

## Effect of Nursing Intervention Protocol on Outcomes of Patients undergoing Lower Limb Ilizarov External Ring Fixation

Shimaa Hessian Mohamed<sup>1</sup>, Hanan Abdelrarik Abdelall<sup>2</sup> & Samia Youssef Sayed<sup>3</sup>

<sup>1</sup>. Assistant Professor of Medical, Surgical Nursing, Faculty of Nursing, Assiut University, Egypt

<sup>2</sup>. Assistant Professor of Medical, Surgical Nursing, Faculty of Nursing, Assiut University, Egypt

<sup>3</sup>. Assistant Professor of Medical, Surgical Nursing, Faculty of Nursing, Assiut University, Egypt

### Abstract

**Background:** Maintaining stability of external fixation is an important part in nursing management by creating plans that teach patients about care of ilizarov ring fixation devices. **Aim:** Assess the effect of nursing intervention protocol on outcomes of patients undergoing Ilizarov external ring fixation. **Design:** A quasi experimental design was used **Sample:** 60 adult patients were randomly assigned into 2 equal groups for a purposive study. **Setting:** The study conducted in the Trauma & Orthopedic Department at the Assiut University Hospital and the affiliation clinic. **Tools:** **I:** Patient's assessment sheet, **II:** Patients' Stirling's Pressure Ulcer Severity Scale, **III:** Chacketts & Otterburn's Grading System and **IV:** Kurz normal ranges of joint motion scale. **Results:** A statistically significant differences between study and control groups related to infection grading, ROM, wound care post implementation of the nursing intervention protocol. **Conclusion:** The nursing intervention protocol has a positive effect on patient outcomes in relation to promoting the wound healing and reducing pin site infection, improving joint function and preventing pressure ulcer. **Recommendations:** The nursing intervention protocol should serve as the basis for routine nursing care for patients with external fixators to improve their outcomes.

**Keywords:** Lower Limb Ilizarov external Ring Fixation, Nursing Intervention Protocol & Outcomes

### Introduction:

External fixation is a crucial aspect of orthopedic surgery, and it is commonly used in traumatology and reconstructive surgery. In orthopedic surgery, the ilizarov device is a type of external fixation that is indicated to stretch or reshape lower limb bones, as a limb-sparing method to treat open bone fractures, and infected nonunion of bones that are not receptive to other methods of fixations (Ferreira et al., 2018).

The device is a special form of external fixator, circular fixator with modular design. A stainless steel (or titanium) ring is attached to the bone with a thick stainless-steel wire (called a "pin" or Kirschner wire). The circular ilizarov frame allows resection of infected bone, repair of defects, and stabilization to sclerosis while maintaining or restoring limb length (Xing, et al., 2020).

Complications encountered during the application of ilizarov apparatus include muscle contractures, joint dislocations, axial deviations, nerve & vascular injuries, premature sclerosis, poor union, complications with pin placement; as osteomyelitis, loose frames or pins, or wire failures, non-union, neurovascular injury, compartment syndrome and pin-related fractures. Late complications are; delayed wound healing, loss of length, joint stiffness, pain and sleep disturbances. Pin site and wound infection may

affect blood vessels and nerves, consequently close monitoring of the color of peripheral skin, temperature and nerve injury postoperatively is needed in an effort to ensure the nonexistence of these abnormalities (Hadeed, et al., 2022).

The neurovascular evaluation of the extremities is achieved to assess sensitive and motor function and peripheral circulation. The neurovascular evaluation consists of pulses, capillary refill, skin color, temperature, sensation, and motor function. Pain and edema also are assessed in the course of this examination. Comparison of evaluation findings bilaterally is significant (Abdullah et al., 2017).

One of the most frequent complication of pins and wires is infection at the pin site insertion. Three levels of pin site infection exist: first level (Pin site reaction), which is characterized by normal/physiologic changes in skin color, warmth at the pin site, and drainage that goes away within 72 hours; second level (Pin site colonization), which is characterized by erythema, warmth at the pin site, drainage that may cause pain; and third level (Pin site infection), include pus, pin loosening, or increased microbial growth on cultures (Mohamed et al., 2021)

External fixation is regularly used to manage patients with lower extremity trauma. Excessive pressure from contact surfaces lead to heel ulcers that generally associated with prolonged bed rest but can also be

secondary to wound complications after surgery. Pressure ulcers at the posterior heel can be because of prolonged pressure, friction or shear. Distortion of tissues will affect in ischemia and subsequent skin breakdown if the ulcer doesn't get relief (**Oscar et al., 2009**).

Post-operative care is a critical in the successful completion of orthopedic surgery and the reduction of wound healing complication after pin insertion that include; observing vital signs, administering medications as prescribed, elevating the affected limb, care for wound once daily by cleaning each pin site with a new sterile cotton-tipped applicator that has been soaked in a solution of 1:1 hydrogen peroxide and normal saline. Dry sterile gauze is wrapped around each pin site (**Said, et al., 2020**).

In particular; prolonged lower limb immobilization makes it challenging to give the best care for patients using external fixator devices, so the nursing protocol provides the post-ilizarov ring fixation follow-up to achieve the best outcomes for those patients. As a result, several nursing care approaches have been developed; including patient exercise to prevent loss of lower limb length & joint stiffness (**Khoris, et al., 2018**).

All range of motion exercises are used to strengthen muscles and joints as a way to increase mobility and prevent re-injury. They are an essential part of a physical therapy, and are established to assist patients return to normal activities as quickly and safely as possible (**Mohamed et al., 2021**).

Patient outcomes are measured or observed as a result of nursing interventions that are documented at specific points during or after treatment and demonstrate that the patient's health status has stabilized or been sustained (**Jin, et al., 2022**). In this study, skills and knowledge are discussed for a patient with ilizarov ring fixation; how to properly care for the pin site, evaluate wound care, and perform ranges of joint motion exercises.

#### **Operational definitions:**

**Nursing intervention protocol:** means interventions that were designed to improve physical joint function and delay disability for patients undergoing ilizarov ring fixation.

**In the scope of this study;** nursing intervention protocol means providing intervention to maintain wound healing, reduce pin site infection and improve joint function and reduce stiffness by engaging in ROM exercises.

**Patients outcomes:** In this study; patient outcomes refers to effects and consequences related to application of Ilizarov external ring fixation (such as pin site infection, joint function as well as pressure ulcer).

