mainly reports on children or young adolescents [2-8].

Materials and Methods

Data Collection

All adult patients who were treated within the five years were retrospectively reviewed. Twenty-three deformed femurs from twenty-two adult patients that were acutely corrected for their angular and rotational deformity were encountered in the study. The device used for the corrections was a monolateral fixator, the Limb Reconstruction System (LRS Orthofix), guided by the Acute Correction Templates. Patient information was collected from the case notes and radiographs. Information concerning age, gender, indication for surgery, type and magnitude of deformity, complications following surgery, additional lengthening, time to fixator removal, and finally, smoking and drinking habits were recorded on excel sheets. Patient confidentiality was kept at all times.

Patient Demographics

Two population groups were derived for analysis,

a. Group A consisted of those who underwent acute corrections only without concomitant lengthening (n=13).

b. Group B consisted of those where the angular and rotational deformity correction was followed by lengthening from the same site (n=10).

The mean age for Group A was 36 years (range 18 to 58), and they were four female and nine male. Group B consisted of a slightly younger population (mean age 28.9 years, range 18 to 40), and they were three female and five male. One male was encountered in both Groups because he underwent bilateral femoral corrections followed by lengthening one femur. The indications for surgery involved deformity of the distal femur due to congenital reasons (five cases), post-infection (five cases), post-traumatic (twelve cases), and degenerative disease (one case). The details for both groups can be seen in (Tables 1, 2A,2B).

Deformity Determination

The magnitude of the femoral deformity was calculated from preoperative anteroposterior and lateral long mechanical axis radiographs as described by [9,10]. When a normal contralateral LDFA (Lateral Distal Femoral Angle) existed for frontal plane deformities, this was used as a reference; otherwise, an LDFA of 87 degrees was considered a standard value. A PDFA (Posterior Distal Femoral Angle) of 83 degrees was considered the standard value for sagittal plane deformities when the contralateral side was abnormal. Preoperative mechanical axis planning determined that the correction should resolve the deformity in two apices in five out of 23 cases. The length had to be restored in ten cases, gradually following the principles of lengthening through callotasis. The magnitude of rotational deformities was calculated from preoperative CT scans. The concomitant tibial deformity was corrected in three cases at the same surgery.

The degree of angular correction achieved was calculated by comparing the preoperative anteroposterior and lateral mechanical axis radiographs to those performed immediately after removing the fixator. Any rotational correction or translation was documented in the operative notes and was considered as such. The final radiographs also evidenced secondary translation. Varus deformity of the distal femur was corrected most commonly (15 cases, range 5-30 degrees of correction obtained), followed by recurvatum deformity corrected in nine cases (range 3-25 degrees). The valgus deformity was present and corrected in eight cases (range 5-26 degrees), whereas rotation was corrected in five cases (range 10 –38 degrees). The preoperative values of the deformities in any one plane have already been demonstrated in Table 1.

Pt	Indication	Age	Gender	Preop Deformity	Vr	Vlg	Rec	Pro	Rot	Site%
1	congenital	42	M	8 vlg	0	8	0	0	0	30
2	Post-traumatic/previous lengthening	39	F	12vr+7rec+20rot	15	0	8	0	20	no data
3	Osteomyelitis/nonunion	37	M	11vlg+5pro	0	11	0	5	0	no data
4	congenital	18	M	30 vr+20rot	30	0	0	0	20	no data
5	Osteomyelitis in childhood	27	F	6vlg+20rec	0	7	20	0	0	no data
6	Post-traumatic/Osteomyelitis/nonunion/refracture	40	M	10vr	13	0	0	0	0	no data
7	growth arrest	32	F	15vr+15rec	10	0	10	0	0	37.6
8	Post-traumatic	46	F	15vr	10	0	3	0	0	30.76
9	Post-traumatic/infection/multiple surgery	28	M	20vr+13rec+10rot	20	0	16	0	10	22.5
10	Post-traumatic/malunion	18	M	5vr+ 20rec	5	0	20	0	0	22.7
11	giant cell excision/infection/multiple surgery	25	F	20vr	15	0	0	0	0	20.7
12	ricketts/previous corrections	32	F	15 vlg	0	26	0	0	0	15
13	Post-traumatic	26	M	5 vlg	0	5	0	0	0	21
14	Post-traumatic	26	M	10vr+6pro+38rot	10	0	0	6	38	47
15	growth arrest	21	M	20 vlg	0	16	0	0	0	23.1
16	Post-traumatic/previous lengthening	48	M	10vr+ 22rec	7	0	10	0	0	13
17	Post-traumatic/previous lengthening	51	M	22 vr	16	0	0	0	0	23
18	osteoarthritis	58	M	10 vr	13	0	0	0	0	13.6
19	Post-traumatic/multiple surgery	42	M	6vr+ 31rec	6	0	14	0	0	17.3
20	Ollier's Disease	18	M	28vlg+22rec+10rot	0	12	25	0	10	18
21	Post-traumatic/poor vascularity/neurological deficit	20	M	23 vlg	0	23	0	0	0	20
22	Post-traumatic	42	M	18 vr	16	0	0	0	0	17.6
23	Congenital /previous lengthening	21	M	20 vr	15	0	0	0	0	25
vlg=valgus, vr=varus, rec=recurvatum, pro=procurvatum, rot =rotation, M=Male, F=Female, Preop=preoperative, Site%=Site of osteotomy expressed as a percentage of the bone length										

Table 1: Details are shown of the 23 cases where acute correction of distal femoral deformity was per-formed. The preoperative deformity is shown. The final postoperative amount of correction achieved and maintained is lying within the yellow area.

