Treatment of Infected Pseudarthrosis of the Tibia Using the Ilizarov Method and the Orr Dressing

Tratamento das pseudoartroses infectadas da tíbia pelo método de Ilizarov associado ao curativo de Orr

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Abstract

Objective This study aims to analyze outcomes and clinical and epidemiological data of infected tibial pseudarthrosis using the Ilizarov method and the Orr dressing.

Methods Data from n = 43 patients diagnosed with infected tibial pseudarthrosis were analyzed by descriptive and inferential statistical methods. In addition, Paley's assessment criteria evaluated bone and functional outcomes. Qualitative variables were presented as the distribution of absolute and relative frequencies. The presentation of quantitative variables followed the D'Agostino-Pearson test.

Results Thirty-seven (86.04%) subjects were males, and six (13.95%) were females. The most frequent age group among patients was 50 to 59 years old (25.6%), with a p-value = 0.8610. The treatment time was longer for the trifocal treatment (23.8 months) when compared to the bifocal treatment (15.6 months), with a p-value = 0.0010* (highly significant). Excellent bone outcomes represented 72.09% of the sample; 23.25% of outcomes were good. Functional outcomes were excellent in 55.81%, good in 6.97%, and regular in 27.90% of subjects. The Orr dressing (using Vaseline gauze) proved effective, achieving wound healing with soft tissue coverage in all patients evaluated.

Conclusions The Ilizarov method resulted in a substantial change in the treatment of bone infections, especially infected pseudarthrosis. The versatility of this method has turned it into an effective tool, allowing the healing of the infectious process and the correction of potential deformities and shortening.

Keywords
- Ilizarov Technique
- pseudoarthrosis
- tibia
- treatment outcome

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Resumo

Objetivo Analisar os resultados e os dados clínicos e epidemiológicos do tratamento das pseudoartroses infectadas da tíbia pelo método de Ilizarov associado ao curativo de Orr.

Métodos Para analisar os dados de n = 43 pacientes com diagnóstico de pseudoartrose infectada da tíbia foram aplicados métodos estatísticos descritivos e inferenciais e os resultados ósseos e funcionais foram avaliados de acordo com os critérios de avaliação de Paley. As variáveis qualitativas foram apresentadas por distribuição de frequências absolutas e relativas. As variáveis quantitativas foram apresentadas pelo teste de DAgostino-Pearson.

Resultados Foi encontrado que 37 (86,04%) eram do sexo masculino, 6 (13,95%) femininos. A faixa etária mais frequente entre os pacientes foi de 50 a 59 anos (25.6%), p-valor = 0.8610. O tempo de tratamento é maior no tratamento trifocal (23.8 meses) quando comparado com o Bifocal (15.6 meses), p-valor =0.0010* (altamente significante). Os resultados ósseos excelentes representaram 72,09%, 23,25% foram de resultados considerados bons. Os resultados funcionais considerados excelentes foram 55,81%, os resultados bons foram 6,97%, resultados regulares foram 27,90. O curativo com gaze vaselinada (curativo de Orr) mostrou-se eficaz, alcançando assim a cicatrização das feridas com cobertura de partes moles em todos os pacientes avaliados.

Conclusões O método de Ilizarov proporcionou uma mudança substancial no tratamentos das infecções ósseas, especialmente das pseudoartroses infectadas. A versatilidade deste método se transformou em uma ferramenta eficaz, permitindo a cura do processo infeccioso, bem como correção das possíveis deformidades e do encurtamento.

Palavras-chave

- pseudoartrose
- tíbia
- resultado do tratamento
- Técnica de Ilizarov

Introduction

Pseudarthrosis is one of the most significant issues faced by orthopedic surgeons globally when treating long tubular bone fractures. In addition to consolidation issues, severe problems such as deformity, infection, and limb length discrepancy accompany the clinical picture.[1]

Fractures may evolve with delayed consolidation or nonunion. Pseudarthrosis is the lack of fracture healing with clinical, radiological, or both evidence that the fracture healing process has ended and that its progression will be highly unlikely.[2]

Pseudoarthrosis requires a treatment that stimulates bone healing, treats the infection, and solves the issues of length discrepancy and angular deformities.[3] In 1951, in Kurgan, Russia, Gavriil Abramovich Ilizarov introduced an external fixation device and successfully developed his method to treat several orthopedic and trauma injuries.[4]

The possibility of bone lengthening safely and predictably by gradual traction, following the principle proposed by Ilizarov, allowed this lengthening under a new biological perspective and the development of a new technique called compression-removal osteosynthesis.[5]

Therefore, this study seeks to analyze the outcomes and clinical and epidemiological data from infected tibial pseudarthrosis treated by the Ilizarov method and the Orr dressing.