#### **Significance of the study:**

External fixation is an essential component of the modern orthopedic surgeries and is commonly used in traumatology and reconstructive surgery. This treatment modality is frequently associated with universal complication (**Jin, et al., 2022**). According to Assuit hospital record, 150 patient admitted for applying external fixation device in last year from January 2022 to January 2023 (**Assuit hospital record , 2022** ).In view of the fact that Ilizarov ring fixation is a common musculoskeletal apparatus use in management of lower limb disorders, which is characterized by rapid onset of complication that may affect the patient's activities of daily living and work as loss of lower limb bone length, joint stiffness, and other complications as pin sit infection ,delayed wound healing (**Mohamed et al., 2020**). These complications enhance the financial problems for both the hospital and the patient and produce additional demands on the time and resources of the medical and nursing staff. Thus, patients with Ilizarov ring fixation need some measures to improve outcomes by educating the patient ROM exercise, wound and pin sites care.

#### **Aim of the study:**

To evaluate the effect of the nursing intervention protocol on outcomes of patients undergoing lower limb Ilizarov external ring fixation

#### **Hypothesis:**

In the current study, the following hypothesis was put forward:

Implementation of a nursing intervention protocol will positively affects outcomes of patients undergoing lower limb Ilizarov external ring fixation (reduce pin sit infection, improve joint function and prevent pressure ulcer).

#### **Methods:**

##### **Research design:**

A quasi-experimental research design was used. This type of studies includes working with independent variables random assignment of participants terms (**Kumar & Kothari, 2020**). The nursing intervention protocol considered the independent variables while the dependent variable was: Wound healing, pin sites infection and joint function.

##### **Setting:**

The study conducted in the Trauma & Orthopedic Department at the Assiut University Hospital &the outpatient clinics. Trauma & Orthopedic department serves the biggest region of population from both rural and urban area. Each department consists of two sectors (male and female) each sector consists of five rooms each room has four beds. Orthopedic department at the third floor & Trauma & department at the fourth floor

**Participants:**

A purposeful sample of (60) adult patients with lower limb Ilizarov external ring fixation were selected according to inclusion criteria: age between 20-65 years from both genders, free from any infections, and able to communicate. They were divided into two equal groups (study and control), 30 patients for each. The study group received nursing intervention protocol and routine hospital care while the control group received the routine hospital care only.

**Exclusion criteria:**

Patients might additionally suffer from mental disorders or altered states of consciousness, other type of external fixation, as well as any co-occurring diseases affecting wound healing including diabetes mellitus, cancer, end stage renal failure, and liver failure

**Sample size**

The sample size was calculated using G power software version 3.1.9.7 based on an expert opinion by Cohen effect size 0.5. The minimum sample size was 26 patients for each group with power (1- $\beta$  err prob) 0.8 and ( $\alpha$  err prob) 0.05. The researchers had obtained 60 patients due to non-response rate that expected to be lost from the participants.

**Tools:** Three tools were utilized to collect data: -

**Tool I: Patient's assessment sheet:** After considering the literature on this study, it was developed by researchers. It had two parts:

**Part (A): Patient's characteristics:** Including 5 items (age, gender, education, marital status, occupation).

**Part (B): Patients medical history:** It includes data related to present medical data as causes of trauma, chronic disease, corticosteroid therapy, and indication of Ilizarov fixation

**Part (C): Neurovascular assessment:** Used to assess skin and vascular status distal to ilizarov fixation. It includes color (normal, pale, cyanosed), skin temperature (cold, hot, warm), swelling (no, marked, moderate), pulse (strong, weak, absent), and capillary refill (early, delayed).

Scoring system:

In case of normal findings = 1, and abnormal findings = zero degree.

**Tool II: Stirling's Pressure Ulcer Severity Scale:**

This is an observational scale adapted from **Pedley, (2004)**, used to assess the severity of pressure ulcers. It includes several variations, 1 and 2-digit scales, where the nature and severity of the ulcer are divided. The 2-digit Stirling Scale is rated out of

4 stages with subgratings in each stage. The 1-digit Stirling Scale include 4 stages with no subgratings ranging

**Scoring system:**

Stage 0: No clinical evidence of a pressure sore

Stage 1: Discoloration of the intact skin

Stage 2: Partial-thickness skin loss damage involving epidermis or dermis

Stage 3: Full-thickness skin loss but not extending to underlying bone

Stage 4: Full-thickness skin loss with extensive destruction

**Tool reliability:**

Cronbach's alpha was 0.87. (Cronbach's alpha of 0.8–0.9 indicates acceptable reliability). The test re-test correlation coefficient was 0.79.

**Tool Validity:**

A high significant correlation (Pearson correlation-0.598) was found. (**Mohan et al., 2014**).

**Tool (III): Checketts & Otterburn's Grading System:**

This scale adopted from (**Checketts et al., 1993**) to assess pin site infection. It was divided into six grades. Grade I: a slight discharge and redness around the pin tract. Grade II: Erythema plus others signs of inflammation as pain and tenderness in the soft tissue. Grade III: Haemoserous discharge not improves with local treatment and antibiotics. Grade IV infections are classified as serious infections because they involve several pins and have extensive soft tissue involvement. Grade V infections are similar to grade IV infections but involve bone, and signs of osteomyelitis. Lastly grade VI: sequestrum formation in bone and persistent sinus continues to form.

**Scoring system of tool III:** This scale consists of (6) grades, minor infections occur in grade I to III, and while major infections ranged from grade IV to VI.

