Changes in the quality of life of patients with Blount’s disease undergoing simultaneous bilateral varus deformity correction with the use of the Ilizarov method.

Type
Research paper

Keywords
Ilizarov method, Genu varum, Blount Disease, External Fixator, Limb deformity

Abstract
Introduction
Blount’s disease is a growth disorder of the proximal tibia, which leads to the varus deformity and internal rotation of this bone. The treatment is mainly surgical and involves proximal tibial osteotomy and deformity correction. The aim of this study was to assess the change in the quality of life of patients with tibia vara deformity who underwent correction via the Ilizarov method.

Material and methods
A total of 23 Blount's disease patients who had undergone bilateral varus deformity correction with the Ilizarov method were included in this study. The following parameters were assessed retrospectively: duration of treatment with Ilizarov frames, baseline and postoperative values of the medial proximal tibial angle (MPTA) and mechanical axis deviation (MAD). The quality of life was assessed with a Short Form (SF)-36 survey.

Results
The study population comprised 13 females and 10 males (mean age of 28.43), in whom the Ilizarov fixators were kept for an average duration of 106.65 days. MAD values diminished significantly after the surgery. We also observed significant increases in the MPTA values. The SF-36 scores increased across all of the questionnaire’s domains, which indicates a significant improvement in the postoperative quality of life.

Conclusions
Simultaneous bilateral correction of the varus deformity with Ilizarov external fixators is a safe and effective treatment method. It helps reduce pain and improve gait, which translates to improving the quality of life in all its aspects. The duration of treatment depends to a large extent on the degree of patient cooperation, their attitude, and self-discipline.
Title: Changes in the quality of life of patients with Blount’s disease undergoing simultaneous bilateral varus deformity correction with the use of the Ilizarov method

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Introduction:

Blount’s disease is a growth disorder affecting the proximal tibia, which leads to a varus deformity and internal tibial rotation (1). In the year 1937, Blount distinguished two clinical variants of this deformity, noting their different age of onset. The infantile, or early-onset, form typically develops during the first three years of life and is usually bilateral. The adolescent, or late-onset, form develops at the age of 11 years or later (2, 3).

Although the etiology of Blount’s disease is unknown, there has been research into its possible correlation with obesity and vitamin D3 deficiency (3, 4). Left untreated, Blount’s disease leads to progressive limb deformity, with the associated mechanical overload of the medial knee compartment and the consequent development of knee osteoarthritis (3, 5).

Conservative management has been unsuccessful. The surgical approaches currently used for varus deformity correction are tibial hemiepiphysiodesis (in patients whose growth plates have not fused yet) and corrective osteotomy (3, 6). Deformity correction may be achieved either intraoperatively with the use of osteotomy and metal implants or gradually, for example with an Ilizarov fixator (7-9). One particularly common technique is proximal
tibial osteotomy. Normalizing the limb mechanical axis reduces the medial overload exerted on the proximal tibia and contributes towards relieving pain and improving gait\(^{(10,11)}\).

There have been literature reports describing various surgical techniques and the successful correction achieved\(^{(7,12-15)}\). Our study aimed to analyze the effect of surgical correction on the quality of life in patients with Blount’s disease. We believe that lower limb deformity correction has a beneficial impact on the patients’ physical and psychological wellbeing, emotions, and social interactions. The scarcity of available reports on assessing the quality of life in patients following lower limb deformity correction prompted us to perform such assessments. We believe that in addition to the commonly adopted geometric criteria used in assessing the shape of the lower limbs, the patients’ subjective impression of their condition and any changes in that impression following surgery should be considered.

The purpose of this study was to assess the change in the quality of life of patients with tibia vara deformity who underwent intraoperative bilateral reconstructive surgery combined with gradual postoperative correction via the Ilizarov method.

Material and methods:

Our study included 23 patients who had undergone bilateral corrective surgery with the Ilizarov method for the varus deformity associated with Blount’s disease. The inclusion criteria were: the accessibility of the patient’s complete medical and radiographic records, follow-up period of >1 year, the patient’s informed consent, and Short Form (SF)-36 questionnaire completion both prior to and one year after surgery. The exclusion criteria
were bilateral limb deformities due to other causes (e.g. metabolic diseases such as hypophosphatemic rickets or Paget’s disease of bone, the lack of an informed consent, and incomplete radiographic records. The study was approved by the Local Institutional Review Board.

The study was conducted in 13 females (57%) and 10 males (43%) at the mean age of 28.43 (age range: 7–60 years) with the mean duration of post-surgery Ilizarov fixator treatment of 106.65 (range: 31–199 days).

