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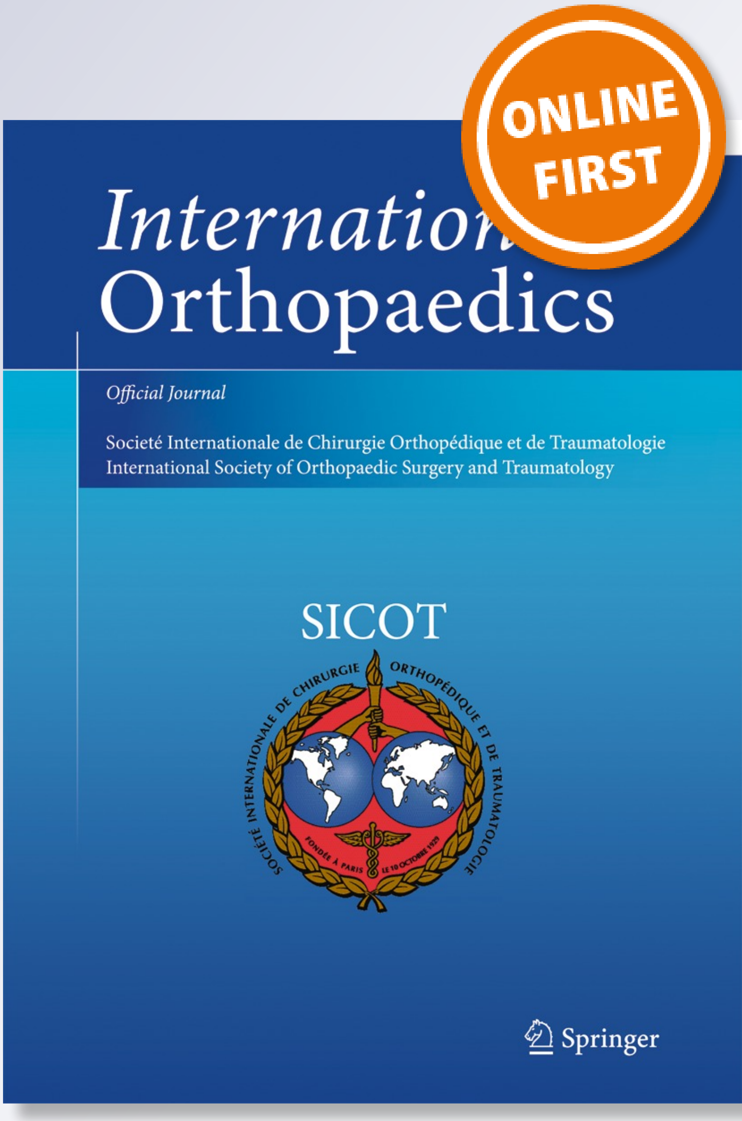
International Orthopaedics

ISSN 0341-2695

International Orthopaedics (SICOT)
DOI 10.1007/s00264-013-2116-x



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ORIGINAL PAPER

Comparative clinical study on deformity correction accuracy of different external fixators

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Received: 20 March 2013 / Accepted: 9 September 2013

Abstract
Purpose In this study, the correction accuracy of Smart Correction spatial fixators and of Ilizarov-type external fixators are compared in terms of deformity complexity.
Methods Seventy-seven (40 male, 37 female) bone segments of 57 patients treated with a Smart Correction device were compared with 94 (51 male, 43 female) segments of 68 patients treated with an Ilizarov fixator. Mean age of the Smart Correction group was 20.69±12.94 years, and or the Ilizarov group 22.45±12.18 years. Patients were categorised according to limb lengthening and the number of deformity planes.
Results A longer correction period was found with Ilizarov (66.53±47.7 days) compared with Smart Correction (49.05±35.6 days) devices. The bone healing index of the Ilizarov group was significantly better compared with the spatial group. Residual deformity after treatment was significantly lower with the Smart Correction device; however, this relationship could not be shown between subgroups. Although there was no significant difference between subgroups, mean residual deformity was higher with the increasing number of planes of the deformity.
Conclusions The Smart Correction fixator is an accurate device that allows ease of application and planning. It demonstrates higher accuracy for correcting deformities compared with an Ilizarov external fixator. With an increasing number of planes, the difference between the two devices becomes even more pronounced. The relationship between the complexity of the deformity and residual deformity may possibly be significantly greater in favour of the Smart Correction fixator in a study with a larger sample size.

