

Original article

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Automated 24-hour control of distraction forces: a new technology for limb lengthening

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Abstract

Introduction The classic Ilizarov technology of transosseous distraction osteosynthesis provides rigid fixation, accurate bone control in frontal and sagittal planes addressing all types of deformities and the limb length. Long-term Ilizarov fixation can be associated with adverse events and distraction forces are to be monitored. A new technology for limb lengthening using automated 24-hour control of distraction force facilitates optimal rate of deformity correction and can reduce Ilizarov fixation when combined with intramedullary titanium pins with a bioactive coating.

The **objective** was to demonstrate continuous distraction force control technology in the correction of varus deformity of the tibia and anatomical lengthening.

Material and methods Simultaneous tibial lengthening and correction of tibial deformity was produced with a new automated distractor (patent RU No. 2763644) measuring forces of the external fixation device every time with the gearbox switching on.

Results and discussion Continuous distraction force control was well illustrated in an Ilizarov patient treated with combined distraction osteosynthesis. The use of the device was associated with a shorter bone consolidation time (IO = 15 days/cm) after sequential distraction osteosynthesis with genu varum eliminated and the bone lengthened.

Conclusion Dynamic distraction force control with a new automated device allowed for monitoring the lengthening process, identifying potential complications, adjusting the distraction rate, reducing osteosynthesis time by two to four times.

Keywords: limb lengthening, tibial deformity, Ilizarov apparatus, transosseous automated distraction apparatus

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INTRODUCTION

It is generally recognized that a reliable solution to the problem of limb deformity correction and segment lengthening was found with the Ilizarov apparatus developed in the mid-20th century, which remains the primary tool in the hands of experienced orthopedic and trauma surgeons. Since first publication, significant changes have occurred in the external fixation device and in surgical techniques. The fixation unit (the shape and material of the supports with connecting elements, the protective coating with anti-inflammatory and bioactive elements), the transport and angular correction units (rods, hinges, long connection plates) have been improving with the invasiveness of surgical interventions decreasing [1–13]. By improving the limb lengthening process, orthopedic surgeons from different countries approached the need to automate the process, which resulted in automatic transport units developed for external fixation devices with a fixed [14–16] first, and then adjustable lengthening rate [17]. The innovation allowed for deformity correction and limb lengthening to be produced simultaneously [13, 18]. The intention to identify a reliable optimal operating rate for the units led to the creation of autodistractors capable of measuring distraction forces to control the process of reparative osteogenesis [19].

The **objective** was to demonstrate continuous distraction force control technology in the correction of genu varum and anatomical lengthening.

MATERIAL AND METHODS

The Ilizarov external fixation device with three automatic distractors has been used for distraction osteosynthesis and was patented as the transosseous automated distraction apparatus (RU patent no. 2763644 C1 “Transosseous automated distraction apparatus and automated transportation unit”, manufactured by the Kurganpribor plant, Fig. 1) [20]. The frame can provide gradual, round-the-clock operation of the transportation units.

The software controls the process of almost unlimited limb lengthening from 0.15 mm/day with 0.025 mm increments with each motor activation, and receives data on distraction times, lengthening rate, distraction forces applied to each rod of the external fixation device, and dynamics of the total distraction forces with the frame over the required period of time (forces are measured with each motor activation).

