



## Original Research

# The Use of Ilizarov Method at the Lower Extremity Deformity Management

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### ABSTRACT

**Objectives:** Complications are common in the treatment of lower extremity congenital or acquired deformities by Ilizarov method. The results to be obtained vary in specific patient groups. In this study, deformities who developed before the age of 16 were compared with those developed after this age regardless of the type of aetiology, in terms of results obtained, treatment durations and complications encountered.

**Methods:** 53 bone deformities with an average of 9.5 (7.5-18) years of follow-up treated by the same surgeon were divided into 2 groups according to the age of deformity onset. Demographics and deformity characteristics of patients were defined, treatment times, bone healing indexes, consolidation/correction rates, problems encountered and results obtained were compared retrospectively. The results were compared with ASAMI functional and bone scoring. Complications were rated according to Paley and relative risk increases between groups were calculated.

**Results:** 26 of the patients were men and 22 were women. The average age was 26.47 (7-57). The mean deformity was 23.98° (7-60) and the mean shortness in 39 patients was 38.65 (10-110)mm. Mechanical axis deviation was corrected in 83% of patients. The Lengthening index was 54.13days/cm in the development group and 63.69 days/cm in adults. Consolidation/correction rate was 2.54 in developmental age and 2.4 (p=0.698) in adults. The risk increased by 1.02 times in terms of problems encountered, 2 for obstacles, 3 times in complications and 1.34 times in total difficulties per case, according to Paley. The duration of stay in the fixator was higher in developmental group (p=0.023). ASAMI functional (p=0.000148) and anatomical (p=0.000242) scores were better in the adult group.

**Conclusion:** Congenital or acquired deformities in the lower extremity can be treated with satisfactory results by Ilizarov method. The development of deformity at an early age makes treatment difficult. Although the bone healing index is lower in this group of patients, which usually has a higher amount of shortness, the treatment is usually longer than that of adult deformities; complications are more frequent and serious. Functional and anatomical results are more unsuccessful.

**Keywords:** Congenital tibial pseudoarthrosis, deformity, distraction osteogenesis, external fixator, fibular hemimelia, Ilizarov, length difference, lower extremity, osteotomy, physeal arrest, poliomyelitis, pseudoarthrosis

Please cite this article as "Armagan R, Kucukkaya M, Ozdemir HM. The Use of Ilizarov Method at the Lower Extremity Deformity Management. Med Bull Sisli Etfal Hosp 2023;57(2):263-271".

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**Submitted Date:** May 14, 2023 **Revised Date:** June 02, 2023 **Accepted Date:** June 02, 2023 **Available Online Date:** June 20, 2023

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Ilizarov method became a solution for many deformities where it was impossible or very difficult to obtain a functional limb and amputations were almost obligatory beforehand.<sup>[1]</sup> However, the treatment process is long and various problems can be encountered.<sup>[2]</sup> The effectiveness of the technique in different patient groups, problems that can be encountered and the solutions that can be brought to them is still being investigated. The Ilizarov method allows a sharp, safe, and gradual correction of the complex deformities independent of its location. Ability of early weight-bearing and rehabilitation reduces complications. Distraction osteogenesis can compensate length differences without the need of grafting.<sup>[3]</sup> Despite these advantages, it is uncomfortable to carry a bulky frame during the treatment period.

Studies on patient groups with various specific etiologies are available in the literature, but there is no study comparing the differences that may occur based on the age of initiation of the pathology encountered.<sup>[4]</sup> The reason why we make group distinction in this way is because we observe that it is more difficult to correct deformities developed at a young age than pathologies that develop in older age due to adaptive changes developed in the extremity over time, independent of whether etiology is congenital or not.

The aim of this study is to reveal the possible differences between patients whose deformity develops in childhood and patients who develop in adulthood in terms of results, problems encountered, and treatment times obtained when the Ilizarov method is used in the treatment of deformity.