Osteotomy

A periosteal sparing opening wedge osteotomy was started with a 4.8mm or a 3,2mm drill, it was then percutaneously performed through a 3-3,5cm incision, and it was finally completed with a 5mm Ilizarov osteotome. The osteotomy level in fifteen cases corresponded with the Center of Rotation of Angulation (CORA). A different level was elected in the rest seven either because the CORA was lying within the knee joint or constraints such as the inadequate soft tissue or bone quality. In those latter cases, an acute correction was followed by acute on table translation. The osteotomy site was measured from the center of the knee joint and was expressed as a percentage of the total bone length.

Limb Reconstruction System

The system we used comprised of a mono-lateral rail with its screw-holding clamps attached and two templates, one angulation template (A), and one rotational (B) (Figures 1 and 2). The templates were selected according to the nature of the deformity, angulation, or rotation and were also used together in cases of complex deformities. The templates were set to reflect the bone's deformity and were attached to the end of the rail.

Figure 1: Different sizes of Monolateral Rail with the clamps attached.

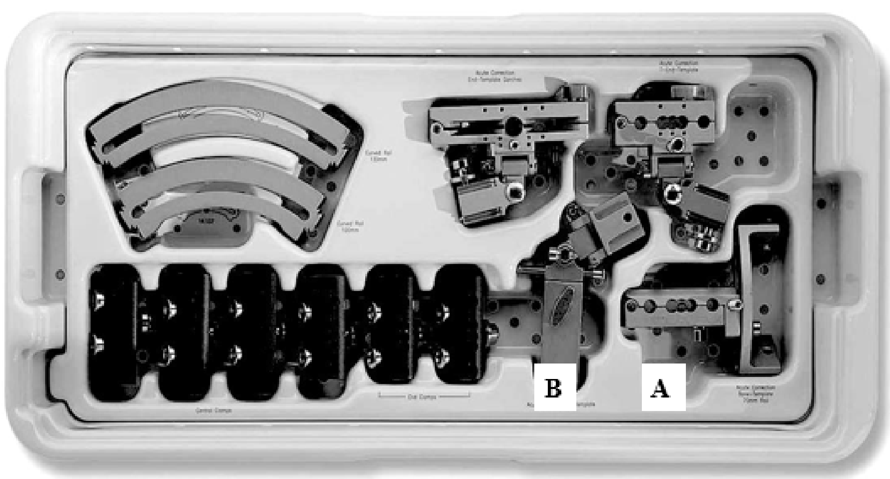

Figure 2: The Adult (Orthofix) LRS Templates for Acute Correction of Deformity. **(A)** The rotational Template. **(B)** The angulation Template.

Operative Technique

The senior Consultant carried out the majority of the operations. A standard technique was followed, as described by Donnan et al. [3]. According to the general application principles, bone screws were inserted on each bone segment on each side of the apex of the deformity, perpendicular to the anatomical axis of the relevant bone segment. The distal screws were positioned through the templates. After the osteotomy was performed, the templates were removed and replaced by clamps attached to the rail. Gentle manipulation of the bone segments followed, and any compensatory translation was undertaken at this stage before the clamps were tightened onto the rail. Once correction had been achieved, osteotomy was slightly compressed. Terminology The final angular correction achieved and measured at the end of treatment from the final set of radiographs was named Maximum Angular Correction (MAC), and the final lengthening obtained at the end of treatment was named Maximum Linear Correction (MLC).In the future, both terms will be used in the text and for the statistical analysis.

Postoperative Management

The patients received immediate physiotherapy in the form of CPM (Continuous Passive Motion). Walking and toe weight-bearing were encouraged for Group A patients who were followed up monthly with biplane (AP/L) mechanical axis radiographs. Group B patients were followed up at two-week intervals during the distraction period and monthly after that.

Healing Time (HT)

The time elapsed between the application and removal of the LRS for both Groups A and B were recorded. Therefore the Healing Time (HT) was defined as the time between surgery and radiological appearance of mature bridging callus plus a safety period during which the whole construct was destabilized without yet being removed (dynamization or neutralization period). The HT reflected the healing process's biology and was related to information extracted from the patients' datasheets. Summarised data for the total number of cases subdivided into two groups A and B according to accompanying lengthening or not is presented in Tables 2A and 2B.

No	AGE	Gender	VAR	VLG	REC	PRO	MAC	TRANS	LENGTH	ROT	SITE%	HT	INDIC
1	32	2	10		10		10	1	0	0	37.6	24	2
2	46	2	10		3		10	1	0	0	30.76	30	2
3	28	1	20		16		20	1	0	10	22.5	26	2+4+5
4	18	1	5		20		20	0	0	0	22.7	16	2
5	25	2	15				15	0	0	0	20.7	23	6+4+5
6	32	2		26			26	1	0	0	15	18	7+3
7	26	1	10			6	10	0	0	38	47	37	2
8	48	1	7		10		14	0	0	0	13	14	2+3
9	51	1	16				16	1	0	0	23	18	2+3
10	58	1	13				13	0	0	0	13.6	34	8
11	42	1	6		14		14	0	0	0	17.3	16	2+5
12	20	1		23			23	0	0	0	20	18	2+5
13	42	1	16				16	0	0	0	17.6	42	2
INDIC=Indication													

Table 2A: Data involving population (no=13) of Group A (no lengthening performed).

