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Orthopaedic complications and iatrogenies during deformity correction of lower limbs in patients with severe osteogenesis imperfecta

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An incidence and severity of adverse effects of postoperative care of patients with osteogenesis imperfecta (OI), the treatment and outcomes are essential elements for the study of the nosologic group in addition to clinical review of surgical outcomes. **Purpose** was to examine complications of surgical orthopaedic treatment, reconstructive procedures and follow-up period of patients with OI types III and IV. **Material and methods** The study included 43 patients aged 33 months to 46 years (14.4 ± 9.74 years). Clinical and radiological features of OI types III and IV were observed in 14 and 29 cases, correspondingly. To analyse the complications the patients were subdivided into three groups depending on the technique applied and patients' age. Group I was composed of skeletally mature patients aged 16 years and older with radiological physeal closure who underwent combined osteosynthesis of elastic intramedullary nailing and Ilizarov external fixation of lower limbs. Group II included skeletally immature patients aged less than 16 years with radiologically visible physis who underwent combined osteosynthesis of elastic intramedullary nailing and Ilizarov external fixation of lower limbs. Group III included skeletally immature patients aged less than 16 years with radiologically visible physis who underwent elastic intramedullary nailing alone. **Results** From a variety of techniques used to correct lower limb deformity in patients with severe OI the combination of elastic intramedullary nailing and Ilizarov external fixation with acute multi-level deformity correction of lower limbs was shown to be most efficacious in children and adults due to lower risk of complications associated with surgical treatment, osteosynthesis and the condition.
Keywords: osteogenesis imperfecta, deformity correction, complication, surgical treatment, iatrogenyt

The incidence of osteogenesis imperfecta (OI) is reported to range from one to 10 000 to one per 20 000 live births [1, 2]. Most common indications to surgical interventions are orthopaedic complications often observed in patients with severe OI Sillence's types III and IV [3] including angular and torsion deformity of limb segments accompanied by functional disorders, pseudarthroses, bone defects, absence of independent ambulation skills and/or verticalisation that cannot be addressed with conservative treatment [1, 2, 4–7]. Telescopic intramedullary rodding in children and intramedullary nailing in adults are currently major techniques of osteosynthesis used to correct orthopaedic pathology of limbs in patients with OI [8–11].

Results of surgical treatment and complications of OI must be evaluated not only with regard to the outcome achieved. Both frequency and severity of adverse effects developing during postoperative period, the treatment and outcomes must be equally studied along with OI related complications. The approach is to differentiate iatrogenies rated at the International Classification of Diseases as adverse effects of prophylactic, diagnostic and medical procedures that result in organism dysfunctions, limitations in usual activities, disability or death, as well as complications related to OI pathogenesis and developed after medical procedures [12–15].

The purpose of this paper is to examine complications of surgical orthopaedic treatment, reconstructive procedures and follow-up period of patients with OI types III and IV.

MATERIAL AND METHODS

Surgical correction of lower and upper limb deformities with intramedullary constructs was performed for 69 patients with OI at the Kurgan Ilizarov Centre in 2003. The retrospective study comprised patients with severe types III and IV OI treated with a combination of external and intramedullary fixation using titanium elastic nails with or without hydroxyapatite coating. The

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inclusion criteria consisted of at least one rod placed at all levels of the deformity correction and at least one year observation following the intervention. Participants were excluded from the review if they had a history of clinical and radiological symptoms of type I OI, other metabolic osteopathies, misplaced intramedullary rods and observation period of less than one year. Finally, the study included 43 patients aged 33 months to 46 years (14.4 ± 9.74 years). Clinical and radiological features of OI types III and IV were observed in 14 and 29 cases, correspondingly. The diagnosis was confirmed by molecular genetic testing in 17 cases including 6 type III, 10 type IV and 1 type VIII.