## Methods

Our study was carried out in accordance with the Declaration of Helsinki, with the approval obtained from the Ethics Committee of Turkish Health Ministry Health Sciences University (No: 3077, Date: December 22, 2020) and informed consent of patients included in the study. Patients with complex deformities treated by the same surgeon with the Ilizarov method in the same clinic between 1995 and 2010 were included without any age and etiology limitations. Patients were divided into two groups taking 16 years of age as a cutout point for pathology initiation. The results obtained in the follow-up compared retrospectively.

Statistical analysis was performed using Minitab Statistical Package for Windows ver: 21.3.1 (Minitab® LLC, Pennsylvania, USA). Two groups were compared with Student t-test for normally distributed parametric values. Non-parametric values or parametric values with non-normal distribution are compared by  $\chi^2$  test. The results were evaluated at a 95% of confidence interval and a value of  $p < 0.05$  consid-

ered significant. The increase in the encountered problems risk rate was also calculated between the groups.

Patients with adequate follow-up included to the study; age, gender, side of deformity, location, etiology, angular value of deformity, mechanical axis deviation, obtained angular correction, improvement in mechanical axis deviation, waiting time after osteotomy, correction time, consolidation time, duration of stay in the fixator, amount of shortness before surgery, amount of lengthening obtained, healing index (HI), ratio of consolidation time to correction time, difficulties (complications, obstacles, and problems) during treatment according to Paley, average difficulty amount per case and additional procedures applied were monitored. Anatomical and functional results obtained in clinical follow-up according to ASAMI scoring were evaluated retrospectively. The mean follow-up time of the patients was 9.5 (7.5–18) years.

## Results

Forty-eight patients were included in the study comparing two groups with 24 patients in each. There were 53 bone deformities in 49 extremities of these patients. The ipsilateral femur and tibia were corrected in four patients and bilateral tibia deformity was corrected in one patient. Etiology of patients and distribution by groups is shown in (Fig. 1).

The mean age was 26.47 (7–57). Location of deformities was 32 metaphyseal and 21 diaphyseal. Nineteen deformities were in oblique, 25 in coronal, nine deformities in the sagittal plan, five patients had multiapical, six patients had combined with translation, and five patients deformity had combined with rotation. The average deformity amount is  $23.98^\circ$  (7–60); the average correction amount is  $20.33^\circ$  (7–54). Mechanical axis deviation, which averaged 18,764 (–16–64) mm before surgery, was reduced to 10,311 (–3–44) mm after surgery and normal value was obtained

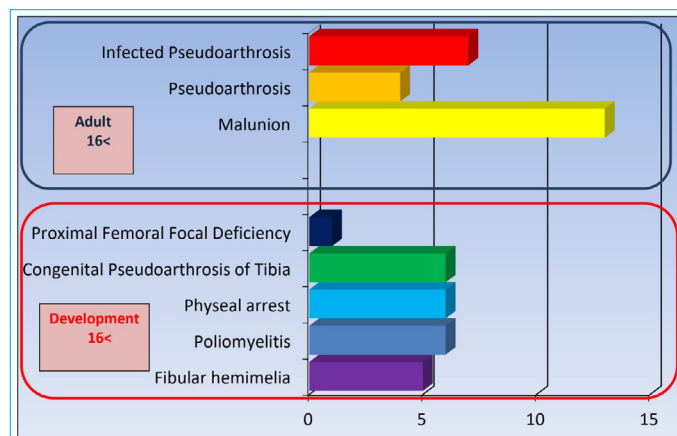
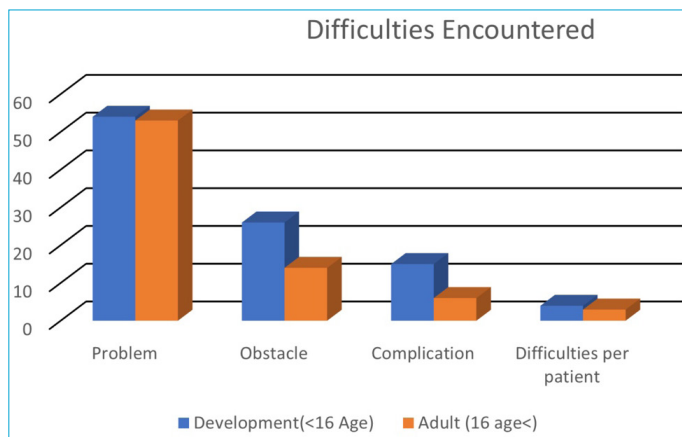


Figure 1. Etiological distribution between groups.



