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ORIGINAL ARTICLE

Estimation of Patient Dose and Associated Radiogenic Risks from Limb Lengthening

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Abstract Limb-lengthening procedures include a series of radiographic examinations to follow the lengthening process and callus formation. We quantified ionizing radiation exposure during lengthening treatment and estimated the risks associated with this exposure in 53 patients undergoing lengthening procedures. Field size and tube voltage of all radiographs and fluoroscopy time during surgery were recorded. According to conversion factor tables of organ doses, the cumulative organ dose was estimated. Location of lengthening, age, complications during lengthening procedure, range of lengthening, healing index, and other factors affecting the duration of the lengthening procedures were analyzed. Average lengthening was 4.8 cm (range, 3.0–12.5 cm). The average cumulative organ dose for a straight lengthening procedure was 3.1 mSv (range, 0.2–12.5 mSv). The average organ dose per centimeter of lengthening was 0.7 mSv/cm (range, 0.03–5.9 mSv/cm). Doses for patients with tibial lengthening (0.3 mSv/cm) were less than doses for patients with femoral lengthening (1.1 mSv/cm). Age, complications, range of lengthening, and healing index did not influence the dosage of radiation per centimeter lengthening. We judge the average patient's exposure during a limb-lengthening procedure as tolerable, but femur lengthening results in a higher cumulative organ dose.

Level of Evidence: Level II, prognostic study. See the Guidelines for Authors for a complete description of levels of evidence.

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Introduction

In distraction osteogenesis based on the Ilizarov method, corticotomy is performed and an external fixator is applied [6, 7]. After the corticotomy, the new bone grows centripetally from each corticotomy surface toward the central fibrous interzone [1].

Persistent monitoring during callus distraction is essential for successful treatment [3, 7, 11]. Because a radiograph offers only a two-dimensional view, most radiographic examinations are made to display two planes perpendicular to one another. Only standardized radiographic techniques enable a comparative and reproducible analysis of morphologic callus changes. The preliminary stage of the new bone can be viewed only through intensifying screens and digital radiographs, because conventional radiographs produce poor images. Apart from assessment of clinical developments that include range of movements of adjoining joints, radiographic examinations are essential to monitor progress and identify problems [3, 11].

Depending on the location of the osteotomy and the lengthening, the organ dose varies as a result of the different radiation sensitivity of organs (eg, uterus, testis, bone marrow, skeleton, colon). The organ dose also depends on the weight of the patient and amount of

fat, radiographic image format, film focus distance, tube voltage, and duration of intraoperative fluoroscopic examinations [2, 15].

Complications can lead to additional radiographs that expose the patient to unanticipated radiation. In the course of treating patients, we encountered recurring questions regarding the risks of radiographs but we did not know the answers. The International Commission of Radiological Protection (ICRP) has published recommendations on avoiding radiation injuries concerning fluoroscopically guided medical procedures [9]. To compare such data, usually the effective dose will be analyzed [14]. In 1990, the IRCP suggested the "effective dose should not be used directly" [8]. Nonstochastic or deterministic effects include skin erythema, permanent epilation, skin necrosis, and cataract of the eye lens (they do not occur for absorbed doses less than 2 Gy) [9]. However, the effects on humans' subthreshold summation included stochastic effects such as cancer induction and hereditary disorders; they even may be induced by or associated with doses close to zero [12]. The probability of such an effect, rather than its severity, increases with absorbed radiation dose [8, 9, 12]. Radiation exposures commonly occurring during operative lengthening procedures or radiographic examinations (ie, radiographs) are associated with a zero probability for induction of deterministic effects but a nonzero probability for induction of cancer or genetic effects [9].

Therefore, we asked whether the following characteristics influenced the cumulative organ dose in patients who underwent callus distraction to correct leg-length discrepancies and whether they should be part of risk assessment in consultations: (1) age; (2) gender; (3) lengthened bone; (4) planned range of lengthening; (5) speed of consolidation; and (6) complication during treatment that needs intervention (eg, under anesthesia).