Keywords Spatial fixator · External fixator · Lengthening · Hexapod

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Introduction

External fixators are one of the oldest devices used in orthopaedic surgery, dating back to Hippocrates [1]. Until Hoffman and Ilizarov performed methodological studies, many orthopaedic biological and mechanical principles were not fully understood, and many devastating complications were encountered [2–4]. With the introduction of spatial fixators, simultaneous six-axis and one-step correction of complex deformities became possible. With a traditional Ilizarov circular fixator, the precise calculation of clinical and radiological parameters, along with precise mounting, is essential. Minor deviations may lead to major residual deformities and increase the treatment period. For complex deformities consisting of translational, rotational and angular deformities, it is not possible to perform a one-step correction. Various components, such as hinges and translation devices connected to rods, are used to achieve correction. In addition, it may be necessary to delay the required lengthening due to deformity correction. Carrying out these steps usually requires changing components, which can be painful for the patient and exhausting for both the patient and surgeon.

Published online: 26 September 2013

Spatial fixators are used to treat the deformity as a combined vector, and correction is performed according to it over a so-called virtual hinge. Pre-operative calculation and mounting errors do not affect postoperative planning. This one-step correction will eventually lead to a much shorter correction period, which may decrease external fixator period. More precise correction of deformities is possible [5]. The mechanical properties of the frame require more studies; however, Paley reports that the Taylor spatial frame is stiffer in all directions [6].

In this study, we hypothesised that spatial fixators provide more accurate deformity correction in a shorter period of time. For this reason, we compared our deformity correction cases that received spatial fixators with cases traditional Ilizarov circular external fixator cases.

Patients and methods

One hundred and thirteen patients operated using a Smart Correction (SC)spatial fixator and 1,116 patients who received a traditional Ilizarov-type circular external fixator (CEF; Tasarim Med, Istanbul, Turkey) were retrospectively evaluated to form the SC and CEF groups. Inclusion criteria were as follows: (1) The patient was operated with an SC or CEF. (2) Adequate documentation with sufficient clinical notes was available, and the patient was appropriate for radiological measurements. (3) The patient was followed up for three months following fixator removal. The following aetiologies were excluded due to inferior bone healing potential and altered bone quality: (1) Congenital tibial pseudoarthrosis; (2) applications due to joint contracture; (3) lengthening over nail or fixator-assisted nailing; (4) applications performed immediately following malignant tumor resection; (5) acute or chronic osteomyelitis; (6) internal segment transports.

Patients in both groups were operated in the same clinic by three senior surgeons using the same surgical techniques. Fixator-to-bone fixation for all patients was performed; both half pins and wires were used. To evaluate the accuracy of deformity correction and contribution of limb-length discrepancy (LLD) to the final results, both main groups were divided into subgroups according to the number of planes of deformity (sagittal, coronal, rotational) and existence of lengthening. Segments with lengthening were tagged as A. Segments without lengthening were tagged as B. The number of planes was noted: from 0 = no deformity to three = sagittal, coronal and rotational deformity.

Following application of inclusion and exclusion criteria, 77 SC and 255 CEF cases remained for further matching. Initial statistical analysis of both device groups consisted of age, sex, aetiological distribution and deformity groups (subgroups). To create a similarly matched CEF group, stratification was used, which returned 94 CEF cases. Pre-operative deformity magnitude was also similar for each SC subgroup with its respective CEF subgroup. Distribution of each subgroup and their demographic data are listed in Table 1. To avoid creating a selection bias regarding learning curve when using the CEF device, only patients operated in the last decade were included in the study. We believe spatial fixators have a significantly shorter period of learning, therefore do not require excluding first applications.

