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Digital monitoring of weight-bearing improves success rates and reduces complications in lower extremity surgeries

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Abstract

The aim of this study is to develop a digital monitoring system to track weight and evaluate its impact on postoperative outcomes after lower extremity surgeries (LES). This parallel randomized controlled trial enrolled 266 patients who underwent LES (fracture or joint replacement) at our medical center between March 11, 2022, and January 10, 2023. Patients were randomly assigned to the intervention and control groups in a 1:1 ratio. The intervention group (n=116) used a cane and shoes equipped with a weight-bearing system after lower limb surgery, while the control group (n=116) used a simple cane and shoes without a weight-bearing system. The primary outcomes included callus formation, duration of union, and success rate of union in the two groups. The intervention group had a significantly higher rate of complete surgical success than the control group (93.9% vs. 79.3%, p=0.001). The intervention group also had a significantly lower risk of non-union than the control group (OR: 2.33, 95% CI: 1.14, 3.48, p=0.001). The mean duration of surgery until the time of union and the meantime of callus formation was significantly lower in the intervention group (p=0.01). The use of a digital monitoring system for weighing in LES significantly increased the success rate and reduced post-operative complications. Therefore, incorporating this system can enhance the rehabilitation process and prevent revision surgeries in patients with LES.

Key Words: weight-bearing; lower extremity; randomized controlled trial; total knee; total hip.

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Fractures, especially those affecting the lower limbs, are a common injury worldwide, with an estimated 50% of individuals experiencing some form of fracture by the age of 65.[1,2] As the global population ages, the incidence of lower limb fractures is expected to increase, particularly in developing countries.[3] These fractures can result in significant disability, leading to a substantial financial burden on healthcare systems.[4,5] For instance, hip fractures alone account for 1.4% of disability-adjusted life years (DALYs), which places a significant strain on healthcare systems and has been increasing in recent years.[6] One of the most important complications following fractures is non-union or malunion. Studies suggest that over 100,000 fractures fail to heal each year, leading to increased treatment costs, lost productivity, and decreased quality of life.[7,8] The failure of a fracture to heal can result in significant economic costs, making it an important public health concern.[9,10] Weight-bearing is a critical factor influencing the occurrence of non-union after surgery. In patients undergoing orthopedic surgery, including those with lower extremity fractures or osteotomies, weight-bearing is often restricted to avoid fixation device failure, delayed fracture healing, or nonunion of bone fragments.[11,12] However, weight-bearing regimens after lower limb fractures remain a significant challenge for orthopedic surgeons, as current protocols are primarily based on expert opinion rather than empirical evidence, and contradictory results have been reported.[13-15] Although physicians and physical therapists typically provide weight-bearing recommendations to patients, these protocols may not