Methods

The Research Ethics Committee approved this study under number 53773621.3.0000.5553.

We retrospectively evaluated 43 medical records of patients diagnosed with infected tibial pseudarthrosis at the Hospital Regional de Sobradinho, Distrito Federal, Brazil, from July 2012 to December 2019. Inclusion criteria were infected tibial pseudarthrosis treated with the Ilizarov method for at least six months after fixation removal in patients over 18 years old, from both genders, who had all the data available in their medical records. Exclusion criteria were uninfected pseudarthrosis, tibial pseudarthrosis treated with other methods, congenital tibial pseudarthrosis, patients younger than 18 years old, and subjects with insufficient data in their medical records.

Data collection from electronic medical records used spreadsheets developed by the authors. Evaluation of bone and functional outcomes results followed the criteria reported by Paley et al.[6] (►**Tables 1** and **2**).

Descriptive and inferential statistical methods analyzed data from n = 43 patients diagnosed with infected tibial pseudarthrosis. Qualitative variables were presented as the distribution of absolute and relative frequencies. Quantitative variables were shown as measures of central tendency and variation. The D'Agostino-Pearson test $D^* = \frac{D - \mathrm{E}\{D\}}{s(D)}$ assessed

Table 1 Criteria for bone outcomes assessment according to Paley et al.

Bone outcomes	Bone consolidation	Lack of infection	Angular deformity lower than 7°	Tibial length discrepancy lower than 2.5 cm
Excellent	All above criteria			
Good	Bone consolidation plus two other criteria			
Regular	Bone consolidation plus one other criterion			
Poor	No bone consolidation, refracture, or lack of any other criterion			

Table 2 Criteria for functional outcomes assessment according to Paley et al.

Functional outcomes	Significant claudication	Equinus deformity	Soft tissue dystrophia	Pain and inactivity
Excellent	Active subject with none of the four criteria			
Good	Active subject with one or two criteria			
Regular	Active subject with three or four criteria			
Poor	Inactive subject regardless of other criteria			

normality. Analysis also employed adhesion chi-square tests, $x^2 = \sum_{i=1}^{k} \frac{(O_i - E_i)^2}{E_i}$, Student's *t*-test $t = \frac{Z}{\sqrt{V/\nu}}$, and Pearson's linear correlation $t = \frac{r\sqrt{n-2}}{\sqrt{1-r^2}}$.[7] An alpha error of 5% was previously set for rejecting the null hypothesis. Statistical processing used the BioEstat version 5.3 and the STATA release 17 software.[8]

Surgical technique and outpatient treatment

Each patient underwent a clinical and radiological evaluation before surgery. Assembly of the Ilizarov apparatus occurred during the perioperative period according to the size of the segment and the verification of the required length and width. Incisions usually followed the topographies of previous surgical scars.

Any implanted material, when present, was removed. An anterior or anteromedial incision allowed the resection of non-viable bone tissue. Necrotic tissue or a bone edge smaller than 2/3 of the regular diameter was deemed non-viable. Resected samples were sent for histopathological study.

Ilizarov external fixators assembly followed the pattern from the Italian school,[5] using 1.8-mm Kirschner wires and 6-mm tapered Schanz pins. The fasteners were extended to the foot to minimize equinus deformity in bone elongations greater than 4 cm or if there was a distal metaphyseal bone failure. Corticotomies employed a Gigli saw (American technique).

The type of bone reconstruction depends on the size of the bone defect. Treatment of bone defects smaller than 4 cm used bifocal bone transport, while those greater than 4 cm underwent trifocal bone transport. Treatment of bone defects larger than 10 cm employed tetrafocal bone transport or reconstruction with a fibula; one patient underwent a tibialization of the fibula.