To analyse the complications the patientы were subdivided into three groups depending on the technique applied and the age. Group I was composed of skeletally mature patients aged 16 years and older with radiological physeal closure who underwent combined osteosynthesis of elastic intramedullary nailing and Ilizarov external fixation of lower limbs. Group II included skeletally immature patients aged less than 16 years with radiologically visible physis who underwent combined osteosynthesis of elastic intramedullary nailing and Ilizarov external fixation of lower limbs. Group III included skeletally immature patients aged less than 16 years with radiologically visible physis who underwent elastic intramedullary nailing alone.

Review of the results in groups I and II addressed acute deformity correction or postoperative gradual realignment following partial acute intraoperative correction according to the Ilizarov principles. More details on the methods of treatment used are presented in our previous publication [16].

Tables 1, 2, 3 present patients' age, types of OI and specific surgical treatment performed for each of the three groups.

Table 1

Age, type of OI and surgery performed in group I

Description	Total for the group	Gradual deformity correction	Acute deformity correction
Number of patients, (type III/IV OI)	13 (2/11)	5 (0/5)	8 (2/6)
Age, years	25.2 ± 9.91 (16–46)	23.0 ± 6.63 (16–32)	26.5 ± 11.74 (16–46)
Interval between surgeries on different limbs and/or segments	189.1 ± 238.24 (31–938)	210.5 ± 269.74 (31–938)	43.8 ± 11.13* (31–59)
Application of HA/Ti (hydroxyapatite coated/titanium rods); number of cases	8/5	5/0	3/5
Length of external fixation; days	110.6 ± 45.27 (35–204)	134.2 ± 48.07 (58–204)	87.0 ± 27.73* (35–120)

Note: * – significant differences from the cases with gradual deformity correction

Table 2

Age, type of OI and surgery performed in group II

Description	Total for the group	Gradual deformity correction	Acute deformity correction
Number of patients, (type III/IV OI)	20 (7/13)	6 (0/6)	14 (7/7)
Age, years	9.2 ± 3.69 (4–15)	11.8 ± 4.07 (4–15)	8.1 ± 2.99 (4–15)
Interval between surgeries on different limbs and/or segments	48.6 ± 57.43 (0–265)	70.5 ± 70.2 (32–265)	21.3 ± 11.61* (0–43)
Application of HA/Ti (hydroxyapatite coated/titanium rods); number of cases	12/8	5/1	7/7
Transphyseal/non-transphyseal reinforcement; number of cases	11/9	1/5	10/4
Use of titanium mesh/ subperiosteal placement of elastic nail; number of cases	5/1	0/0	5/1
Length of external fixation; days	63.1 ± 37.25 (20–152)	90.5 ± 39.04 (34–152)	43.2 ± 19.19* (20–82)

Note: * - significant differences from the cases with gradual deformity correction

Table 3

Age, type of OI and surgery performed in group III

Description	Total for the group
Number of patients, (type III/IV OI)	10 (5/5)
Age, years	10.7 ± 6.39 (2.75–17)
Interval between surgeries on different limbs and/or segments	33.0 ± 11.61 (18–51)
Application of HA/Ti (hydroxyapatite coated/titanium rods); number of cases	2/8
Transphyseal/non-transphyseal reinforcement; number of cases	9/1
Use of titanium mesh/ subperiosteal placement of elastic nail; number of cases	2/2

The data indicated to deformity correction produced in both acute and gradual manner for type IV OI and primarily in adults with lower risk of unstable external fixation due to lower bone mineral density. Acute deformity correction alone was performed in a more severe type III OI with intramedullary nailing used stand-alone in 5 cases (35.7 %) or in combination with external fixation in the rest 9 patients (64.3 %). It should be noted that non-transphyseal introduction of intramedullary nail in children of group II (n=9) was erroneous. Subperiosteal reinforcement using titanium nickelide mesh combined with or without elastic rod placed subperiosteally was applied for acute deformity correction only primarily in patients with a more severe type III OI. Evaluation of iatrogenic complications and complications of OI developed after reconstructive intervention included adverse effects, the patterns, the time of the manifestations, relations between OI type, operative treatment performed and the treatment produced to eliminate the complications.