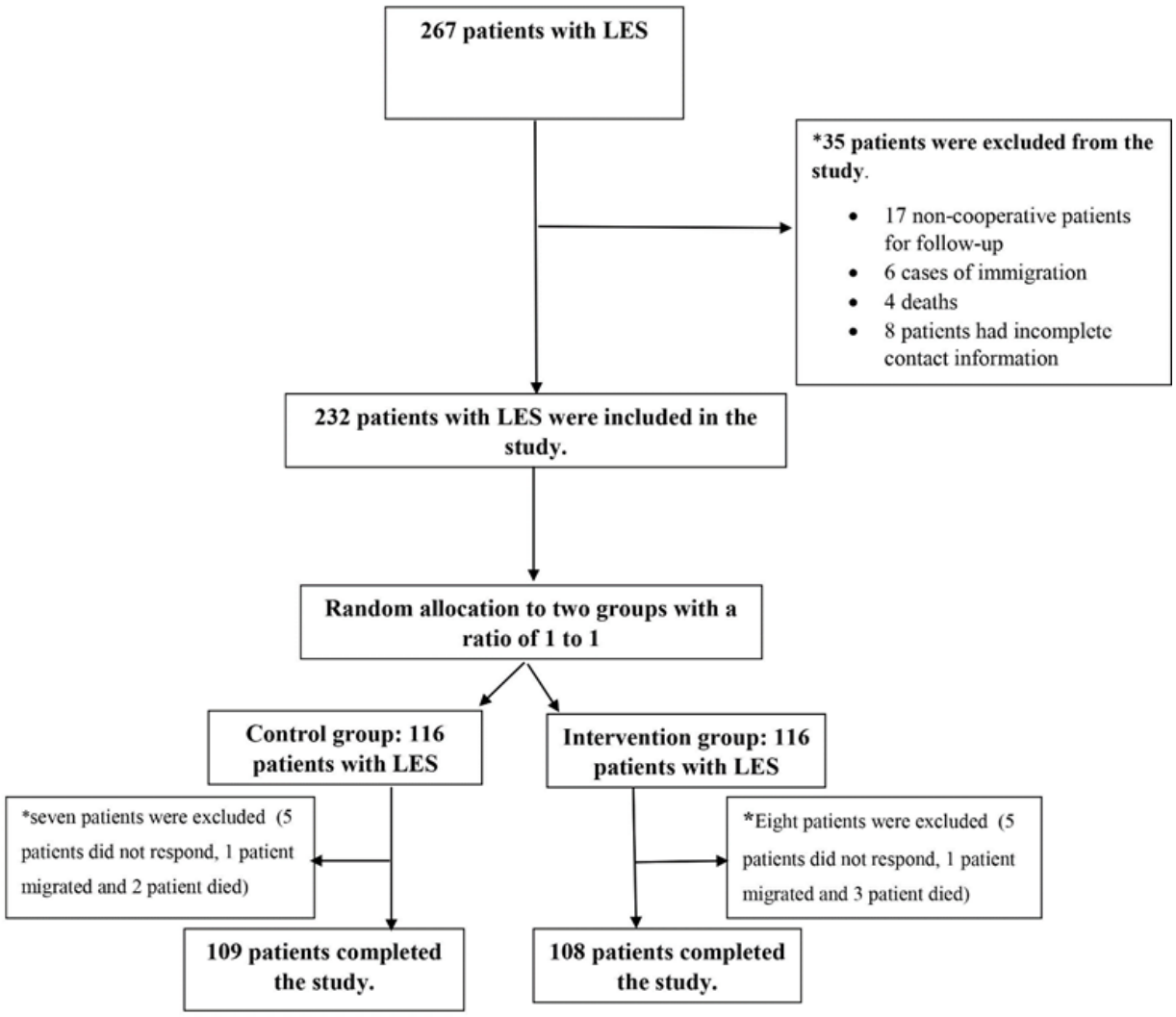

Fig 1. *Flow chart of patients entering the study*

accurately reflect dynamic activities, such as walking, leading to patient confusion and noncompliance with partial weight-bearing regimens. This problem may be attributed to the lack of a quantitative method for estimating load on the lower limb and the absence of a biofeedback system to alert patients when pre-set weight limits are exceeded, further underscoring the need for a comprehensive digital monitoring system to aid patient recovery.[13,14]

Accordingly, this study aimed to develop a novel digital monitoring system to track weight-bearing in patients following lower extremity surgeries and to evaluate the efficacy of weight-bearing restrictions in these patients. The system developed in this study provides a quantitative method for estimating load on the lower limb during dynamic activities, which may facilitate patient compliance with prescribed weight-bearing regimens. Furthermore, this system incorporates a biofeedback mechanism to alert patients when pre-set weight limits are exceeded, potentially improving outcomes following lower extremity surgeries.

Materials and Methods

Patients and Design

All procedures performed in this study involving human participants were in accordance with the ethical standards and approved by the Ethics Committee of the Iran University of Medical Sciences (Ethical number: IR.IUMS.REC.1400.1117) and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The study aimed to investigate the effect of a specific intervention on a cohort of 267 patients with LES who were referred to medical centers between March 11,

Table 1. *Comparison of demographic characteristics in two groups based on ITT*

Variable	**Group**		**p value**
	Intervention	**Control**	
Age (year)	44.75±12.18	48.15±12.85	0.21
Gender ● Male ● Female	 33 (28.4%) 83 (71.6%)	 41(35.3%) 75(64.7%)	0.19
PMH ● Yes ● NO	 23(19.8%) 93(80.2%)	 26(22.4%) 90(77.6%)	0.49
BMI (kg/m^2)	24.91 ± 2.19	25.36 ± 2.21	0.67
Follow-up (Week)	14.65 ± 4.21	16.86 ± 4.33	0.11
Cause of surgery ● Fractures ● Knee joint replacement ● Hip joint replacement ● Ankle joint replacement	 59(50.9%) 28(24.1%) 25(21.6%) 4(3.4%)	 64(55.2%) 24(20.7%) 26(22.4%) 2(1.7%)	0.17
Trauma Type ● High energy ● Low energy	 63(78.6%) 17(21.4%)		
Smoker ● NO ● Yes	 85 (73.3%) 31 (26.7%)	 88(75.7%) 28(24.3%)	0.55

2022, and January 10, 2023. Out of these patients, 232 were included in the study.