No	Age	Gender	Var	Vlg	Rec	Pro	Mac	Trans	Length	Rot	Site%	Mlc	Ht	Indic
1	42	2		8			8	0	1	0	no data	30	14	1
2	39	2	15		8		15	1	1	20	no data	10	60	2+3
3	37	1		11		5	9	0	1	0	no data	40	48	4
4	18	1	30				30	0	1	20	no data	24	36	1
5	27	2		7	20		20	0	1	0	no data	20	32	4
6	40	1	13				10	0	1	0	no data	55	60	2+4+5
7	26	1		5			5	0	1	0	21	2.33	20	2
8	21	1		16			16	0	1	0	23.1	14	24	2
9	18	1		12	25		25	0	1	10	18	23	29	9
10	21	1					15	1	1	0	25	22	60	1+3
INDIC=Indication, For VAR/VLG/PRO/TRAS/LENGTH/ROT: 0=no, 1=yes For GENDER: 1=male, 2=female, For INDICATION: 1=congenital,2=post-traumatic,3=previous lengthening,4=infection,5=re-fracture +/multiple sur-gery,6=tumor,7=metabolic,8=osteoarthritis,9=Oll ier's disease														

Table 2B: Data involving population of Group B (no=10). Lengthening followed the operation.

Bone Healing Index (BHI)

For every patient in Group B, the overall Healing Time (in days) was recorded. The length gained in each case was recorded, and the mean length gained was 24mm (range 14 to 55 mm). For each patient of Group B, the Bone Healing Index (BHI) was calculated. BHI is defined universally as the total number of days needed for the lengthened bone to heal per millimeter of linear displacement achieved and is expressed in days/mm [11].

BHI = HT / MLC

BHI is an index that reflects the bone biology during lengthening and allows comparisons between similar clinical series.

Complications

The Complications were classified according to severity scale from Grade I (minimal) to Grade IV (severe), and their incidence was recorded. The incidence of complications was studied across the overall patient population (Groups A and B, number of cases=23). According to severity, the complications were classified in four Grades as per Donnan et al. [3]. Grade I represented those that resulted in no long-term functional or anatomical impairment and needed no surgery or anesthesia to be corrected (pin tract infections, mild transient contractures). Grade II included those being of no long-term significance but required surgery to be corrected (insertion of pins/wires, soft tissue releases, manipulation, or osteoclasis of the regenerate femoral angulation>10 degrees). Grade III represented those that resulted in significant functional or anatomical problems, which could spontaneously improve or be correctable by surgery (length discrepancy, joint subluxation, femoral angulation>15 degrees). Complications were graded as Grade IV when they were irremediable by conventional treatment (osteomyelitis, joint dislocation, permanent nerve injury). The incidence of complications is shown in combination with the rest of the patients' data in Table 3.

Pt	Complications	Grade	Var	Valg	Rec	Pro	Rot	HT	Lengthening
1	pin-tract infection	I	0	8	0	0	0	14	Yes
2	discrepancy due to anterior bowing ,stiff knee	III	15	0	8	0	20	60	Yes
3	insertion of screws for further correction of valgus	II	0	11	0	5	0	48	Yes
4	clamp jammed, further correction needed	II	30	0	0	0	20	36	Yes
5	stiff knee, pin infection	I	0	7	20	0	0	32	Yes
6	stiff knee ,pin infection	I	13	0	0	0	0	60	Yes
7	exchange of fixator	I	10	0	10	0	0	24	No
8	residual varus 5dg	II	10	0	3	0	0	30	No
9	Pin-tract infection	I	20	0	16	0	10	26	No
10	knee instability reconstructed	II	5	0	20	0	0	16	No
11	residual shortening , stiff knee	III	15	0	0	0	0	23	No
12	Pin- tract infection	I	0	26	0	0	0	18	No
13	Nil	0	0	5	0	0	0	20	Yes
14	Nil	0	10	0	0	6	38	37	No
15	Pin-tract infection-stiff knee	I	0	16	0	0	0	30	Yes
16	residual 3dg varus+12dg recurvatum	II	7	0	10	0	0	14	No
17	Stiff knee-MUA, pin-site infection	II	16	0	0	0	0	18	No
18	stiff knee-MUA, Cellulitis	II	13	0	0	0	0	34	No
19	residual 18 dg recurvatum	III	6	0	14	0	0	16	No
20	residual varus 12 deg, MUA knee	II	0	12	25	0	10	29	Yes
21	Pin-tract infection	I	0	23	0	0	0	18	No
22	surgical contracture releases	II	16	0	0	0	0	42	No
23	fracture post removal of fixator-reapplication LRS	III	15	0	0	0	0	60	Yes
vlg=valgus, vr=varus, rec=recurvatum in degrees, HT=Healing Time expressed in weeks, dg=degrees, MUA=Manipulation Under Anaesthetic. The Complication Grading system we have used is shown in Table 2.3.2.									

Table 3: The complications and their grade are shown together with details of the corrections achieved (magnitude, nature, healing time, presence of lengthening).

Statistical Analysis

Due to the small sample size, we have elected to use the non-parametric tests Spearman's correlation and Mann-Whitney test. We believe that the presence or absence of lengthening alters the biological process significantly. Therefore correlations were tried separately across different groups. Parameters reflecting the bone biology like the HT or the BHI were studied separately for either Group A (acute correction alone) or B (acute correction followed by lengthening) and in combination, concerning the following: age, gender, site of osteotomy, MLC, MAC, and the nature of the correction. As for Group B, we decided to encounter both BHI and HT as indices of bone repair during lengthening so that our results could be compared with those of the existing literature [11]. Parameters reflecting the method's safety as the incidence and severity of complications were studied across the whole population (Groups A+B) because we believe that this better expresses the overall efficiency of the method under a variety of circumstances. The accuracy of the method was then calculated across the whole population. Significant correlations were marked with * or **. Non-parametric correlations were to be preferred because of the small amount of data.