Microsoft Excel 2016 was used for statistical analysis of quantitative data. The results of descriptive statistics were presented in the form of M ± σ, where M is sample mean, and σ being standard deviation. Statistical dispersion of independent variables was employed for comparisons.

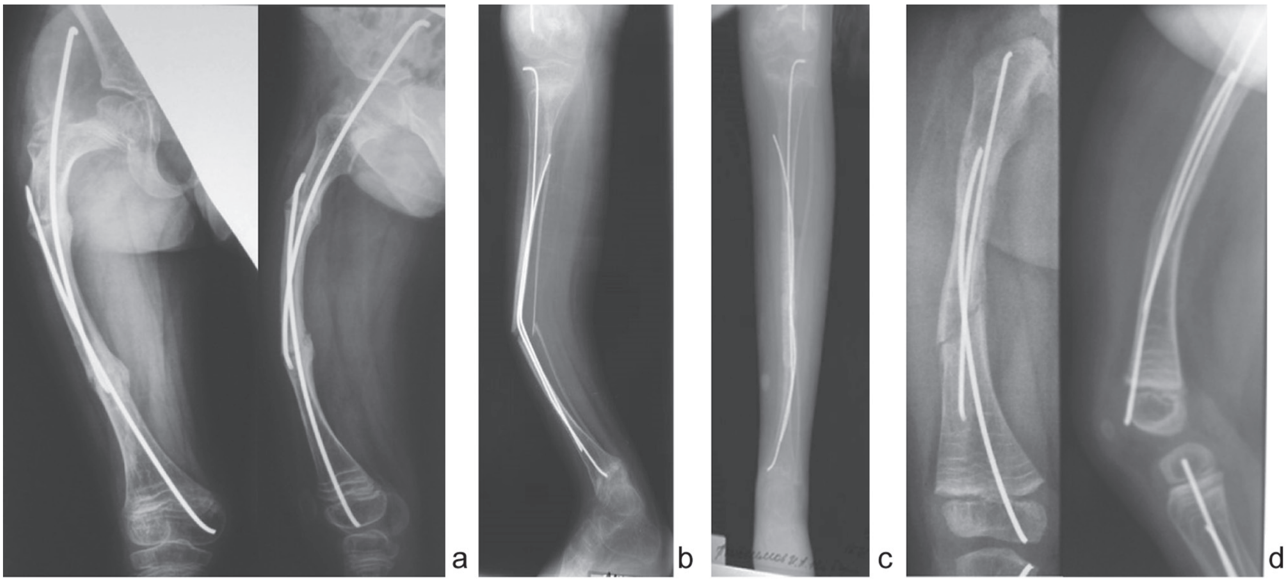
RESULTS

The cohort of patients developed total 107 adverse effects and pathological conditions throughout the whole period of observation including reoperations. Two groups were identified including surgery related pathological conditions and iatrogenies and complications having pathogenetic associations with underlying disease (OI related complications).

Figure 1 demonstrates several iatrogenies and complications observed in patient of the series. Complications of surgical treatment are presented in Tables 4, 5, 6. The incidence of complications in the cohort of patients was 2.3 per one case. There is a difference between types of complications observed in subgroups -- gradual correction entails inflammatory complications and unstable external fixation accompanied by secondary bone displacement numbering 13 out of 16 per subgroup (81.3%). Wires, half-pins were replaced and external fixation device reassembled during a stand-alone procedure in 6 patients and at the next surgical intervention produced for another segment or lower limb in the rest of the cases. Delayed bone consolidation was rather common in acute deformity correction numbering 4 out of 14 complications (28.6 %). Failures of intramedullary nailing included absence of reinforcement of one of the osteotomies in 9 segments with two rods (4 segments with gradual and 5 with acute deformity correction). The incidence of complications in the group of patients was 1.6 per one case. Inflammatory complications and unstable external fixation were quite common with this group of patients. The incidence of the complications was much higher with gradual deformity correction numbering 14 out of 21 complications observed (66.6 % complication of the subgroup). Nevertheless, wires were replaced and external fixation device reassembled at the next elective surgery in 7 patients.

