

Study on Outcome of Complex Lower Limb Problems treated by Ring External Fixator and Evolvement of Practices toward its Acceptability

¹Sandeep Shrivastava, ²Sohael M Khan, ³Romil Rathi, ⁴Gaurav Mundada, ⁵Pradeep K Singh, ⁶Shounak Taywade

ABSTRACT

Introduction: In the developing world, there is still lack of accessibility and availability of adequate health care. In rural population this further gets limited, due to meager immediate resource at disposition and lack of availability of transports to adequate set ups. This cross-sectional study is undertaken among our rural patients who had undergone this treatment to understand what difficulties they had faced during such treatments and their acceptability toward such treatment. This study was undertaken with the aim to find out the acceptability and adaptability among the rural population for Ilizarov ring fixators.

Materials and methods: The study consisted of 88 consecutive cases (91 lower limbs) of all age groups, who completed the treatment by Ilizarov methodology between July 2005 and July 2012. A retrospective analysis of the procedure was done through the medical records in terms of preoperative, intraoperative, and after the complete treatment. These were analyzed for limb lengthening in centimeters, correction of deformities, total wearing duration, and final outcome. Subsequently, these patients/parents were interviewed with a questionnaire to assess the self-accessibility (ease) toward self-care; self-distraction; self-adaptability—comfort during wearing time and the difficulties faced.

Results: Overall the functional outcome was excellent in 18, good in 50, fair in 8, and poor in 4. Out of 91 patients, 67 (73.6%) followed up and could be evaluated for adaptability toward Ilizarov fixator. Overall, 91.04% were satisfied with the treatment by Ilizarov fixator. In the remaining the main reason for not accepting the Ilizarov method was difficulty in commuting in the public transport, ugly and threatening looks of fixator with so many wires crossing the leg.

Conclusion: Ilizarov method is a very effective tool for managing the complex lower limb problems, especially among the population with low resources. It will ensure delivery of a very low-cost solution offered to the needy patients, wherein otherwise due to multiplicity of problems, integral solution is difficult to achieve within their resources.

Keywords: Acceptability, Fixator, Ilizarov, Rural.

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INTRODUCTION

In the developing world, there is still lack of accessibility and availability of adequate health care. In rural population this further gets limited, due to meager immediate resource at disposition and lack of availability of transports to adequate set-ups. Hence, often, they present late, with avoidable complications, such as deformities, nonhealing wounds, infections, and nonunions, all together.

In such scenarios, the goal of treatment includes many things together, such as primary soft tissue reconstruction, infection control, deformity correction, and repair for nonunion and bone losses. Only the Ilizarov methodology with ring external fixators provides a single-stage integral solution to all of these, due to its versatility to tackle all these issues combined comprehensively. The use of such external fixator for the purpose of distraction histogenesis has been applied successfully to a wide range of orthopedic problems caused by diverse etiologies, such as congenital bone diseases, metabolic conditions, infections, complex traumatic injuries, and neglected deformities.

But the complexity of application, long fixator wearing, and meticulous daily care of fixator are held to be few main reasons, why orthopedic surgeons and patients are seemingly not willing for such comprehensive solution. Overall it is projected as if complexity of problems associated with Ilizarov ring fixators makes it less relevant for practical utility, especially in populace which is less knowledgeable, illiterate, and living with low quality of living standard, like in rural India.

Prioritizing and respecting the values of such rural patients, and over time learning from our own experiences, we have adopted small practices which are user-friendly and cost-effective toward their adoption

¹Dean and Professor, ²Assistant Professor and Consultant
^{3,4,6}Assistant Professor, ⁵Surgeon

^{1-4,6}Department of Orthopaedics, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India

⁵Department of Spine Surgery, Dr L H Hiranandani Hospital Mumbai, Maharashtra, India

Corresponding Author: Sohael M Khan, Assistant Professor and Consultant, Department of Orthopaedics, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India
Phone: +919890310177, e-mail: drsohaelkhan@hotmail.com

to Ilizarov fixators. These have helped us to overcome common problems and convince the needy to adopt this treatment option as matter of choice.

This cross-sectional study is undertaken among our rural patients who had undergone this treatment to understand what difficulties they had faced during such treatments and their acceptability toward such treatment. We followed up patients for outcome of the treatment and patient's acceptability toward fixator.

RESEARCH METHODOLOGY

It is a cross-sectional study with questionnaire-based single intervention. Level of evidence generated is Level III/IV.

AIMS AND OBJECTIVES

This study is undertaken with the aim to find out the acceptability and adaptability among the rural populace of Ilizarov ring fixators. The key objective is to understand their difficulties and overcome them by ensuring successful outcomes.