**Tool IV: Kurz normal ranges of joint motion scale:**

It was developed by **Kurz, (2013)** this scale used to assess joint function illustrating the normal ranges of joint motion for different parts of the body by using a goniometry with standardized technique. A goniometer is a protractor type of instrument used to measure the joint angle at both extremes in the total range of movement. Depends on the joint and motion being assessed, the universal goniometer has been shown to have good to excellent reliability, and is more reliable than visual estimation especially with inexperienced examiners. (**Viraj et al., 2022**)

**Scoring system of Kurz normal ranges of joint motion scale:**

Joint motion	Descriptiion	Normal
<b>Hip ROM:</b>		
- Flexion	- Flex knee and bring thigh to abdomen.	110-130 degrees
- Extension	- Move thigh backward	30 degrees
- Abduction	- Swing thigh away from midline.	45-50 degrees
- Adduction	- Bring thigh toward and across midline.	20-30 degrees
- Internal rotation	- Flex knee and swing lower leg away from midline.	40 degrees
- External rotation	- Flex knee and swing lower leg toward midline	45 degrees
<b>Knee ROM:</b>		
- Flexion	- Touch calf to hamstring.	130 degrees
- Extension	- Straighten out knee.	15 degrees
- Internal rotation	- Twist lower leg toward midline	10 degrees
<b>Ankle ROM:</b>		
- Flexion	- Flex ankle so toes point up.	45 degrees
- Extension	- Flex ankle so toes point down.	20 degrees
- Pronation	- Turn foot so the sole faces in.	30 degrees
- Supination	- Turn foot so the sole faces out.	20 degrees

**Tools face validity:**

Face validity: After the researcher created the instruments, the part-validation of the instruments was reviewed by a group of five experts. Two of the experts were orthopedists, and the others were medical-surgical nursing staff. The experts reviewed the content validity of the instruments, making changes according to their recommendations on clarity, adequacy, and completeness.

**Tools reliability:**

It refers to the degree the thing it is supposed to be measuring. Test reliability of this tools was assured with Cronbach's alpha =0.82

**Nursing intervention protocol:**

It was designed by the researcher depending on literature reviews (Xing, et al., 2020, Hadeed, et al., 2022, Abdullah et al., 2017 & Mohamed et al., 2021). This protocol aimed to provide nursing intervention regarding Ilizarov ring fixation to maintain wound healing, reduce pin site infection and improve joint function and reduce stiffness by engaging in ROM exercises. It prepared in a simple Arabic language and illustrated photos. It will include (introduction, definition of ilizarov ring fixation, indications, contraindications, complications, advantage, disadvantage, wound and pin site care ,dressing, pain management, nutrition, ROM exercises and walking (calf stretch, plantar flexion stretch, straight leg raise, knee flexion and extension), medication , indication for calling doctor and follow up.

**Fieldwork:**

Data collection took a period of one year, began from September 2021 and ended in September 2022, and the study was divided into 4 phases.

**Phase I- Preparatory phase:**

During this period; the hospital's administrator, nursing supervisors, and orthopedic departments received formal approval. It also includes a recent review of relevant literature to collect necessary data for study following a review of literature; the study materials and nursing intervention protocol were developed.

**Pilot Study:**

It was conducted on 10% of participants (6 patients) who met the selection criteria to assess the effectiveness, the applicability and clarity of the tools, estimate the time needed for data collection, and test the feasibility of conducting the. The data obtained from the pilot study were analyzed; No modification for data collection instrument, so the 10% of subjects were included. The pilot study found that the average time needed to complete the tools (30 min)

**Phase II- Assessment phase:**

Once the study was approved to conduct the intended research, a patient's interview was conducted with patients to discuss the goal and nature of the study. Ethical precautions were taken to ensure privacy and confidentiality of the participants. Participation was completely voluntary.

**Phase III: Implementation phase**

- The researcher went to the orthopedic department, made a random assignment of patient to study and control. During the first week from the study, the patient was assigned to the study group, and the patient admitted during the second week was assigned to the control group, which was repeated for all weeks.
- After discussing their rights and the study's nature and goal with each patient individually, the

researchers obtained their consent to participate in the study.

- **For the study group:** After the patient completes the structured interview questionnaire and the study tools, the researchers go through the implementation of nursing intervention protocol. They receive routine hospital care
- The meeting was done in the morning and afternoon shifts.
- Three sessions were conducted with study participants.
- Each session lasted between 20 and 30 minutes including 10 minutes for discussion and feedback.
- **At the first session:** The researchers introduce themselves, establish a line of communication, and conduct an initial assessment, simple information was included (definition of ilizarov ring fixation, indications, contraindications, complications, advantage, disadvantage of ilizarov). This meeting lasted between 20 and 30 minutes including 10 minutes for discussion and feedback.
- **At the second session:** the researchers explain to the patient, medication, pain management, wound and pin site care, dressing, and nutrition. Indications for seeking medical care and follow up were discussed.
- **At the third session:** The practical part of intervention was demonstrated by the researcher to the patient: dressing, ROM exercise (Calf stretch, Plantar flexion stretch, Straight leg raise, knee flexion and extension) and walking with ilizarov.
- Arabic illustrated copies of the nursing intervention protocol were provided for every patient within the study group.
- For control group they receive routine hospital care and after data collection, copies of the nursing intervention protocol were provided for every patient.

**Phase III: Evaluation phase:** Patients from the study and control group were seen (2 times one time monthly) for two months after discharge. The time and place for follow up were arranged within the out patients clinic of orthopaedic at Assiut University Hospital for reevaluation. Comparison was done between two groups in order to measure the effect of the nursing intervention protocol on pin site infection, pressure ulcer and joint function

### **Ethical considerations:**

The research proposal was approved by the Ethical Committee in the Faculty of Nursing, Assiut University. Official approvals were obtained from Trauma & Orthopedic Department at the Main Assiut University Hospital and the outpatient clinics. The study adhered to accepted ethical standards for clinical research. Patients who participated in the

study were given the opportunity to give their consent after being informed of its scope and objectives. The study participants had no risk when the research was applied. Anonymity and confidentiality were guaranteed. Each participant had the right to decline participation or withdraw from it at any time.