Materials and Methods

We retrospectively reviewed the radiographic records of 60 patients who underwent callus distraction to correct leg-length discrepancies between 1990 and 1998. We excluded patients with simultaneous angular deformity corrections. We also excluded seven of the 60 patients because of lack of availability of all radiographs, leaving 53 patients whose data we used for estimation of organ doses. Other than idiopathic leg-length discrepancies, the main diagnoses were: tumors (Ewing's sarcoma, osteosarcoma, enchondroma), osteomyelitis, hip dysplasia, achondroplasia, posttraumatic shortening, Klippel-Trenaunay-Weber syndrome, and Legg-Calvé-Perthes syndrome. The average age of the 53 patients was 14.9 years (range, 5–32 years). Twenty-seven patients (13 males, 14 females) underwent osteotomy and lengthening of the femur, and 26 patients (17 males, nine females) underwent lengthening of the tibia. The average presurgical leg-length discrepancy of the patients was 5.3 cm (range, 3.0–12.5 cm; male, 5.67 cm; female, 5.0 cm).

We used various fixator systems; 40 patients (21 males, 19 females) had unilateral fixators applied (Orthofix™ LRS™ or Orthofix™ GVL™; Orthofix Inc, McKinney, TX). Ten patients (seven males, three females) were treated with an Ilizarov apparatus or Taylor Spatial Frame (TSF)™ and three patients (two males, one female) with the ExFiRe™-System (Ilizarov apparatus; TSF and ExFiRe: Smith & Nephew Inc, Memphis, TN). The average lengthening was 4.8 cm (range, 2.0–9.5 cm) (Table 1).

The following data were collected from the patients' records: age, gender, diagnosis, presurgical limb-length discrepancy, type of fixator, location of osteotomy (tibia or femur), amount of lengthening, duration of appliance of the fixator, healing index according to Paley [3, 8], and occurrence of mechanical complications during the lengthening procedure (eg, premature or delayed consolidation, the need for new anesthesia between applying and removing the fixator).

Field size and tube voltage of all radiographs and fluoroscopy time during surgery were recorded. From the radiographic records, we identified: radiation at surgery (radiograph duration, voltage, radiation diameter, radiation dose per surface area), dates of all radiographs, type of examination, number of images, image format (18 × 43 cm, 18 × 24 cm, 20 × 60 cm, 24 × 30 cm, 30 × 40 cm, 35 × 43 cm, 40 × 120 cm), voltage, and if made in digital or conventional form. The evaluation included all radiographs obtained during the date from surgery (applying of fixator) until the end of the treatment, with followup time of clinical importance (removal of fixator plus 0.5 years). According to conversion factor tables of organ doses taken from technical parameters of typical radiographic techniques of the German Research Center for Environmental Health (www.gsf.de), the cumulative organ dose for each patient was estimated [13]. The dose per lengthened centimeter and the dose per month while wearing the fixator also were calculated. The chosen unit is millisievert (mSv) to point out that it is for the equivalent dose and not for the absorbed energy dose (which commonly is denoted in Gray [Gy]) [2, 14]. Both units are related to 1 J/kg.

We obtained descriptive statistics on age, gender, operated bone, fixator application time, healing index, range of lengthening, amount and place of applied radiographs, total dose, dose per lengthened centimeter, dose per month during treatment, and amount and possible influence of complications. We formed six groups to determine whether the absorbed radiation dose was influenced by the

Table 1. Results with descriptive statistics for 53 patients

Variables	Characteristic groups*	Number of patients	Mean estimated organ dose (mSv)	F-test (variance of the probability distribution of the estimated organ doses in the characteristic groups)	Mean organ dose per month (mSv/month)	Mean organ dose per centimeter (mSv/cm)
Age (years)	Younger, < 14	26	2.6	0.06074	0.4	0.6
	Older, > 14	27	3.5		0.6	0.8
Osteotomy site	Tibia	26	1.2	0.00004	0.2	0.3
	Femur	27	4.8		0.8	1.1
Range of lengthening	Shorter, < 4.8 cm	30	2.1	0.05299	0.3	0.7
	Longer, > 4.8 cm	23	4.3		0.7	0.6
Consolidation†	Faster (< 50 d/cm)	34	3.2	0.43601	0.5	0.5
	Slower (> 50 d/cm)	19	2.7		0.4	1.0
Complications	Yes	23	2.8	0.84645	0.4	0.7
	No	30	3.2		0.6	0.7
All		53	3.06		0.5	0.7
Range		5–32	0.19–17.7		0.03–3.11	0.03–5.9
Standard deviation		6.34	3.72		0.63	1.02

* The characteristic group gender, which did not have any influence (F-test 0.98484), was omitted in the table for clarity; †healing index according to Paley [3, 8]: fast, less than 50 days/cm; slow, greater than 50 days/cm.

