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Effect of elastic intramedullary nailing on lower limb lengthening in acquired shortenings: a prospective study

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Abstract

Introduction Lengthening and correction of limb deformities using Ilizarov external fixation is a frequent standard operation. However, the risk of complications associated with limb lengthening, including superficial or deep infection, contractures, secondary deformity, and fractures after device removal associated with delayed bone consolidation, remains significant.

The **purpose** of the work was to identify the features of bone lengthening with an external fixator in combination with elastic intramedullary nails, titanium or titanium with a composite hydroxyapatite coating, in the conditions of shortening of the lower extremities of acquired etiology.

Materials and methods The study included 64 patients, of which 31 patients underwent monofocal lengthening of the femur, 33 patients underwent monofocal lengthening of the tibia.

Results The mean external fixation indices (EFIs) of the groups compared for similar lengthening types (femoral or tibial lengthening) did not differ significantly for the types of intramedullary nails implanted. In femoral lengthening, a significant effect on the EFI had the nail type and the ratio of “nail diameter / medullary canal diameter”. The dependence of EFI on the nail type in tibial lengthening was associated with the ratio “nail diameter / internal diameter at the osteotomy site” ($p = 0.023$). Two-way ANOVA showed that the effect of the nail type on EFI depended on the nail diameter/ internal diameter at osteotomy site ratio in the tibial lengthening group ($p = 0.034$).

Discussion In acquired shortening of the lower extremities, there is no difference in EFI by using titanium elastic nails or intramedullary nails coated with composite hydroxyapatite. The use of a combined technique, in any case, has advantages: it provides good and excellent results without serious complications during lengthening in patients with shortening of acquired etiology. The strong positive correlation between the bone diameter/internal cortical distance ratio at the osteotomy site, coupled with the significant influence of the nail type and nail diameter on EFI, suggests that both factors should be considered together in future studies.

Conclusion In shortening of the lower extremities of acquired etiology, the use of a combined bone lengthening technique, comprising an external fixator in combination with elastic intramedullary nailing, provides good and excellent results without serious complications.

Keywords: limb lengthening, Ilizarov apparatus, elastic intramedullary nailing, hydroxyapatite

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INTRODUCTION

The incidence of leg length discrepancy requiring surgical intervention is approximately 1:1000 [1]. Acquired lower limb length discrepancy (ALLD) and deformities are among the most common reasons for referral to an orthopaedic surgeon [2–6]. Surgical treatment options for this pathology include the use of circular external fixators, lengthening with a fully implanted electromagnetic rod, or lengthening over intramedullary nails using external devices [2, 7–12].

Lengthening and correction of limb deformities using external fixation based on the principles of the Ilizarov method is a common standard operation [9, 13, 14]. However, the risk of complications associated with limb lengthening, including superficial or deep infection, contractures [15–17], secondary deformity and fractures after removal of the device associated with delayed bone consolidation [16, 18, 19], remains an essential problem. It is also necessary to consider the negative long-term psychological burden associated with restrictions in everyday life in these patients [20].

Limb lengthening with elastic intramedullary rods/nails has been described in the literature [21–24]. This combined method provides a number of advantages: additional stability of the bone fragment position, prevention of secondary displacements, especially translation, and fractures after removal of the device, reduction of the duration of external fixation. Considering the elastic nature of the implants, gradual correction of the limb axis is possible in case of severe deformity; the small diameter of the nails makes them suitable for narrow medullary canals; installation of the nails through the metaphysis eliminates injury of the growth zones [21–24]. Animal studies have shown that this method also spares the intramedullary blood supply [25].

Experimental studies have shown that elastic HA-coated nails have a stimulating effect on bone consolidation [7, 8, 26, 27]. But the role of such composite coatings in elongation of healthy bone tissue in the clinical conditions remains unclear [28].

The **purpose** of the work was to identify the features of bone lengthening with an external fixator combined with elastic intramedullary nails, titanium or the ones with composite hydroxyapatite coating, in shortening of the lower extremities of acquired etiology.

