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MEASUREMENT OF DOSED COMPRESSION AND DISTRACTION OF TIBIA FRACTURES TREATED WITH ILIZAROV CIRCULAR EXTERNAL FIXATION

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Abstract: Complicated tibia fractures are still connected with significant problems of healing. Hence, the external Ilizarov fixators are applied, and then they are sometimes converted to internal fixators. The aim of this work is to investigate the effects of different levels and timing of mechanical stimulation in the treatment of tibia with measuring strain gauges. Different levels of mechanical stimulus would lead to different degrees and rates of healing. The evaluated timing of stimulus application is a critical factor for the success of the treatment response.

KEYWORDS: traumatology, tibia, fracture, Ilizarov fixator, measurement, dosed compression, dosed distraction

1 Introduction

Open fractures of the tibia of the III degree according to the Tscherne classification are most often caused by high-energy mechanisms and due to frequent complications, not only in soft tissue healing (infection), but also in complications in fracture healing (delayed healing, nonunion, bone infection), treatment is still a significant problem. In the first phase of treatment, the standard method of fracture treatment is treatment with external fixators, either static or dynamic. For more information see [1].

After soft tissue healing, external fixation is then converted to internal fixation. If it is not possible to convert external fixation, it is possible to continue treating the tibia fracture with external fixation until healing. The most advantageous for this method of treatment are external fixators (EF) of the bilateral circular (ring) type (Ilizarov), which allow for timely and simple dosed loading of the limb with body weight, without the risk of bone breakage at the fracture site; see [2].

The aim of this work was to investigate the effects of different levels and timing of mechanical stimulation in the treatment of fractures using Illizarov fixators with measuring sensors. We assumed that different levels of mechanical stimulus would lead to different degrees and rates of healing. Furthermore, we assumed that the timing of stimulus application would be a critical factor for the success of the treatment response; see [3].

Rehabilitation continued even after the patient was discharged to home treatment, when the patient received sensory inserts, where the doctor had set the load rate values on the treated limb; see [4].

The work also builds on older works related to biomechanical research and measurement, see [5] to [7].

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2 Measurement of Pressure at the Fracture Site

The Ilizarov external fixator (EF) is a circular (ring) modular system that uses Ki (Kirschner) wires to enable reduction and stabilization of a lower leg fracture. The advantage of this method is not only stable osteosynthesis of the fracture, but also its minimal invasiveness, when using Ki wires we perform percutaneous reduction of the fracture and its stabilization with axial and transverse lateral compression. Ki wires are percutaneously inserted 3-5 cm above and below the fracture site and subsequently fixed into external fixation rings, thereby minimizing the possibility of damage to soft tissues and the skeleton at the fracture site. Using external fixation rings, compression is then performed at the fracture site and its dynamic stabilization. In oblique and comminuted fractures, transverse-lateral compression using tensile Ki wires can also be used. For more information see [5] to [12].

Distraction of the outer rings of the external fixation then achieves firm stabilization of the fracture, where the Ilizarov-type EF allows the transfer of forces through the EF outside the fracture site when the limb is loaded with body weight. We have proven this by clinical measurements in patients with a tibia fracture treated with the Ilizarov external fixator with strain gauge measuring elements; see Fig. 1.

Fig. 1 Model of external fixator with measuring sensors

The first part of the research was focused on the creation and production of a removable strain gauge unit that, when connected to the EF system, would enable the measurement of force transmission during walking to the fracture site. The force transmission (distribution) is explained in Fig. 2.

The research was focused on the creation of a strain gauge unit that allows connection to a circular EF without violating the stability of the fracture. The strain gauge measuring device allows the measurement of the force load between the Ilizarov EF rings; see Fig. 3.

The effect of compression and distraction in fractures represents an increase in the stability of the fixation, compression improves the strength of the entire structure and the internal stability of the bone. Distraction generates significant resistance in the surrounding soft tissue envelope, which exerts higher pressure on the fixation frame, thereby significantly increasing the stability of the structure.