Table 1 Distribution of patients among groups and subgroups: demographic data and aetiologies

	Smart correction (SC)			Circular external fixator (CEF)		
No. segments (patients)	77 (57)			94 (68)		p=0.764; χ^2 0.09
Sex (M/F)	40/37			51/43		
Average age	20.69±12.94			22.45±12.18		t:−0.92; p=0.361
Aetiologies	Acquired	18	24.30 %	20	21.30 %	χ^2 1.18; p=0.882
	Developmental	6	8.10 %	12	12.80 %	
	Nonunion	9	12.20 %	11	11.70 %	
	Congenital	35	47.30 %	42	44.70 %	
	Trauma	6	8.10 %	9	9.60 %	
Subgroups	A-0	16	20.80 %	20	21.30 %	χ^2 2.27; p=0.943
	A-1	11	14.30 %	13	13.80 %	
	A-2	10	13.00 %	16	17.00 %	
	A-3	3	3.90 %	6	6.40 %	
	B-1	11	14.30 %	14	14.90 %	
	B-2	7	9.10 %	5	5.30 %	
	C	9	11.70 %	11	11.70 %	
	D	10	13.00 %	9	9.60 %	

Numbers indicating complexity of the deformity: 0 for only lengthening without deformity, 1 for only one plane, 2 for two plane deformity and 3 for deformities with sagittal, coronal and rotational deformity

A segments with lengthening, *B* segments without lengthening, *C* with nonunion, *D* with trauma

Deformity analysis was performed with the method suggested by Paley et al. [7–9]. Frontal and sagittal deformities were measured with X-rays using mechanical axis. Rotational deformity measurements were obtained from clinical photos. Center of rotation of angulation (CORA) was measured for each plane, and resultant deformity vector was calculated to be used for pre- and postoperative accuracy comparisons. Total external fixator time (days), latent period (days), correction period (days), consolidation period (days) and bone-healing index as suggested by Paley et al. (days/cm) [10, 11] were calculated and compared. The follow-up period was calculated as months from fixator removal to last visit. Complications were grouped as problems, obstacles and sequelae [12]. The accuracy of deformity correction was measured using residual deformity at the final follow-up. Each subgroup's average residual deformity was noted and compared with their respective opposites. Statistical analyses were performed with Number Cruncher Statistical System (NCSS) 2007 Statistical Software (Utah, USA) and MedCalc Statistical Software (Mariakerke, Belgium). In addition to descriptive statistical methods (average, standard deviation), chi-square test for qualitative data, stratification for CEF sampling and Mann–Whitney *U* test to compare two samples were also used. Results were evaluated according to a $p<0.05$ significance level.

Results

The two main groups (SC and CEF) were compared, as were the subgroups with their respective opposite. The average correction period for the CEF group was significantly longer than for the SC group. The average consolidation period was similar between the two groups. The bone-healing index of the CEF group was better than that of the SC group. All results are summarized in Table 2.

The consolidation periods for all patients with and without derotation were also compared. The average periods were 135.79±66.25 and 149.89±68.31, respectively, for the SC and CES groups. This difference was statistically insignificant ($p=0.530$). In addition, there was no difference between groups regarding derotation.

Table 2 Results of two main groups: Smart Correction (SC) and Ilizarov circular external fixator (CEF)

	SC	Ilizarov	*P* value
Correction period (days)	49.05±35.6	66.53±47.7	**0.011**
Lengthening performed (mm)	29.01±32.06	31.81±31.59	0.982
Total fixator period (days)	214.21±98.07	211.93±83.05	0.911
Consolidation period (days)	159.26±77.85	141.44±63.01	0.177
Bone-healing index (d/cm) (A subgroups)	64.61±37.58	50.79±39.77	**0.001**
Follow-up (days)	281.08±169.73	516.97±531.33	0.02

Number of days spent for deformity correction and lengthening was better for patients treated with SC device. However, bone healing index was superior for Ilizarov

Deformity correction and accuracy

Overall initial deformity of the SC and CEF groups was statistically similar (18.68±14.48 and 21.22±15.78, respectively; $p=0.516$). The measured residual deformity at the end of the treatment was significantly higher for the CEF group (11.96±11.12) compared with the SC group (7.73±8.19; $p=0.012$). Accuracy of deformity correction with increasing complexity and the effect of lengthening over accuracy were evaluated using subgroups. Subgroups with nonunion (C) and trauma (D) patients were excluded, as it is not possible to compare results in a similar manner with patients with deformity. Table 3 lists pre-operative and residual deformity measurements.