MATERIALS AND METHODS

A non-randomized prospective study of treatment results in patients with acquired shortenings and deformities of the lower extremities was conducted. All patients included in the study were diagnosed with acquired lower limb length discrepancy (post-traumatic, consequences of neonatal osteomyelitis, consequences of poliomyelitis or spastic hemiparesis, classified according to the GMFCS system as level I–II). All patients underwent monosegmental lengthening using a combined technique of external fixation and elastic intramedullary osteosynthesis. The follow-up period after dismantling the external fixation device was 10–12 months. The study did not include patients who underwent simultaneous correction, polysegmental lengthening, patients with congenital shortening or systemic pathology, as well as those who underwent lengthening without elastic reinforcement.

The results were analyzed in two groups: monofocal lengthening of the femur (group F, $n = 31$) and monofocal lengthening of the tibia (group T, $n = 33$). These groups were divided into subgroups: lengthening over titanium elastic nails (F-Ti and T-Ti) and over titanium nails coated with hydroxyapatite (HA) (F-HA and T-HA).

Surgical technique

Under general anesthesia, in the supine position, a wire/half-pin external fixation device was installed on the femur or tibia considering the deformity, and a percutaneous corticotomy was performed. Then elastic intramedullary nailing was performed: retrograde for the femur and antegrade for the tibia. The choice of the diameter of the elastic nails was determined arbitrarily by the surgeon, focusing on the diameter of the bone marrow canal. Titanium nails without HA coating were used in 29 patients (intramedullary elastic pediatric nails from MEDIN, Nove Mesto na Morave, Czech Republic). Titanium nails with HA coating (Orthopediatrics, modified by Metis LLC, Tomsk, Russia) were used in 24 limb lengthening operations. Long bone canals were not drilled. The Ilizarov apparatus was used in 51 cases, and CORA and ACA were used for hinge placement (Fig. 1). Three patients were treated with the Taylor Spatial frame (TSF) (Smith & Nephew, Memphis, Tennessee, USA), in which CORA was integrated into the distraction and correction program as a reference point (Fig. 2). Before surgery, after consultation with the treating physician, patients were given the opportunity to choose between non-coated or HA-coated titanium itramedullary nails.

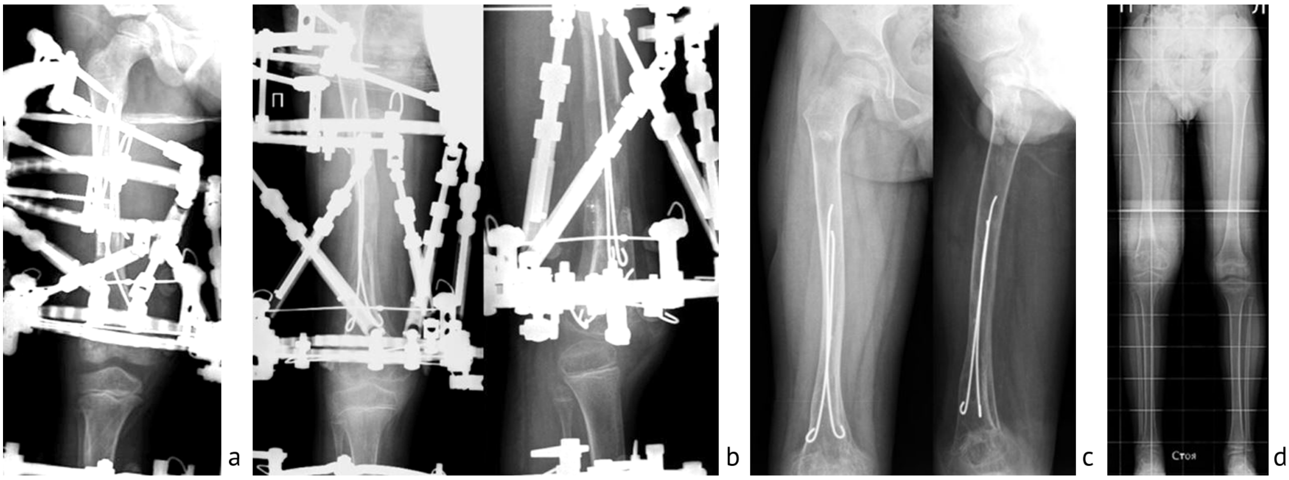

Fig. 1 Radiographs of the femur of a patient of the F-HA subgroup: *a* femoral osteotomy, initial position of intramedullary elastic nails; *b* at the end of the distraction period; *c* after removal of the external fixation device; *d* after removal of intramedullary nails, remodeling of the distraction regenerate