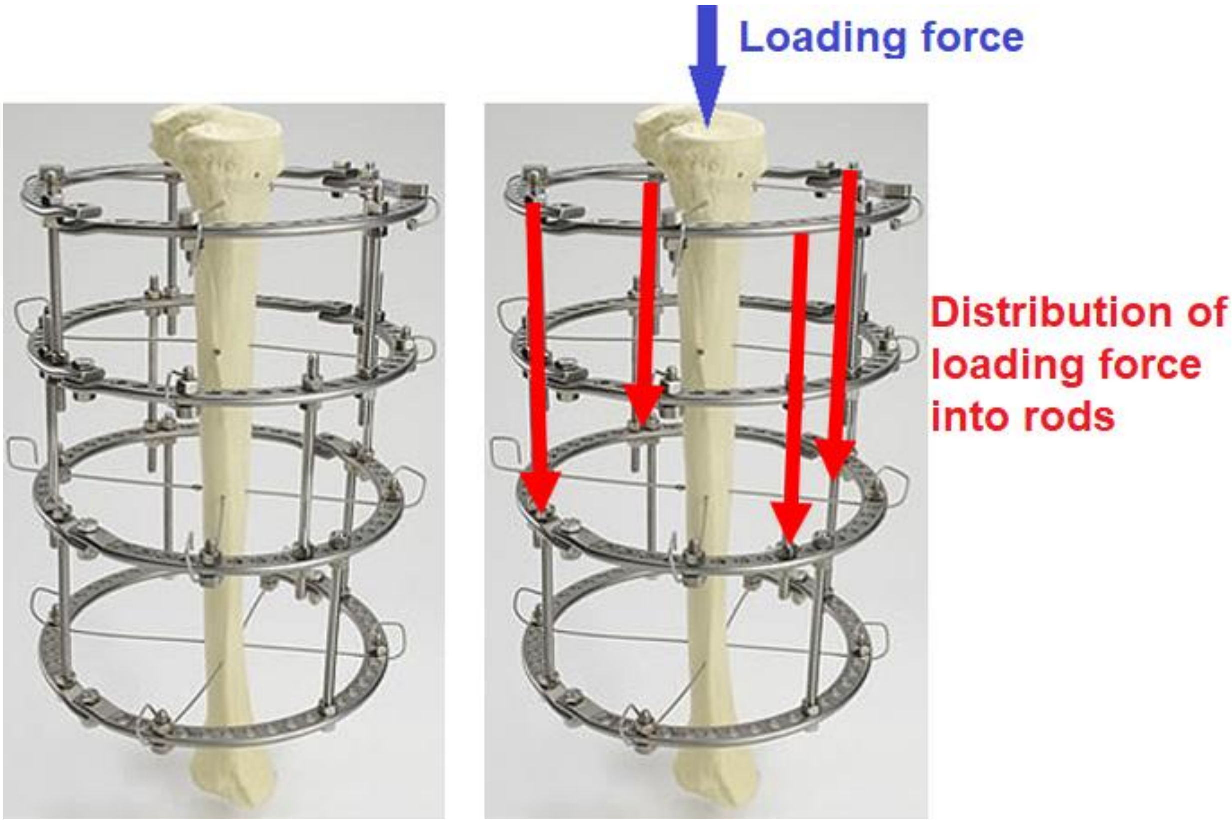

Fig. 2 The force transmission (distribution) in an external fixator.