The mean follow-up period was 6.1 years (range: 1.5–10.2 years, SD- 2.88 years).

We evaluated the duration of treatment with an Ilizarov external fixator, the baseline and postoperative values of the medial proximal tibial angle (MPTA) and mechanical axis deviation (MAD). The patients’ quality of life was assessed with SF-36 questionnaires(16).

Preoperative planning was conducted based on panoramic radiographic images of the lower limbs. Obtaining reliable radiographic images requires a correct patient positioning, with the patellae facing directly forward. This helps accurately determine the extent of deformity.

Corrective surgery is indicated when the MAD exceeds 15 mm.

The obtained radiographic images were used to mark the MPTAs and the center of rotation of angulation (CORA) and to plan the position of the Ilizarov rings. The surgical procedures were conducted under regional anesthesia. During the initial part of the procedure, a 0.5-cm segment of the fibula was resected. Then, a three-ring Ilizarov external fixator was mounted, with the hinges positioned over the predetermined CORA. Once the fixator was in place, proximal tibial corticotomy was performed through a small incision. Initial deformity correction was performed under fluoroscopy. The same steps were repeated for the other limb.
The patients were mobilized on the first postoperative day and taught how to walk with full weight-bearing with the use of forearm crutches. The patients were discharged on postoperative day 3–5, depending on the progress in their ambulation. The initial outpatient follow-up assessments were scheduled in 2-week intervals, and the later ones in 4-week intervals. The patients underwent rehabilitation, with exercise therapy targeted at the ankle and knee joints to improve the range of motion and prevent contractures. Over time, as they were making progress in their mobility, the patients were encouraged to walk without crutches or walkers.

The decision to remove Ilizarov fixators was made once clinical and radiographic signs of bone union were observed. Firstly, the fixator was removed from one of the limbs, and the patient was advised to avoid any weight-bearing on that limb for 2–4 weeks. Then, one month later, the other fixator was removed. This protocol made it easier for patients to walk, while simultaneously helping add more weight onto the bone regenerate in the other limb during the final weeks of treatment.

The statistical analysis to test the research hypothesis was conducted with STATISTICA 13.3 (StatSoft Polska sp.z.o.o, Cracow, Poland) software. This software helped obtain the basic descriptive statistics and conduct the final analysis. The mean differences between groups were calculated with a mixed-design analysis of variance model (ANOVA). The level of significance was set at $\alpha = 0.05$.

Results:
Statistical analysis of the MAD values prior to and after left and right knee surgery revealed considerable differences. However, it was only the effect of treatment (i.e. the main effect) that proved significant ($F(1, 44) = 514.12, p < 0.001, \eta^2 = 0.92$), whereas the interaction effect showed no statistical significance ($F(1, 44) = 0.16, p = 0.691, \eta^2 < 0.01$). Postoperative MAD values were significantly lower than baseline values, with this difference observed both in the left and right limbs, with no differences between the sides observed at either time point (before or after surgery) (Graph1).

Statistical analysis of the left and right MPTA values before and after surgery also demonstrated significant differences; however, also solely in terms of the main effect ($F(1, 44) = 514.12, p < 0.001, \eta^2 = 0.92$), with the interaction effect showing no statistical significance ($F(1, 44) = 0.16, p = 0.691, \eta^2 < 0.01$). The postoperative MPTA values, both in the left and right limb, were significantly higher, with no differences between the sides (left vs. right) at neither time point (Graph2).

Changes in the quality of life were analyzed based on SF-36 survey scores. The SF-36 survey includes 8 domains relating to the specific aspects of daily life, including physical and psychological wellbeing, pain, and social functioning.

“Physical functioning”

The analysis of baseline and postoperative scores in the female and male groups showed a significant increase in scores, irrespective of the patient sex ($F(1, 21) = 51.62, p < 0.001, \eta^2 = 0.71$), with no significant interaction effect ($F(1, 21) = 0.02, p = 0.890, \eta^2 < 0.01$) and hence no intergroup differences at the individual time points.

“Role limitations due to physical functioning”
The scores in this domain of the survey were significantly higher after surgery, irrespective of the sex ($F(1, 21) = 48.47, p < 0.001, \eta^2 = 0.70$), with the interaction effect showing no significance ($F(1, 21) = 0.37, p = 0.548, \eta^2 = 0.02$). Due to violated assumption of homogeneity of variance and normal distribution, the calculations were repeated with a series of nonparametric tests – The conclusions this yielded were the same, i.e. there were no significant differences between the group of males and females at any study time point. Both groups were found to be similar in terms of baseline scores, postoperative scores, and the values of score changes.