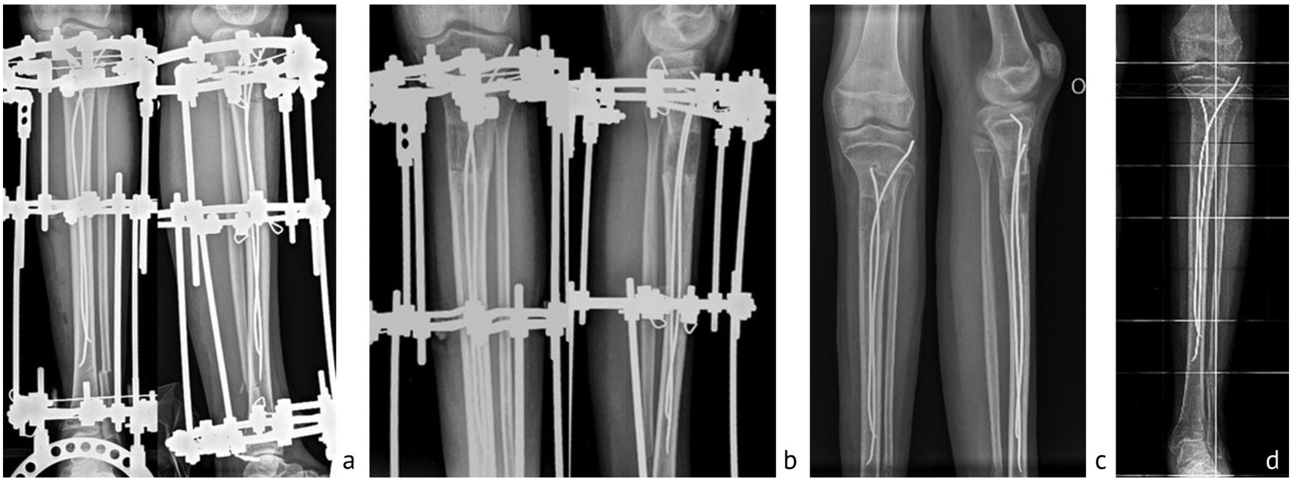

Fig. 2 Radiographs of a patient of the T-Ti subgroup: *a* proximal osteotomy of the tibia, initial position of the elastic nails; *b* at the end of the fixation period, bone fusion; *c* after removal of the external fixation device; *d* 14 months after removal of the external fixation device, bone callus remodeling

In all patients, lengthening and deformity correction were progressive and were initiated on days 5–7 after the operation. Associated deformities were corrected gradually. Upon achieving consolidation (X-ray picture and clinical test), the device was removed and a plaster cast was applied for 3–4 weeks. All complications and treatment outcomes were classified according to the Lascombes system [29]. Treatment results were classified retrospectively, 10–12 months after removal of the device, depending on the obtained lengthening magnitude and the complications that arose, the treatment performed and their impact on the final result. In each group and subgroups, we analyzed factors that could affect the EFI (the number of days of external fixation divided by the lengthening measured in cm), complications and the outcome of treatment:

— age;
— magnitude of elongation (cm and % of the original length of the segment);
— ratio of the diameter of the nail to the diameter of the narrowest part of the medullary canal;
— ratio of the diameter of the nail to the internal distance between the cortical plates at the level of osteotomy;
— type of elastic intramedullary nails used (HA-coated or not).

Subgroup data were compared for EFI, complication risks, and treatment outcomes.

Statistical analysis was performed using AtteStat 12.0.5 software. Means, standard deviations, and ranges were used to describe continuous variables. The nonparametric Mann – Whitney test was used to compare parameters of age, lengthening, nail diameter/intramedullary canal ratio, or osteotomy site diameter in subgroups. Differences in the frequency of patients' gender were assessed between subgroups using the chi-square test. The Post-hoc Conover test was used for subgroup comparisons (Ti nails vs Ti HA-coated nails) for differences in mean values of EFI as the dependent variable. Two-way analysis of variance was used to evaluate the simultaneous effect of nail types (the first determinant) and one of the quantitative parameters (the second determinant: age, amount of elongation, nail/medullary canal ratio, nail/osteotomy internal diameter ratio), classified into ordinal categories EFI. Spearman's rank correlation coefficient was used to assess the correlation between continuous measures in each subgroup. Significance was set at $p < 0.05$ for all comparative statistics.