A. Investigating Safety of the Method -Incidence of Complications

The incidence of complications was studied across both Groups A and B. The parameters that were considered possibly responsible for complicating the biological process of bone healing were correlated to the complication rate as follows:

'Complications' were correlated to:

a. HT

b. MAC of both Groups A+B

c. age of the patient

d. the occurrence of translation following correction

e. concomitant correction of rotation if present

Correlations between Complications and the MLC of Group B were not possible due to the small sample size. Jonckheere-Terpstra test was used to investigate HT's relation to the Grades of complications (4 grades: 0, I, II, III). The results are shown in Tables 4A-D.

Jonckheere-Terpstra Test

	ht
Number of Levels in complic	4
N	23
Observed J-T Statistic	104,000
Mean J-T Statistic	91,000
Std. Deviation of J-T Statistic	17,741
Std. J-T Statistic	,733
Asymp. Sig. (2-tailed)	,464
a Grouping Variable: complic	

Table 4A: Correlations between the Severity of Complications and HT.

Ranks			
	Complic	**N**	**Mean Rank**
mac	,00	2	3,25
	1,00	8	13,25
	2,00	9	13,11
	3,00	4	11,38
	Total	23	
age	,00	2	8,50
	1,00	8	11,19
	2,00	9	13,78
	3,00	4	11,38
	Total	23	

Test Statistics[a,b]		
	mac	**age**
Chi-Square	3,921	1,307
df	3	3
Asymp. Sig.	,270	,728
a = Kruskal Wallis Test b = Grouping Variable: complic		

Table 4B: NPar Kruskal-Wallis Test between Complications, MAC and the age of patients.

Ranks			
	Complic	**N**	**Mean Rank**
rot	,00	2	16,00
	1,00	8	10,31
	2,00	9	12,56
	3,00	4	12,13
	Total	23	
rot = rotation			

Test Statistics[a,b]	
	rot
Chi-Square	2,102

df	3
Asymp. Sig.	,551
a = Kruskal Wallis Test b = Grouping Variable: complic	

Table 4C: NPar Kruskal-Wallis Test between Complications and rotation (n=23).

complic * trans Crosstabulation				
Count				
		trans		
		,00	1,00	Total
Complic	,00	2	0	2
	1,00	5	3	8
	2,00	7	2	9
	3,00	2	2	4
Total		16	7	23
trans = translation				

Chi-Square Tests				
	Value	**df**	**Asymp. Sg. (2-sided)**	
Pearson Chi-Square	2,074[a]	3	,557	
Likelihood Ratio Linear-by-Linear	2,602	3	,457	
Association	,540	1	,462	
N of Valid Cases	23			
a = 6 cells (75,0%) have expected count less than 5. The minimum expected count is ,61.				

Table 4D: Correlations between Complications and Translation.

B. Investigating Accuracy-Clinical Angular Accuracy of the Method

The method's accuracy was expressed by the variance of the differences between the measured (preoperative) values of the deformity and the final correction achieved and maintained (after removal of the fixator). The lower is the variance; the higher was the accuracy. The accuracy measured herein refers solely to the correction of the angular deformity once any rotational deformity was fully corrected (accuracy 100%), and the translation is investigated in the following paragraph. The analysis was conducted for the values displayed in Table 5. The results are shown in Table 6 and 7. Standard deviation was calculated for VAR (Varus), VLG (Valgus), and REC (Recurvatum) corrections. For PRO (Procurvatum) corrections, the standard deviation was zero (procurvatum correction accuracy equals 100%). The frequency of variance was calculated separately for each direction of correction (Table 7), and accuracy within groups is shown in Table 8. To investigate any impact of lengthening on Levene's test's angular accuracy, each direction of correction Table 9.

Pt No	VAR1	VLG1	REC1	PRO1	MAC	VAR2	VLG2	REC2	PRO2	VAR1-VAR2	VLG1-VLG2	REC1-REC2	PRO1-PRO2
1		8			8		8				0		
2	12		7		15	15		8		3+		1+	
3		11		5	11		11		5		0		0
4	30				30	30				0			
5		6	20		20		7	20			1+	0	
6	10				13	13				3+			
7	15		15		10	10		10		5-		5-	
8	15		0		10	10		3		5-		3+	
9	20		13		20	20		16		0		3+	
10	5		20		20	5		20		0		0	
11	20				15	15				5-			
12		15			26		26				11+		

13		5			5		5				0		
14	10			6	10	10			6	0			0
15		20			16		16				4-		
16	10		22		10	7		10		3-		12-	
17	22				16	16				6-			
18	10				13	13				3+			
19	6		31		14	6		14		0		17-	
20		28	22		25		12	25			16-	3+	
21		23			23		23				0		
22	18				16	16				2-			
23	20				15	15				5-			
VAR1, VLG1, REC1 PRO1=preoperatively measured deformity; VAR2, VLG2, REC2, PRO2=finally achieved correction; MAC=Maximum Angular Correction achieved; VAR1-VAR2=VARdiff=Varus variance; VLG1-VLG2=VLGdiff=Valgus variance; REC1-REC2=RECdiff=Recurvatum variance; PRO1-PRO2=PROdiff=Procurvatum variance.													