“Role limitations due to emotional problems”
In this case also the main effect of the procedure turned out to be significant, with the postoperative scores significantly higher than the baseline ones ($F(1, 21) = 6.75, p = 0.017, \eta^2 = 0.24$), and was observed both in the male and female groups, between which there were no differences at neither time point, i.e. there was no significant effect of interaction ($F(1, 21) = 1.75, p = 0.200, \eta^2 = 0.08$).

“Energy/Fatigue”
Analysis of pre- and postoperative scores in the female and male groups showed a significant increase in scores, irrespective of the sex ($F(1, 21) = 30.76, p < 0.001, \eta^2 = 0.59$), with no significant interaction effect ($F(1, 21) = 0.36, p = 0.552, \eta^2 = 0.02$), which indicates that the baseline and postoperative scores and the resulting score changes were similar in both study groups.

“Emotional wellbeing”
The ANOVA results, like in the case of the survey domains presented above, showed a statistical significance of the effect of treatment (main effect) \( (F(1, 21) = 34.68, p < 0.001, \eta^2 = 0.62) \), with no significance of the interaction effect of sex \( (F(1, 21) = 0.92, p = 0.348, \eta^2 = 0.04) \). Both groups showed a significant increase in scores for this domain, with no differences between the groups observed either at baseline or after the procedure.

“Pain”

Pain scores also showed a significant effect of treatment (main effect) \( (F(1, 21) = 55.07, p < 0.001, \eta^2 = 0.72) \); with the scores significantly higher at the postoperative time point observed in both male and female groups; with no significant inter-group differences at the two time points (no significant interaction effect) \( (F(1, 21) = 1.21, p = 0.284, \eta^2 = 0.05) \).

“Social Functioning”

Analysis of the baseline and postoperative scores in the male and female groups showed a significant increase, irrespective of the sex \( (F(1, 21) = 32.56, p < 0.001, \eta^2 = 0.61) \), whereas the interaction effect was not significant \( (F(1, 21) = 1.46, p = 0.241, \eta^2 = 0.06) \). These results indicate that both groups showed a similar change in scores, and that their scores were similar at individual time points.

“General Health”

The general health domain scores were significantly higher after the procedure, irrespective of the sex \( (F(1, 21) = 46.06, p < 0.001, \eta^2 = 0.69) \), with the interaction effect showing no significance \( (F(1, 21) = 0.94, p = 0.344, \eta^2 = 0.04) \). Both study groups showed similar baseline scores, postoperative scores, and change in scores.
The health change domain also showed a significant effect of treatment ($F(1, 21) = 23.74$, $p < 0.001$, $\eta^2 = 0.53$), with significantly higher scores at the second time point; however, the interaction effect was not significant ($F(1, 21) < 0.01$, $p = 0.999$, $\eta^2 < 0.01$), which indicates that the baseline and postoperative scores and the change in scores were similar in both study groups.

The results are presented in Table 3. Statistical analysis of the obtained SF-36 scores revealed an improved quality of life in all the assessed patients. In addition, the achieved MPTA and MAD fell within the physiological ranges for those parameters.

Discussion:

Orthopedic surgery outcome assessments more and more commonly include a subjective component in the form of patient-reported outcomes measures (PROMs)(17). These measures use specific questionnaires in which patients describe various aspects of their physical, emotional, and social wellbeing without supervision by a physician. PROM analysis helps assess the impact of individual procedures on pain severity and quality of life (18-20).

External fixators have been used for lower limb deformity correction for a long time(21-24). Distraction osteogenesis helps achieve good outcomes in the treatment of congenital and
acquired deformities(9, 10, 25-28). Restoration of a neutral mechanical axis in the lower limb
prevents destruction of the articular cartilage, reduces pain, and facilitates an effective gait
pattern.

Bilateral genu varum deformity may develop in adolescents and adults as a result of Blount’s
disease, rickets, or skeletal dysplasia(9).

There have been a number of reports on treatment outcomes in unilateral varus deformity
correction. However, reports on the simultaneous treatment of both limbs are scarce. Kim et
al. described their results in 48 patients treated with Ilizarov fixators for bilateral genu
varum deformities due to various skeletal dysplasias(28). Those authors observed a mean
lengthening amount of 7.4 cm and the MAD reduction by 9.3 mm. Park et al. performed 21
genu varum correction surgeries in 11 patients(10). Those authors achieved a mean
reduction in the MAD from 28.3 mm to 5.8 mm. Feldman et al. treated 19 patients (22
tibiae) with Taylor spatial frames (TSF)(29). As a result, the MAD was reduced from 53.9 mm
to 1.4 mm, and the mechanical MPTA was increased from 71.4 degrees to 87.9 degrees. Li et
al. reported treatment outcomes in 14 patients with obesity(30). The postsurgical MAD
value was improved from 90 mm to 10 mm and the mechanical MPTA from 66 degrees to 88
degrees.