The study was conducted in accordance with the ethical standards of the Declaration of Helsinki of the World Medical Association "Ethical Principles for Scientific Medical Research Involving Human Subjects" as amended in 2000, and the "Rules of Clinical Practice in the Russian Federation" approved by Order of the Ministry of Health of the Russian Federation dated June 19, 2003 No. 266. Patients or parents of patients, authorized employees of social institutions confirmed their consent to conduct the study and publish the results without personal identification.

RESULTS

Demographic data (age, gender), the affected segment and type of surgical intervention, the lengthening magnitude, the relationship between the diameter of the nail and the radiographic parameters of the medullary canal, as well as the EFI value are reflected in Table 1 and Table 2 (values are given as mean and standard deviation, range in parentheses). Within the groups, we did not find a statistically significant difference between lengthening using non-coated or HA-coated Ti-nails in mean age, gender, lengthening value, the ratio between the diameter of the nails and the medullary canal at the narrowest point or the osteotomy site. Moreover, the average values of EFI in the subgroups of non-coated or HA-coated Ti-nails compared with similar types of elongation (F-group or T-group) were not significantly different.

Table 1

Demographic, clinical and radiographic data of the femoral lengthening group

Parameter	Subgroup F-Ti (n = 16)	Subgroup F-HA (n = 15)	p-value
Age (years)	16.7 ± 5.8 (7.6 – 32.6)	16.1 ± 7.3 (7.3 – 24.2)	0.916^{mw}
Female to male ratio	8/8	7/8	0.928*
Lengthening (cm)	4.5 ± 1.7 (3.0 – 7.1)	4.7 ± 1.8 (2.5 – 6.5)	0.820^{mw}
Lengthening (%)	11.4 ± 4.1 (6.9 – 21.4)	12.6 ± 4.9 (6.2 – 23.6)	0.661^{mw}
Ratio of the nail diameter to the narrowest part of bone marrow canal	0.18 ± 0.08 (0.11 – 0.26)	0.18 ± 0.06 (0.07 – 0.25)	0.547^{mw}
Ratio of the nail diameter and internal distance between the cortices at the osteotomy level	0.11 ± 0.04 (0.05–0.22)	0.10 ± 0.04 (0.06–0.13)	0.822^{mw}
IEF (days/cm)	26.5 ± 9.2 (19.1 – 42.9)	28.1 ± 6.2 (20.4 – 39.3)	0.713^{mw}

Note: ^{mw} — Mann – Whitney тест; * — chi-square test.

Table 2

Demographic, clinical and radiographic data of the tibial lengthening group

Parameter	Subgroup T-Ti (n = 17)	Subgroup T-HA (n = 16)	p-value
Age (years)	15.7 ± 7.9 (6.1 – 31.8)	16.3 ± 3.4 (10.7 – 24.5)	0.34^{mw}
Female to male ratio	8/9	7/9	0.67*
Lengthening (cm)	3.5 ± 0.91 (2.0 – 5.5)	4.0 ± 1.3 (2.5 – 6.0)	0.058^{mw}
Lengthening (%)	12.9 ± 3.23 (6.7 – 14.6)	14.7 ± 4.45 (6.0 – 21.7)	0.188^{mw}
Ratio of the nail diameter to the narrowest part of bone marrow canal	0.21 ± 0.044 (0.15 – 0.28)	0.21 ± 0.08 (0.11 – 0.30)	0.565^{mw}
Ratio of the nail diameter and internal distance between the cortices at the osteotomy level	0.11 ± 0.03 (0.08 – 0.19)	0.1 ± 0.03 (0.05 – 0.13)	0.472^{mw}
IEF (days/cm)	34.9 ± 9.6 (23.2 – 48.8)	32.7 ± 7.65 (23 – 44.3)	0.285^{mw}