**Figure 2.** Comparison of difficulties encountered.

in 83% of patients. Mean 32,895 (10–90) mm of 38.65 (10–110) mm shortness was compensated in 39 patients. The rate of consolidation to correction time was calculated as 2.46. The difficulty encountered per case was 3.08 (Fig. 2). According to ASAMI, results were, anatomically excellent in 31, good in 12, moderate in five patients; functionally excellent in 23, good in 17, and medium in eight patients. The values of treated deformity parameters in both groups are also given (Table 1).

Comparing statistically the results obtained from developmental and adult groups, respectively, mean HI was

lower in developmental group (54.13 [38.12–62.25] and 63.69 [56.45–64.5] day/cm [p=0.873]). The rate of consolidation to correction+/-lengthening was higher than adults in developmental age (2.54 [1.33–3.85] and 2.4 [1.78–3.6] [p=0.698]). The angular correction rate was also faster in developmental age (1.28° [0.71–2.3] and 1.07° [0.63–2] [p=0.083]). However, these observed differences did not make statistical sense. Difficulties encountered in the treatment process were pin site problem (100%), severe pain (78%), temporary joint stiffness (34%), axial deviation (17%), joint contracture (26%), neuropraxia (13%), knee subluxation (8%), and refracture (4%). According to Paley difficulties encountered were significantly higher in developmental pathologies in all types but statistically relevant especially in complications (problems (54/53 [p=0.783]), obstacles (26/13 [p=0.050]), and complications (15/5 [p=0.003])). The proportion of total difficulties encountered per case (3.95/2.95) was also significantly more frequent in developmental age (p=0.012). Risk ratio increased by 1.02 times in terms of problems, by 2 for obstacles, by 3 times in complications, and by 1.34 times in total difficulties encountered per case. The duration of stay in the fixator was also significantly higher in developmental pathologies than in adults (217.54 (77–442) and 164.54 (92–365) (p=0.023)). The results obtained as ASAMI functional (p=0.000148) and bone (p=0.000242) scores were significantly better in the adult group. The comparison of results between groups

Group	Development period	Mature period
Number of subjects (n)	24	24
Extremity	25	24
Side	11R-14L	11R-13L
Gender	14E-10K	12E-12K
Age	Average 20.20 (7–56)	Average 33.33 (18–57)
Deformity location	20 Tibia-7 Femur	21 Tibia-4 Femur
Deformity type	20 Single plane-4 Complex	16 Single plane-8 Complex
Deformity quantity	Average 21.91 (12–60)	Average 25.16 (7–42)
Correction quantity	Average 21.25 (12–54)	Average 23.33 (7–39)
Pre-operative mechanical axis deviation	Average 13 (–16–64)	Average 24.45 (7–42)
Post-operative mechanical axis deviation	Average 10.5 (3–44)	Average 10.08 (–3–19)
Leg length discrepancy	23/24 Patient Average 5.17 (1–12)	16/24 Patient Average 2.87 (1–5.5)
Lengthening	23/24 Patient Average 4.1 (1–9)	16/24 Patient Average 2.73(1–5.5)
Latens time	Average 5.66 (2–7)	Average 7.2 (5–9)
Correction time	Average 57.54 (28–110)	Average 42.58 (15–74)
Consolidation period	Average 161.04 (49–341)	Average 121.5 (56–291)
Stay in the fixator	Average 217.54 (77–442)	Average 164.54 (92–365)