### **Analytical statistics**

It was done by using the computer program SPSS" version. 22". The result presented as mean  $\pm$ , standard deviation or number and percentage. T-test used to significance for the numerical variables. The chi-square test for association was used to determine if there was a relationship between two categorical variables. A correlation coefficient —Pearson correlation is a numerical measure of some type of correlation, meaning a statistical relationship between two variables. The level of statistical significance was set at  $P < 0.05$

**Result:****Table (1): Frequency & percentage distribution of demographic characteristic of study vs. control group among patients with lower limb Ilizarov external ring fixation (n=60)**

Demographic characteristic	Study (n=30)		Control (n=30)		Total (n=60)		X <sup>2</sup>	P.value
	n.	%	n.	%	n.	%		
<b>Age group</b>								
20- <30 year	8	26.7	6	20.0	14	23.3	5.49	0.139
30-<40 years	12	40.0	14	46.7	26	43.3		
40-<50 years	7	23.3	2	6.6	9	15.0		
50 - 65year	3	10.0	8	26.7	11	18.4		
<b>Gender</b>								
Male	21	70.0	17	56.7	38	63.3	1.15	0.284
Female	9	30.0	13	43.3	22	36.7		
<b>Level of education</b>								
High education	5	16.7	8	26.7	15	25.0	5.84	0.120
Secondary education	6	20.0	12	40.0	16	26.7		
Read and write	10	33.3	4	13.3	14	23.3		
Illiterate	9	30.0	6	20.0	15	25.0		
<b>Marital status</b>								
Single	14	46.7	10	33.3	24	40.0	2.78	0.249
Married	16	53.3	18	60.0	34	56.7		
Divorced	0	0.0	2	6.7	2	3.3		
<b>Occupation</b>								
Employee	10	33.3	12	40.0	22	36.7	1.61	0.657
Student	6	20.0	8	26.6	14	23.3		
Farmer	9	30.0	5	16.7	14	23.3		
House wife	5	16.7	5	16.7	10	16.7		

A chi-square test In order to compare the variance in proportions, test analysis was utilized.

T-test analysis was used to compare the mean difference between the two groups

**Table (2): Frequency &percentage distribution of patients' related to medical history for both group (n=60)**

Medical data	Study (n=30)		Control (n=30)		Total (n=60)		X <sup>2</sup>	P.value
	n.	%	n.	%	n.	%		
<b>Causes of trauma</b>								
Arthrodesis	2	6.7	0	0.0	2	3.3	9.22	0.100
Electrical burn	1	3.3	0	0.0	1	1.7		
Fire arm injury	2	6.7	0	0.0	2	3.3		
Foot deformity	6	20.	11	36.	17	28.		
Fracture	14	46.	9	30.	23	38.		
Motor accident	5	16.	10	33.	15	25.		
<b>Chronic disease</b>								
Gastrointestinal disease	25	83.	20	66.	45	75.	5.96	0.114
Chest disease	4	13.	6	20.	10	16.		
Kidney disease	1	3.3	0	0.0	1	1.7		
Cardiovascular disease	0	0.0	4	13.	4	6.7		
<b>Corticosteroid therapy</b>								
Yes	6	20	8	26.	14	46.	9.32	0.002**
No	24	80	22	73.	46	76.		

Fisher's exact test for qualitative data between the two groups

Chi square test for qualitative data between the two groups \*\*Significant level at P value < 0.01

**Table (3): Comparison between the study and control groups in accordance to indications of ilizarov fixation (n=60)**

Indications of ilizarov fixation	Study (n=30)		Control (n=30)		Total (n=60)		X2	P.value
	n.	%	n.	%	n.	%		
Stabilization of severe open fractures	10	33.3	10	33.3	20	33.3	7.8 7	0.164
Correction of extremity malalignments and length discrepancies	8	26.7	12	40.1	20	33.3		
Stabilization of bony disruption in poly trauma patients	5	16.7	6	20.0	11	18.3		
Closed fracture with severe soft tissue injuries	2	6.6	2	6.6	4	6.7		
Arthrodesis	5	16.7	0	0.0	5	8.3		

Fisher's exact test for qualitative data between the two groups (2\*2variable)

Chi square test for qualitative data between the two groups or more

**Table (4): Frequency & percentage distribution of patients according to a neurovascular assessment of affected limb in both groups 2 month post implementation of nursing intervention protocol (n=60)**

Neurovascular assessment of affected limb	2 month post protocol implementation						X2	P. value
	Study (n=30)		Control(n=30)		Total (n=60)			
	n.	%	n.	%	n.	%		
<b>Color</b>								
Pale	1	3.3	1	3.3	2	3.3	6.69	0.035*
Cyanosed	0	0.0	6	20.0	6	10.0		
Normal	29	96.7	23	76.7	52	86.7		
<b>Temperature</b>								
Hot	0	0.0	6	20.0	6	10.0	6.67	0.01*
Normal warm	30	100.0	24	80.0	54	90.0		
<b>Swelling</b>								
Marked	5	16.7	10	33.3	15	25.0	18.56	0.001**
Moderate	3	10.0	19	63.4	22	36.7		
No	22	73.3	1	3.3	23	38.3		
<b>Pulse</b>								
Weak	0	0.0	9	30.0	9	15.0	10.59	0.001**
Strong	30	100.0	21	70.0	51	85.0		
<b>Capillary refill</b>								
Early	30	100.0	22	73.3	52	86.7	9.23	0.002**
Delayed	0	0.0	8	26.7	8	13.3		

Fisher's exact test for qualitative data between the two groups (2\*2variable) Chi square test for qualitative data between the two groups or More \*Significant level at P value < 0.05, \*\*Significant level at P value < 0.01

**Table (5): Comparison between study and control groups accordance with Stirling's pressure ulcer severity scale 2 months post implementation of the nursing intervention protocol (n=60)**

Items of Stirling's pressure ulcer severity scale	2 month post protocol implementation						X2	P. Value	
	Study (n=30)		Control (n=30)		Total (n=60)				
	n.	%	n.	%	n.	%			
1. No clinical evidence of a pressure sore	25	83.3	17	56.7	42	70	14.03	0.003**	
2. Discoloration of the intact skin	5	16.7	7	23.3	12	20			
3. Partial thickness skin loss	0	0.0	5	16.7	5	8.3			
4. Full-thickness skin loss & necrosis of subcutaneous tissue but not extending to underlying bone	0	0.0	1	3.3	1	1.7			
<b>The common site for pressure ulcer</b>									
- Heel	5	16.7	12	40	17	28.3			
- Ankle	0	0.00	1	3.3	1	1.7			

Chi square test for qualitative data between the two groups or more \*\*Significant level at P value < 0.01

**Table (6): Comparison between study and control groups related to grades for pin site infection 2-month post protocol implementation (n=60).**

Grades of pin site infection	2 month post protocol implementation						X2	P. value		
	Study (n=30)		Control (n=30)		Total (n=60)					
	n.	%	n.	%	n.	%				
<b>1. One month post protocol implementation</b>										
Grade I	10	33.3	12	40.0	22	36.7	4.90	0.001**		
Grade II	3	10.0	13	43.3	16	26.7				
Grade III	0	0.0	2	6.7	2	3.3				
No Infection	17	56.7	3	10.0	20	33.3				
<b>2. Two month post protocol implementation</b>										
Grade I	3	10.0	5	16.7	8	13.3				
Grade II	0.0	0.0	10	33.3	10	16.7				
Grade III	0	0.0	4	13.3	4	6.7				
No Infection	27	90	11	36.7	38	63.3				