There was no difference between each SC subgroup regarding final residual deformity ($p>0.05$). However, residual deformity in the A-0, A-1 and A-2 CEF groups were statistically lower than the A-3 CEF group ($p=0.002$, $p=0.028$, $p=0.015$, respectively). Residual deformity of the B-1 CEF group was statistically lower than that of the B-2 CEF group ($p=0.014$). Bone-healing index for lengthened segments (A groups) were superior for CEF patients (50.79±39.77 days/cm),compared with SC patients (64.61±37.58 days/cm). The average number of re-evaluations and replanning performed for deformity at the outpatient clinic was 1.6±0.7 for SC patients. No data were available for CEF patients.

We encountered 46 problems, 11 obstacles and seven sequelae for SC patients and 76 problems, 20 obstacles and five sequelae for CEF patients. Most complications were pin-tract problems and joint stiffness, which resolved by the end of treatment (74.6 % for SC and 69.7 % for CEF). For both SC

Table 3 Pre-operative and final residual deformity for each subgroup

	Subgroup	SC	CEF	*P* value
Preoperative deformity	A-0	4.49±8.3	4.84±5.39	0.457
	A-1	21.28±13.06	22.2±11.63	0.839
	A-2	29.29±13.79	34.95±14.03	0.282
	A-3	25.91±17.77	43.45±10.54	0.302
	B-1	22.94±10.6	23.05±12.23	0.784
	B-2	23.64±12.1	24.98±13.9	0.935
Residual deformity	A-0	6.19±6.57	8.59±8.98	0.501
	A-1	7.4±8.84	13.26±12.93	0.218
	A-2	11.31±9.43	13.42±11.15	0.61
	A-3	16.67±9.57	26.6±13.41	0.302
	B-1	7.37±4.3	7.61±7.56	0.762
	B-2	5.92±10.99	15.97±5.67	0.056

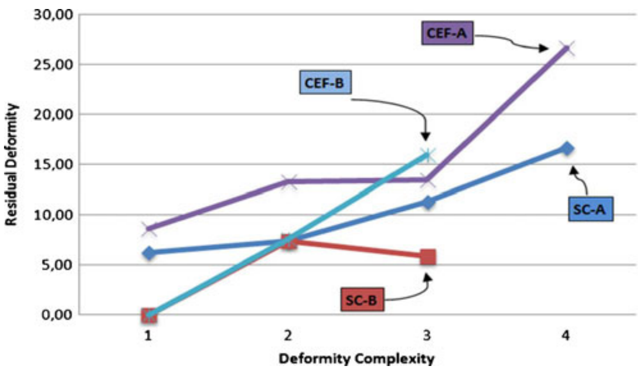

Fig. 1 Increase in residual deformity with increasing deformity complexity. *Horizontal line* (X axis) represents the number of planes of the deformity, from A-0 to A-3 and B-1 to B-3. The *Y axis* is residual deformity at the end of treatment

and CEF patients, lengthening did not create any significant difference in the complication rate when the A and B groups were compared.

Discussion

Spatial fixators are based on identical biological properties and host response as those of a traditional Ilizarov fixator, with possibly better mechanical properties and ease of use [6]. With the introduction of hexagonal strut geometry, the precise displacement of the proximal and distal fragments relative to each other is achieved. However, this improvement comes with a price: increased cost. Spatial fixator costs are six- to ten-times higher than traditional Ilizarov circular external fixators. For