**Table 2.** Comparison of treatment parameters, complications encountered and functional, and bone results

Statistical comparison of the results of both groups			
Parameter compared	Development period	Mature period	Statistical value
Consolidation/(Correction+Lengthening)	Average 2.54 (1.33–3.85)	Average 2.4 (1.78–3.6)	p=0.698
Angular correction speed	Average 1.28 (0.71–2.3)	Average 1.07 (0.63–2)	p=0.083
Stay in the fixator	Average 217.54 (77–442)	Average 164.54 (92–365)	p=0.023
Healing index	Average 54.13 (38.12–62.25)	Average 63.69 (56.45–64,5)	p=0.873
Problems according to Paley	54	53	p=0.783
Obstacles according to Paley	26	13	p=0.050
Complications according to Paley	15	5	p=0.003
Average trouble per case	3.95	2.95	p=0.012
ASAMI bone	9 perfect, 9 good, 6 average	21 perfect, 3 good	p=0.000242
ASAMI functional	6 perfect, 10 good, 8 average	18 perfect, 6 good	p=0.000148

is given (Table 2). In addition, the ratio of the amount of lengthening needed to the initial length of the lengthened bone in the congenital group was significantly higher compared to the adult group (27.7% [14.2–57.1%] and 8.08% [0–18.7%][p=0.000]).

## Discussion

The adverse effects of malalignment on cartilage have been demonstrated; however, there is no reliable evidence defining the amount of malalignment that will cause arthritis and will need prophylactic osteotomies.<sup>[5,6]</sup> Main parameter in malalignment test is deviation of mechanical axes beyond normal. According to Wagner,<sup>[7]</sup> in patients who will have a length difference of 4 cm or more at adulthood lengthening is indicated.

The age at which treatment should be started is a different topic of debate. In congenital pathologies such as fibular hemimelia, it is recommended to make the first intervention between the ages of 1.5–4 years.<sup>[8]</sup> Wagner<sup>[7]</sup> believes that 4.5 to 6 year olds are not psychologically suitable for these procedures and recommends to postpone the treatment to 8 years of age if possible. In our series, the earliest treated patient is 7-year-old fibular hemimelia patient and no remarkable psychological distress has been developed. In order not to aggravate adaptive soft-tissue and bone deformities, it is desirable to start the treatment at younger ages. Nakase et al.<sup>[9]</sup> claimed that if the intervention is initiated under 20 years of age, the number of complications would be reduced. However, as in our series, patients often refer to treatment at adulthood, when the difference in length and deformities became more exaggerated. This transforms a group of patients who can be treated with very different strategies and low complication rates in childhood to a more complicated one. To emphasize this

situation, while allocating cases to groups, we decided like Tsididakis et al.<sup>[4]</sup> 16 years of age as a turning point for the initiation of pathologies when bony development would be largely completed.

HI has been shown to be related to various factors in the literature. Fischgrund et al.<sup>[10]</sup>, in terms of distraction osteogenesis, emphasized that metaphyseal osteotomies heal faster than diaphyseals, femorals from tibialis, and bifocals from unifocals, those made with Ilizarov than those performed with monolateral and that the healing speed slows down with the age especially after the age of 20 years. He also emphasized that the effect of the lengthening amount on HI is more pronounced in small amounts of lengthening. Aldegheri.<sup>[11]</sup> reported HI as an average of 36 days/cm in the femur and stated that he was more affected by etiology than age and lengthening amount. Antoci et al.<sup>[12]</sup>, in his study, emphasized that, in children, this ratio varies according to if etiology is congenital or acquired in nature. Horn et al.<sup>[13]</sup> found HI in children as 2 months/cm in acquired deformities and 2.2 months/cm in congenitals. Aronson.<sup>[14,15]</sup> found that this index increased as the amount to be lengthened increased. In children, HI averaged 0.87 months/cm and, in adults, it was 1.5 months/cm. Paley et al.<sup>[8]</sup> found HI to be mean of 1 month/cm in children lengthened only, 1.2 months/cm in children corrected in combination to lengthening and 1.7 cm/month in adults. As mentioned above the values specified in the literature vary remarkably. In our opinion, variability of this value is due to the difficulty in forming homogeneous groups of patients for which patient standardization is achieved. Apart from the variability of numerical values reported, in our opinion, trends indicated are consistent. Our data also support the decrease in HI in younger patients.