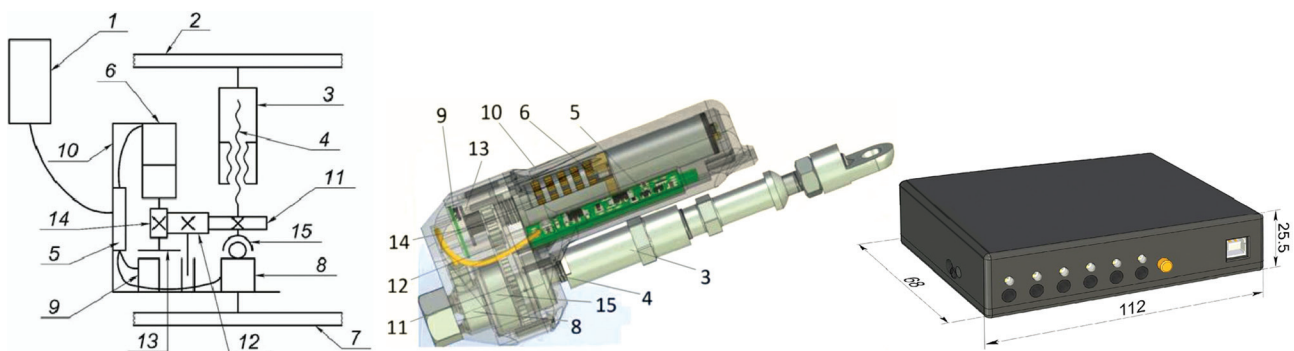


Fig. 1 Diagrams and photos of the transosseous automated distraction device and automatic transportation unit [20]

The transosseous automated distraction device comprises supports connected by automated transportation units, each incorporating a housing, a geared motor electrically connected to a controller, and a lead screw with a nut. The automatic transport unit is configured with a gear transmission connecting the lead screw and the geared motor. The lead screw nut is made of a cold-flowing, antifriction fluoropolymer and installed with end-on tightening. Mounted within

the housing is a sector disk secured to one of the gears of the gear transmission and the rotation sensor, electrically connected to the controller. The controller is located within the housing of the automatic transportation unit. A longitudinal force sensor is installed at the lead screw attachment point and electrically connected to the controller. Gradual transport of the rings of the external fixation device is achieved by reducing the apparatus's weight and dimensions providing feedback in the form of monitoring the forces at the lead screw attachment point [20].

Clinical observation methods are represented by radiological monitoring of reparative bone regeneration using the Shimadzu Sonialvision 4 system (Japan).

A titanium implant of two hydroxyapatite-coated wires, 15 cm long and 1.8 mm in diameter, was placed intramedullary into the tibia to stimulate bone formation. The implant was coated at the Tomsk Polytechnic University using the MAO (microarc oxidation) technology [21]. Hydroxyapatite (Fluidinova, Portugal) was used as a component for the production of composite materials.

A *clinical example* demonstrates correction of genu varum in a 65-year-old patient diagnosed with congenital varus deformity of the tibiae of 20° , stage 2 gonarthrosis. The procedure was performed using transosseous distraction osteosynthesis with the Ilizarov external fixator in automatic mode. The patient suggested that the deformities (Fig. 2a) had been present since birth and had dreamed of correcting them his entire adult life. The patient developed moderate pain in his knee joints in the last 2–3 years. His physically active lifestyle as a military service member allowed him to run, swim and hike regularly. The surgery performed 09.07.24 included subcondylar partial corticotomy of the left tibia, combined osteosynthesis of the tibia with the Ilizarov apparatus.