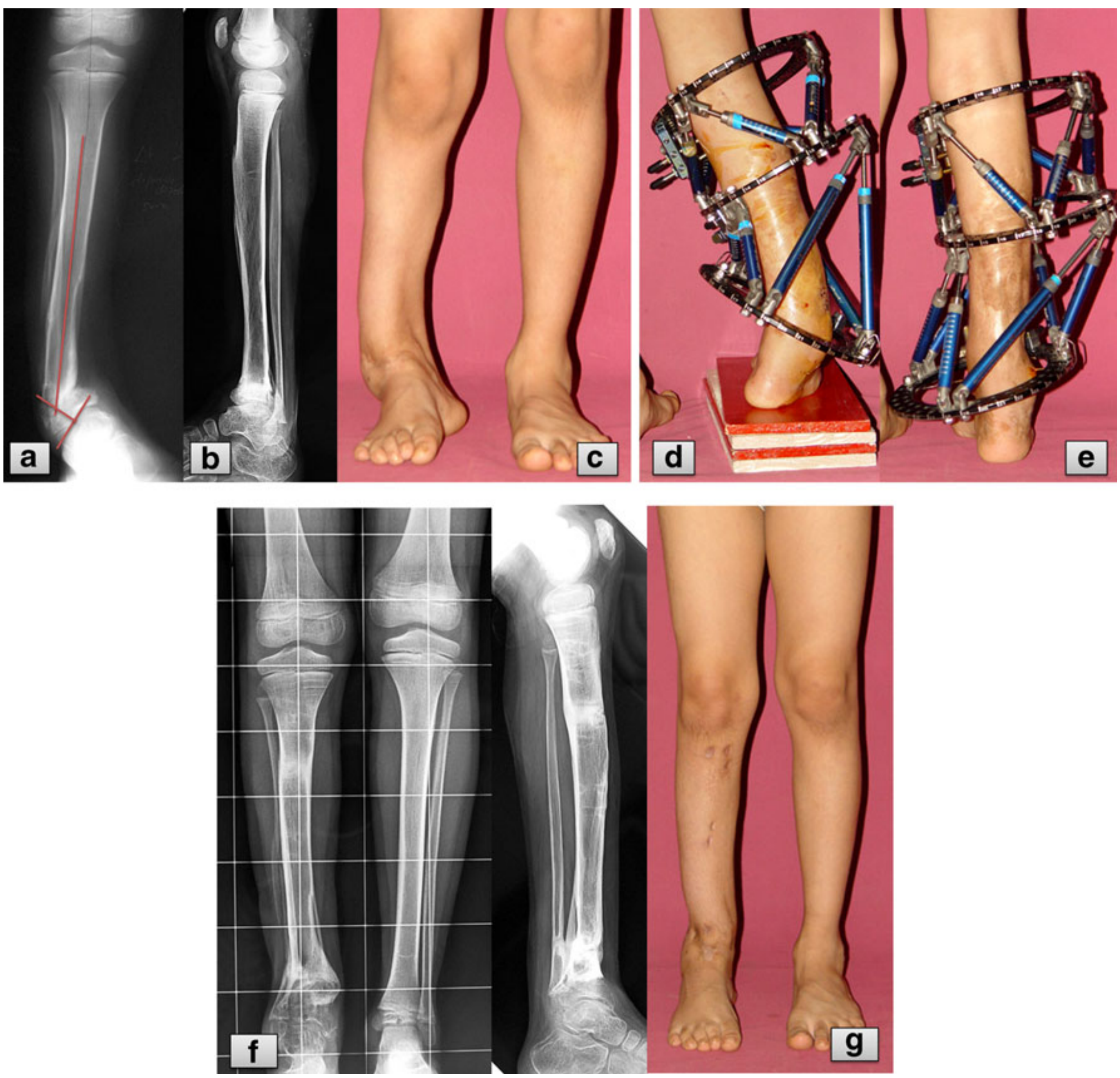

Fig. 2 Eight-year-old male patient with a posttraumatic distal tibial deformity with limb-length discrepancy (**a**–**c**). Proximal osteotomy was planned for lengthening, and a distal osteotomy for deformity correction. For this purpose, a preshaped frame was mounted (**d**) and correction performed simultaneously with lengthening (**e**). As seen in the postoperative X-rays and clinical photo of the patient, distal tibial deformity is corrected and plantigrade foot achieved. A slight shortening still exists, requiring a further, simple lengthening procedure (**f**, **g**)

this reason, it is essential to identify patient groups for which spatial fixators would play a significantly effective role.