According to Mishima et al.<sup>[16]</sup>, HI should be 50 days/cm for a successful lengthening in patients with fibular hemime-

lia. Song et al.<sup>[17]</sup>, in patients with poliomyelitis, found this value as 1.8 months/cm for those made with Ilizarov only and 2 months/cm for those made over a nail. Harbacheuski et al.<sup>[18]</sup> determined HI as 2.2 months/cm in lengthening patients. Liu et al.<sup>[19]</sup> found this value to be 66.54 days/cm in 282 patients treated with bone transport. Rozbruch et al.<sup>[20]</sup> reported the fixator time in 38 non-union patients as 216 (SD=102) days and 344 (SD=172) days in those who are infected. In our study, the developmental age group con-

sisted mainly of patients who were expected to have a high HI etiologically. For a healthier comparison, the adult group was selected of patients with pathologies where HI was expected to be high also, like complex malunions that may require lengthening and non-unions with or without infection. Lower HI found in younger developmental age group suggests that the age factor is dominant (Fig. 3). In addition to bone regeneration time, time for union prolonged fixator time and has increased HI in the non-union. Higher an-



**Figure 3.** A 24-year-old male patient with an unappropriate positioned right knee ankylosis due to a pedestrian accident which resulted physal damage and needed multiple soft-tissue interventions for cover. Clinical and radiological pictures during treatment of oblique plane deformity combined with rotation.

gular correction speed contributed to the decrease of HI in the developmental group. The higher rate of consolidation time to the correction time in the developmental group can be explained by the fact that more frequent and higher amounts of lengthening have been made in this group. Our developmental HI value is closer to the value obtained by Horn et al.<sup>[13]</sup> with Taylor frames in the literature. In the adult group, our value is close to the value obtained by Liu et al.<sup>[19]</sup> in bone transport patients with Ilizarov. The etiological parallelism of the groups may have contributed to this similarity. In terms of average fixator stay time, treatment in the developmental group lasted longer.

To reduce HI, combinations have been added to the Ilizarov technique. Paley et al.<sup>[8]</sup> has shown that by combining rigid intramedullary nails, HI can be reduced significantly. Popkov et al.<sup>[21]</sup> found additional rigid nails unsuitable in patients with open physes. The use of elastic intramedullary nails for this purpose decreased HI by 28.2–40.1%. In acquired femoral pathologies, by bifocal lengthening (59.9%) HI reduction can be achieved.<sup>[22]</sup> Harbacheuski et al.<sup>[18]</sup> have able to reduce the fixator time from 6.2 months to 4.5 months using plates and decreased the HI from 2 months/cm to 1.5 months/cm.