Note: ^{mw} — Mann – Whitney test; * — chi-square test

The Conover test did not reveal a statistically significant effect of the type of intramedullary nails on the EFI in the subgroups. The F-statistic was 0.363 with p = 0.342 for femoral lengthening and 1.063 for tibia lengthening with p = 0.157. However, two-way ANOVA revealed a significant simultaneous effect of the nail type and nail diameter/medullary canal diameter ratio on EFI in femoral lengthening (p = 0.029). The effect of nail type on EFI during tibia lengthening was associated with the ratio of nail diameter/internal diameter at the osteotomy site (p = 0.021). Moreover, this test showed that the effect of nail type (non-coated vs. HA-coated Ti-nail) on EFI depended on the nail/internal diameter ratio at the osteotomy site in the T-G group (p = 0.029).

The relationship between treatment parameters and EFI determines a significant negative correlation of the elongation value (both absolute and expressed in %) with EFI both for elastic HA-coated nailing in femur lengthening, and for elastic titanium nail in tibial lengthening (Table 3). Moreover, Spearman's rank correlation coefficient demonstrated a statistically significant positive correlation between the nail diameter/internal diameter ratio at the osteotomy level and EFI in tibial lengthening (T-HA subgroup) and a significant positive correlation between age and EFI in the F-HA subgroup.

Table 3

Significant correlations between the studied parameters and EFI (Spearman coefficient)

Parameter		EFI value	p-value
Femur lengthening (subgroup F-HA)	cm	−0.509	0.031
	%	−0.558	0.018
Tibial lengthening (subgroup T-Ti)	cm	−0.589	0.017
	%	−0.565	0.022
Relationship between the nail diameter and the internal distance between the cortical plates at the level of osteotomy (subgroup T-HA)		0.776	0.008
Age (subgroup F-HA)		0.549	0.025

The severity and incidence of complications encountered are shown in Table. 4. One patient had concomitant complication: wire breakage and subsequent secondary displacement, which frame adjustment under general anesthesia. There was a case of premature bone consolidation that required reosteotomy. In another case, external migration of an intramedullary and uncoated with HA nail occurred, which required its premature removal. In 48 patients, intramedullary nails were removed within 4 to 13 months after removing the external fixator.

Table 4

Complications

Type of complication	Femur lengthening				Tibial lengthening			
	F-Ti		F-HA		T-Ti		T-HA	
	N	%	N	%	N	%	N	%
Superficial infection	2	12.6	3	20.1	3	17.7	2	12.6
Wire-tract osteomyelitis	–		1	6.7	–		–	
Parasthesia, transitory paresis	–		–		1	5.9	1	6.3
Wire breakage	1	6.3	1	6.7	–		–	
Secondary fragment displacement	–		1	6.7	1	5.9	–	
External migration of an elastic intramedullary nail	1	6.3	–	–	–		–	
Premature bone union	–		1	6.7	–		–	
Fracture after external frame removal	1	6.3	–	–	–		–	
Persistent knee contracture	–		1	6.7	–		–	

A complication of deformity in the lengthening zone, which required unscheduled surgical intervention after removal of the device, was observed in one case in group F(subgroup F-Ti). In two cases of secondary displacement, unscheduled operations were performed for apparatus adjustment with additional wire/half-pin insertion. In one case, the complication was wire breakage (F-HA subgroup), in the second case it was instability of the proximal support on the tibia (T-Ti subgroup).

We did not observe any cases of intramedullary elastic nails blockage with wires or half-pins of the external fixator during the distraction stage. In 10 cases, peri-wire infection was successfully treated with oral antibiotics. In only one case of wire infection, the complication was associated with thermal necrosis of the bone and required curettage 2 months after removing the device. The range of motion in the knee or ankle joint was restored in 63 patients at the last follow-up examination. Temporary paralysis of the peroneal group was noted in two cases. Subsequently, the nerve function was completely restored after conservative treatment.

Evaluation of the results according to the Lascombes classification (Table 5) after a year showed that the triad of the conditions (planned lengthening value, duration of external fixation and functional recovery) was achieved in 60 patients (93.8 % of cases). In three cases, the EFI was more than 45 days/cm (46.3, 46.4 and 48.8 days/cm).