MATERIALS AND METHODS

The study is conducted at tertiary care center and teaching hospital located in a rural area. It analyzes 88 consecutive cases (91 lower limbs) of all age groups, who completed the treatment by Ilizarov methodology between July 2005 and July 2012.

A retrospective analysis of the procedure was done through the medical records in terms of preoperative, intraoperative, and after the complete treatment. These were analyzed for limb lengthening in centimeters, correction of deformities, total wearing duration, and final outcome. Subsequently these patients/parents were interviewed with a questionnaire to assess the self-accessibility (ease) toward self-care; self-distraction; self-adaptability-comfort during wearing time and the difficulties faced. They were asked to rate their experiences in terms of acceptability toward such treatment, willingness to undergo same if need rearises, and recommendation to others to undergo such treatment. Also

they were asked about overall satisfaction, including the affordability (cost effectivity) of such treatment.

OBSERVATION AND RESULTS

Out of 91 limbs treated with Ilizarov method, majority (59%) were male patients. The average age was 35.2 years. The region-wise distributions for performed surgeries were 19 in femur, 24 corrections around knee joint, and 48 in tibia. The disease-wise distribution was 9 cases of congenital deformities, 14 cases of bone and joint infections, 34 cases of complex trauma, 12 cases of bone tumors, and 22 cases of degenerative and other problems (Table 1); 41 patients underwent bone lengthening. The maximum lengthening achieved was 24 cm and minimum 3 cm, with the mean length of 9.4 cm and healing index of 24.5 days (Table 2); 31 patients underwent deformity corrections, of which 13 were multiplanar and 18 uniplanar (Table 3). In 19 cases, the fixator was applied for stabilization only. The mean fixator wearing in lengthening cases was 231.3 days, for deformity cases was 96.1 days, and in stabilization cases was 84.6 days, with average fixator time being 137.3 days. The major complications and unplanned interventions were needed due to premature consolidation in two cases, refracture (reapplication of fixator) in one case, equinus contracture (tendo-achilles lengthening) in one case, delayed/precarious union (bone marrow aspiration) in three cases, and pin site cellulitis in two cases. In addition, 11 cases needed further realignments. At the final follow-up, four patients had residual shortening of more than 2 cm, three had residual deformity of more than 10°cm, and one had delayed union. Overall the functional outcome was excellent in 18, good in 50, fair in 8, and poor in 4 (Tables 3 to 5).

Out of 91 patients, 67 (73.6%) followed up, and could be evaluated for adaptability toward Ilizarov fixator. Moreover, 76.11% were educated only up to high school level. Despite being low on literacy, majority of them could manage self-care including pin-site dressings and distraction; 94.02% opined that they were comfortable during wearing time; 95.52% would prefer to be treated with Ilizarov fixator next time, if need be so. For most of them a prefixator counseling helped them to get an

Table 1: Various causes of deformity in patients

<i>Congenital</i>	<i>n</i>	<i>Infection</i>	<i>n</i>	<i>Posttraumatic</i>	<i>n</i>	<i>Tumors</i>	<i>n</i>	<i>Others</i>	<i>n</i>
Congenital pseudorthosis of tibia	5	Primary Femur Tibia	2 4	Acute trauma	11	Giant cell tumour	10	Osteoarthritis knee	7
Tibial hemimelia	1	Secondary	7	Malunion	7	Aneurysmal bone cyst	1	Genu varus	8
Proximal femoral defect	2	Bony ankylosis of knee	1	Nonunion	5	Osteosarcoma	1	Genu valgus	3
Other	1			Knee injury	1			Knee contracture	4
Total	9		14		34		12		22

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Table 2: Amount of lengthening achieved in different patients by Ilizarov technique

Indication	Complex: 13	
	Simple: 18 Uniplanar: apical/oblique	Multiplanar: Translational/ rotational
Osteoarthritis	5	0
Pediatric genu varus with or without procurvatum/recurvatum deformity	3	2
Pediatric genu valgus	3	0
Knee contractures	5	0
Tibial hemimelia	0	1
Nonunion	1	4
Malunion	1	6

insight into what was forthcoming and meeting with similar patient helped them to make a decision. The average cost of fixator borne by them was Rs. 7,650 (USD 150), with maximum Rs. 105,000 for a six-ring carbon fiber assembly by only 1 of them. For most (64.10%) of them it was less than Rs. 5,000 (USD 100). Overall, 91.04% were satisfied with the treatment by Ilizarov fixator (Table 5).

In the remaining, the main reason for not accepting the Ilizarov method as priority one was difficulty in commuting in the public transport, ugly and threatening looks of fixator with so many wires crossing the leg. None of them reported care of fixator being highly cumbersome and totally unmanageable at home.