following parameters: age (older than 14 years or younger than 14 years), gender (male or female), lengthened bone (femur or tibia), range of lengthening (short [less than 4.8 cm] or long [greater than 4.8 cm]), speed of consolidation according to Paley's healing index (fast [less than 50 days/cm] or slow [greater than 50 days/cm]), and complications (yes or no). To divide the patients into groups for the characteristic groups age, range of lengthening, and healing index, we divided the collective at the mean value. For example, the mean of the range of lengthening was 4.8 cm; thus, we examined if there was a difference in the variance of the probability distribution in the group of patients with less than 4.8 cm lengthening in comparison with the group of patients with 4.8 cm or greater lengthening concerning the cumulative organ dose (with use of the F-test). The null hypothesis was these parameters would not influence the total of organ dose applied during limb-lengthening procedures.

Results

The location of the lengthened bone (femur versus tibia) influenced the absorbed dose; doses for patients undergoing tibia lengthening (0.3 mSv/cm) were four times less than doses for patients undergoing femur lengthening (1.1 mSv/cm) (Table 1). The total organ dose for lengthening procedures at the femur (4.8 mSv) was four times greater than for tibial lengthening procedures (1.2 mSv). The average number of radiographs needed during an entire treatment was 30.6 (nearly equal between femur [32.2] and tibia [28.0]). The average cumulative organ dose for a limb-lengthening procedure on the lower extremity can be estimated at 3.1 mSv (range, 0.19–17.7 mSv). On average, the tibia was examined 14 times and every time two radiographs were taken, resulting in an average of 28.9 radiographs per patient (26 patients). This resulted in an average of six images per lengthened centimeter. When we subtracted the images before and after treatment (after removal of the fixator), we obtained an average of four images per lengthened centimeter during the distraction and consolidation phases. Age and gender of patients did not influence the amount of organ dose for limb-lengthening procedures. Mechanical complications during the lengthening procedure, the range of lengthening, and the healing index also did not influence the applied organ dose (Table 1).

Discussion

Limb-lengthening procedures include a series of radiographic examinations to follow the lengthening process and callus formation. Given the potential for various radiation-related complications, we therefore determined the range of dosages of radiation during the treatment. We then determined whether age, gender, lengthened bone, range of lengthening, healing index, and occurrence of

complications during limb-lengthening procedures influenced the cumulative organ dose as a result of the radiographic examinations.

For readers to properly interpret the study data they realize standardized xray procedures were used to determine the absorbed radiation dose. Many radiologic institutes have requirements from and/or are monitored by external agencies for complying with standardized specifications regarding tube voltage, film-focus distance, etc. We did not verify those specifications and they likely vary from country-to-country. The only way to estimate the cumulative organ dose is to revert to phantom examinations (we used the Monte-Carlo model), as in vivo studies for test purposes cannot be performed owing to high radiation doses that are not ethically justifiable. The goal of our retrospective study was not to determine individually dangerous values for distinct patients, but solely to define the range of those values.

None of the studied parameters influenced the organ dose except which bone was lengthened (tibia or femur). For lengthening procedures of the femur, a four times higher organ dose per lengthened centimeter was estimated than that for lengthening of the tibia. This may be explained best as a result of the anatomic location closer to the radiosensitive organs.

Other disturbance variables like insufficient radiographic technique or disproportionally more images in patients undergoing femur lengthening procedures could be excepted [14]. The stochastic effect caused by radiography in limb-lengthening procedures is not measurable in a cohort study [12, 15]. The influence of radiographs on soft tissues and callus formation is unclear. We cannot see any coherence between slow callus formation and radiation dose (or number of radiographic examinations or intraoperative fluoroscopy time). Contrary to this idea, a recent study by Zhou et al. shows the positive effect of irradiation to promote mineralization of fracture callus in a rat model [16].

Mechanical complications, slower distraction (greater healing index), and longer treatment in cases of greater lengthening were not appropriate to increase the cumulative organ dose. Our clinical impression was those circumstances led to a greater number of radiographic examinations [1, 3, 4]. We used state-of-the-art assessment for callus examination from survey radiography and did not consider any alternatives like ultrasound, computed tomography, or densitometry [4, 5, 10, 11]. Our protocol involved obtaining radiographic examinations (two planes) every other week during the distraction phase and every 6 weeks in the following consolidation phase. The studies concerning the possibilities and limits of ultrasound to monitor callus formation in osteogenesis are not consistent [4, 10]. Hughes et al. suggested obtaining a presurgical computed tomography scan, immediate postsurgical plain radiographs in two planes, ultrasound investigations weekly from Weeks 1 to 8, plain radiographs in two planes every month, and densitometry every 2 to 4 weeks from Week 8 after surgery until the fixator is removed [5].