Table 5

Results of lengthening

Category	Femur lengthening		Tibial lengthening	
	F-Ti	F-HA	T-Ti	T-HA
I	14	11	14	16
IIa	–	2	1	–
IIb	2	1	–	–
III	–	1	3	–

The radiographic analysis showed that the consolidation index in these cases was lower than 45 days/cm. Since these patients did not show delayed consolidation, the increased EFI should be attributed to delayed removal of the external fixator caused by problems other than the lengthening process. However, we classified these three outcomes as grade IIIa. We also classified one case of persistent extension contracture of the knee joint after femoral lengthening as category III results, which required a quadriceps muscle release operation in combination with knee arthrotomy in the long term.

DISCUSSION

Shortening of one of the lower extremities, including due to acquired etiology, even if it seems insignificant, may cause the development of secondary pathology. Length discrepancy of more than 1 cm changes the biomechanics of movements, leading to scoliotic deformity of the spine, gait disorders and early deforming arthrosis of large joints [30–33]. The difference in leg length, which affects standing posture, gait balance, and pelvic balance, needs to be corrected [34]. The development of a new generation of motorized intramedullary extension nails enables to perform limb lengthening, providing precise control of the distraction mode, and avoiding the inconvenience of external fixation [1, 10, 12, 13]. However, open growth plates, the severity of the deformity, history of bone infection, and small diameter of the medullary canal significantly limit the use of such devices [13, 35, 36]. The literature reports recommend the external fixation method for limb lengthening and correction of severe deformities of acquired etiology [11, 13, 37–40].

Lengthening with external fixation devices is a complex procedure with a long treatment period. There is a significant risk of complications, including septic complications, an increase in the consolidation index, delayed bone healing and fractures after removal of the device [16, 19, 22, 29, 41–43]. Over the past twenty years, progress in limb lengthening with external fixators has been aimed at reducing the duration of external fixation and reducing the number of complications. Thus, stimulation of the regenerate with low-intensity pulsed ultrasound reduced the consolidation index from 45 days/cm to 33 days/cm according to the results of a study by Salem et al. [8] and from 48 days/cm to 30 days/cm according to the results of a study by El-Mowafi et al. [7]. Their small samples represent the results of limb lengthening in patients with acquired shortening.

Many authors note that the average external fixation index is lower during limb lengthening in patients with acquired pathology than in patients with congenital shortening. Ganger et al. [3] noted that the EFI is 2.1 months/cm for femoral lengthening and 2.8 months/cm for tibia lengthening. In a study by Antoci et al. [14] the average value was 32 days/cm; no significant difference was observed with the results of lengthening in congenital shortenings. Nakase et al. [44] reported an index of 1.45 months/cm in patients with an elongation of at least 2 cm, and Horn et al. [11] reported an index of 2.0 months/cm (range 0.8–6.0 months/cm) in patients with acquired limb length difference. Our study showed that the average values of EFI for combination with intramedullary reinforcement are lower than in the above studies.

In our previous study, the consolidation index was significantly lower with the use of intramedullary elastic nails, on average 7 days/cm, compared with the traditional Ilizarov method [45]. Saraph et al. [46] used two curved Ender nails to lengthen the tibia and found the advantages of stable osteosynthesis, a lower rate of infectious complications compared to the traditional technique, as well as the ability to prevent fractures and deformity of the lengthened tibia. Lampasi et al. [24] did not encounter any secondary displacements during the distraction phase, nor the development of infection and fractures after removal of the nail in femur lengthening with a monolateral fixator and elastic intramedullary reinforcement. Moreover, they reported two cases of premature consolidation due to intensive formation of distraction regenerates. Bukva et al. [22] and Launey et al. [19] also showed the effectiveness of using elastic intramedullary nailing to reduce the consolidation index during limb lengthening and reduce the risk of complications and fractures after removal of the device. Launey et al. [21] highlight the benefits of using intramedullary nails to prevent secondary displacement during lengthening of small diameter bones, particularly the forearm.

It has been proven that elastic intramedullary nails coated with hydroxyapatite promote bone formation and ensure osseointegration by stimulating osteogenic activity in the medullary canal [28, 47]. The purpose of this study was not only to demonstrate the features of a combined technique for lengthening the tibia and femur in patients with acquired limb length discrepancy, but also to compare the effect of bioactive titanium elastic intramedullary nails on treatment results, and thereby to evaluate the influence of demographic and specific mechanical factors on bone union during distraction osteosynthesis and, accordingly, on the outcome of treatment.