All participants underwent lower extremity surgery, such as a fracture or joint replacement, performed by three highly experienced surgeons. Informed consent was obtained from all participants prior to the surgery. The surgeon and data analyst were blinded to the study group allocation. Patient sampling was conducted using an access method, and then patients were randomly assigned to either the intervention or control group using the Excel statistical software with a ratio of 1:1.

Inclusion and Exclusion criteria

The present study included patients who underwent lower limb surgery, including fractures of the foot, ankle, tibia, knee, femur, and hip, as well as hip and knee joint replacement. Patients over 5 years of age who provided informed consent were included in the study. Exclusion criteria were infection, death during the study period, lack of information, associated fractures in the upper limbs, and secondary surgeries or revisions in the lower limbs. A total of 217 patients, 108 in the intervention group and 109 in the control group, were included in the final analysis (Figure 1).

Study groups and randomization

The intervention group consisted of 116 patients who underwent lower limb surgery and utilized a specialized cane and shoes equipped with a weight-bearing limitation system post-surgery.

Meanwhile, the control group comprised 116 patients who used crutches and normal shoes without a weight-bearing system after surgery. To ensure equal sample ratio and balance between the two groups, a random block method with block sizes of 6 was employed. The Rand-between function was utilized to generate a random chain from Excel software. The randomization and allocation of patients into the intervention and control groups were conducted by an epidemiologist. In this study, both groups were provided with the cane and shoes, and no financial burden was imposed on the patients.

Table 2. *Comparison of the overall WOMC score and ROM in the two groups.*

Variable	Group		p value
	Intervention	Control	
Total WOMAC Score (Mean±SD)	75.25±12.18	66.22±13.25	0.096
ROM (Mean±SD)	109.21±18.54	76.1±23.22	0.024

Weighing system

In this study, a digital weight control device bio cane made by Ortho Biomed company of Canada was used to limit weight bearing after surgery. The device contains three or four sensors that calculate the weight required for the lower limb and send the received signals to the patient's smartphone. The patient is informed via a warning system in case of applying more weight than the set weight. The information is uploaded to a reliable global server located in Canada, which is accessible to both the patient and their specialist doctor via an installed smart application. The device consists of two parts: a hardware section and a software section. The hardware section includes sensors detecting the pressure caused by weight, a Bluetooth transmitter, and storage memory used in the tip of the cane and the sole of the shoe. The software section includes an app that can be installed on all mobile phones, tablets, and notebooks. The software takes the raw information received from canes and shoes and displays it in the application menu in simple and understandable charts. Real-time information is automatically recorded in the system memory every time the patient walks, and the patient's performance is recorded and can be seen through the software. The equipment of this machine includes two parts: a cane load cell and shoe load cell, with the cane being the master and the shoe the slave in the communication system. Two load cells, one in the heel and one in the toe, are connected in parallel to accurately read information while walking. The information in this section is processed by an Arduino board with an ATmega328 processor. The power supply of this board is an easy-to-replace book battery. The device uses a rechargeable lithium polymer battery, which uses a TP4056 charger IC for its charging circuit.

Intervention

After the surgery for lower limb fractures, all patients were provided with special shoes or a cane, and the intervention group was given a weight sensor in their shoes and cane. The treatment team provided training to all patients on how to use the equipment and instructed the control group on how to move and act after surgery. The intervention group used the device until they had fully healed, with the attending physician determining the length of usage. The device collected signals that were sent to the patient's smartphone, and if the weight exceeded or fell below the set limit, an alarm would inform the patient about the weight imposed. In this group, the treating physician monitored their patients remotely on a daily basis, checked their treatment process, and sent necessary recommendations to the patient through the software messenger, if required. The kit on the stick and the application would warn the patient if they exceeded or fell short of the prescribed weight. By knowing about these issues and providing appropriate orders on time, the doctor prevented the failure of the treatment, such as broken implanted platinum, a broken bone, nun-union or malunion. The device determined the amount of weight be used as a number for each patient according to their condition and surgery type, and any cases where the weight exceeded the set limit during the day were recorded as a warning.