No delayed consolidation was ever observed in children.

There was a new complication observed in absence of divergence of transphyseal nails coated with hydroxyapatite due to the interlocking in the medullary canal. The scenario predisposes a deformity at the level of new bone that can occur during the growth and would require additional transphyseal titanium rods. Other failures of intramedullary reinforcement included non-transphyseal elastic nails coated with hydroxyapatite that would be unreasonable for the need of persisted segment reinforcement throughout skeletal growth. Non-transphyseal elastic nails were subsequently replaced with transphyseal titanium rods in four cases. A lethal outcome occurred at the very end of reconstructive treatment with deformity correction of all segments of lower limb completed at five days of the removal of external fixation device.



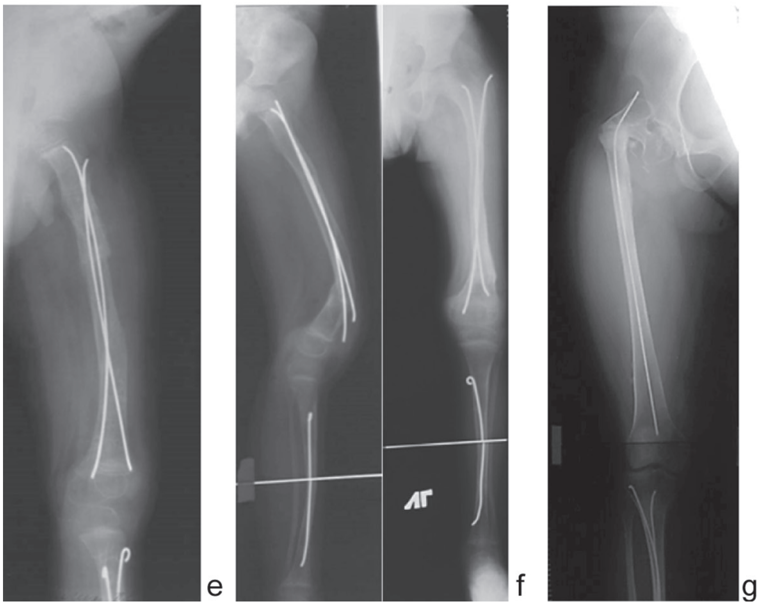


Fig. 1 Radiological instances of complications showing (a) delayed consolidation at the proximal osteotomy and angular deformity, proximal migration of antegrade elastic nail in a radiograph of the femur of patient K. at one year of double correcting osteotomy and intramedullary reinforcement; (b) fracture of tibia and fibula with elastic nail in situ in a radiograph of the right tibia of patient A. at 9 months of deformity correction; (c) deformity correction and subperiosteal reinforcement with titanium mesh in a radiograph of the right tibia of the same patient; (d) undisplaced fracture of the femur with intramedullary transphyseal rods in place in a radiograph of the femur of patient B.; (e) failure to follow the technique with both retrograde intramedullary nails instead of transphyseal introduction in a radiograph of patient D.; (f) bone fracture at the nail entry level below reinforced bone in a radiograph of patient D at 18-month follow-up; (g) delayed consolidation and malalignment at the osteotomy site with a single intramedullary nail introduced in a radiograph of the right femur of patient E.