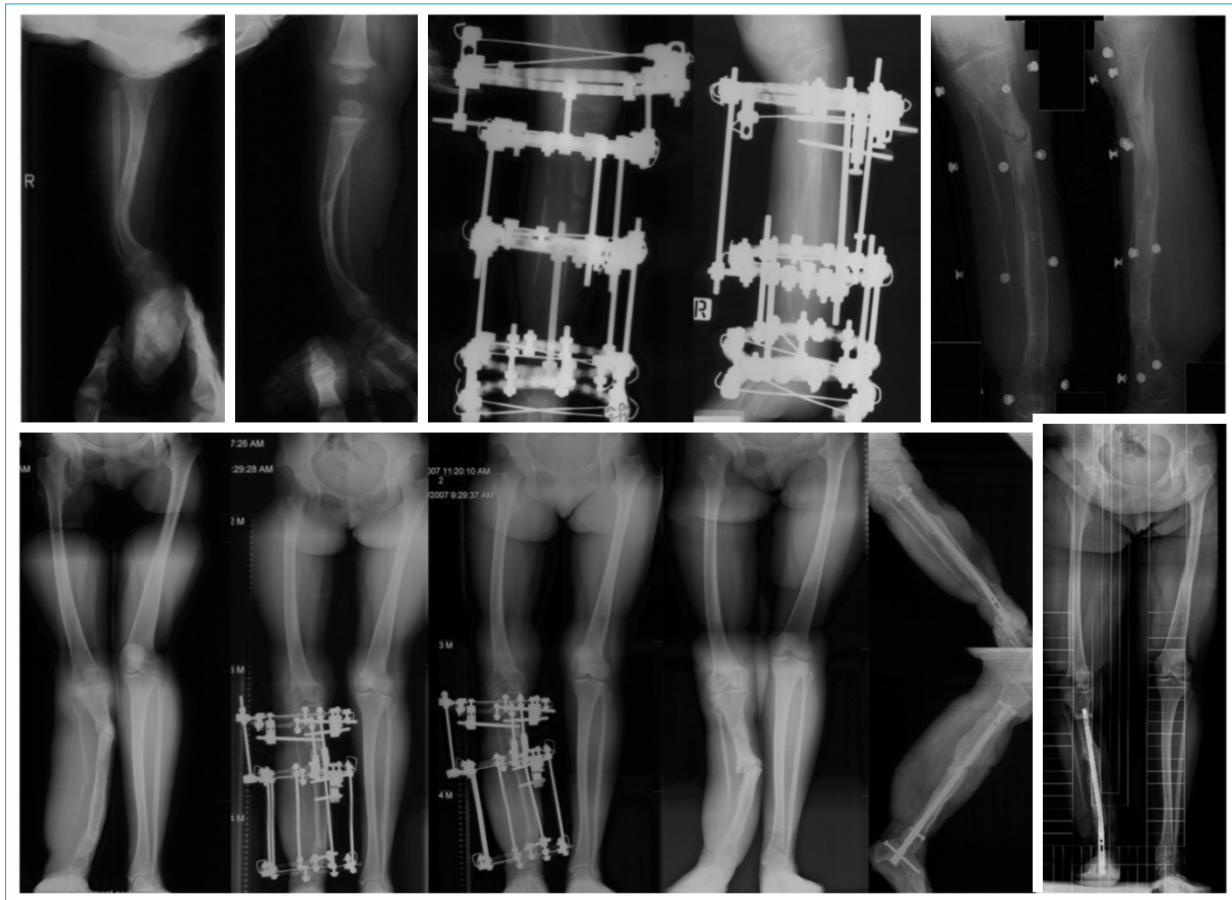
Aronson et al.<sup>[3]</sup> found that (in 95% of patients) 10% of all pins had difficulty; he also noted late deformities (9%), contractures (7%), and neuropraxias (3%). Liu et al.<sup>[19]</sup> detected pin site infection (65.9%), mechanical axis deviation (40.78%), joint stiffness (23.76%), soft-tissue entrapment (22.34%), and delayed healing (13.48%). Dhal et al.<sup>[23]</sup> reported 18% minor joint limitations. In patients with low body mass index and in those with less tibial defects, pin site infection probability is reduced. The amount of axis deviation is lower in osteotomies performed from mid 1/3 of the tibia. Joint stiffness is frequent in older patients with long femoral defects treated by bifocal osteotomy. The difficulties encountered in our series were diverse and rates consistent with literature.

Complication rates may vary widely (1%–200%) in the literature even for the same patient groups due to the differences in the author's perception of difficulty.<sup>[2]</sup> Dhal et al.<sup>[23]</sup> emphasized that although overall complications decreased from 72% to 25% with experience, the number of minor complications would not decrease with experience. In addition, it has been stated that the number of complications to be encountered is determined by the amount of lengthening needed and the problems that already existed rather than the type of fixator to be used. Aronson.<sup>[14]</sup> suggested that extending bone length by more than 20% and previous interventions would increase the frequency of complications to be encountered.