Various studies have been performed with spatial fixators, mostly case reports or case series [13–19]. Few comparative studies have been published [5, 20]. In this study, Ilizarov CEF and spatial fixators were compared in similar patient groups. Our main purpose was to reveal criteria for which spatial fixators allowed a significantly more accurate correction than CEF. For this purpose, corrected segments were distributed among subgroups, according to deformity complexity and existence of lengthening.

Evaluation of the overall SC and CEF group data reveals a significantly more accurate deformity correction with lower residual deformity (7.73±8.19 to 11.96±11.12, respectively; $p=0.012$) in a shorter period (49.05±35.6 to 66.53±47.7 days, respectively; $p=0.011$) for the SC group. However, faster simultaneous correction did not provide a lower fixator period for SC as expected.; total consolidation and fixator time was similar. The bone healing index is used to evaluate the total fixator time required to gain length (days for each cm in this study) [10, 11]. This value is an indirect method of assessing both correction and consolidation efficiency of a device. Although a faster correction with a faster consolidation improves scores, the opposite leads to a decreased result. As spatial fixators have a stiffer structure and perform correction and lengthening simultaneously, it was expected that they would have an improved bone healing index. On the contrary, our average bone healing index was lower for CEF patients (50.79±39.77) than SC patients (64.61±37.58). Kristiansen et al. compared spatial fixator with CEF in terms of lengthening index (months/cm, which is identical to the bone healing index in our study). Lengthening indices and amounts were statistically similar for both groups. However, number of segments with reduced callus formation requiring bone grafting was higher in the spatial fixator group [20]. Additional evaluation of bone quality for lengthening cases with and without deformity, with a higher number of cases, is necessary to fully verify these results.

Increasing deformity leads to a higher residual deformity at the end of treatment. This difference tends to be even higher for cases with more complex deformities and existence of lengthening, as shown in Fig. 1. CEF cases with lengthening (A groups) tended to complete treatment with increased deformity compared with SC cases in all subgroups, regardless of deformity complexity. On the other hand, in patients without lengthening (B groups), there was no difference between groups for one- and two-plane deformities. However, due to an insufficient number of patients, the average difference calculated between the respective subgroups was not statistically significant.

Simultaneous correction is one of the major advantages of spatial fixators. Traditional Ilizarov-type external fixators require the sequential correction of each component of the deformity due to the limited mobility of the device. Some spatial fixators require an initial correction based on mounting following residual deformity correction [21, 22]. Smart Correction software is intended to correct all deformities in one step, regardless of the mounting parameters. The average planning number was 1.6±0.7 for the SC group, and only seven cases required three. There were no planning data available for the CEF group to make a comparison. A sample case with a multiplanar deformity correction achieved with a one-step correction is shown in Fig. 2.

It is generally accepted that derotation during lengthening and deformity correction has an adverse effect on regenerate quality and leads to an increased consolidation period and increased number complications, such as plastic deformation and regenerate fracture. In our study, no group or subgroup with derotation presented increased consolidation or complication rates compared with cases without derotation ($p>0.05$).

The main weakness of this study is patient distribution and number of patients in each subgroup. Assessing all deformity groups together creates a wide deformity distribution with a high standard deviation. Focusing on a small group would give more accurate results. We had a heterogeneous patient population regarding aetiology, which was necessary to increase the number of patients. Also, a prospective randomised study design would provide more valuable results than a retrospective study.

Conclusion

The SC fixator demonstrates higher deformity correction accuracy than an Ilizarov external fixator. With an increasing number of planes, the differences between the two devices become more pronounced. The relationship between deformity complexity and residual deformity may be statistically more significant in favour of the SC fixator in a study with a larger sample size. In contrast to severl advantages of a spatial fixator, inferior bone healing index score suggests a possible low-quality regenerate, which requires further studies.

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