The surgical wound at the resection site of non-viable bone tissue remained open. Wound size varied according to the dimensions of the bone resection; it could be smaller than 4 cm in bifocal transports, larger than 4 cm in trifocal transports, and even greater than 10 cm in major resections. Dressings consisted of gauze moistened with sunflower oil. These deep dressings were changed weekly at the orthopedics outpatient facility per the Orr technique.[9] No additional procedures were performed, such as plastic surgery.

Table 3 Characterization of n = 43 subjects diagnosed with infected tibial pseudoarthrosis

General features		Frequency	χ^2
Categories	n = 43	%	p-value
Age range			**0.8610**
20 to 29 years	7	16.3	
30 to 39 years	9	20.9	
40 to 49 years	7	16.3	
50 to 59 years	11	25.6	
60 years or older	9	20.9	
Gender			**<0.0001***
Female	6	14.0	
Male	37	86.0	
Reason for trauma			**<0.0001***
Firearm	2	4.7	
Hit and run	3	7.0	
Motorcycle accident	16	37.2	
Fall from own height	1	2.3	
Not specified	21	48.8	
Laterality			**0.7604**
Right	20	46.5	
Left	23	53.5	

*Chi-square test for adherence to equal expected proportions.

Table 4 Treatment details and complications in n = 43 subjects diagnosed with infected tibial pseudoarthrosis

Treatment and complications		Frequency	χ^2
Feature	**n = 43**	**%**	**p-value**
Treatment time (months)			**0.0063***
11 months or less	9	20.9	
12 to 23 months	19	44.2	
24 to 35 months	12	27.9	
36 months or more	3	7.0	
Type of treatment			**<0.0001***
Bifocal	20	46.5	
Trifocal	20	46.5	
Tetrafocal	2	4.7	
Tibialization of the fibula	1	2.3	
Complication			**<0.0001***
Regenerating tissue fracture	2	4.7	
Osteolysis/pin loosening	1	2.3	
Pin path infection	38	88.3	
Refracture	2	4.7	

*Chi-square test for adherence to equal expected proportions.

Patients were usually discharged from the hospital within the first 48 hours after surgery. Subjects received prescriptions for oral antimicrobial and analgesic agents to take during the first week per the pre-established hospital protocol. After surgical resection, antibiotics were discontinued or even not used at all; antibiotic therapy was reserved only for cases of infection in the pins and wires path.

We asked the patients to keep the limb elevated and use an elastic orthosis for passive ankle dorsiflexion. Weight-bearing was encouraged from the third week after surgery. In addition, physical therapy was widely recommended but often impaired or neglected due to socioeconomic factors.

Bone transport started in the second or third week after surgery. The speed for each regenerating tissue construction was 0.5 mm per day, divided into two daily manipulation steps.

After wound closure by second intention healing and bone transport completion, the patient underwent a new surgical procedure for grafting autologous spongy bone from the iliac crest in the pseudarthrosis foci.

Following grafting, the patient underwent a monthly radiological evaluation to verify pseudarthrosis union, regenerating tissue consolidation, and potential complications. Fixator removal occurred after complete device dynamization, pseudarthrosis consolidation, regenerating tissue corticalization on at least three of the four sides, lack of pain on bone palpation, and when the patients supported a total load on the affected limb. After removing the device, subjects used protective orthoses such as boots for at least one month to avoid refractures.

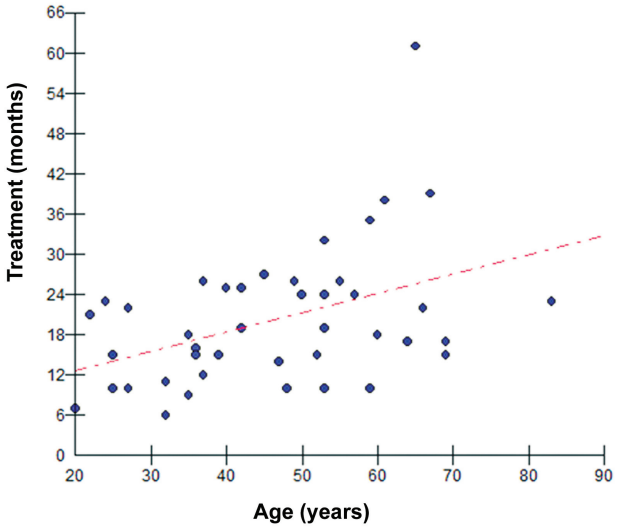

Fig. 1 Correlation between the subjects' age (years) and treatment time (months) of n = 43 patients diagnosed with infected tibial pseudarthrosis.