Antoci et al.<sup>[12]</sup> and Dhal et al.<sup>[23]</sup> emphasized that complications are more frequent in patients with congenital etiology due to the higher ratio (15%<) of lengthened bone to initial bone length. Calder et al.<sup>[24]</sup> emphasized that complication rates are 48–75% higher with congenital deformities, lengthening of more than 4–5 cm from the femur are at risk of fractures and contractures, and knee subluxation can be observed up to 50% of patients. Fischgrund et al.<sup>[10]</sup> stated that complications are common in highly lengthened bones (48–65%) independent of etiology and method, refracture risk is increased (3%). The importance of eliminating hip dysplasia and knee instability before starting to lengthen is emphasized. It was also found that the difficulty rates of the femur and tibia were equal. In unilateral lengthening, complications are more frequent than bilateral lengthening. Horn et al.<sup>[13]</sup> stated that complications and additional procedures needed are higher in congenital deformities and that there is no difference between femur and tibia. Aldegheri.<sup>[11]</sup> highlighted the difference between the difficulties encountered in lengthening done for extremity inequality (15%) and in those done for short stature.

Tsibidakis et al.<sup>[4]</sup> emphasized that complications are more frequent when correcting complex multiplanar proximal tibia deformities in children. Complications increase with age and the number of pre-operative problems. The number of these problems is independent of whether the etiology is congenital or acquired. Naudie et al.<sup>[25]</sup> reported that lengthening in pathological bones is riskier for complications than in post-infectious and post-traumatic ones. Performing bone transport with Ilizarov method halved the complications according to Cierny and Zorn.<sup>[26]</sup> Liu et al.<sup>[19]</sup> encountered 0.91 minor, 0.53 major complications per bone transport patient. Paley et al.<sup>[2]</sup> had 1.15 minor and 1 major complication per patient. Spiegel et al.<sup>[27]</sup> observed 0.88 minor and 0.52 major complications. Catagni et al.<sup>[28]</sup> emphasized that lengthening in fibular hemimelia is a treatment vulnerable to problems independent of the method used. Mishima et al.<sup>[16]</sup> remarked that results and complications are related to existing problems in fibular hemimelia. Rodriguez-Ramirez et al.<sup>[29]</sup> could not relate preexisting problems to results and complications. Miller and Bell.<sup>[30]</sup> had 25 problems in 12 successful fibular hemimelia treatments. Song et al.<sup>[17]</sup> highlighted the frequency of major complications such as deformity recurrence, subluxation, and arthrosis in patients with poliomyelitis (Fig. 4).<sup>[31]</sup>

Acquired deformities in adulthood are usually accompanied by pathologies that adversely affect the potential for regeneration and healing, such as soft-tissue loss and/or infection. Additional time is spent in the fixator to achieve



**Figure 4.** Radiological pictures of a female 8-year-old patient with the right congenital tibia pseudoarthrosis. First stage of the treatment was corrective osteotomy, resection of the pathological site, and reconstruction by compression distraction with Ilizarov frame. During the 2<sup>nd</sup> lengthening period, she had knee subluxation at age 14 and she had two tibial refractures, first treated with Ilizarov frame at age 15 and the last one treated with retrograde nailing at age 19.

union. Secondary adaptive changes are less frequent and lighter. Therefore, despite the frequency of complications of prolonged fixator time, joint problems are less common. The data in our series also confirm a higher rate of lengthening required in congenital deformities. Adaptive changes accompanying the deformities that occurred in the developmental period contributed to the high complication rate in this group.

Tetsworth and Paley.<sup>[32]</sup> were able to lower MAD from 48 mm to 9.6 mm in 28 complex deformities with Ilizarov. Nakase et al.<sup>[9]</sup> have reduced MAD from 20 mm to 5 mm in patients with acquired physeal damage deformities. He concluded that correction of both deformity and length inequality provides better results in patients with physeal damage. In our patients, MAD was corrected to normal values in 83% of patients. 32,895 (10–90) mm of shortness with an average of 38.65 (10–110) mm leg length discrepancy was compensated. In polio patients to improve gait quality, approximately 1 cm of shortness was intentionally accepted. This has contributed to the finding that the amount of

our lengthening acquired is less than shortening. We found that Ilizarov method is successful in correcting the alignment parameters and eliminating length inequality that may be biomechanically harmful.