Table 5: The measured (preoperative) values of the deformity are shown as well as the final correc-tion achieved and the difference between the two.

		vardiff	vlgdiff	recdiff
N	Valid	15	8	9
	Missing	8	15	14
Mean		-1,4667	-1,0000	-2,6667
Median		,0000	,0000	,0000
Std. Deviation		3,20416	7,42582	7,26292
Variance		10,267	55,143	52,750
Range		9,00	27,00	20,00

Table 6: Standard deviation is shown for VAR (varus), VLG (valgus) and REC (recurva-tum) corrections.

vardiff					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	-6,00	1	4,3	6,7	6,7
	-5,00	4	17,4	26,7	33,3
	-3,00	1	4,3	6,7	40,0
	-2,00	1	4,3	6,7	46,7
	,00	5	21,7	33,3	80,0
	3,00	3	13,0	20,0	100,0
	Total	15	65,2	100,0	
Missing	System	8	34,8		
Total		23	100,0		

vlgdiff					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	-16,00	1	4,3	12,5	12,5
	-4,00	1	4,3	12,5	25,0
	,00	4	17,4	50,0	75,0
	1,00	1	4,3	12,5	87,5
	11,00	1	4,3	12,5	100,0
	Total	8	34,8	100,0	
Missing	System	15	65,2		
Total		23	100,0		

recdiff					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	-17,00	1	4,3	11,1	11,1
	-12,00	1	4,3	11,1	22,2
	-5,00	1	4,3	11,1	33,3
	,00	2	8,7	22,2	55,6
	1,00	1	4,3	11,1	66,7
	3,00	3	13,0	33,3	100,0
	Total	9	39,1	100,0	
Missing	System	14	60,9		
Total		23	100,0		

Table 7: Frequency of variance calculated separately for each direction of correction.

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
vardiff	,00	12	-2,3333	2,90245	,83787
	1,00	3	2,0000	1,73205	1,00000
vlgdiff	,00	2	5,5000	7,77817	5,50000
	1,00	6	-3,1667	6,52431	2,66354
recdiff	,00	6	-4,6667	8,31064	3,39280
	1,00	3	1,3333	1,52753	,88192
mac	,00	14	15,5714	5,09471	1,36162
	1,00	9	15,8889	8,00694	2,66898
Group A (,00) without lengthening performed Group B (1,00) with accompanying lengthening					

Table 8: Accuracy within Groups is shown.

		Levene's Test for Equality of Variances	
		F	**Sig.**
vardiff	Equal variances assumed	2,316	,152
	Equal variances not assumed		
vlgdiff	Equal variances assumed	,091	,773
	Equal variances not assumed		
recdiff	Equal variances assumed	5,426	,053
	Equal variances not assumed		
mac	Equal variances assumed	1,799	,194
	Equal variances not assumed		

Table 9: Levene's test for equality of Variances.

Accuracy and Translation

The translation itself was considered part of the Clinical Inaccuracy. The correlation of recorded translation was investigated concerning the Maximum Angular Correction (MAC) finally achieved. Non-parametric test was preferred due to the small samples analyzed. The results are shown in Table 10.

Ranks				
	trans	**N**	**Mean Rank**	**Sum of Ranks**
mac	,00	16	11,75	188,00
	1,00	7	12,57	88,00
	Total	23		

Test Statistics(b)	
	mac
Mann-Whitney U	52,000
Wilcoxon W	188,000
Z	-,269
Asymp. Sig. (2-tailed)	,788
Exact Sig. [2*(1-tailed Sig.)]	,820(a)
a Not corrected for ties. b Grouping Variable: trans.	

Table 10: Mann-Whitney Test for correlation between TRANS and MAC:

Results

Clinical Results for Group A (no lengthening performed)

- The mean MAC in any one plane for Group A was 15.9 degrees, ranging from 10 to 26 degrees. The age of the patients ranged between 18 and 58 years (average 36 years).
- There were nine male and four female patients.
- The osteotomy site was predominantly metaphyseal at a mean of 22.8% of the total bone length ranging from 13% to 47% of the total bone length.
- The mean Healing Time (HT) for Group A was 24.3 weeks (range 14 to 42 weeks).
- No statistically significant correlations were possible between HT and each of the following; the patient's age and gender, the site of the osteotomy, the MAC values, and the occurrence of translation following the osteotomy .by the use of non-parametric tests (Tables 11a-c).

			ht	**age**	**mac**	**site**
Spearman's rho	ht	Correlation Coefficient	1,000	,110	-,235	,340
		Sig. (2-tailed)	.	,722	,440	,255
		N	13	13	13	13
	age	Correlation Coefficient	,110	1,000	-,423	-,342
		Sig. (2-tailed)	,722	.	,150	,253
		N	13	13	13	13
	mac	Correlation Coefficient	-,235	-,423	1,000	-,249
		Sig. (2-tailed)	,440	,150	.	,413
		N	13	13	13	13
	site	Correlation Coefficient	,340	-,342	-,249	1,000
		Sig. (2-tailed)	,255	,253	,413	.
		N	13	13	13	13

Table 11A: Nonparametric Correlations between HT and age, MAC, site.

	ht
Mann-Whitney U	18,000
Wilcoxon W	54,000
Z	-,295
Asymp. Sig. (2-tailed)	,768
Exact Sig. [2*(1-tailed Sig.)]	,833(a)
a = Not corrected for ties. b = Grouping Variable: trans.	