Table 3: Different deformity corrections in different planes; total-31

	Bone lengthening	Deformity corrections	Stabilization: 19
Mean fixator wearing time	231.3 days	96.1 days	84.6 days
Further significant interventions	(a) Premature consolidation: 2 (b) Refracture: 1 (c) Resurgery: 3 [2 Congenital pseudarthrosis of tibia, 1 chronic Osteomyelitis] (d) Tendoachillis lengthening: 1 (e) Bone marrow aspiration: 3	Realignment: 11	Pin-induced cellulitis: 2
Radiological union	All patients	All patients	All patients
Clinical	Residual deformity >2 cm: 4	Residual deformity: Malalignment of more than 10°: 3	Delayed union: 1 patient

Table 4: The key outcome result

Criteria	Excellent	Good	Fair	Poor
Nonunion or infection	None	None	None	Yes
Neurovascular injury	None	Minimal	Moderate	Severe
Deformity				
Varus/valgus	None	2-5	6-10	>10
Procurvatum or recurvatum	0-5	6-10	11-20	>20
Rotation	0-5	6-10	11-20	>20
Shortening	0-5 mm	6-10 mm	11-20 mm	>2 cm
Mobility				
Knee*	Full	>80%	>75%	<75%
Ankle	Full	>75%		<50%
Pain	None	Occasional	Moderate	Severe
Gait	Normal	Normal	Mild limp	Significant
Activities of daily living	Possible to near-normal levels	Partially restricted but not limiting his abilities	Moderately restricting and effecting his some abilities	Dependent for majority of activities
Study	18	50	8	4

*In case of knee arthrodesis, this criteria excluded

Table 5: Functional result

Level of education	No formal: 9	School level: 42	College level: 16
Self-care	49: easy	11: Difficult but could manage on own	7: Depended on others
Self-distraction (58/67)	42: easy	7: Difficult but could manage	9: Depended on others
Comfortable	Yes: 63	No: 4	-
Does precounseling helped you	Yes: 54	No: 3	Could not understand: 10
Cost	2,000-5,000: 43	5,000-10,000: 13	>100,000: 1 (carbon rings)
Will opt for again	Yes: 64	No: 3	-
Overall satisfaction	Yes and would recommend: 61	Yes, but not recommended: 3	No: 3

DISCUSSION

The Ilizarov method was introduced in the Western world during the late 1980s. The authors have been using this method since 1992. It has been widely popularized and applied to the treatment of components of the complex deformities due to various etiologies, such as congenital diseases, polytrauma, bone malignancy, and infections.¹⁻⁴ Ilizarov technique is not precluded by previous surgery, and the Ilizarov device can be reapplied in the event of refractures.^{5,6}

It has great versatility allowing for simultaneous multi-axial gradual correction and bone lengthening, both internally and externally. This technique is particularly beneficial when other methods have failed or in patients with angulation threatening fracture, shortening exceeding 5 cm, compound injuries when soft tissue coverage is a major problem, and for early weight bearing. If necessary, it even allows for combination of two or three techniques which can be used sequentially or simultaneously in an effort to obtain union.⁵⁻⁸

The basic principle of the Ilizarov treatment is distraction histogenesis. Ilizarov ring forms external stabilizing framework to the affected limb. Weight bearing of body is transmitted through the rings and fracture site is literally spared, allowing only microaxial compression, which is conducive to healing. So early mobilization is the great advantage of this system. In addition, the regeneration has a very powerful biological environment, which tends to burn the infection away.¹⁻¹⁰

The disadvantage of this technique from the patient's point of view is mainly in terms of initial cost, burden of caring daily the pin/wire sites, restriction of full function of limb especially the range of motion of knee, the weight of the fixator, and finally the long wearing duration.^{7,10-14} In addition, the cosmetic ugliness of fixator where in several wires going across the limb and hardware tends to dissuade it as the primary choice of treatment. Also the patients' movement in public, including going to school, traveling in transport system like buses, is also a social taboo.

The outcome of our study, as mentioned earlier, including mean union time, fixator wearing, and healing index, is almost the same as mentioned in other studies with no significant statistical differences. The major complications specially related to pin/wire site infection (only 2) are on lower side as compared with literature.^{3,7,8,10-14} Overall results in terms of radiological and clinical outcomes are also comparable with other similar studies.^{1,7-10,15}

The final outcome is toward much better one with almost 68/91 patients able to go back to their normal activities of life. The poor results were mainly in patients who could not manage the self-distraction and care, and

were depended on others for the same. Two of them were elderly ladies and one had bilateral hand injury. Their dependency was chiefly due to great apprehension that they may do it wrongly. One was a small child (5 years old) with both parents working, leaving him to be in maid's custody, most of the time.