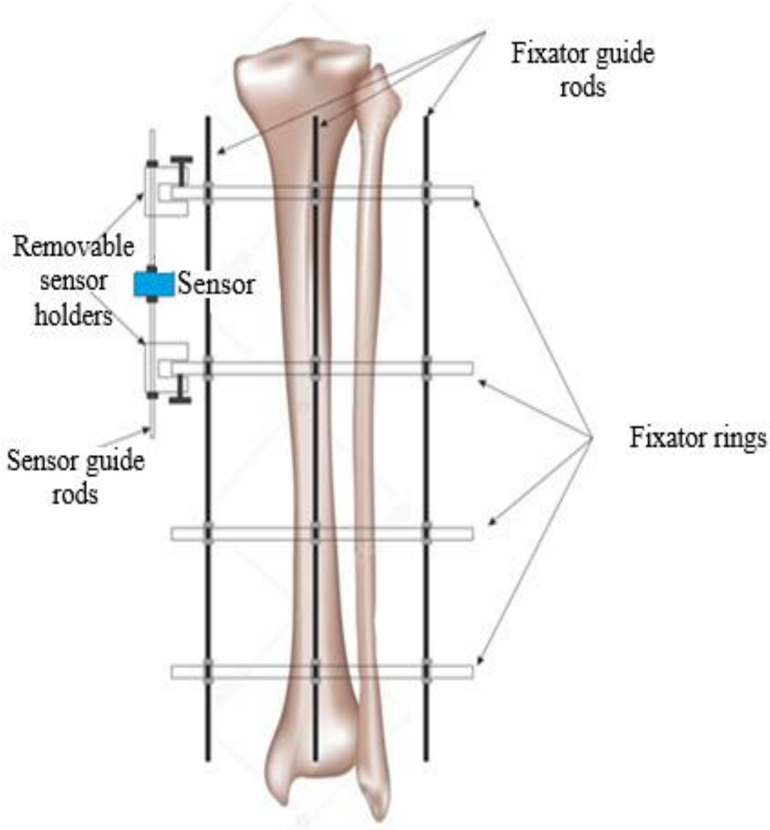

Fig. 3 Schematic drawing of the fixation device with force sensor

The key moment for successful bone healing is early loading and functional stability. Early loading accelerates fracture healing and significantly accelerates callus formation. Here we based our experiment on: Marjolein C.H. van der Meulen, who proves that stimulation at the fracture site has a positive effect on healing, see Fig. 1 and [14]. The compression-distraction method using an external circular Ilizarov fixator not only accelerates the healing of bone fractures, but is also suitable for prolonged healing or for the treatment of sub-arthritis. The original Ilizarov method of guided distraction is also suitable for the treatment of shorts and other limb discrepancies after fracture healing; see Fig. 4 and 5.

Fig. 4 Circular external fixator equipped with four sensory sensors

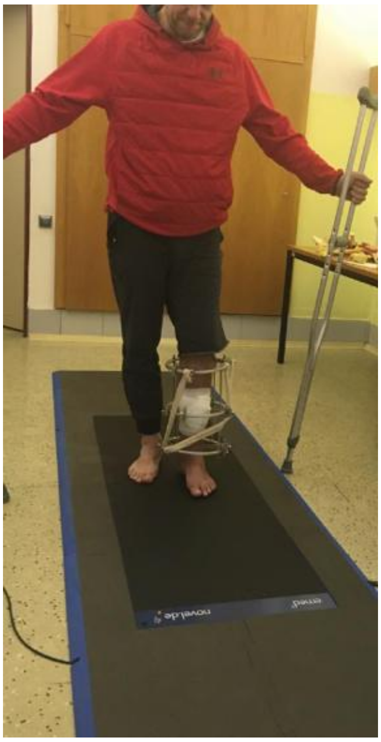

Fig. 5 Patient with Ilizarov fixation during load measurement on a plantographic walkway

However, to date, the compression and distraction forces, their correct timing and their effect on subsequent fracture healing have not been precisely determined. So far, the forces have only been estimated. The developed type of fixator with strain gauge sensors allows these forces to be precisely defined. Based on a clinical study, the compression and distraction forces and their correct timing within the framework of fracture healing can then be determined, which will allow for a shorter healing time, which also means a significant socio-economic benefit for society.

3 Software solution

The LabVIEW development environment was used as the SW solution - a graphical development environment for system design. This graphical programming language from National Instruments enables a revolution in the development of test, measurement and control applications. It is possible to use measurement and control hardware effectively, analyze data, especially in terms of costs. For more details, see [15].

A measurement loop with a division of input signals that are filtered from noise was used as the basis. Signal capture is implemented using a DAQ assistant module that allows calibration of sensors.

All measured data is displayed on the user interface display. The control SW or user interface has 2 phases of measurement without recording and measurement with recording to a file. Since the sensors are not always in the zero position after assembly, the user interface has a zero button (Tare). Pressing it will reset the sensor forces to zero.

For later analysis, the records can be saved to a file containing the measured data. The user interface also allows for notes to be added.

The National instruments measurement solution was used for the measurement:

- USB strain gauge card NI-9237 C Series Strain/Bridge Input Module
- 1-Slot chassis NI cDAQ™-9171 NI CompactDAQ One-Slot Bus-Powered USB Chassis, see Fig. 3, 4, 5 and 6.

Fig. 6 NI-9237 USB strain gauge card

The strain gauge card provides 50 kS/s/channel, full bridge, 4-channel sensing. The NI-9237 input module includes all the signal conditioning needed to power and measure up to four bridge-based sensors simultaneously. The module provides strain or load measurements with zero inter-channel phase delay. It also features 60 VDC isolation and 1000 Vrms transient isolation, which provides common mode noise filtering and increased safety.

Four RJ50 connectors provide direct connectivity to most sensors and offer a solution with minimal cabling requirements.

4 Sensors

The MCF30 force sensor with a nominal range of 500 N was selected for the tension/pressure measurement, see Fig. 4 to 7 and reference [16]. This sensor was chosen precisely for its characteristic features:

- bridge connection of strain gauges,
- small dimensions
- measurement of tensile and compressive forces
- suitability for industrial and laboratory purposes.