Table 11B: Non parametric correlations between HT and TRANS.

	ht
Mann-Whitney U	16,000
Wilcoxon W	61,000
Z	-,311
Asymp. Sig. (2-tailed)	,756
Exact Sig. [2*(1-tailed Sig.)]	,825(a)
a = Not corrected for ties. b = Grouping Variable: gender.	

Table 11C: Nonparametric correlations between HT and gender.

Clinical Results for Group B (lengthening performed)

- The mean MAC for Group B was 15.3 degrees (range 5 to 30), and the mean MLC was 24mm (range 23.3-55mm).
- The age of the patients ranged between 18 and 42 years (average 29 years).
- There were seven male and three female patients.
- Information about the osteotomy site was grossly missing, and no correlations were tried involving this particular parameter.
- The mean Healing Time (HT) for Group B was 38.3 weeks averaging from 14 to 60 weeks, and the mean BHI was 13.5 days/mm (range 7.6 to 42 days/mm).
- No significant correlation was found between HT and any of the following; age, gender, MAC, or MLC (Table 12a-c). However, when BHI was studied instead of HT, no correlation was found between BHI and MAC, but a small negative correlation between BHI and MLC was shown (sig=0,002) attributed to the mathematical definition of BHI =HT/MLC.

Correlations						
			bhi	age	mac	mlc
Spearman's rho	bhi	Correlation Coefficient	1,000	-,387	,427	-,883**
		Sig. (2-tailed)	.	,304	,252	,002
		N	9	9	9	9
	age	Correlation Coefficient	-,387	1,000	-,688*	,280
		Sig. (2-tailed)	,304	.	,028	,482
		N	9	10	10	10
	mac	Correlation Coefficient	,427	-,688*	1,000	-,036
		Sig. (2-tailed)	,252	,028	.	,920
		N	9	10	10	10
	mlc	Correlation Coefficient	-,883**	,280	-,036	1,000
		Sig. (2-tailed)	,002	,432	,920	.
		N	9	10	10	10
** = Correlation is sighnificant at the 0.01 level (2-tailed). * = Correlation is sighnificant at the 0.05 level (2-tailed).						

Table 12A: Nonparametric correlations between BHI and age, MAC and MLC.

Nonparametric Tests-Mann-Whitney Test

Ranks				
	gender	N	Mean Rank	Sum of Ranks
bhi	1,00	7	4,29	30,00
	2,00	2	7,50	15,00
	Total	9		

Test Statistis b	
	bhi
Mann-Whitney U	2,000
Wilcoxon W	30,000
Z	-1,464
Asymp. Sig. (2-tailed)	,143
Exact Sig. [2*(1-tailed Sig.)]	,222[a]

Table 12B: Correlations between BHI and gender

			ht	mac	mlc
Spearman's rho	ht	Correlation Coefficient	1,000	,178	,227
		Sig. (2-tailed)	.	,622	,528
		N	10	10	10
	mac	Correlation Coefficient	,178	1,000	-,036
		Sig. (2-tailed)	,622	.	,920
		N	10	10	10
	mlc	Correlation Coefficient	,227	-,036	1,000
		Sig. (2-tailed)	,528	,920	.
		N	10	10	10

Table 12C: Correlations between HT and MAC, MLC.

Results Involving Bone Repair Biology

Effects of the method on the Bone Healing Time (HT) or Index (BHI)

- The age of the patient and the gender did not seem to relate to the Healing Time or the Bone Healing Index in both Groups (Tables 11a-c and 12a-c).
- No correlation was shown between HT and either of the MAC or MLC for the range of values studied herein (Tables 11a-c and 12a-c).
- The translation did not seem to affect the HT (Table 13b).
- Although no significant correlation was shown for HT and ROT by the use of the non-parametric Spearman's test (Table 13a), a positive Pearson correlation was shown between BHI and ROT (Table 14). The latter possibly indicates that the presence of rotational deformity corrected at the same site may slow down the healing process. However, our sample size is relatively small to justify the previous hypothesis.
- Although no significant correlation was shown for HT and SITE by using the non-parametric Spearman's test (Table 13a), a positive Pearson correlation was shown between BHI and SITE (Table 14). The latter possibly indicates that an osteotomy performed at the distal metaphyses has higher healing potential. However, our sample size is relatively small to support this with confidence.

			ht	site
Spearman's rho	ht	Correlation Coefficient	1,000	,374
		Sig. (2-tailed)	.	,139
		N	17	17
	site	Correlation Coefficient	,374	1,000
		Sig. (2-tailed)	,139	.
		N	17	17

Table 13A: Correlations between HT and site of osteotomy (n=17).

	ht
Mann-Whitney U	47,500
Wilcoxon W	183,500
Z	-,569
Asymp. Sig. (2-tailed)	,569
Exact Sig. [2*(1-tailed Sig.)]	,579(a)
a = Not corrected for ties. b = Grouping Variable: trans	

Table 13B: Correlations between HT and TRANS

			ht	rot
Spearman's rho	ht	Correlation Coefficient	1,000	,372
		Sig. (2-tailed)	.	,080
		N	23	23
	rot	Correlation Coefficient	,372	1,000
		Sig. (2-tailed)	,080	.
		N	23	23

Table 13C: Correlations between HT and ROT (n=23)