Over time, learning from our own experiences, we have been able to develop a set of best practices which we have imparted uniformly to all the cases treated since 2005. This includes bringing down the cost of fixators, an inventory generated, and many parts of fixators reutilized after adequate cleaning and asepsis including rings, distraction rods, nuts, bolts, wire clamps/ cubes, and connecting plates. Almost everything except the wires and pins, which have direct fixator-human interface, have been reused. This conserved our resources to huge proportions and the cost of a typical four-ring set is now limited to maximum of Rs. 5,000 to 10,000 only (USD 100-200) from initial cost, which was about 10 times more. This has increased the accessibility to the fixator both by patient and doctors to a huge extent, so that now cost is not at all a constraint. We have avoided the use of rings made locally, as has been done in certain studies, as qualities of such rings are mostly of dubious nature.

The Ilizarov frame is usually bulky and, while facilitating early ambulation, may nonetheless prevent full patient participation in activities of daily living. The bulkiness of rings can be lessened by the use of carbon rings but they are very costly. We have adopted its use as far as possible (especially in pediatric age group) and due to the generation of inventory have been able to control the cost as well. One of the recent developments to decrease the time that patients spend in the frame is the combined use of external fixator and internal fixation, such as an intramedullary nail.^{3,15,16} These can be used sequentially (lengthening and then nailing) or simultaneously (lengthening over the nail). These approaches eliminate the bulky frame while at the same time protecting the still unstable callus site from fracture. We have now adopted such approach and this has again helped us in increased adaptability and acceptability of the Ilizarov fixators in the patients.

There are two main practices prescribed for managing pin/wire site and skin interfaces.^{7-10,6,17} The traditional occlusive one in which such sites are covered with sterile dressings after adequate cleaning and usually such dressing are applied alternate days. But the problem in rural part of India is accessibility to such sterile dressings. Hence, we have shifted to the other method, open dressing of pin sites, and wherein the patient cleanses the interface with spirit (alcohol 70%) and then applies a thin layer of povidine-iodine ointment every day. This is simple and easily doable. We provide them the tubes

containing such ointments at the time of discharge from hospital. Additionally, daily cleaning of such sites does not allow formation of any scab/crust, which is the tipping point for infection and loosening of pin/wires. Also in case of any discharge happening from pin site, they are able to note immediately and refer back. This shift of practice has hugely benefited the patients as it has lowered the rate of pin site infections to a minimum and hence, avoided painful bearings also of fixator, enabling them to wear the fixator for long durations without much threats and being pain free.

We have used simple nail-paints to mark the positions of movement of nuts in reference to rings and distraction rods. These marks were reinforced by the patients easily. They were able to understand the progress easily independent of their level of education.

It helped them immensely to monitor their progress and any deviations were noted urgently and early; interventions whenever needed, instead of at regular short periods, were sought, which put their precious resources to strain.

The patients have been encouraged to move uninjured joints as much as possible, bear weight as early as possible, and resume their functional status as soon as possible. Additionally, whenever edema is noted, they are directed to elevate the limb over and above the level of heart in lying down position. This is standard practice recommended by almost all studies and is the most effective way of keeping the limbs in maximal functional status and increasing the acceptability to wear the fixator for needed duration.

To avoid the social embarrassments to such patients, they were asked to wear loose full pants/pyjamas which were open and buttoned from side; hence, the fixators were never exposed to the public and it provided safety from dust and dirt, which is so common in rural areas.

Lastly but most importantly, a detailed counseling before fixator application and if possible arranging interaction with another similar patient and educating them to the safe maintenance of frame helped for wide acceptance of such the treatments.

This study specially emphasizes about patients' acceptability about the ring fixator and adaptability with the fixator. The patients' ability to perform self-daily distraction with accuracy and self-care of pin tracts was taken into account. The concern to keep the cost low and reduce the bulkiness of rings definitely increased their comfort of wearing it, including a very good adaptability toward the fixator. Patients' preoperative counseling and education helped them again gain insight into things, which may go wrong, and hence, they were additionally

cautious against such happenings.

Such small practices are very effective in the acceptance of the treatment by the patients and helped them to undergo treatment, which is very cost-effective and judicious. Ilizarov ring fixator is a very effective and acceptable tool for the management of complex orthopedic lower limb problems and remains relevant to all societies including the low resourced populace.

CONCLUSION

Small, safe, easy reproducible but significant practices as detailed earlier are very effective means of affirming the acceptability and adaptability of the Ilizarov methodology, a very effective tool for managing the complex lower limb problems, especially among the populace with low resources. It will ensure delivery of a very low-cost solution offered to the needy patients, wherein otherwise due to multiplicity of problems, integral solution is difficult to achieve within their resources.

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