Results

This study analyzed data from n = 43 patients diagnosed with infected tibial pseudarthrosis. ►**Table 3** characterizes

Table 5 Post-treatment functional outcomes in n = 43 subjects diagnosed with infected tibial pseudoarthrosis

Functional outcomes assessment		Frequency	χ^2
Features	**n = 43**	**%**	**p-value**
Claudication			**0.3602**
Yes	18	41.9	
No	25	58.1	
Equinus deformity			**<0.0001***
Yes	5	11.6	
No	38	88.4	
Dystrophia			**<0.0001***
Yes	2	4.7	
No	41	95.3	
Pain/inactivity			**<0.0001***
Yes	4	9.3	
No	39	90.7	
Discrepancy lower than 1.5 cm			**0.0008***
Yes	33	76.7	
No	10	23.3	

*Chi-square test for adherence to equal expected proportions.

Table 6 Treatment time per functional outcomes assessment in n = 43 subjects diagnosed with infected tibial pseudoarthrosis

		Treatment time (months)		
	n	Average	Standard deviation	p-value
Reason for trauma				**0.2876**
Firearm	2	16.0	14.1	
Hit and run	3	23.7	4.0	
Fall from motorcycle	16	19.3	12.8	
Fall from own height	1	25.0	—	
Not specified	21	20.9	8.9	
Type of treatment				**0.0100***
Bifocal	20	15.6	6.4	
Trifocal	20	23.8	11.6	
Tetrafocal	2	33.5	2.1	
Tibialization of the fibula	1	21.0	—	
Claudication				**0.0469****
Yes	18	24.2	12.1	
No	25	17.6	7.6	
Equinus deformity				**0.4272**
Yes	5	23.8	10.7	
No	38	19.9	10.2	
Dystrophia				**n/a**
Yes	2	37.0	2.8	
No	42	19.5	9.7	
Pain/inactivity				**0.1509**
Yes	4	37.3	19.3	
No	39	18.6	7.2	

*Student's t-test (Bifocal x Trifocal)
**Student's t-test (Claudication x No claudication)

the treated patients. The age group between 50-59 years was the most frequent, accounting for 25.6% of subjects. Males were 86% of the sample, and the left tibia was the most affected bone (53.5%). The most frequent trauma reason was motorcycle accidents (37.2%).

As shown in ►**Table 4**, it is possible to estimate the treatment time per the following equation: **Treatment time = 6.7 + Age * 0.2895**, indicating that the correspondence is directly proportional (►**Fig. 1**). Treatment lasted 12 to 23 months in 44.2% of patients. Treatment consisted of bifocal and trifocal bone transport in 46.5% and 46.5%, respectively, of subjects. Infection at the pin path occurred in 88.3% of patients.

►**Table 5** describes the post-treatment functional outcomes assessment. Please note that 58.1% of the patients had no claudication, and 95.3% did not present dystrophy. ►**Table 6** characterizes the treatment time, which is longer in patients with claudication (24.2 months) compared to patients with no claudication (17.6 months), with a p-value = 0.0469* (statistically significant) (►**Fig. 2**).

Pathological anatomy findings were available for only eight of the 43 patients evaluated, and these eight samples were positive for osteomyelitis. Cultures were not usually requested as we decided not to use antibiotics after bone resection and reconstruction.

Bone and functional outcomes were retrospectively evaluated based on the information from the medical records of all patients after the end of treatment using the criteria reported by Paley et al.[6] (►**Table 1**).

Most (72.09%) patients had excellent bone outcomes (►**Fig. 3**) and 23.25% presented good outcomes. No patient had regular bone outcomes, and 4.65% had poor bone outcomes. All patients presented bone infection resolution and pseudarthrosis union. Regular and poor outcomes resulted from deformities, residual discrepancies, or refractures.