Correlation							
		bhi	age	mac	mlc	site	rot
bhi	Pearson Correlation	1	,175	-,371	-,573	,740**	,543**
	Sig. (2-tailed)	.	,435	,089	,005	,001	,009
	N	22	22	22	22	16	22
age	Pearson Correlation	,175	1	-,464 *	-,026	-,243	-,263
	Sig. (2-tailed)	,435	.	,026	,906	,346	,225
	N	22	23	23	23	17	23
mac	Pearson Correlation	-,371	-,464 *	1	,046	-,441	,151
	Sig. (2-tailed)	,089	,026	.	,836	,076	,491
	N	22	23	23	23	17	23
mlc	Pearson Correlation	-,573 **	-,026	,046	1	-,390	-,134
	Sig. (2-tailed)	,005	,906	,836	.	,121	,542
	N	22	23	23	23	17	23
site	Pearson Correlation	,740	-,243	-,441	-,390	1	,657 **
	Sig. (2-tailed)	,001	,346	,076	,121	.	,004
	N	16	17	17	17	17	17
rot	Pearson Correlation	,543 **	-,263	,151	-,134	,657**	1
	Sig. (2-tailed)	,009	,225	,491	,542	,004	.
	N	22	23	23	23	17	23
** = Correlation is significant at the 0.01 level (2-tailed). * = Correlation is significant at the 0.05 level (2-tailed). rot=rotation.							

Table 14: Significant positive correlations are shown between BHI and site, rot.

Clinical Safety of the Method: Correlations Involving the Complication Incidence and Severity.

- No statistically significant relationship was found between the incidence of complications and each one of them; MAC (sig=0,270), AGE (sig=0,728), ROTATION (sig=0,551) and TRANSLATION (sig=0,557) variables across the whole population. Neither of the parameters HT or MLC could be significantly correlated to the incidence or the severity of complications (Table 4a-d).
- Although formal statistical analysis could not be conducted due to the small size sample and its high variability, exciting observations were possible from careful inspection of Table 3.

Grade I complications comprised mainly of pin site treatable infections and minor soft tissue contractions overcome by physiotherapy. No Grade IV complications were observed. Grade II and III complications occurred with even low magnitude corrections (10 and 15 degrees) irrespectively the plane of correction (frontal or sagittal). The highest incidence of Grade II and III complications was observed with corrections of varus deformities (8 corrections), followed by corrections of recurvatum (4 corrections). The higher relative incidence of Grade II and III complications was recorded amongst the Group A population (eight out of thirteen in A) instead of five out of ten for B). Interestingly, all patients that suffered Grade III complications had previously undergone either lengthening procedures (three out of four) or multiple surgeries and grafting due to bone loss, at the level or below the level of the osteotomy. All of the above are pure observations that seem to have occurred at random.

Clinical Accuracy of the Method

Angular Accuracy

The final clinical corrections achieved are presented herein in brief:

- Out of the fifteen corrections of varus deformity: five were accurately corrected, three were overcorrected, and seven were under-corrected.
- Out of the eight corrections of valgus deformity: four were accurately corrected, two were overcorrected, and two were under-corrected.
- From the nine corrections of recurvatum deformity: two were accurately corrected, four were overcorrected, and three were under-corrected.
- From the two corrections of procurvatum deformity, all were accurately corrected.
- All rotational deformities were fully corrected.

The angular accuracy was calculated separately for each direction of correction (Tables 6 and 7). The accuracy for correction of procurvatum deformities reached 100%, whereas, for varus, valgus and recurvatum deformities, the standard deviation was calculated SD=3, SD=7, and SD=7, respectively.

Effect of Lengthening

In order to investigate the impact of lengthening on the overall accuracy of the method, Levene's test for equality of variances was performed (Table 9). It seems that lengthening affects the accuracy of correction in the sagittal plane as long as recurvatum deformity is concerned. It is possible that lengthening may influence the angular accuracy in all directions of correction, but our sample is relatively small to justify this hypothesis.

Accuracy and Secondary Translation

Translation occurred in seven out of 23 cases, five within Group A and two of Group B. The incidence of translation was less in Group B. These facts seemed reasonable once further lengthening across the mechanical axes partially compensates for the initial translation that may occur during surgery. No statistically significant correlation was shown between the occurrence of translation and the Magnitude of the Angular Correction (MAC) (sig=0,820, Table 10). The translation was mainly attributed to osteotomy being performed elsewhere than at the calculated CORA level.

Discussion

The technique of acute correction of the deformity has advanced with the development of sophisticated templates. However, it requires careful analysis of the underlying deformity and the understanding of the biological environment's compliance and, finally, meticulous patient selection. The LRS equipment is uncomplicated for the surgeon and is characterized by a steady and short learning curve (personal experience and contacts). Although we are still developing the surgical technique, certain principles in applying the mono-lateral fixator or the preoperative planning remain unchanged [12]. We aim to establish a reproducible, accurate, and safe surgical technique. We also need to define the 'ideal' adult candidate who will benefit from the advantages of the specific low risk and minimally invasive procedure that produces immediate postoperative effects by using a mono-lateral device that is better tolerated than a circular frame. The fixator's use is less invasive than other means of surgical stabilization, such as the blade plates or the IM nails. No bone graft is used, and the osteotomy site is not exposed [13-15].