Follow up

In both the intervention and control groups, patients were followed for a period of 4 to 24 weeks depending on the type of surgery and the attending physician's diagnosis. During this follow-up period, patients in both groups were visited by an orthopedic surgeon every 4 weeks, and the frequency of visits was increased to once every two weeks if deemed necessary by the attending physician. Radiography (X-rays) was used as a standard method for monitoring and evaluating the progress of treatment in all patients who underwent surgery, and the same dose of radiation was used for both the intervention and control groups. The follow-up of patients was conducted by a team of two orthopedic surgeons and a radiologist.

Data collection

The study collected data in two parts: demographic information of the patients at the time of admission (including age, sex, body mass index (BMI), underlying diseases, and smoking status), surgical outcomes, and radiographic findings after the operation. The surgical

Table 3. *Comparison of postoperative outcomes in the two groups.*

Variable	Group		p - value
	Intervention	Control	
Non- union ● Yes ● NO	 7(6.1%) 109(93.9%)	 24(20.7%) 92(79.3%)	0.001
Malunion ● Yes ● No	 2 (1.7%) 114 (98.3%)	 6(5.2%) 110(94.8%)	0.001
Infection ● Yes ● NO	 23(19.8%) 93(80.2%)	 26(22.4%) 90(77.6%)	0.49
Duration of Union	3.06 ± 1.21	6.22 ± 2.13	0.001
Mean time of callus formation (Week)	6.09 ± 1.7	10.14 ± 2.54	0.001

outcomes and radiographic findings that were investigated included the rate of swelling, callus formation, duration of follow-up, the time required for fusion, range of motion (ROM), western ontario and mcmaster universities (WOMAC) score, and postoperative complications for both the intervention and control groups.

The WOMAC scoring system, which includes three components (pain, motion limitation or joint stiffness, and physical performance), was completed blindly during a face-to-face interview with the patient by an orthopedic resident (other than the first year). The WOMAC scoring system is a widely accepted criterion for assessing the reliability and validity of the Iranian population.[14,15]

Primary and secondary outcomes

The primary outcome of this study was to evaluate the formation of callus and the rate of union success in the intervention and control groups. The secondary outcomes included a comparison of the time required for sutures, the need for revision, the incidence of infection, and other complications related to the procedure in both groups.

Statistical analyses

The data were analyzed using the SPSS version 22 statistical software (IBM Corp., Armonk, N.Y., USA). Descriptive statistics and central indices were used to estimate the mean and median in the two groups. The normality of the distribution of variables within the two groups was assessed using the Kolmogorov-Smirnov test. The Intention-to-treat (ITT) analysis approach was used for data analysis. If the distribution of variables was normal, the t-test was used to compare the quantitative variables in the two groups.

However, if it was not normal, the Mann-Whitney non-parametric test was used. The Chi-Square statistical test was used to analyze qualitative variables in the two groups.

The odds ratio (OR) in the 95% confidence interval (95% CI) was used to report the effect size in the two groups. To control confounding variables, multivariate logistic regression analyses were used in addition to randomization in the design stage. Statistical significance was set at a p-value of less than 0.05.

Results

Demographic finding

In this study, a total of 232 patients were included, with 116 patients in both the intervention and control groups. The majority of the patients were male (68.1%) and the overall mean age was 46.81 ± 13.18 years, ranging from 20 to 75 years. The mean follow-up duration was 15.77 ± 4.25 weeks. The mean total BMI was 25.13 ± 2.23 kg/m2. About 27.8% of cases had a history of smoking. Among the surgeries performed, 123 (53.02%) were for lower limb fractures and 109 (46.98%) were for joint replacements (6 ankle joint replacements, 52 knee joint replacements, and 51 hip joint replacements). In terms of trauma classification, 99 (80.5%) of fractures were of high energy type and 24 (19.5%) were of low energy type. Anticoagulant drugs were used in all patients.

Table 1 shows that there were no significant differences in demographic characteristics between the two groups ($p>0.05$).