One of the few studies on bilateral correction of the genu varum deformity was conducted
by Özkul et al(9). Those authors performed a gradual correction in 25 patients (50 tibiae)
with the use of Smart frame fixators and achieved a considerable improvement in the MAD,
mechanical MPTA, and posterior proximal tibial angle (PPTA) values. Those authors
emphasized that a gradual correction lowers the risk of such complications as peroneal
nerve injury, compartment syndrome, and delayed union.
Our observations do not support this theory, since in our experience it is the valgus deformity correction surgery that is associated with a high risk of peroneal nerve injury. The pressure inside the lateral fascial compartment of the leg does not rise significantly during genu varum correction. Thus, our team routinely performs initial varus deformity correction in an intraoperative setting. We believe that this helps the patient to adapt more rapidly to walking with use of forearm crutches and facilitates rehabilitation. Erect X-ray images help verify the achieved correction, and the degree of patient satisfaction determines whether we decide to further increase or decrease the extent of correction.

In the topic of corrective surgeries of the tibia, the issue that continues to provoke discussion is whether or not and, if so, how to perform fibular osteotomy\(^6\), \(^9\), \(^29\). Sachs et al. achieved similar outcomes with and without fibular osteotomy in a small group of patients undergoing deformity correction\(^6\). Those authors emphasized the risk of peroneal nerve injury depending on the exact location of fibular osteotomy. Eidelman et al. performed 10 corrective surgeries without fibular osteotomy in 8 children\(^31\). MAD correction was achieved via the use external fixators, with the hinges positioned at the level of the proximal tibiofibular joint. Those authors did not observe any neurological complications. Dilawaiz et al. performed 39 corrective surgeries in children\(^32\). After the procedure, two of the patients developed transient sensory and motor dysfunction of the hallux. An analysis of all the cases with neurological complications revealed that the surgeon had performed fibular osteotomy too close to the area deemed to be high-risk according to Kirgis and Albrecht\(^33\). Studies in cadavers define the high risk zone as the area located 6 cm to 13 cm distal to the fibular head\(^33\), \(^34\).

Our team routinely performs fibular osteotomy during corrective surgeries of the tibia. We use a posterolateral approach at the middle third or at the level of the middle and distal
thirds of the fibula. Fibular osteotomy is performed in an oblique, nearly sagittal, rather than transverse plane to allow for longitudinal sliding and prevent the fibular bone fragments from becoming caught against each other. We have not observed any peroneal nerve dysfunction with this technique.

The most common complication of the Ilizarov method are skin infections at the sites of Kirschner wire insertion (9, 10, 35). Those, however, usually respond to oral antibiotics. Five out of our patients (21% of the study group) developed skin infection. The rate of inflammatory complications was comparable to that reported in literature (10, 35, 36). These complications did not affect the final treatment outcome in any of the patients. We used local antiseptics and oral antibiotic therapy administered for 10–14 days, which was sufficient to control the infection. None of our patients developed bone marrow inflammation. Moreover, we observed no cases of deep vein thrombosis or neurological dysfunction in the lower limb.

Our findings are similar to or slightly better than those reported in literature. Detailed data are presented in Table 1.

Analysis of changes in the quality of life showed a significant improvement in all domains of the SF-36 survey, irrespective of the patient’s sex. All patients experienced improved pain levels along with an improved emotional status and interpersonal relations. The possibility of functioning in the society and engaging in any occupation with no disability-associated limitations were an added value following treatment completion.

Simultaneous surgery of both lower limbs means that the patient must begin to get up and bear full weight on the limbs immediately after the surgery. Our observations indicate that despite the use of the same technique in both limbs, almost always some differences emerge in terms of time of bone healing, rapidity of regaining function, and the possibility of
There seems to be an association between the patient’s attitude and pain tolerance and the duration of treatment with an Ilizarov fixator. We suspect a correlation between the type of the patient’s personality and his or her psychological condition, and the duration of bone healing and self-discipline in regaining limb function. This issue requires further studies and conducting evaluations and analyses, particularly at the time of qualifying patients for surgery.