Fig. 7 Strain gauge force sensor

Figure 8 shows screenshots of the user interface for the fixator measuring unit.

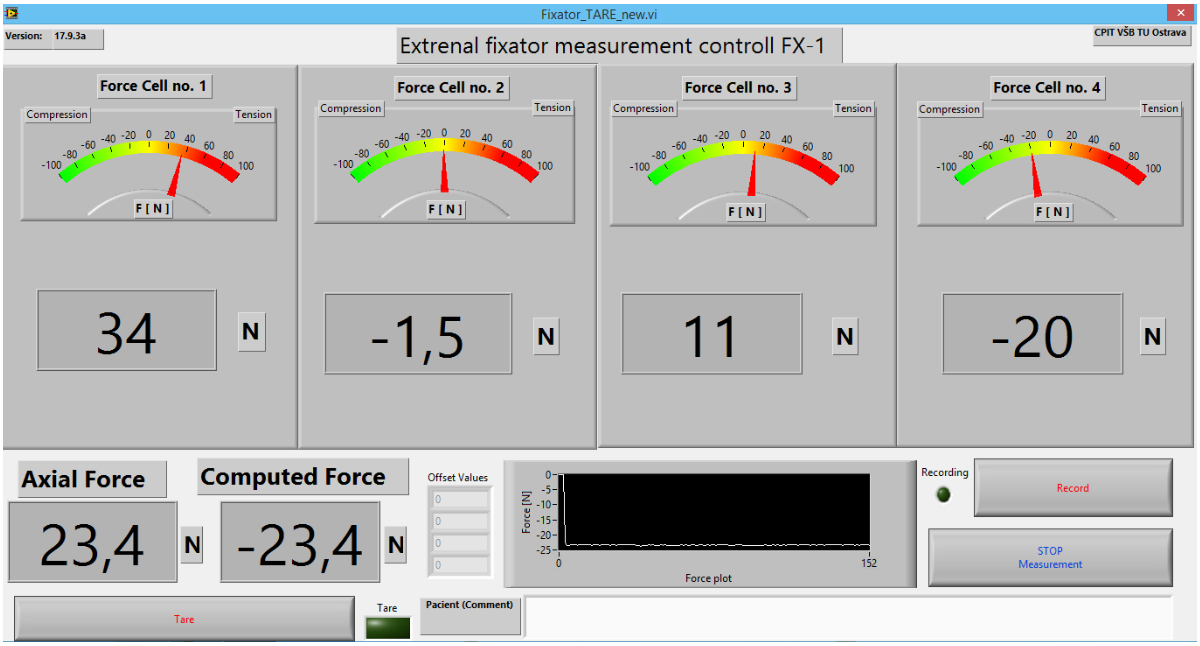

Fig. 8 User interface screen during measurement (LabVIEW sw)

The user interface consists of 4 displays (separate for each sensor). This display has a basic analog load indicator and a precise digital display.

The lower part of the user interface is dedicated to the final value of the device and control. There is also a display for displaying the load over time.

The axial force is the actual force on the sensors and is calculated as its inverse value.

The Tare button allows zeroing the sensors, which is followed by the display of the zeroing offsets (signaled by a green indicator). There is also a field for writing a comment or note.

The lower right corner contains two buttons (Record and Stop). When the Record button is pressed, the measured values are saved to a file, which is signaled by a green indicator. The STOP button ends the measurement.

5 Results and Evaluation

5.1 Demographic data

A total of 143 patients out of 181 patients were included in the study after applying all entry and exclusion criteria. Of these, group A, a total of 71 patients with the use of strain gauges (49.7%) and group B, which included 72 patients without the use of strain gauges (50.3%).

The groups differed in age and gender at entry: patients in group A with gauges were younger (48.3 ± 16.1 vs. 57.0 ± 15.1 years; p = 0.001, t-test; medians 47.0 [35.0–60.0] years vs. 58.0 [46.0–68.0] years, Mann–Whitney) and more often men (67.6% vs. 47.2%; p = 0.022, chi-square). Weight (86.4 ± 21.1 vs. 82.2 ± 18.2 kg; p = 0.207) and BMI (28.3 ± 6.4 vs. 28.8 ± 6.4 kg/m^2; p = 0.674) did not differ (Table 5.1). The p-value expresses the probability that we would obtain a result in the study that is at least as extreme as the one we observed if the null hypothesis were true.