Table 4

Complications of surgical treatment in group I

Complications	Total for the group (n = 13)	Gradual deformity correction (n = 5)	Acute deformity correction (n = 8)
Pin tract infection with Ilizarov external fixation that required pin replacement	14	9	5
Unstable Ilizarov rings that required wire replacement and frame reassembly	4	4	–
Incomplete deformity correction that required additional stage of surgical treatment for realignment	1	–	1
External migration of intramedullary rods, soft tissues irritated with rods that required either rod replacement or revision	6	2	4
Delayed bone healing without deformity	2	–	2
Delayed bone healing, nonunion and developing angular deformity	3	1	2

Table 5

Complications of surgical treatment in group II

Complications	Total for the group (n = 20)	Gradual deformity correction (n = 6)	Acute deformity correction (n = 14)
Pin tract infection with Ilizarov external fixation that required pin replacement	16	12	4
Unstable Ilizarov rings that required wire replacement and frame reassembly	3	2	1
Incomplete deformity correction that required additional stage of surgical treatment for realignment	10	4	6
Interlocked hydroxyapatite coated nails with no divergence in the medullary canal	2	2	–
Pulmonary thromboembolism	1	1	

Table 6

Complications of surgical treatment in group III

Complications	Total for the group (n = 10)
External migration of intramedullary rods, soft tissues irritated with rods that required either rod replacement or revision	4
Interlocked hydroxyapatite coated nails with no divergence in the medullary canal	1
Torsional bone displacement	3
Delayed bone healing without deformity	1
Delayed bone healing, angular deformity and nonunion that required surgical correction	2

On average, the incidence of complications in the group of patients was 1.1 per one case. External fixation complications that were common for the first two groups were unlikely to develop in the group; however, a new complication of secondary torsion bone displacement was noted prior to bone consolidation. Frequency of external migration of intramedullary rods or soft tissues irritated with rods was 36.4 % and was close to that of other groups (20% in group I and 32.3 % in group II). However, a stand-alone surgical procedure was always necessary for the treatment of the complications.

Delayed bone consolidation after correcting osteotomy requires special considerations. It should be noted that the complication was seen to develop in seven from eight patients who had correcting cunei-form osteotomy of the femur produced with an oscillating power saw. Deformity was corrected acutely in seven cases. Adverse effects associated with the complication included tobacco smoking in adult patients, early bisphosphonate administration (less than 4 months and with no signs of adequate bone callosity) in children of group III whose delayed bone consolidation ended up with nonunion and angular deformity. On the contrary, the delayed bone consolidation was never seen with percutaneous osteotomy in adults or acute deformity correction using the combined techniques including cunei-form osteotomy in children of group II.

On the whole, the encountered complications of surgical treatment being interpreted as iatrogenies can be grouped according to the International Classification of Diseases as follows, I26.9 (n = 1), T84.1 (n = 23), T84.3 (n = 37), M84.1 (n = 5), M 84.2 (n = 3) and M21.8 (n = 4).

The review of complications having pathogenetic associations with IO showed bone fractures, recurrent deformities, new deformities developing with the reconstructive deformity correction of lower limbs. Types of complication, the reasons are presented in Table 7.

Table 7 demonstrates the need of re-correction of deformities much later developing in Group II due to transphyseal reinforcement with elastic titanium rods primarily used for the patients. On the other hand, greater intervals in segment reinforcement between the limbs resulted in considerable increase in pathological fractures of non-operated limbs during the treatment in cases of gradual ipsilateral deformity correction of group II. The phenomenon was not observed in group I due to the decreased incidence of bone fractures in adult patients with OI. There were also nondisplaced fractures observed in adequately reinforced segments of 5 patients that required short (up to 4 weeks) immobilisation using plaster cast or brace with good ambulation maintained. Displaced fractures of reinforced segments were noted to occur in children with either significant traumatic injury or at the epimetaphyseal level, in adults with improper intramedullary nailing spanning a part of the whole segment. Finally, the scheduled replacement of intramedullary nails was produced in three cases of Group II and three cases of Group III throughout the whole period of observation. An average number of surgeries per one case depending on the correction technique used and complications encountered during the observation period are presented in Table 8.