Chi square test for qualitative data between the two groups or more

\*\*Significant level at P value < 0.01

**Table (7): Comparison between study and control groups related to normal ranges of joint motion of lower limb with ilizarov external fixator 2 month post protocol implementation (n=60)**

Joint range of motion	2 month post protocol implementation				Total (n=60)		X2	P. value
	Study(n=30)		Control (n=30)		n.	%		
	n.	%	n.	%				
<b>Hip;</b>								
Normal	30	100.0	28	93.3	58	96.7	2.07	0.150
Abnormal	0	0.0	2	6.7	2	3.3		
<b>Knee;</b>								
Normal	30	100.0	22	73.3	52	86.7	9.23	0.002**
Abnormal	0	0.0	8	26.7	8	13.3		
<b>Ankle;</b>								
Normal	30	100.0	23	76.7	53	88.3	7.93	0.005**
Abnormal	0	0.0	7	23.3	7	11.7		

Fisher's exact test for qualitative data between the two groups (2\*2variable)

\*Significant level at P value < 0.05,

\*\*Significant level at P value < 0.01



**Table (1):** Shows that the age of the study and control groups ranged between 30 and 40 years old (40.0% , 46.7 %) respectively. (70.0%) of the study group were males compared with above half (56.7%) among control group. Concerning to marital status above half of the both groups were married (53.3%, 60.0%), regarding to level of education, the study group shows about a third (33.3 %) of the study sample who could read and write compared with less than half of the sample (40.3%) had a secondary education. Employee patients represented (33.3%, 40% respectively) in study & control groups.

**Table (2):** Regarding to frequency percentage distribution of present medical history; (36.7%) of the control group had foot deformity and (46.7 %) of the study group had fracture in lower limb. Regarding the chronic disease, the majority of both groups had GIT diseases (83.3 %, 66.7%) respectively. Related to corticosteroid therapy; below quarter of the study group take corticosteroid therapy (20%) compared with (26.0%) of the control group. A significance statistical difference was found between study and control group in the items of uses corticosteroid therapy p value =0.002\*\*

**Table (3):** As we show from this table, the ilizarov device was indicated to stabilization of open fractures in one third (33.3%) of both groups. The ilizarov fixation device was indicated for correction of malalignments in both groups (26.7% & 40.1% respectively). As well as less than a quarter in both groups (16.7%, 20.0%) respectively used the ilizarov apparatus to stabilize bony disruption and soft tissue in poly trauma patients. A little from both groups (6.7%) used the ilizarov apparatus for fracture management. Furthermore (16.7%) of the study group used ilizarov apparatus to manage arthrodesis.

With regard to the neurovascular assessment of the affected limb, **table (4):** Reveals that nearly three quarters of the study group (73.3%) had no swelling compared to the control group (63.4%) mild swelling. The vast majority (96.7%, 76.7%) of both groups had normal skin color in their lower limbs. In terms of the affected limb's pulse, 100% of the study group had a strong pulse, compared to 70% of the control group. Regarding capillary refill, every member of the study group (100%) has early capillary refill, while in the control group the percentage was (73.3%). Two months after the nursing intervention protocol was implemented, there was a significant statistical difference between the two groups regarding the neurovascular assessment of the affected limb (p= <0.001\*\*).

**Table (5):** Shows that the control group experienced a 16.7% skin thickness loss compared to (0.00%) skin thickness loss in the study group. The most common site for pressure ulcer in both groups is heel. Two

months after the nursing intervention protocol was implemented, there was a statistically significant difference between the two groups on every item of Stirling's pressure ulcer severity scale (p value = p= 0.003\*\*).

**Table (6):** This table shows that, one month after the protocol was implemented, (40%) of the control group had Grade I, (43.3%) grade II, and (6.7%) grade III pin sit infections, while (10%) of the study group had Grade I and the same percent had grade II. Just 10% of the study group had grade I pin sit infections in the follow-up phase, two months after the protocol was implemented, and 90% of them were infection-free, compared to 16.6% for grade I, 33.3% grade II, and 13.3% grade III in the control group. One and two months after the protocol's adoption. There was a statistically significant difference identified in the rates of pin site infection between the two groups one & two months after the protocol was implemented (p= <0.001\*\*). In our study we consider minor infections from grade I to III, and major infections from grade IV to VI.

**Table (7):** Demonstrates that a statistically significant differences regarding all items of Kurz normal ranges of lower limb joint function (knee, ankle range of motion) between both groups p≤ 0.05.

## Discussion:

The current study was conducted to investigate the effect of the nursing intervention protocol on the outcomes of patients with Ilizarov ring fixation. The results of the current study showed a significant improvement in lower limb joint function, wound care, and the incidence of pin-site infection following the implementation of the nursing protocol. Also the results demonstrate that the defined methodology is successful and that the set hypotheses were realized.

In relation of patient demographics; the current study revealed that vast majority of study and control group their ages ranged between 30 and 40 years old. This supported with the study by **Ebraheim et al., (2018)**, who founded that the mean age of the study's participants was (30.9±8.43). But this result is disagree with study of **Siddiqui et al.,(2019)**, that found the patients' mean age to be 53 ± 4 years. According to **WHO, (2021)**, individuals under 45 account for over 50% of traumatic injury-related deaths, and trauma generally affects the young, and healthy people. As regarding to the gender; the present study revealed that most patients in the study and control groups were male. Such findings are consistent with a study conducted in (2011) by **Nikolopoulos et al.**, who discovered that over 50% of patients undergoing Ilizarov fixation were male. These results may be due to the fact that young males are at high risk for accidents and fractures than

females due to frequent exposure to street and high level of activity-related injuries

According to occupation, the largest percentage of patients in both groups who were employed. This may be because of the nature of their work, which makes them more susceptible to accidents and fractures. This result is consistent with research by **Morsy, et al., (2021)**, which discovered that most patients exposed to trauma were workers.