Table 1 Basic descriptive characteristics of the patient population

Charakterics	**Group A**	**Group B**	***p***
Patients analyzed, n (%)	71 (49.7 %)	72 (50.3 %)	
Age (years)			
Mean ± SD	48.3 ± 16.1	57.0 ± 15.1	
Median (IQR)	47.0 (35.0-60.0)	58.0 (46.0-68.0)	0.001*[a,b]
Range	18-82	18-85	
Sex			
Males, n (%)	48 (67.6 %)	34 (47.2 %)	0.022*[c]
Females, n (%)	23 (32.4 %)	38 (52.8 %)	
Comminuted fractures (AO type C – i.e. fully intraarticular diaphyseal fracture)	50	43	0.220*[c]
Weight (kg), mean ± SD	86.4 ± 21.1	82.2 ± 18.2	0.207 [a]
BMI, mean ± SD	28.3 ± 6.4	28.8 ± 6.4	0.674 [a]

Note:

* Statistically significant at the p < 0.05 level; a Student's t-test; bMann-Whitney test; cChi-square test

SD = standard deviation; IQR = interquartile range; BMI = Body Mass Index.

5.2 Compression

We measured the compression applied to the fracture in the 6th week after surgery in the force range of equivalent mass 6-57 kg (average 26 kg), which represented 9-52% (average 16%) compared to the patient's weight.

In the 12th week after surgery, the compression was in the force range of equivalent mass 25-70 kg (average 45 kg), which represented 27-68% (average 27%) of the patient's weight.

In the 18th week after surgery, the compression was in the force range of equivalent mass 49-130 kg (average 83 kg), which represented 59-105% (average 51%) compared to the patient's weight (Tab. 2).

Table 2 Compression pressures measured using MCF30 strain gauges in group A

Week	**Compression pressure average in %**	**Load share in %**
6. week	9 – 52 %	100-60 %
12. week	35 - 68 %	60-30 %
18. week	59 - 105 %	30-10 %

The values show that with the healing period, the compression at the fracture site increased and the load share decreased. This corresponds to a desired increase in muscle strength and muscle volume, an increase in the load carried by the skeleton and a decrease in the load carried by the circular external fixator.

The above solution also confirmed the suitability of using MCF30 strain gauges to measure the applied compression of a circular external fixator on a tibia fracture.

5.3 Healing time

Healing was monitored and evaluated using X-rays snapshots. Fracture healing was defined as bridging ≥3 out of 4 cortices on control X-rays. This was also in the absence of rest pain and full weight-bearing of the limb. Statistical analyses was applied in the following evaluation; see [17].

Non-union was defined as the absence of signs of healing after ≥9 months from surgery.

In group A, most patients healed between 140 and 230 days. In group B, it was between 85 and 180 days. This shows that both groups have a fairly wide range (i.e. the results naturally have a large dispersion, i.e. not all patients are the same), so the variability of the results is high in both groups.

The statistical analysis revealed a shift in the distribution of healing times towards longer values in group A compared to group B.

The median (average healing time) is higher in patients in group A (approximately 188 days) compared to group B (approximately 120 days) and the difference is statistically significant ($p < 0.001$, Mann–Whitney U test).

The interquartile ranges are comparably wide, group A 140–230 days, group B 85–180 days, indicating similar central variability (which is very high, as shown by the range of healing times in both groups), but the overall position of the distribution is consistently higher in group A. The size of the difference corresponds to a medium-sized effect between the groups (Cohen's $d = 0.56$) (Fig. 5.1). Explanation: The interquartile range (IQR) indicates how much the values differ within the middle of the set. It is essentially the "range" within which the middle 50% of patients lie.

The difference is where the range is: in group A the values are shifted higher (they took longer to heal).

Cohen's number d = 0.56 is a number that tells how big the difference is between the groups. A value around 0.5 means a medium-sized difference.

In conclusion, it can be summarized that both groups of patients heal in very different lengths of time, but in group A it generally takes longer than in group B. The difference is not huge, but it is significant enough to be said to be moderately significant; see Tab. 3 and Fig. .

Table 3 Results of healing time and incidence of pin-site infections for individual groups

Charakteristics	**Group A**	**Group B**	***p***
Healing time (days)			
mean ± SD	188,4 ± 74,0	143,7 ± 85,2	<0,001* [a]
median (IQR)	188,0 (140,0-230,0)	120,0 (85,0-180,0)	<0,001*[b]
range (min-max)	70-357	35-420	
PIN infection, n (%)	9 (12,7 %)	39 (54,2 %)	<0,001*[c]

Note:

* Statistically significant at the p <0.05 level; aStudent's t-test; bMann-Whitney test; cChi-square test

SD = standard deviation; IQR = interquartile range; BMI = body mass index.