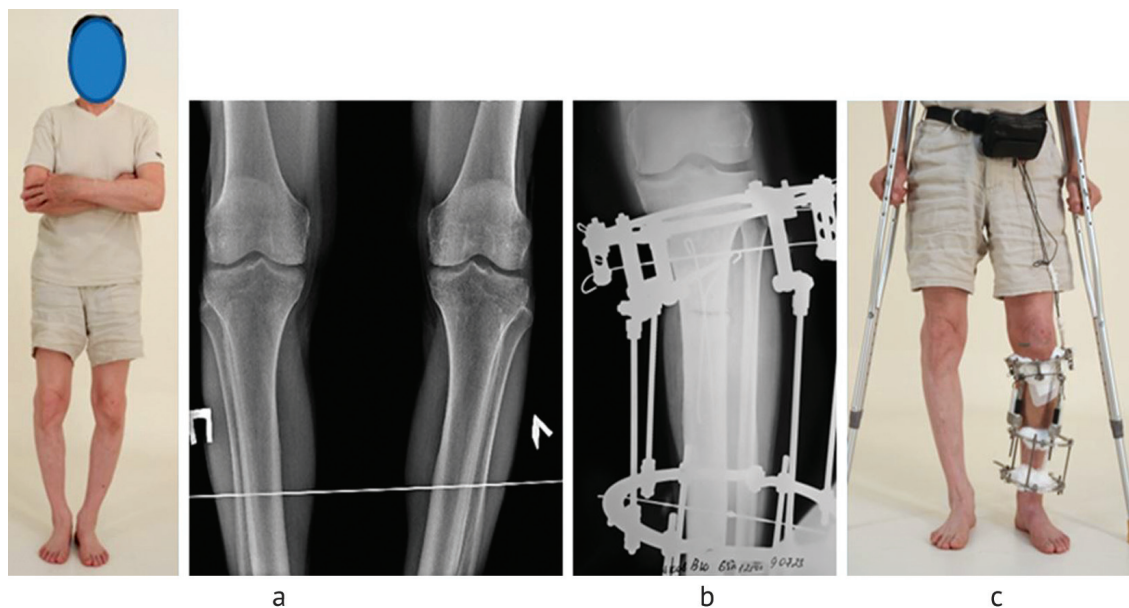


Fig. 2 Photograph and radiographs of the patient before treatment (a); postoperative radiograph of the left tibia (b); photo of the patient during automated lengthening of the tibial bones and simultaneous correction of the deformity (c)

The surgery started with the intramedullary insertion of a bioactive hydroxyapatite (HA)-coated implant. Using a 5-mm-diameter burr, oblique holes (one each on the lateral and medial aspects of the bone) communicating with the medullary canal were created in the cortex of the proximal metaphysis of the bone to be lengthened through pre-existing soft tissue punctures. Two bioactive HA-coated pins were inserted through the holes. With the pin entered the canal to the specified depth, the excessive length of the pin was cut off, the end bent and inserted under the fascia of the limb segment [22].

With implant inserted, the soft tissues were sutured tightly, and transosseous osteosynthesis of the tibia was performed using the Ilizarov external fixator and a standard technique that allowed for simultaneous tibia lengthening and deformity correction. At the final stage of the surgery, a narrow, 6 mm-wide chisel was used to perform a partial corticotomy at the apex of the tibial deformity, ensuring maximum bone preservation at the lateral aspect. The wounds were sutured tightly, aseptic dressings applied, a control radiograph produced and the frame systems stabilized (Fig. 2b). Fibula was osteotomized in the lower third.

RESULT

The deformity was gradually corrected postoperatively under the constant control of the distraction forces of the Ilizarov frame. Three automated distractors were placed postoperatively (the leading distractor locating along the medial aspect of the tibia, two supporting distractors being along the anterior-lateral and postero-lateral aspects of the tibia) in such a way that the hinges were projected at the level of the continued bisector of the genu varum angle [23]. Distraction was performed at a rate of 1 mm/day along the leading rod (0.025 mm in 40 increments per day) following a seven-day latency. The patient was encouraged to walk with crutches bearing weight on the operated leg (Fig. 2c). Dynamic, rapid increase in the distraction forces to 200N allowed the doctor to increase the distraction rate to 3 mm/day after two days (Fig. 3); the level of distraction forces continued to gradually increase over the course of a week.