Regarding the impact of age and lengthening magnitude, our results are consistent with those published by Fischgrund et al. [48] and Koczewski et al. [42]. Age has a significant impact on the timing of consolidation. In children, bone union occurs faster than in adult patients. In our study, the age-EFI correlation was statistically positive in the subgroup with femoral lengthening using HA-coated nails. In contrast to age, based on the lengthening value (cm or %) we determined a negative significant correlation with EFI (in the subgroup of femoral lengthening using HA-coated nails and in the subgroup of tibial lengthening using titanium intramedullary nails). These data suggest that the factors that have an effect on bone consolidation time during lengthening using the combined technique are similar to those with the traditional Ilizarov lengthening technique. Since these correlations are present in combined lengthening, it may be concluded that the biological conditions of the Ilizarov method for bone consolidation are preserved in the conditions of elastic intramedullary reinforcement.

As for EFI for different types of intramedullary nails (titanium vs. titanium with composite hydroxyapatite coating), we did not find any significant differences. We assume that in the patients with acquired shortening, included in the study, without abnormal bone tissue regeneration, mechanical stimulation of bone formation is sufficient to ensure consolidation of the lengthened bones over a period of similar duration. In practice, there have been no obvious advantages in using intramedullary nails with osteoinductive hydroxyapatite coating in comparison with titanium rods for regeneration of bone tissue without compromised histogenesis. On the other hand, the impact of intramedullary nail diameter on the biological properties of bone regeneration during limb lengthening has only been partially revealed. Our study revealed a positive significant correlation between the ratio "rod diameter / internal distance between cortical layers at the osteotomy site" in the T-HA subgroup. This result, in comparison with the significant impact of the type of nails and the ratio of "rod diameter / diameter of the medullary canal or internal diameter at the osteotomy site" on the EFI, revealed using two-way analysis of variance, means that both factors (diameter and type of elastic nail) should be considered together in future clinical and experimental studies.

In our study, we did not observe delayed formation and maturation of the distraction regenerate. As for complications, a fracture occurred only in one case at the site of lengthening after removal of the device. Danzinger et al. noted two cases of fractures after removal of the device in five patients with post-traumatic deformities [49]. Stanitski et al. described the development of deformity at the site of lengthening after removal of the apparatus in six cases out of 62 patients who had their tibia lengthened using the Ilizarov apparatus [50]. Ganger et al. [3] described the deformity at the site of lengthening after removal of the device in one patient (4.5 %). In contrast to these data, Horn et al. [11] found no fractures or other serious complications during leg lengthening in patients with acquired limb shortening.

It should be emphasized that there are specific complications of lengthening associated with the use of intramedullary elastic nailing: migration of intramedullary nail (1 case) and premature bone union (1 case). In this series of patients, they were treated surgically without consequences (Fig. 3).

In summary, the treatment results in our patients were achieved without deterioration in the function of the limb in 63 out of 64 cases. Treatment results were assessed as good or excellent in all cases. Limitations of this study are related to a small patients' sample, heterogeneity of the series, and patients with only a moderate difference in limb length were included in the study. However, it should be noted that in other series of lengthening in acquired pathologies of the lower extremities, the patient populations were usually heterogeneous [7, 11, 14, 22].