Bone regenerate formation also depends on factors that are independent of the patient’s attitude towards the therapeutic process. Comorbidities, such as diabetes mellitus or kidney disease, and certain medications may delay bone healing (37). Our team makes careful, rational judgments when qualifying patients for corrective surgeries and always considers potential obstacles in the treatment process. Due to its minimally invasive character, the Ilizarov method is dedicated for those patients in whom wound healing delay can be anticipated.

One limitation of our study was the small size of the analyzed study group. This was due to the specific character of the evaluated condition but also the rarity of bilateral deformity correction. Many centers perform corrective osteotomy surgeries with the use of implanted plates, which require reduced weight-bearing on the limb for several weeks after surgery. The patients who receive Ilizarov fixators can ambulate with full weight-bearing from postoperative day one; therefore, it is possible to correct both limbs simultaneously without rendering the patient bedridden for long periods of time.

Conclusions:

Simultaneous varus deformity correction with the use of Ilizarov external fixators is a safe and effective treatment method. It helps reduce pain and improve gait, which translates to
improving the quality of life in all its aspects. The duration of treatment depends to a large extent on the degree of patient cooperation, attitude, and self-discipline. (Figure 3)

Conflict of Interest: The authors declare that they have no conflict of interest

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

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|                           | Before surgery |                  | After Surgery |                  |
|---------------------------|----------------|------------------|---------------|------------------|
|                           | M              | SD               | M             | SD               |
| All patients (N = 23)     |                |                  |               |                  |
| SF-36 physical functionig | 50,22          | 22,54            | 86,52         | 13,52            |
| SF-36 role limitations due to physical health | 32,61          | 36,49            | 88,04         | 21,15            |
| SF-36 role limitations due to emotional problems | 50,73          | 43,65            | 79,71         | 37,26            |
| SF-36 energy/fatigue      | 53,70          | 14,56            | 73,04         | 16,22            |
| SF-36 emotional well-being | 51,48          | 17,98            | 76,87         | 16,27            |
| SF-36 pain                | 45,11          | 19,95            | 82,50         | 13,84            |
| SF-36 social functioning  | 57,07          | 23,48            | 83,15         | 18,31            |
| SF-36 general health      | 33,26          | 22,44            | 66,52         | 16,06            |
| SF-36 health change       | 36,96          | 19,76            | 61,96         | 18,26            |
| Women (n = 13)            |                |                  |               |                  |
| SF-36 physical functionig | 50,00          | 22,17            | 86,92         | 13,00            |
| SF-36 role limitations due to physical health | 34,62          | 34,67            | 94,23         | 10,96            |
| SF-36 role limitations due to emotional problems | 43,60          | 47,89            | 84,62         | 37,55            |
| SF-36 energy/fatigue      | 54,23          | 16,94            | 75,38         | 16,52            |
| SF-36 emotional well-being | 50,15          | 19,71            | 79,08         | 16,75            |
| SF-36 pain                | 40,77          | 19,75            | 82,88         | 15,06            |
| SF-36 social functioning  | 59,62          | 24,56            | 80,77         | 20,17            |
| SF-36 general health      | 29,62          | 23,14            | 66,92         | 18,43            |
| SF-36 health change       | 34,62          | 19,20            | 61,96         | 18,26            |
| Men (n = 10)              |                |                  |               |                  |
| SF-36 physical functionig | 50,50          | 24,20            | 86,00         | 14,87            |
| SF-36 role limitations due to physical health | 30,00          | 40,48            | 80,00         | 28,38            |
| SF-36 role limitations due to emotional problems | 60,01          | 37,84            | 73,33         | 37,85            |
| SF-36 energy/fatigue      | 53,00          | 11,60            | 70,00         | 16,16            |
| SF-36 emotional well-being | 53,20          | 16,34            | 74,00         | 16,03            |
| SF-36 pain                | 50,75          | 19,76            | 82,00         | 12,85            |
| SF-36 social functioning  | 53,75          | 22,86            | 86,25         | 16,08            |
|                           | M     | SD   | M     | SD    |
|---------------------------|-------|------|-------|-------|
| SF-36 general health      | 38,00 | 21,76| 66,00 | 13,29 |
| SF-36 health change       | 40,00 | 21,08| 65,00 | 17,48 |

*M – średnia, SD – odchylenie standardowe*
Graph 1

*Marginal means along with the 95% confidence interval for the variable MAD before and after surgery for the left and right sides.*
Graph 2

Marginal means along with the 95% confidence interval for the variable medial proximal tibial angle before and after surgery for the left and right sides.
Bilateral varus deformity- ap view
Bilateral correction of varus deformity with Ilizarov External Fixator