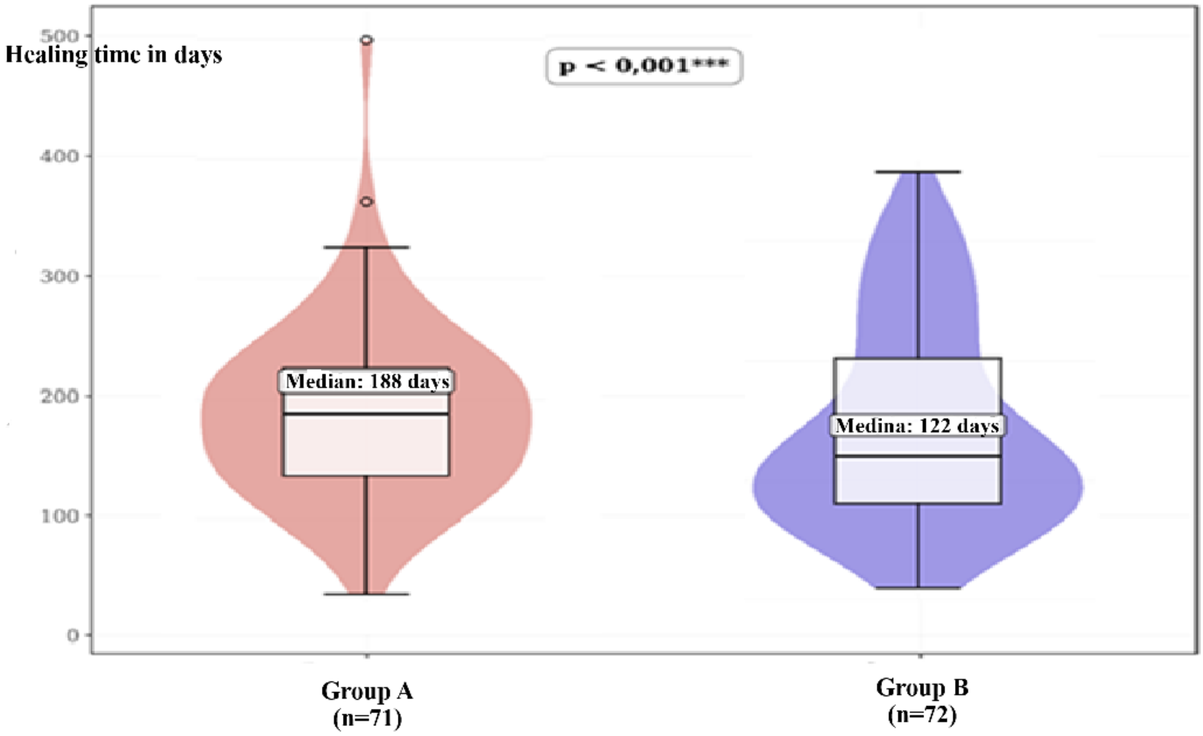

Fig. 9 Violin plot of the distribution of healing times in group A and group B

5.4 Incidence of pin-site infection

The pin-site effect is related to the tissue sites where KI wires are inserted during the application of the fixator, where infections can occur in extreme cases [17], [18], [19].

The incidence of infections at the KI wire insertion site was significantly lower in group A (9/71; 12.7%) than in group B (39/72; 54.2%; p <0.001, chi-square) (Fig. 10). The corresponding absolute risk difference is −41.5 percentage points (95% CI −55.4 to −27.6). Relatively, patients in group B had a 4.27× higher risk of infection than patients in group A (RR 4.27; 95% CI 2.24–8.16). Visualization with 95% confidence intervals demonstrates a large separation between groups and is in full agreement with the tabular significance test.