Acute deformity correction can evidently reduce surgical stress on the patient during the natural development of bone and with the growth complete. Combined pediatric technique of transphyseal titanium mailing and Ilizarov external fixation using a lightweight assembly was accompanied by less iatrogenies and OI related complications throughout the period of observation.

Table 7

IO related complications HO seen at the beginning of reconstructive treatment

Complications	Group 1 (n = 13)	Group 2 (n = 20)	Group 3 (n = 10)
Bone fracture prior to reinforcement that required surgical treatment; n	1	6	–
Fracture of reinforced bone that required surgical treatment or reduction under general anesthesia; n	3	–	2
Nondisplaced fracture of reinforced bone segment that required immobilisation; n	1	2	2
Recurrent deformity that required surgical correction; n	6	7	4
Period of time prior to correction of recurrent deformity; days	920.5 ± 513.73	1246.4 ± 164.97*	835.3 ± 199.8
Bilateral varus deformity of the femoral neck and pathological fracture	–	–	1

Table 8

Average surgical procedures performed per one case

Group 1		Group 2		Group 3
gradual correction	acute correction	gradual correction	acute correction	
5.4	3.0	5.7	2.1	2.7

DISCUSSION

Major orthopaedic manifestations of OI include a low bone mineral density and skeleton strength, fractures and deformities of long bones, skull deformities, hypermobile joints and others [1, 2]. Refractures, limb deformities, continuous immobilisation and absence of weight-bearing result in a lower bone mineral density, delay in reaching key motor milestones that affect the physical, social and emotional well-being of children [4, 5]. Plates, large rigid nails, stand-alone external fixation devices are not widely accepted for severe OI [1, 10, 17].

Intramedullary rodding is considered to be the most effective method for OI. Telescopic transphyseal intramedullary rods allow for bone reinforcement all along the length during development. This is achieved by rigid and elastic rods transepiphyseally inserted into the medullary canal [7–9, 18]. Locking plates and excessively rigid fixation generally should be avoided in adult patients [17].

Boutard et Laville reported transphyseal elastic reinforcement with titanium rods applied for 14 patients with severe OI [8]. The authors reported no case of rod divergence, however, the replacement was needed in 75% of the pediatric patients with children's growth. There were 2.5 surgeries performed per case on average. Frequency of major complications was 25 % including fractures, implant migration, nonunion, bone shortening due to impaction [8, 11]. The Fassier-Duval telescopic rod is considered to be a successful solution in intramedullary elastic transphyseal telesciopic system for pediatric deformity correction of long bones [7, 10, 18]. However, the technique of using Fassier-Duval rod is associated with a 35% complication rate: rod or part of construct migration (10.5 % to 23.7 %), deformed telescopic system (18.8 %), nonunion and bone divergence (7.2 %), limited telescoping (2.1 %), broken rods (6.9 %), fractures at earlier osteotomy sites with intramedullary telescopic system introduced (20 % to 25 %) [19–21]. Stand-alone intramedullary rods suggest a strict immobilisation period with bracing from 4 to 6 weeks that also leads to additional reduction in bone mineral density [19–21]. In addition to that, telescopic rods and elastic intramedullary reinforcement fail to prevent secondary torsional bone displacement at early postoperative period [6, 19]. Kong et al. reported the advantages of combined flexible intramedullary nailing and external fixation used for osteopenic femoral shaft fractures including control of angulation, rotation at the fracture site and early weight-bearing [22].