Functional outcomes (►**Table 2**) were excellent in 55.81% of patients (►**Fig. 4**); in addition, functional outcomes were good in 6.97%, regular in 27.90%, and poor in 9.30% of subjects.

Regarding complications during treatment, we observed that, at some point, all patients had infections related to the Schanz pins and Kirschner wires. In one subject, the pin came loose, requiring an additional procedure for surgical

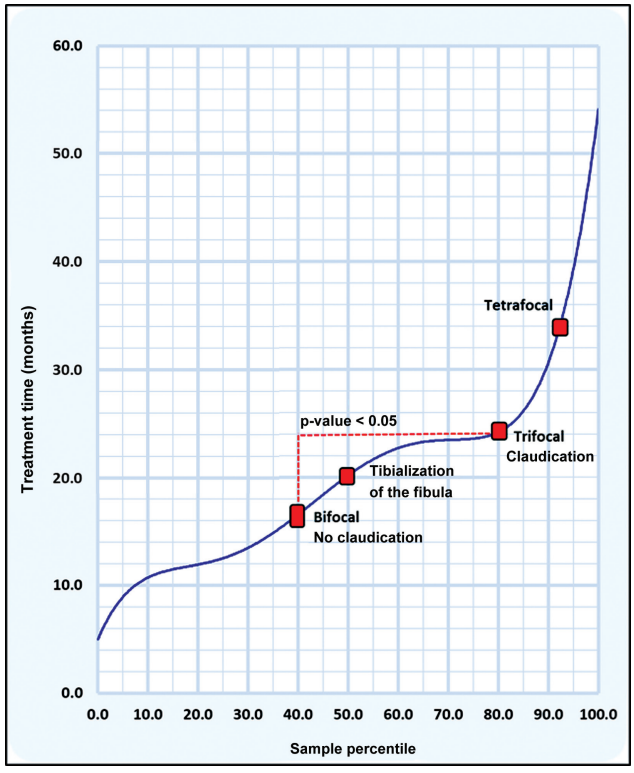

Fig. 2 Treatment time according to the type of treatment and claudication in n = 43 patients diagnosed with infected tibial pseudarthrosis.