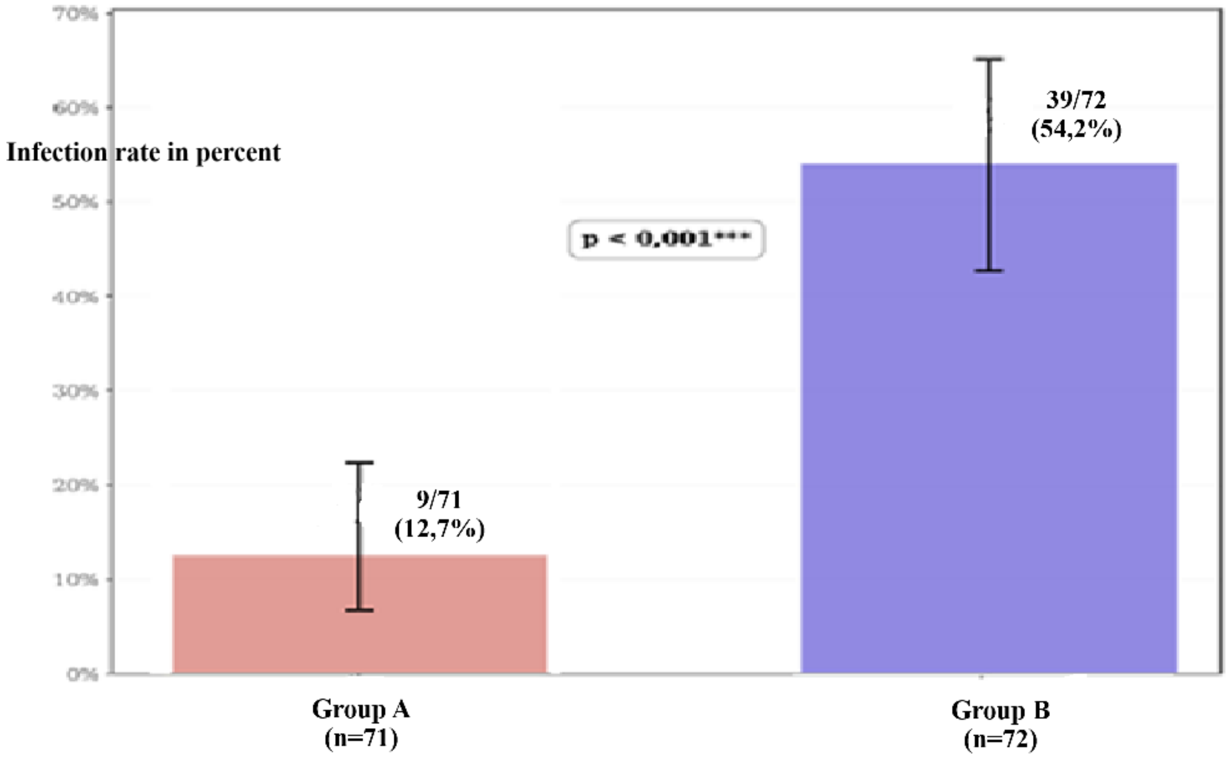

Fig. 10 Graphical representation of the incidence of pin-site infections in groups A and B

This can be explained by the fact that in group A 9/71 (12.7%) patients had an infection, in group B 39/72 (54.2%) patients.

This fact alone shows that infections occurred much more frequently in group B.

• $p < 0.001$, chi-square

- The statistical test says that the difference is not random. The probability that such a large difference would have occurred by chance is less than 0.1%.
- The result is highly significant.

• Absolute risk difference (−41.5 p.p.)

- The difference between 12.7% (group A) and 54.2% (group B) is 41.5 percentage points.
- The negative sign is there because group A had a lower risk.
- In other words: 41.5% fewer patients in group A got sick.

• 95% CI −55.4 to −27.6

- The confidence interval says: we are 95% sure that the true difference in the incidence of pin track infections is between −55.4 and −27.6 p.p.
- This means that if the study were repeated, group A would always fare much better.

• Relative risk (RR 4.27)

- Patients in group B had a 4.27-fold higher risk of infection than patients in group A.
- The confidence interval (2.24–8.16) shows that this is not a coincidence.

In group B, infections occurred much more often – more than half of the patients, while in group A only about one in eight. The risk was more than fourfold in group B. Statistically, this is a very convincing and reliable difference. The pin-site effect was therefore more pronounced in group B.

However, the interpretation remains associative – longer healing may reflect the indication of the sensor in more clinically complex cases. In group A, a lower proportion of closed fractures is evident (grade 0: 49.3% vs. 58.3%) and, conversely, a slightly higher proportion of open injuries across grades 1–3 (grade 1: 8.5% vs. 4.2%; grade 2: 25.4% vs. 22.2%; grade 3: 16.9% vs. 15.3%). When aggregating "open vs. closed", this corresponds to more open fractures in group A (~50.7% vs. ~41.7%) (Fig. 11). This slight shift towards higher severity in group A is consistent with the assumption of "confounding by indication" (statistical bias of results) and may partly contribute to the longer healing time observed in this group.