Comparison of WOMAC and ROM scores

The data analysis revealed that the overall mean WOMAC score for the intervention group was 75.25 and for the control group was 66.22, but the difference between the two groups was not statistically significant (p=0.096). On the other hand, the mean range of motion (ROM) in the intervention group was significantly higher than the control group (p=0.024). (Table 2)

Comparison of postoperative outcomes

The rate of complete surgical success in the intervention group was significantly higher than in the control group 93.9% vs. 79.3% (p 0.001) The chance of non-union in the control group was significantly higher than in the intervention group. (OR: 2.33, 95%CI: 1.14, 3.48, p: 0.001) The mean duration of surgery until union in the intervention group was significantly less than the control group. Also, the mean duration of callus formation in the intervention group was significantly less than in the control group. (p: 0.01) No significant difference was observed in the rate of infection and other complications in the two groups (p>0.05) (Table 3).

Discussion

Weight bearing on damaged orthopedic organs, particularly lower limbs, is a significant challenge for orthopedic surgeons as it can have a significant impact on the success rate of surgery and its complications.[13] Current recommendations for weight bearing after orthopedic surgeries are based on surgeon's experience, and there are no standard guidelines for contact weight bearing. Patients often find it difficult to adhere to the recommended weight training guidelines.[16-18] Results indicated that the success rate and range of motion in the intervention group were significantly higher than the control group.

The intervention group also had significantly lower rates of non-union and malunion. The mean time of union and the time of callus formation in the group that used the weight-bearing monitoring system were significantly lower than the control group. There was no significant difference in the total mean WOMAC score between the two groups, although this may be due to short-term patient follow-up. In the intervention group, seven patients had problems during the study, including non-use of insoles due to foot swelling, plate fracture due to excessive weight bearing, and joint ROM limitation. In contrast, the control group had more problems during follow-up, including early weight bearing, excessive weight bearing, Achilles tendon shortening, and limited joint range of motion. Previous studies have shown that the use of weighting systems in orthopedic surgery has been associated with reducing complications and accelerating the rehabilitation and functional process.[16,19,20]

Stoller et al., evaluated the role of using feedback and analysis systems to partially improve weight bearing and improve postoperative outcomes in lower extremity fractures in a 2021 study.[20] The system was based on sensor pads to measure pressure distribution and display it on a smartphone app to provide real-time visual and acoustic feedback during post-surgery. The results showed that this system reduces the rate of complications and enables a faster rehabilitation process, which was consistent with the results of our study. In a parallel randomized controlled trial, Raaben et al., showed that the use of biofeedback systems during rehabilitation after proximal femur fractures in the elderly was promising and effective to accelerate the improvement of the rehabilitation process and improve the success rate in surgery.[19] Hustedt et al., demonstrated that biofeedback devices have been introduced for patients with orthopedic surgeries that are able to monitor the amount of weight bearing and provide feedback in patients after surgery.[21]

They showed that the use of biofeedback devices can improve the rehabilitation process. In a 2018 study, Raaben et al., investigated the effect of using a real-time visual biofeedback system on weight bearing in people with lower limb fracture in two conditions of full weight bearing and weight bearing with lower touch after limb fracture.[22] The results showed that the use of real-time visual biofeedback system led to improved treatment compliance after lower limb fracture and improved treatment results.

One of the study's main weaknesses was the short-term follow-up of patients, which may affect the more accurate estimation of performance indicators such as WOMAC. Prospective studies with long-term follow-up are necessary to provide more accurate performance indicators. The study's strengths included the development of an intelligent weighing system for the first time and the estimation of the outcomes and complications of the use of this system in a randomized controlled trial study with a large sample size.

In conclusion, the findings of our study demonstrate that implementing a digital monitoring system for weight bearing in lower extremity surgeries resulted in a significant increase in surgical success rates and a reduction in postoperative complications. Consequently, integrating this system into the rehabilitation process can enhance outcomes and decrease the need for repeat surgeries in patients undergoing lower limb procedures.

List of acronyms

BMI - body mass index
DALYs - disability-adjusted life years
LES - lower extremity surgeries
ROM - range of motion
WOMAC - western ontario and mcmaster universities

Contributions of Authors

All authors were involved in the conceptualization, as well as the design of the research strategy, performed analyzed the data. All authors were involved in the writing and final editing of the manuscript. All authors approved the final edited Early Release.

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Conflict of Interest

The authors declare no competing interests.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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