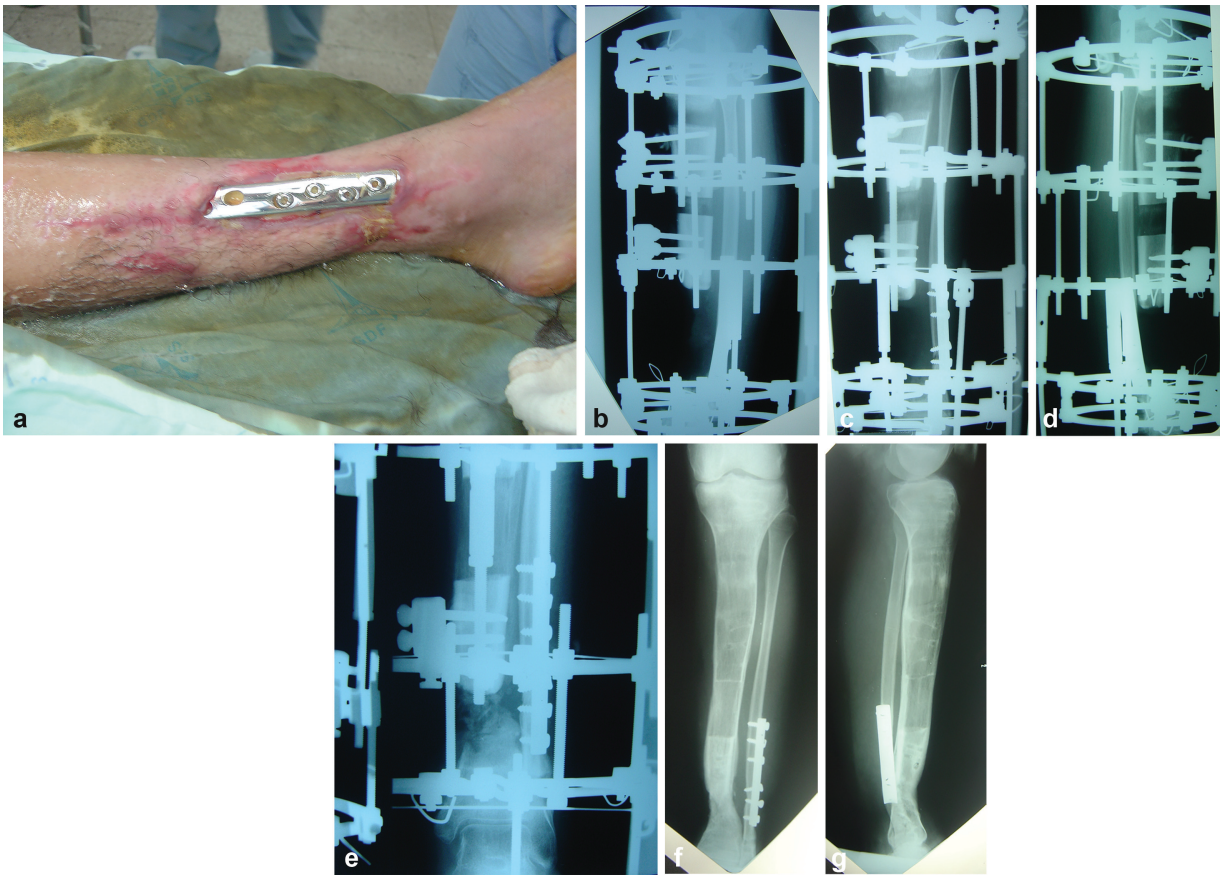

Fig. 3 **(a)** Male subject with pseudarthrosis of the right and left tibia and synthesis material exposure; **(b)** Radiograph after material removal, bone resection, and assembly of the Ilizarov fixator aiming at trifocal bone transport; **(c, d)** Radiograph showing bone transport; **(e)** Radiograph showing the status near transport completion; **(f, g)** Consolidated fracture.

debridement of the path and fixation of a new pin. In another patient, this infectious process led to instability of the distal fixator block, successfully treated with a new device revision procedure.

Two patients had refracture after fixator removal and were treated conservatively with plaster casts and boot-type orthoses. One patient presented a fracture of the regenerating bone and underwent treatment with a boot-type immobilizing orthosis, which resulted in bone healing without deformities.

Regarding soft tissue outcomes, no patient required additional procedures such as skin flaps or grafts. The dressing consisted of gauze moistened with liquid Vaseline or sunflower oil (Orr technique),[9] achieving wound healing by secondary intention in all evaluated subjects.

Discussion

Ilizarov postulated new biological concepts and techniques for an external fixation system that revolutionized the treatment of pseudarthrosis. With minimal osteosynthesis, this system allows deformity correction, infection eradication, limb equalization, and bone defect elimination while maintaining joint function and permitting early bodyweight loading.[6]

Epidemiological (age, gender, and laterality) data were consistent with another study[3] including 20 patients with infected unilateral tibial pseudarthrosis treated using the Ilizarov method. This study consisted of 16 male and four female patients with a mean age of 32 years (range, 17-74). As for the affected side, nine (45%) injuries were on the right side, and 11 (55%) were on the left side.

Regarding treatment options and time, in the present study, bifocal and trifocal bone transports were the most used techniques, and the mean treatment time was 20.34 months. An Indian study[9] employed bifocal transport in 85% of patients. In contrast, an American study[5] had 10 patients undergoing monofocal compression-distraction treatment, seven patients receiving bifocal treatment, and three subjects undergoing a bifocal treatment combined with infected bone resection.

These data differ from other studies[6,10] since one found a mean consolidation time of 12.57 months, and the other had a mean follow-up time of 40.8 months. Other authors,[11] however, observed that 85% of patients underwent a bifocal transport.

Our bone outcomes were consistent with those reported by Maini et al.,[12] who observed 70% of excellent outcomes, 10% of good outcomes, no regular outcomes, and 20% of poor outcomes. These findings are similar to those reported by

Fig. 4 **(a)** Male subject during the immediate postoperative period of Ilizarov fixator placement to treat an infected pseudarthrosis; **(b, c)** Patient during treatment; **(d, e, f, g)** Functional outcome after Ilizarov fixator removal.