We subdivided complications of our series into iatrogenies developed during and as a result of surgical treatment and complications of OI occurred at the follow-up period and determined by pathogens of the underlying disease. The lowest rate of iatrogenies was observed in children who underwent transphyseal reinforcement combined with lightweight Ilizarov fixation that was applied for a short period of time. In addition to the lowest rate of complications with no infection and unstable external fixation the practice was helpful in avoiding problems of delayed bone consolidation observed in Groups I and III and secondary torsional displacement being typical for stand-alone intramedullary rodding (Group III). A short period of external fixation, early ambulation of patients maintaining axial weight-bearing on the operated limb [16] and fast transition to operative deformity correction of the contralateral limb were important for preventing fractures of non-reinforced segment of the contralateral limb. Transphyseal introduction of elastic rods was reasonable and associated with pathogenetic mechanisms of OI in children. An attempt of transphyseal introduction of hydroxyapatite coated rods in our series resulted in absence of rod divergence in three cases with the segment developing and pathological fracture at the level of new non-reinforced bone in one case. In the rest of the cases preventive titanium rods were placed in a transphyseal manner.

Pediatric non-transphyseal introduction of hydroxyapatite coated rods was erroneous and predisposed to recurrent deformity and fracture of non-reinforced bone at long-term follow-up. On the other side, introduction of elastic hydroxyapatite coated rods was indicated for adults and children with longitudinal bone growth being nearly complete. In addition to reinforcement effect the implants could provide bone stability due to osteoinductive processes that prevented the migration. Reinforcement with regular titanium intramedullary rods was often accompanied by the partial migration from the bone that required revision of the loose ends. Inadequate reinforcement (absence of two rods all along the bone) did not prevent bone displacement that was observed in 75 % of fractures occurred at long-term follow-up of Group I and should be taken into consideration in surgical treatment.

Less invasive osteotomy and refusal from oscillating power saw was essential for lower risk of nonunion that was typical for Fassier-Duval intramedullary system [23]. In the presence of factors having negative impact on osteogenesis (smoking) less invasive osteotomy combined with intramedullary reinforcement and gradual deformity correction could be advocated for adults with type IV OI instead of acute deformity correction and cuneiform bone resection but a high risk of infection should be considered due to a long period of external fixation. Some authors report deformity correction of lower limbs in children with type IV OI using solely an external fixation device [24, 25]. Therapy with bisphosphonate is to be excluded for a reasonable period of time to reduce the risk of nonunion after osteotomy. Pamidronate administered postoperatively was shown to be associated with a higher risk of delayed osteotomy healing and nonunion as described by Munns et al. [20]. The bisphosphonate infusion protocol includes an infusion-free interval of 4 months after surgery with signs of callus formation [23]. An optimal balance between the number of surgical procedures performed, recurrent deformity and re-correction rate was detected with pediatric techniques of simultaneous deformity correction and transphyseal rodding combined with (on average, 2.1 surgeries per one case during the course of the observation interval) or without external fixation (on average, 2.7 surgeries per one case during the course of the observation interval). The findings can be comparable with the data of stand-alone elastic transphyseal reinforcement indicating to 2.5 surgeries per one case [8] and are close to those found with the application of Fassier-Duval telescopic rod [7, 18, 21]. The worst rate of the number of surgeries per one case in our series was observed in gradual deformity correction with the Ilizarov external fixator (5.4 in adults and 5.7 in children). It is important to study the results of treatment, the likelihood and frequency of re-operations at a longer follow-up term. Children with OI are shown to improve ambulation, gross motor function, mobility and quality of life at one-year follow-up [18] and our findings are on par with the observations. However, some decline in functional status associated with OI complications can be noted in patients at four-year follow-up as reported in the same study [18].

CONCLUSION

From a variety of techniques used to correct lower limb deformity in children and adults with severe OI included in the study the combination of elastic intramedullary nailing and external fixation with acute multi-level deformity correction of lower limbs was shown to be most efficacious due to lower risk of complications associated with surgical treatment, osteosynthesis and the condition. Transphyseal reinforcement with elastic titanium rods and a maximally short interval between interventions on different legs are essential for children. Elastic hydroxyapatite coated rods applied with spontaneous potential longitudinal growth of limb segments exhausted has shown to exhibit maximum advantages.

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