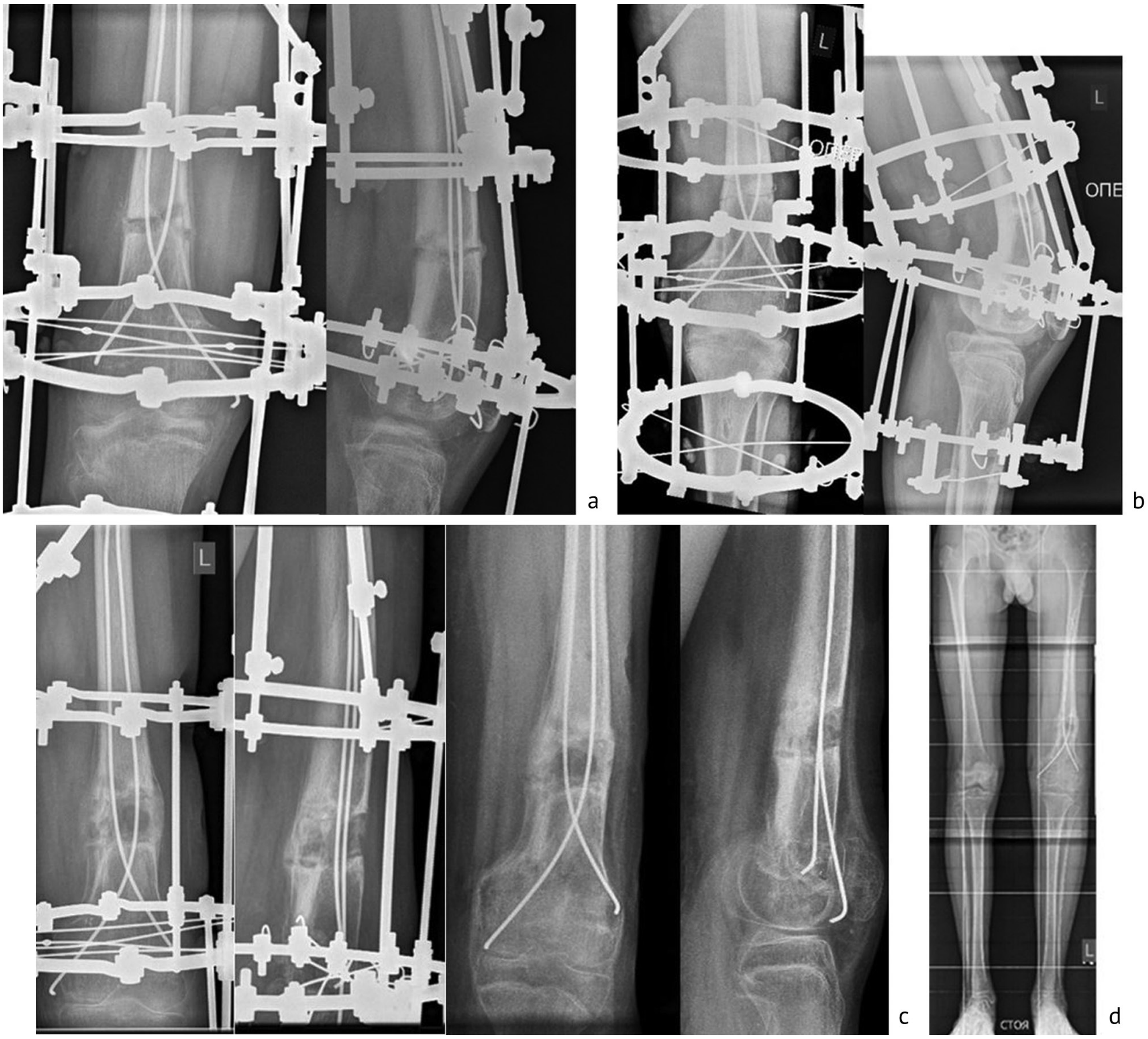

Fig. 3 Radiographs of femoral lengthening case complicated by premature consolidation, patient of the F-HA subgroup: *a* distal femoral osteotomy, retrograde nailing; *b* premature consolidation (radiography on the 21st postoperative day), requiring reosteotomy; *c* at the end of the fixation period, bone consolidation, the device is removed; *d* 40 days after removal of the external fixation device

CONCLUSION

Our prospective study showed that limb lengthening using both elastic titanium nails and composite HA-coated nails provides good to excellent results in femoral and tibia lengthening in patients with acquired lower limb length discrepancy. The use of the technique reduces EFI and the risk of complications, including severe ones, in comparison with traditional techniques without the use of intramedullary elastic nails. In acquired limb shortening and not associated with pathologically altered bone tissue, there were no differences in EFI between the use of intramedullary titanium nails and HA-coated titanium nails. The positive and significantly high correlation between nail diameter/internal distance between cortices at the osteotomy site and EFI, as well as the significant influence of nail type and nail diameter on EFI, means that both factors (diameter and type of elastic intramedullary nail used) should be considered together in future research.

Conflict of interests *None*

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