McNally et al.,[11] who had 60% of excellent outcomes, 15% of good outcomes, 25% of regular outcomes, and no poor outcomes. However, they do not agree with another study[13] reporting 22% of excellent outcomes, 36.34% of good outcomes, 22% of regular outcomes, and 18.18% of poor outcomes.

Two other studies presented comparable findings.[6,14] The first reported the following bone outcomes: 60.87% excellent, 26.09% good, 8.7% regular, and 4.35% poor. The second obtained 50% excellent, 29% good, 3.6% regular, and 17.4% poor outcomes.

Functional outcomes were excellent in 55.81%, good in 6.97%, regular in 27.90%, and poor in 9.30% of our patients. This scenario is similar to another study,[14] reporting excellent, good, regular, and poor outcomes in, respectively, 55%, 30%, 5%, and 10% of the sample.

These data differ from four other studies[6,13,15,16] presenting the following conclusions: the first had 26.7% excellent, 40% good, 10% regular, and 28.3% poor functional outcomes; the second reported 5.56% excellent, 22.22% good, 33.33% regular, and 38.89% poor functional outcomes; the third showed 25% excellent, 39.2% good, 14.3% regular, and 2.15% poor functional outcomes; at last, the fourth study presented 64% excellent, 28% good, 4% regular, and 4% poor functional outcomes.

Certain complications and intercurrences are frequent and inherent to external fixators, including infection in pin and wire paths, joint contractures, vascular and nervous injuries, and loss of device stability. However, certain complications are specific to bone transport in pseudarthrosis.[17]

Premature consolidation and delayed ossification of the regenerating tissue are complications arising from the lack of rhythm balance and stretching periodicity. Other complications include regenerating tissue angular deformity and fracture, often resulting from early device removal or the patient falling during or after treatment.[18]

Fig. 5 **(a)** Example of Orr vaseline gauze dressing; **(b)** Male subject; intraoperative image of the Ilizarov fixator for tetrafocal tandem bone transport; **(c)** Immediate postoperative radiograph of the Ilizarov fixator for tetrafocal transport; **(d)** A few weeks after initiation of bone transport and Orr dressing changes; **(e)** Patient after transport completion, removal of Ilizarov fixator, and Orr dressing changes; **(f)** Radiograph after Ilizarov fixator removal and tetrafocal transport.

As for complications during treatment, all patients had infections related to Schanz pins and Kirschner wires at some point. Another study supported this observation,[18] concluding that superficial infection in pins and/or wires path can occur in up to 100% of cases and is always present at some stage of treatment.

Regarding soft tissue outcomes, no patient required additional procedures such as skin flaps or grafts. The use of Vaseline gauze dressings (Orr dressing) resulted in wound healing with soft tissue coverage in all patients evaluated.

War surgeon H. Winnett Orr[9] introduced the treatment of acute osteomyelitis through drainage and placement of an aseptic dressing inside and around the wound, not removing or changing it for several weeks. Two or four dressings are often enough to ensure healing; meanwhile, the limb is immobilized with a cast, and dressings replacement occurs through a window in the cast.

This Vaseline gauze tampon dressing has been used since World War I (►**Fig. 5**). Solid Vaseline impregnates the gauze and does not allow the penetration of vascular neoformation buds in its margins. At the same time, however, it allows the flow of secretions. Tissue growth gradually pushes the tampon out and, when reaching the skin, the epithelium from the wound edges covers the defect.[19]

Conclusion

The Ilizarov method led to a substantial change in the treatment of bone infections, especially infected pseudarthrosis. The versatility of this method made it an effective tool since it allows the healing of the infectious process and the correction of potential deformities and limb shortening.

Most of the literature corroborates epidemiological data and bone and functional outcomes of this study. As such, we demonstrated the method's effectiveness, which resulted in infectious process resolution, bone consolidation, and reasonable functional recovery for the evaluated subjects.

Complications are inherent to the treatment due to the usual prolonged period until healing. They must be understood and properly managed by the attending physician and the patient to minimize these complications as much as possible.

Soft tissue management is also a significant factor to consider. Vaseline gauze dressing proved to be an effective and inexpensive option for treating soft tissues, as it eliminates the need for additional surgical procedures, saving resources and resulting in less physical and emotional distress for patients.

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Conflict of Interests

The authors declare no conflict of interests.

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