The results of the current study also demonstrated that the clinical and patient demographic information, including age, gender, marital status, and level of education, had no statistically significant differences among the studied patients. These results proved the homogeneity of the study and control groups, ruling out any confounding factors that might have had an impact on the outcomes for patients undergoing lower limb external fixation after the nursing protocol intervention.

According to the study's current medical conditions, below one-half of the study patients had a fracture in their lower limb. This is in line with the findings of **Fahad et al. (2019)**, who assert that the Ilizarov external fixator is more appropriate for treating various lower limb fractures because it can correct deformities, provide a stable mechanical environment, and allow weight bearing. For these reasons, we also advise using the device.

Related to corticosteroid therapy; a few of the patient in the study group take corticosteroid therapy, This supports a study by **Hamahashi, et al., (2017)** that reported an oral corticosteroid therapy are frequently effective treatments for such illnesses and Kirschner wire replacement are required for deep infections involving soft tissues and bone, but considerably slows the healing process.

Regarding the indication for ilizarov fixation, the current study shows that less than a quarter of both groups used the ilizarov apparatus to stabilize soft tissue and bony disruption in patients with poly trauma, while more than 25% of the control group used ilizarov for stabilizing severe open fractures. In the same line **Testa et al. (2019)** proven in their study that, the ilizarov external fixation technique has been used for the last 50 years to treat long-bone nonunion fractures. Their study demonstrated that this technique was effective in promoting bone segment regeneration in non-union fracture patients.

The current study's findings demonstrated that; the ilizarov fixation device was indicated for correction of malalignments and length discrepancies in both groups. These findings corroborate those of **Mohammed et al. (2017)**, who demonstrated that the ilizarov fixation procedure allows for the realization of compression, distraction, bone-lengthening, and deformity correction. Application of the Ilizarov

external fixator is especially helpful even when there are significant soft tissue defects, which are often treated with musculocutaneous flaps. Internal fixation can be complicated by bone loss, deformity, or failure of previous internal fixation. Nevertheless, it is a valid alternative treatment to internal fixation. The stability of the fixation provided by the Ilizarov technique allows for early weight-bearing ambulation and joint mobilization, which is an advantage . Furthermore, this supports the findings of **Giannoudis et al. (2021)**, who show a high union and a low rate of serious complications, indicating that external ring fixation is a secure and reliable course of treatment for these injuries.

Regarding neurovascular assessment vast majority of both groups had normal skin color in affected lower limb. Above half of the study group had no swelling, strong pulse, and early capillary refill while in the control group less than half of them had moderate swelling, weak pulse, and delayed capillary refill. A statistically significant difference was founded between both groups regarding neurovascular assessment of affected limb 2 months post implementation of the nursing intervention protocol  $p = <0.001^{**}$

The results of this study showed that, after the protocol was implemented, the majority of study group patients had a lower risk of developing pressure ulcers than the control group, which nearly half of the patients had intact skin discoloration. A significant difference in all items of the Stirling's pressure ulcer severity scale between the two groups two months after the nursing intervention was put into place. These findings are consistent with those of **Mohamed & Ibraheem (2019)**, who discovered that almost one-third of the control group was at a higher risk of developing a pressure ulcer. This outcome demonstrated that the nursing protocol's implementation improved patients' outcomes by lowering their chance of pressure injury exposure. This support the study hypothesis derived from these findings.

Also, the present finding found that the most common site for pressure ulcer in both groups is heel. This is supported by the study of **Luboz et al. (2015) & Oscar et al. (2009)**, they mentioned that pressure ulcers in the heel are extremely common, and numerous studies have looked into possible causes. The tissues in the posterior heel may be susceptible to ischemia due to the high metabolic demand for oxygen by the epidermis and the arrangement of adipose tissue, which is perpendicular to the skin and can cause deep lesions if excessive force is concentrated there. Tissue distortion will result in ischemia and ultimately skin breakdown if the ulcer is not healed.

In our study patients with lower extremity trauma are commonly managed with external fixation. Heel ulcers are caused by contact surfaces applying too much pressure. In addition to being frequently linked to extended bed rest, wound problems following application of external fixator may also be the cause of posterior heel ulcerations.

Pin tract infection is still a difficult clinical issue, particularly when limb lengthening or deformity correction procedures are involved (Tucci et al., 2019). A frequent side effect of external fixation that puts a heavy strain on the patient and the healthcare system is pin site infections. These infections can lead to more clinic visits needed for the patient during their treatment (Nikolas H. et al. 2016).

The current study found that; Over one-third of the study group developed Grade I pin sit infections one month after the nursing protocol was implemented, in contrast to the vast majority of the control group. In the same line with the study of Hamahashi et al., (2017) he mentioned that pin tract infection was the most typical complication seen in the study population during treatment with an ilizarov fixator. According to a recent study (Ceroni et al., 2016), pin site irritation and infection are caused by excessive movement at the fixator pin-bone interface.

The percentage of pin site infection was improved during follow-up phase, two months after the protocol's implementation, in which all members of the study group were free of Grade II and III pin site infections. Statistically significant difference was founded between both groups regarding pin site infection one- and two-months post intervention.

This agree with the study by Abouelala et al., (2023) who stated that maintaining nursing care and monitoring the ring fixation site are the most effective ways to prevent infection at the pin site. This is in line with a study by Shehata et al., (2021) who explained that a statistically significant difference was observed in relation to pin site infection between the two groups following the implementation of the teaching nursing protocol. This result is consistent with the findings of Elmagd et al. (2020), who observed that although the minority in the study group represented by grade (I) after providing of nursing protocol, the majority of the control group represented by grades II and III.

The study findings demonstrate that all of the Pauly Pin tract infection scale grading items with regards to both groups showed statistically significant differences. This is in line with a study by Bader & Atiyah (2017), which found that the most frequent side effect of external fixation is a pin tract infection.

From researcher point of view; the reduction in pin site infections can be attributed to the nursing protocol intervention and its positive effects, which

placed an emphasis on important information and recommended practices for pin site care. patients with Ilizarov external ring fixation require complex nursing care. Developing programs that educate patients' families about on-site care is another responsibility of the nurses.

According to study finding, 10% of the study participants experienced pin site infections and was managed by changing the dressing regularly. This is explained why nursing care for pin site infection should provide as a routine care for those patients.