During the entire treatment, an average of 30.6 radiographs was taken when lengthening of 4.8 cm was performed. The resulting cumulative organ dose was 3.1 mSv, which is considered lower than that required to provoke deterministic effects. More than this, it is the cumulative dose over the entire time of the lengthening procedure, therefore the risk of radiation-induced cancer is very low [9, 12]. There is likely no absolutely harmless dose, but the resulting dose does not exceed the cumulative organ dose of annual natural radiation exposure (for comparison only: Germany, 3.55 mSv/year; US, 3.6 mSv/year; UK, 2.23 mSv/year).

With the estimated doses the patient's risk for cancer and mutagenicity should not be increased compared with occupationally exposed persons as those in Category A (in Germany, medical staff, radiologic institutions; in the United States, nuclear energy workers) for whom the organ dose is set at 20 mSv/year as the limiting value. The radiogenic risk estimation for fatal cancer is in accordance with the recommendations of the ICRP determined by multiplying mean gonadal dose with the mean genetic defects risk factor of 0.01 Sv^{-1} [8]. The organ dose during a straightforward lengthening procedure of the lower limbs amounts to 0.7 mSv per lengthened centimeter.

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References

1. Aronson J, Good B, Stewart C, Harrison B, Harp J. Preliminary studies of mineralization during distraction osteogenesis. *Clin Orthop Relat Res.* 1990;250:43–49.
2. Drexler G, Panzer W, Petoussi N, Zankl M. Effective dose: how effective for patients? *Radiat Environ Biophys.* 1993;32:209–219.
3. Fischgrund J, Paley D, Suter C. Variables affecting time to bone healing during limb lengthening. *Clin Orthop Relat Res.* 1994; 301:31–37.
4. Gruber G, Konermann W. Possibilities and limitations of ultrasonography in corticotomy/callus distraction. *Orthopade.* 2002;1: 172–175.
5. Hughes TH, Maffulli N, Green V, Fixsen JA. Imaging in bone lengthening: a review. *Clin Orthop Relat Res.* 1994;308:50–53.
6. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues. Part I. The influence of stability of fixation and soft-tissue reservation. *Clin Orthop Relat Res.* 1989;238:249–281.
7. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues. Part II. The influence of the rate and frequency of distraction. *Clin Orthop Relat Res.* 1989;239:263–285.

8. International Commission on Radiological Protection. 1990 Recommendations of the ICRP (ICRP Publication 60). *Ann ICRP.* 1990;21.
9. International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures (ICRP Publication 85). *Ann ICRP.* 2000;30.
10. Matsuyama J, Ohnishi I, Sakai R, Bessho M, Matsumoto T, Miyasaka K, Harada A, Ohashi S, Nakamura K. A new method for evaluation of fracture healing by echo tracking. *Ultrasound Med Biol.* 2008;34:775–783.
11. Paley D. Current techniques of limb lengthening. *J Pediatr Orthop.* 1988;8:73–92.
12. Perisinakis K, Damilakis J, Theocharopoulos N, Papadokostakis G, Hadjipavlou A, Gourtsoyiannis N. Patient effective dose and radiogenic risks from fluoroscopically assisted surgical reconstruction of femoral fractures. *Radiat Prot Dosimetry.* 2004;108:65–72.
13. Petoussi-Henss N, Zankl M, Drexler G, Panzer W, Regulla D. Calculation of backscatter factors for diagnostic radiology using Monte Carlo methods. *Phys Med Biol.* 1998;43:2237–2250.
14. Poretti GG. Radiation exposure of a population due to diagnostic x-ray examinations: some critical remarks. *Phys Med Biol.* 1985;30:1017–1027.
15. Regulla D, Griebel J, Nosske D, Bauer B, Brix G. Acquisition and assessment of patient exposure in diagnostic radiology and nuclear medicine. *Z Med Phys.* 2003;13:127–135.
16. Zhou XZ, Zhang G, Dong QR, Chan CW, Liu CF, Qin L. Low-dose X-irradiation promotes mineralization of fracture callus in a rat model. *Arch Orthop Trauma Surg.* 2008 Apr 22 [Epub ahead of print].