Other advantages include the possibility of accurate adjustment of the correction throughout the postoperative period. Lengthening can be added if needed. A certain amount of relative lengthening which accompanies the valgus osteotomies is usually welcomed, and the relative degree of shortening that follows the varus osteotomies is well tolerated and never has been a problem for the patient. No casting or bracing is used after surgery, and the patient can mobilize his or her legs freely. Partial weight-bearing is allowed when adequate callus is evident on the radiographs, usually after the sixth postoperative week. Our method addresses difficult cases multiply operated and previously failed. Pre-existing infection, extensive soft tissue stripping, non-union, or a fully sealed medullary canal can complicate conventional corrective surgery (IM nail, blade plates) by a high incidence of intraoperative or postoperative complications as well as a new flair of infection.

It is challenging to compare our results to those in pre-existing literature. The majority of relevant papers report on non-homogeneous cases where femoral and tibial deformities are included [4-8,14,15]. Lengthening may well coexist [3-6]. The degree of angular correction is not always reported, and the site of osteotomy can be both diaphyseal or metaphyseal [3,6-8,15]. When a monolateral fixator is used for acute correction of femoral deformity, the population treated consists mainly of children or adolescents [2-4,14]. However, we can compare our results to those of Gugenheim et al. and those of Noonan et al. because they refer to mature femoral segments [6,7]. For Gugenheim, external fixator use is only temporary, and the definitive stabilization is achieved with an IM nail. The mean MAC in their series is approximately

9.5 degrees, which is relatively low compared to our 15.9 degrees for Group A. They report a mean Healing Time of 13 weeks (range 6 to 39 weeks), whereas, in our series, the mean HT was 24.3 weeks (range 14 to 42 weeks).

Their prevalence in terms of reduced HT is possibly related to the use of the IM nail for definitive stabilization because, as we have already shown, MAC (within a specific range) does not seem to affect the HT. They also report a lower incidence of complications (two Grade II complications out of 14 cases) than the eighth Grade II-III complications out of our own 13 cases of Group A) according to our grading system. Their advantage seems to be that they operate on primarily healthy bone segments. Our results for the lengthened cases of Group B are comparable to those of the five adult cases of Noonan et al. that similarly underwent lengthening [6]. A mean BHI of 64.2 days/cm is calculated from their report for a MAC of 19.6 degrees. Unfortunately, this sample is tiny. Three out of five segments suffered Grade II complications that required further surgery. The mean MAC for Group B was 15.3 degrees, and the mean BHI 135days/cm in our series. They interestingly report that the age of the patient and the bone's maturity had the most significant effect on the incidence of complications and the BHI by increasing them both.

The latter seems reasonable as their series comprises adult and adolescent populations; therefore, comparisons between the different age groups are possible. Our series comprises of purely adult cases where the relative difference within the same age group as we have shown does not influence the bone biology. Fixator Assisted Nailing (FAN) technique is a newly introduced and up-and-coming technique [16]. Accuracy of correction of SD=1 is reported together with fast healing. However, the method is technically demanding, and yet it is not applicable in infected cases. The main argument for using our adults' technique is their lower osteogenic capacity, which could require long periods of treatment and a higher incidence of complications [2,3]. We have shown that a relatively safe, reliable, and precise acute distal femoral osteotomy can be performed using the Orthofix System. Considering the prolonged BHI, we would instead reserve this method for the adult with a history of complex surgery, complicated by infection where conventional surgery with a faster healing rate is not feasible. Lengthening from the same site seems to have an advantage as it can compensate for any secondary translation and perhaps angular inaccuracy produced during or after the osteotomy once it restores the mechanical axes [17].

Conclusions

We can conclude that when our method addresses adult limb reconstruction problems, treating time is more extensive than adolescent limb reconstruction. However, within the same age group (adults), age, or gender do not affect the final healing time. There is some evidence that a metaphyseal performed osteotomy heals faster. The magnitude of deformity corrected expressed either in degrees or in millimeters as long as it remains within the ranges studied in our study does not seem to affect the healing time or complicate the overall biological process. The severity of complications is possibly related to the pre-existing pathology of the bone segment under treatment. Simultaneous correction of angulation and rotational deformity through the same osteotomy is likely to slow down the healing process, possibly impairing the blood supply, which may need longer to recover.

Our method is proved more accurate for correcting varus and procurvatum deformities compared to valgus and recurvatum ones. The LRS resists greater muscle forces during valgus and recurvatum deformity correction. Displacing muscle forces seem to be the significant contributing factor in the In Vivo resulting inaccuracy. This fact leads to the concept of enhancing the posteromedial strength of the system. The magnitude of correction does not seem to affect the accuracy of the method within the range studied. Lengthening itself, because it is conducted across the femur's mechanical axes, may compensate for some occurring angular inaccuracy, especially if a recurvatum deformity is present (and possibly for secondary translation as well).

We can support and enhance our technique summarising our results as follows;

a. Mean Acute angular correction of 15.6 degrees (range 5-30 degrees) is possible and safely performed in adults (with or without length added) by using the Limb Reconstruction System.

b. The osteotomy should be better performed metaphyseal at approximately 22.8% of the bone length.

c. Valgus and recurvatum deformities could deliberately be overcorrected, and the LRS system should be medially and anteriorly strengthened by placing off-the-rail pins connected in a 'Delta' OR other configuration.

d. The rotational deformity is advisable to be corrected from another osteotomy site, if possible.

e. The patient should somewhat be informed of the delay in treatment (HT may be extended as long as 24 weeks if correction alone is performed).

f. This delay could be addressed by stimulating factors that improve the biological environment, such as using percutaneously injected BMPs (Bone Morphogenic Proteins) or applying the external electromagnetic field.

g. For accompanying lengthening, a BHI of 135days/cm might be considered reasonable.

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