According to the researchers, the application of the nursing protocol intervention resulted in statistically significant differences in the occurrence of pin site infection between the control group and the study group. It is helpful to be aware of expected complications in order to prevent or detect them early, which can improve the risk-benefit ratio. It was also necessary to reduce related complications by educating patients about this type of care prior to their discharge and giving them a handbook to guide their at-home care.

The results of this study showed that, after the nursing protocol was implemented, there were statistically significant differences in both groups for every item on the Kurz scale for normal ranges of lower limb joint function (knee and ankle range of motion)  $p \leq 0.05$ .

Similarly, Manzari et al. (2018) reported that a significant enhancement in range of motion for function of lower limb from admission to discharge. Additionally, this is in line with a study by Raman & Subbu (2019), which found that patients who perform gradually joint ROM and regular physiotherapy had very good functional recovery of lower limb joints. When placing the ilizarov device for the foot, performing exercises may be difficult at first because the weight of the device may be heavy, but exercises must be done to avoid joint stiffness and muscle weakness.

The researchers found that range of motion exercises are important to strengthen muscles and joints as a way to increase mobility and prevent re-injury. They are an essential to be established to assist patients return to normal activities as quickly and safely as possible. They make a patient flexible by gradual increasing the range of joint and muscle movement, and lowering swelling and stiffness

### Conclusion:

The nursing intervention protocol has a positive effect on patient outcomes in relation to promoting the wound healing and reducing pin site infection, improving joint function and preventing pressure ulcer

**Recommendations:**

- The nursing intervention protocol should serve as the basis for routine nursing care for patients with external fixators to improve their outcomes.
- Inform the patient about the importance of regular check-ups, range-of-motion exercises, and pin site care to avoid complications that could lower their quality of life.
- Encourage more investigation or researches to pinpoint the obstacles leading to failure of the ilizarov fixation.
- It is advised that the current study be repeated using a larger probability sample drawn from various geographic regions for the generalization of the findings.

**References:**

- **Abdullah A., Everett L., Noha S., Khalid B., Abdulmohsen A., Nezar A., Arin A., & Abdullah M., (2017):** Cross-Cultural Adaptation and Psychometric Properties Testing of the Arabic Anterior Knee Pain Scale Med SciMonit,29 (3), 1559–1582.
- **Abouelala F. Ramadan S. & Gamal Z. (2023):** Effect of Self-management protocol on Early Outcomes among Patients with Lower Limb External Fixator IEJNSR. International Egyptian Journal of Nursing Sciences and Research (IEJNSR), 3 (2), 77.
- **Assuit hospital record, (2022).**
- **Bader, T. &Atiyah, H. (2017):** Effectiveness of an educational program on orthopedic nurses' knowledge concerning pin track infection of external fixation in Al-Emamin AL- Khadamin Medical City; 6, (4), 15-21.
- **Bailey I.S., Karran S.E., & Toyn K., (1992):** Community surveillance of complications after hernia surgery. BMJ, 304(6825):469–471
- **Cam R., Korkmaz. (2014):** The effect of long-term care and follow-up on complications in patients with external fixators ,Int J NursPract, 20(1):89-96
- **Ceroni D., Grumetz C., & Samara E. (2016):** Prevention of pin-tract infection to treatment of osteomyelitis during paediatric external fixation , Journal of Children's Orthopaedics, 10,(6),78-87. <https://doi.org/10.1007/s11832-016-0787-8>
- **Checketts RG, MacEachern AG, Otterburn M., (2000):** Pin track infection and the principles of pin site care. In: Goldberg A, De Bastiani A, Graham Apley A, editors. Orthofix external fixation in trauma and orthopaedics. Berlin, Heidelberg, New York: Springer; 97-103.
- **Ebraheim, M. Khorais, A., & Barakat, A. (2018):** Self-care program: quality of life and satisfaction among patients with external skeletal fixation. IOSR Journal of Nursing and Health Science, 7(4), 71-83
- **Elmagd, N., Hossny, E., &Hussien, R. (2020):** Nursing performance associated with providing complete preventive nursing care and its relation with incidence of pin site infection: turn the lens inside. Egyptian Nursing Journal, 17(2), 87
- **Fahad S, Habib AA, Awais MB, , Umer M, FCPS, & Rashid HU, (2019 ):** Infected Non-union of Tibia Treated with Ilizarov External Fixator: Our Experience , **Malays Orthop J.** 13(1): 36–41.
- **Ferreira A., Silva D., Priore L., Garcia C., Ducatti M., Botta A., Waiteman M., & Azevedo F., (2018):** "Differences in pain and function between adolescent athletes and physically active with patellofemoral pain". Physical Therapy, 33(1), 70–75.
- **Giannoudis V.P., Ewins E., & Taylor D.M., (2021):** Clinical and Functional Outcomes in Patients with Distal Tibial Fracture Treated by Circular External Fixation: A Retrospective Cohort Study. Strategies Trauma Limb Reconstr; 16(2):86–95.
- **Hadeed A, Werntz R, & Varacallo M. (2022):** External Fixation Principles and Overview. Bookshelf. A service of the National Library of Medicine, National Institutes of Health. Stat Pearls Publishing LLC. Available at: <http://www.ncbi.nlm.nih.gov/books/nbk547694/>.
- **Hamahashi, Y. Uchiyama, Y. Kobayashi, and M. Watanabe, (2017):** Delayed methicillin-resistant Staphylococcus aureus-induced osteomyelitis of the tibia after pin tract infection: two case reports, (in eng), J Med Case Rep, 11(1), 23-40. doi: 10.1186/s13256-016-1187-x. J Med Case Rep
- **Healey F, (1995):** The Reliability and Utility of Pressure Sore Grading Scales, journal of tissue viability, 5(4), 111-114. [https://doi.org/10.1016/S0965-206X\(14\)80109-5](https://doi.org/10.1016/S0965-206X(14)80109-5)
- **Igor D., Terri N. Mladen J. , Milica S. Ialosevic T. Miljevic & Tamara M (2019):** Gastrointestinal Tract Disorders in Older Age Can J Gastroenterol Hepatol , 10 (1),155 .
- **Jin L., Zhang S., Zhang Y., Lin X., Feng D. & Hu K. (2022):** Management algorithm of external fixation in lower leg arterial injury for limb salvages. BMC International Medical Research, 48(2), 56-78.
- **Kedar G.,Vaidyanath R. , Girish S. , Gautam T. Vinod P., & Lokesh S. (2020):** Use of Southampton Scoring for Wound Healing in Post-surgical Patients: Our Experience in Semi-urban, Arch Clin Biomed Res, 5 (1): 36-41. DOI: 10.26502/acbr.50170148
- **Khorais, A., Ebraheim, M. &Barakat, A. (2018):** Selfcare program: quality of life and satisfaction among patients with external skeletal fixation. IOSR Journal of Nursing and Health Science, 7(4), 71-83.