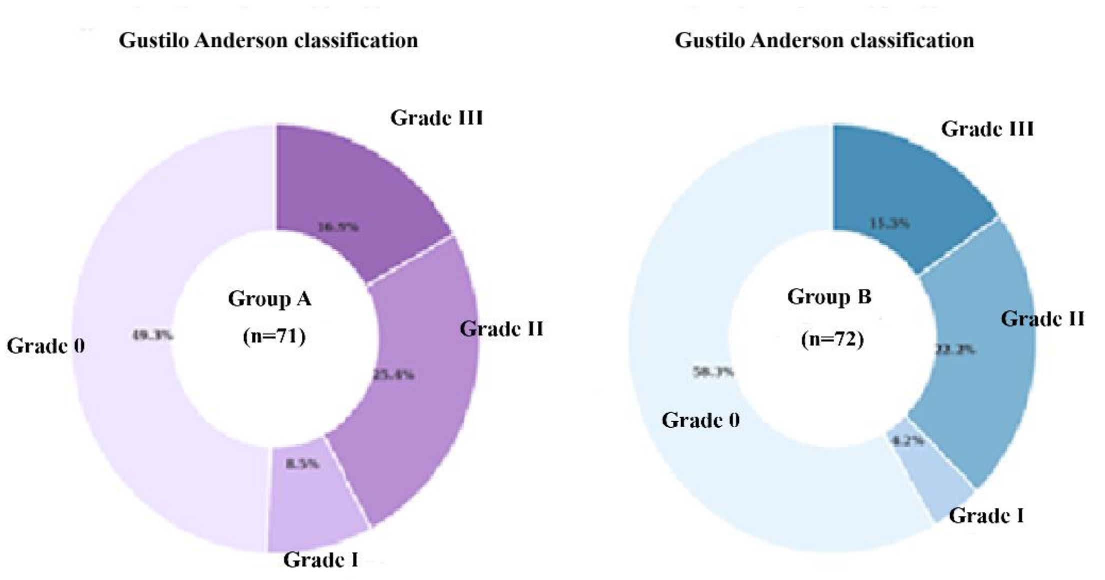

Fig. 11 Distribution of participants in group A and group B according to the Gustilo-Anderson classification.

Explanation: This is a statistical interpretation of the results and tries to explain why the difference between the groups cannot be understood as just a "straight line". An association interpretation means that a connection is observed, but it is not certain that one thing causes the other (i.e. a connection with the correlation of the compared data). Here, the longer healing may be related to the use of the sensor, but it may also be because the sensor is more often given to patients with more complex fractures. In group A, there were fewer closed fractures (49.3% vs. 58.3%) and fewer open fractures (together about 50.7% vs. 41.7%). Open fractures are more serious, they heal more slowly, and their healing takes longer. Confounding by indication is a technical term for a situation where a treatment (or method) is more often used in patients who are "more difficult cases" from the start. Then it may seem that the method leads to worse results, but in fact it is because the worse patients received it. Group A had more serious (open) fractures than group B. This may artificially prolong healing time in group A without being caused by the method itself.

CONCLUSION

The strain gauge sensor product for the external fixator is a summary of the latest findings from the fields of medicine and biomechanics and mechanical/materials engineering. It shows a multidisciplinary connection that brings maximum efficiency.

Before this type of fixator, the FNO had no information about the forces introduced between the treated bones. The correct timing and their effect on the subsequent healing of the fracture. Until now, the forces were only estimated. The developed type of fixator with sensors allows these forces to be defined precisely.

Based on a clinical study, the compression and distraction forces can then be determined, their correct timing within the framework of fracture healing, which will allow the desired reduction in healing time.

In the monitored group of patients with severe open fractures of the tibia of the III and IV degrees, the median treatment time was reduced to 80 weeks compared to the comparison group, where it was 93.5 weeks.

Another outcome of our clinical trial is our recommended method of working with an external fixator, consisting of performing dosed compression and distraction at the fracture site, which contributed to the shortening of treatment in the monitored group.

Our hypothesis that the healing process on the bone surface (i.e. cortical healing) can be monitored using ultrasonography was confirmed, we demonstrated a correlation with monitoring fracture healing using X-ray images.

The application of a new innovative external fixator equipped with pressure sensors at the fracture site brought the discovery that the load of the limb with the external fixator does not transfer pressure compression forces to the fracture site, but rather the pressure compression forces at the fracture site on the external fixator are primarily determined by the pressure between the rings of the external fixator at the fracture site.

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