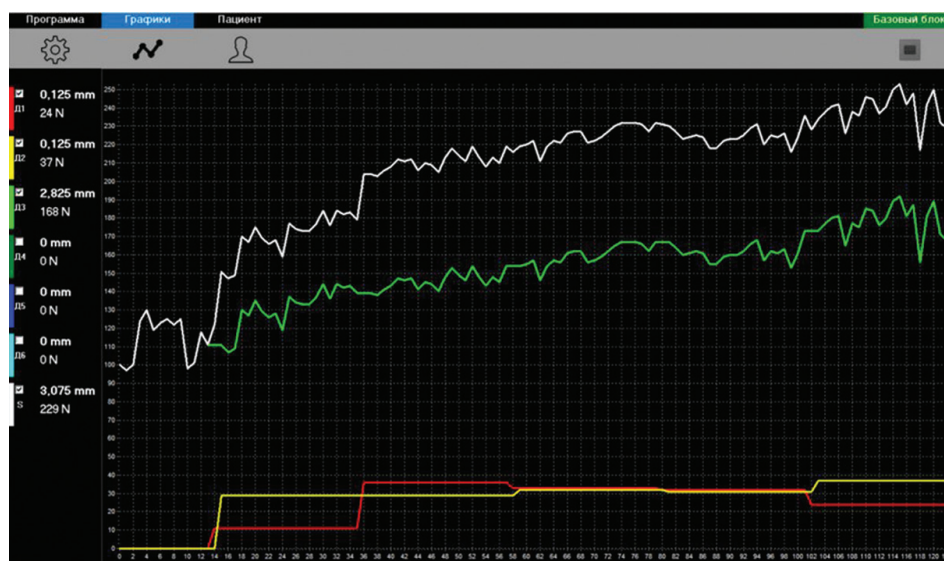


Fig. 3 Dynamics of distraction forces in the first six days of lengthening: the green graph showing dynamics in the forces with the leading autodistractor, the red and yellow colors demonstrating dynamics of the forces with the supporting rods of the frame, the white graph reflecting dynamics with the total force exerted by the Ilizarov external fixator

The continued dynamic increase in distraction forces indicated the preservation of the direct connection between the bone fragments due to the periosteum at the lateral aspect. A clicking sound the patient heard after 7-day distraction (July 22, 2024) with the functioning distractor was accompanied by moderate pain. The attending physician reported no Ilizarov maladjustments. Measured distraction forces suggested they dropped sharply to 20 N after reaching 290 N indicating disruption in the bone (Fig. 4).

Based on accurate clinical, radiographic and biomechanical data, distraction was discontinued for two days and restarted at a rate of 1 mm/day with daily monitoring of distraction forces. Subsequent dynamic monitoring revealed a gradual increase in distraction forces to 190 N. Concurrent

clinical monitoring indicated gradually completed correction of genu varum and distraction was discontinued on July 31, 2024 with the intended objective achieved (Fig. 5).

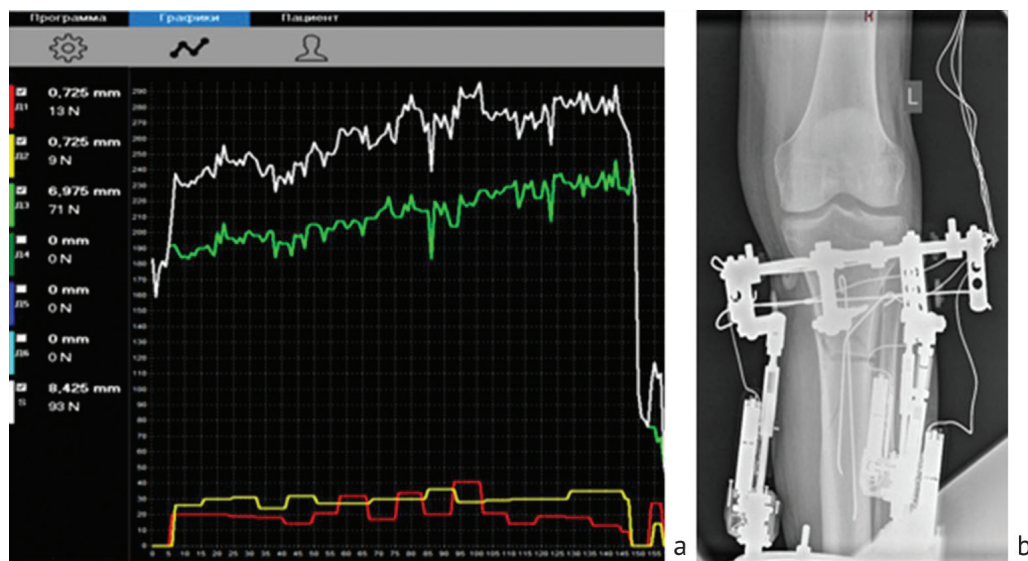


Fig. 4 Dynamics of distraction forces with a sharp drop in the resistance level (a); control radiograph of the left tibia on the day of the disruptive event in the distraction forces (b)