Liu et al.<sup>[19]</sup>, in a series of 282 patients of bone transport, acquired excellent or good results rates of 99.39% for ASAMI bone and 79.43% for ASAMI function. Rozbruch et al.<sup>[19]</sup>, in 38 non-union patients with or without infection, achieved unions in 71% with first intervention, in 95% with a second, 36 of them had good or excellent results for ASAMI bone, and 34 for ASAMI function. Paley et al.<sup>[1]</sup> achieved excellent results in 36 of 38 patients with fibular hemimelia.<sup>[8]</sup> In our 12 congenital etiology patients, the mean rate of regenerated bone to initial bone length was 27.7% (14.2%–57.1%). In five of the patients, it was necessary to apply protective intramedullary nailing to prevent refracture. ASAMI results were good or excellent in 66.66% for anatomy and in 50% for function. Although there are some authors in the literature who recommend early amputation in this patient group because the poor results expected despite long and

meticulous treatment. We agree with Catagni et al.<sup>[28]</sup> and Paley et al.<sup>[1]</sup> that with Ilizarov method satisfactory results can be achieved despite the difficulties.

Various methods using additional nails and plates have been developed to reduce long frame wearing times of Ilizarov technique that impairs the quality of life of patients and causes complications.<sup>[33]</sup> Calder et al.<sup>[34]</sup> found that in compliant patients with nails, complications especially late fractures can be prevented. Nails should not be used in patients before 14 years of age and obese. Nails used to fix osteotomies performed close to the joint line, especially in osteoporotic metaphyseal bone will increase complications. Jain et al.<sup>[35]</sup>'s meta-analysis emphasized that though intramedullary nails are comfortable in lengthening there is no strong evidence for their reduced complication rates. Harbacheuski et al.<sup>[18]</sup> observed up to 27% varus and plate fractures with additional plating. As literature emphasize, these alternative methods have their own limitations and are still in the development phase.

## Conclusion

According to results obtained from our study, we concluded that regardless congenital or acquired nature of the etiology deformities occurred before 16 years of age correction with the Ilizarov method provides more unsatisfactory results with more frequent complications compared to deformities occurred at adulthood. Although Ilizarov treatment allows successful results in a relatively difficult and risky group of patients, it does not eliminate the risks completely that require to be informed to patients in advance. Although the major risks are reduced to an acceptable level with this technique, patients should be informed that problems or complications that require additional intervention may be encountered, especially in deformities that occur during the developmental age. Although the potential for regeneration in childhood is better, our study did not find any significant differences compared to adult groups in terms of HI and correction time/consolidation time rates. Since the average age is smaller, the average HI value detected in the developmental period group was expected to be advantageous. Despite this expectation, similarity of values found to adult groups values can be explained by the difficulties in adaptation of the soft-tissues that remain rudimentary at development age group and by the length differences which are more frequent and exaggerated. The inconvenience that most of the corrections are made in adulthood must be noticed. As a conclusion, it can be foreseen that the treatment will be longer and complications will be more frequent in pathologies that occur at the developmental era.

## Disclosures

**Ethics Committee Approval:** The study was approved by the Ethics Committee of University of Health Sciences Türkiye, Sisli Hamidiye Etfal Training and Research Hospital, Health Application and Research Center (No: 3077, dated 22.10.2020).

**Patient informed consent:** Enlightened informed consent has been obtained from each patient before the surgical intervention concerning treatment process and data collection for the study.

**Peer-review:** Externally peer-reviewed.

**Conflict of Interest:** None declared.

**Authorship Contributions:** Concept – R.A., M.K., H.M.O.; Design – R.A., M.K., H.M.O.; Supervision – R.A., M.K., H.M.O.; Fundings – H.M.O.; Materials – R.A., M.K.; Data collection &/or processing – R.A., M.K.; Analysis and/ or interpretation – R.A., H.M.O.; Literature search – R.A., M.K.; Writing – R.A., M.K., H.M.O.; Critical review – R.A., M.K., H.M.O.

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