- **Liu Y, Yushan M, LiuZ, Chuang Ma & Yusufu A., (2020):** Complications of bone transport technique using the Ilizarov method in the lower extremity: a retrospective analysis of 282 consecutive cases over 10 years *BMC Musculoskeletal Disorders*, 21( 354), 55-70.
- **Luboz V, Perrier A. Budki M, Diot B, Cannard F, Vuillerme N, & Payan Y. (2015):** Influence of the calcaneus shape on the risk of posterior heel ulcer using 3D patient -specific biomechanical modeling. *Ann Biomed Eng*; 43(2):325-35.
- **Manzari S.Z., Ardebili M.F., & Bozorgnejad M. (2018):** Effect of educational program based on exercise therapy on burned hand function, 3 (1), 39-46
- **Mohamed, M., Mansour, N., Mohamed Taha, N., & Moghazy, A. (2021):** Nurses performance regarding orthopedic patients with external fixation at Zagazig University Hospitals. *Egyptian Journal of Health Care*, 11(1), 115-126.
- **Mohamed, S.S. & Ibraheem, R.A., (2020):** Effect of preventive bundle care on nurses' knowledge, compliance and patients' outcome. *Evidence-Based Nursing Research*, 1 (4), 86. <https://doi.org/10.47104/ebnrojs3.v1i4.86>
- **Mohammed, R., Atinga, E., Sitati, F., & Gakuya, E., (2017):** Pin tract infection after uniplanar external fixation of open fractures at a national, teaching and referral hospital. *East and Central African Journal of Surgery*, 22(1), 42- 48.
- **Mohan A, Vadher J, Ismail H, & Warwick D. (2014):** Original Scientific Reports , The Southampton Dupuytren's Scoring Scheme, 28-33
- **Morsy R, Sheta H, & Mohamed R. (2021):** Effectiveness of Nursing Guidelines regarding Self-Care Strategies for Patients with External Skeletal Fixation. *Journal of Nursing Science Benha University*, 2(2): 526-545.
- **Nikolopoulos N., Babis, G. C., Evangelopoulos, D. S., Kontovazenitis, K., & Soucacos, P. (2011):** High energy tibial plateau fractures treated with hybrid external fixation. *Journal of orthopaedic surgery and research*, 6(1), 35.
- **Nikolas H. Kazmers, Austin T. Fragomen, and S. Robert Rozbruch. (2016):** Prevention of pin site infection in external fixation: a review of the literature. *Journal of Reconstruction* v.11 (2).
- **Oscar E Castro-Aragon , Jay H Rapley, & Saul G Trevino, (2009):** The use of a kickstand modification for the prevention of heel decubitus ulcers in trauma patients with lower extremity external fixation , *J Orthop Trauma*, 23(2):145-7.
- **Pedley GE. (2004):** Comparison of Pressure Ulcer Grading Scales: a study of clinical utility and inter-rater reliability, *International Journal of Nursing Studies*, 41 (2): 129-140.
- **Pedley GE., (2002):** Comparison of pressure ulcer grading scales: a study of clinical utility and inter-rater reliability. *International Journal of Nursing Studies*; 41:129-140. Elsevier Publishing. <http://www.ncbi.nlm.nih.gov/pubmed/14725777>
- **Raman G. & Subbu P. (2019):** Post burn flexion contracture of hand: a prospective study *International Surgery Journal , Bai SPL Int Surg* , 6 (8), 2823-2827
- **Said, D., Elbana, H., ELAbasi, E., Abd El-aziz, T., & Mohamed, Z. (2020):** Nurses safety practices provided for patients undergoing external fixationsurgeries. *Journal of Novel Research in Healthcare and Nursing*, 7(3), 493-523.
- **ShehataY., Badr O, Mohammed Y,& EL-shenawie H, (2021):** Effect of safety measures educational protocol on the incidence of infection, satisfaction, and anxiety level among orthopedic patients with external fixation. *International Journal of Novel Research in Healthcare and Nursing*, 8(1), 557- 569.
- **Siddiqui A. , Siddiqui F , Bashar M., Adeel M., Muhammad I., & Katto (2019):** Impact of Ilizarov Fixation Technique on the Limb Functionality and Self-esteem of Patients with Unilateral Tibial Fractures , *Cureus PMC*, 11(1), 10.
- **Testa, G.; Vescio, A.; Aloj, D.C. Papotto, G.; Ferrarotto, L.; Massé, A.; Sessa, G.; Pavone, V. (2019):** Definitive Treatment of Femoral Shaft Fractures: Comparison between Anterograde Intramedullary Nailing and Monoaxial External Fixation. *J. Clin. Med.*, 8, 1119.
- **Tucci G., Romanini E., Zanolli G., Pavan L., Fantoni M. & Venditti M., (2019):** “Prevention of surgical site infections in orthopaedic surgery: a synthesis of current recommendations” *European Review for Medical and Pharmacological Sciences*, 23(2), 224-239
- **Viraj N. Gandbhir, & Bruno Cunha, (2022):** Goniometry ,*National Library of Medicine.National Centre for Biotechnology Information*
- **Xing, J., Sun, N., Li, L., Geng, S., & Li, Y. (2020):** Factors influencing self-care in outpatients with external fixation in China. *Journal of Surgery*; 22-79.
- **Yuenyongviwat V, & Tangtrakulwanich B., (2011):** Prevalence of pin-site infection: the comparison between silver sulfadiazine and dry dressing among open tibial fracture patients. *J Med Assoc Thai. ; 94(5):566–569*

This is an open access article under  
[Creative Commons by Attribution Non-Commercial \(CC BY-NC 3.0\)](https://creativecommons.org/licenses/by-nc/3.0/)  
[\( https://creativecommons.org/licenses/by-nc/3.0/ \)](https://creativecommons.org/licenses/by-nc/3.0/)