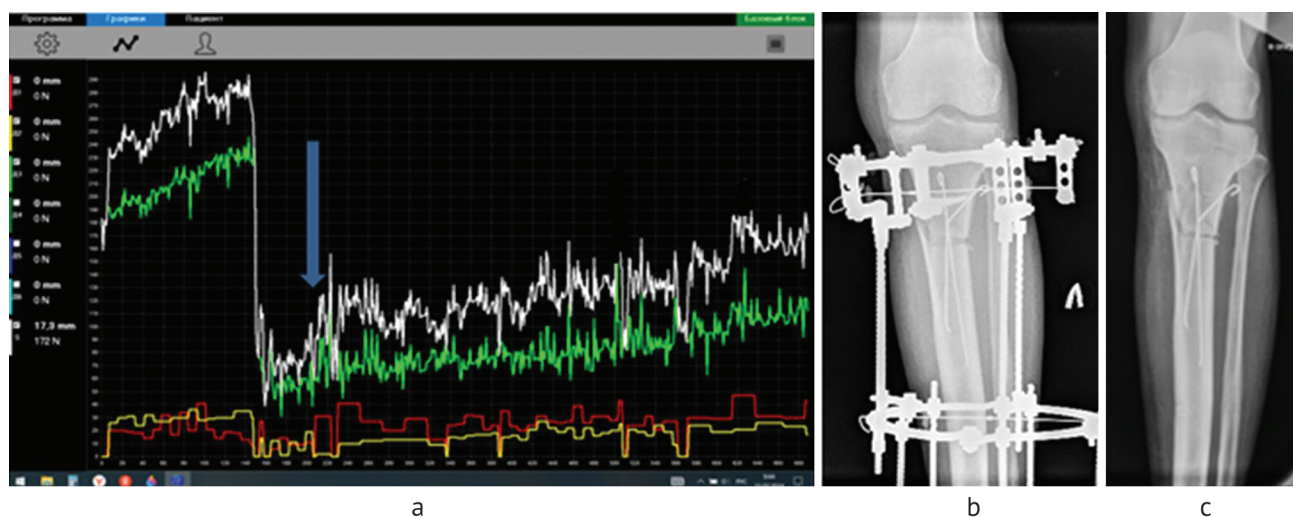


Fig. 5 Dynamics of distraction forces recorded on 31.07.24: the arrow indicates the re-start of lengthening along the leading rod (a); control radiograph of the left tibia on the day of accomplished distraction period (b) and on the day the external fixation device was removed (c)

Two weeks later, the Ilizarov apparatus was removed following a clinical consolidation test. The overall osteosynthesis index (OSI) was 15 days/cm (Fig. 5c). The functional length of the left limb exceeded that of the right limb by 4 cm after correction of the deformity; there was no swelling, and skin sensitivity was preserved. Range of motion in the ankle joint was unlimited, and measured within 120° in the knee joint. A clinical consolidation test revealed no mobility in the distraction regenerate site and the patient could gradually increase weight-bearing while walking and consider another surgery to correct genu varum on the right.

The surgical technique used on the right tibia was identical to that used on the left tibia (Fig. 6a). Distraction using the leading distraction rod was initiated at a seven-day latency. The dynamics of distraction forces reflected a gradual increase in the resistance of the elongated tissues from 10

to 200 N suggesting the bone integrity (Fig. 6a). A radiograph of the tibia bones demonstrated relatively rapid bone consolidation after deformity correction (Fig. 6b). The Ilizarov fixation of the right tibia lasted 21 days, which generally corresponded to the osteosynthesis index of 22 days/cm.

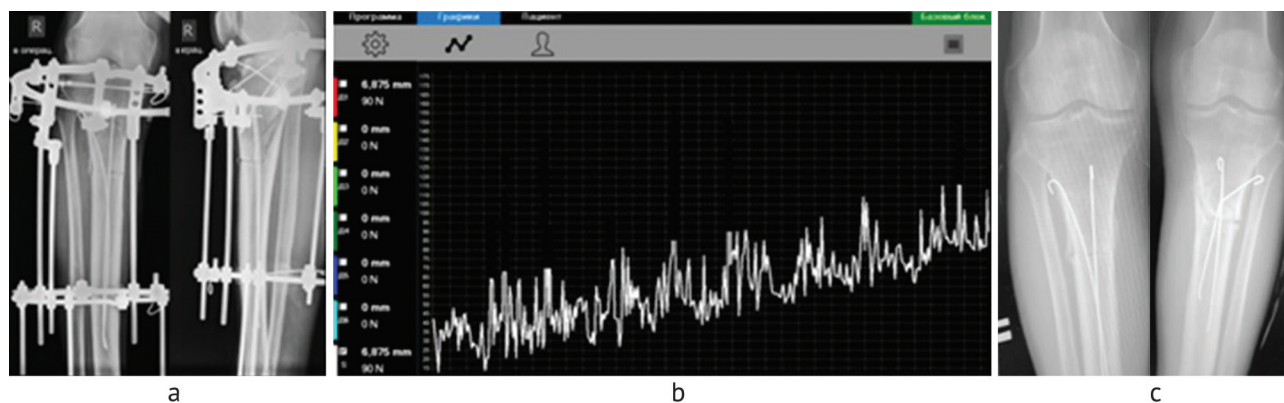


Fig. 6 Radiographs of the right tibia on the day of surgery (a), dynamics of distraction forces during correction of genu varum on the right side (b), radiographs of both tibiae after the treatment completed (c)

One month after removal of the external fixator, the patient could walk with full weight-bearing using no additional supporting devices with his limb length being equal. His range of motion in the knee joint measured 120° with the limb alignment being satisfactory for the patient.

Therefore, the autodistractor with force control used in combination with intramedullary implants coated with hydroxyapatite can provide optimal conditions for distraction regeneration, and increased bone formation activity is manifested in the formation of a distraction regenerate bone, accompanied by a pronounced periosteal reaction and increased cross-sectional area of the bone.

DISCUSSION

The new transosseous automated distraction device [20], unlike other autodistractors, is capable of controlling distraction forces. Data is collected on a control unit. The data are transmitted to a dedicated computer application [19], which analyzes the distraction force data and sets the distraction rate. The new technology allows for the correction of segmental deformities and restoration of the required limb length maximizing the potential for reparative osteogenesis. The new device provides monitoring of the dynamics of distraction forces to facilitate identification of incomplete bone osteotomy, premature bone consolidation, regenerate ossification and regenerate rupture. There is a considerable difference between the new distraction device assisting early detection of adverse events and the autodistractor developed by Shevtsov, Burlakov and Nemkov [24, 25] and have long been used in clinical practice.

We have previously shown that automatic high-fraction distraction can provide optimal conditions for reparative osteogenesis, and endosseous implants with a hydroxyapatite coating additionally stimulate the process and allow an increase in the distraction rate to 3 mm/day [26]. The overall duration of osteosynthesis is significantly reduced: IO = 2–3 days/cm during lengthening of the tibia in large experimental animals and IO = 15 days/cm in clinical settings.

CONCLUSION

Dynamic control of distraction forces with the new automated distractor allows for monitoring the lengthening process and promptly diagnosing potential complications, adjusting the distraction rate to the optimal level and reducing osteosynthesis time by two to four times

compared to international literature data. The use of the new automated distractor helps reduce the incidence of complications associated with prolonged limb fixation using the Ilizarov external fixation device.

Conflict of interest None of the authors has any potential conflict of interest.

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Protocol of the Ethics Committee No. 1(76) dated November 29, 2024.

The patient's consent for publication of the findings was obtained and recorded in the patient's medical history.

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