



## **Effect of Self-management protocol on Early Outcomes among Patients with Lower Limb External Fixator**

**Fatma Mohmmmed Abouelala<sup>(1)</sup>, Sara Talat Ramadan Sayed Ahmed<sup>(2)</sup>, Zeinab Gamal Mohamed Ellatif Abouelezz<sup>(3)</sup>**

(1) Lecturer of Medical Surgical Nursing, Faculty of Nursing, Kafrelsheikh University, Egypt.

(2) Fellow of Medical Surgical Nursing, Student Hospital, Mansoura University, Egypt.

(3) Fellow of Medical Surgical Nursing, Student Hospital, Mansoura University.

Lecturer of Medical Surgical Nursing, Faculty of Nursing, Misr University for Science and Technology, Egypt.

### **Abstract**

**Background:** An essential aspect of a successful treatment plan is the maintenance of stability and utilizing of external fixation through designing plans that educate patient regarding self-management of external fixator devices. **Aim:** Evaluate the effect of the self-management protocol on the early outcomes among patients with lower limb external fixator. **Design:** A quasi experimental design was used. **Subject:** A purposive sample of sixty adult patients was randomly divided into 2 equal groups 30 for each. **Setting:** The study was carried out in the orthopedic departments and the outpatient clinic at Main Mansoura University hospital. **Tool:** "External fixation Patient's assessment sheet" it was composed of six parts; 1. Patients' demographic and clinical data, 2. Chacketts Otterburns Grading System. 3. External Fixation Patients' health Knowledge Questionnaire, 4. Patients' self-reported practices, 5. The exercise of self-Care agency scale, 6. Patient's satisfaction scale. **Results:** Statistically significant improvement of infection grading, knowledge and self-reported practices, self-care agency scores post implementation of the self-management protocol. Therefore, there was a high significant positive correlation between infection grading with patients' knowledge, self-reported practices and exercise of self-care agency scores for the study group at ( $p < 0.001$ ), additionally, 70.3% of the patients in the study group were satisfied with the protocol. **Conclusion:** The self-management protocol has a positive effect regarding reduction the incidence of pin-site infection, increase level of knowledge, self-reported practices, and patient's satisfaction. **Recommendations:** Engage the self-management protocol in the routine nursing care.

### **Keywords:**

Early Outcomes, Lower limb External Fixator, Self-management Protocol.

## Introduction

External fixator devices have been regarded as the gold standard of care for numerous fracture types that cannot be treated by traction or casting. An external fixator is used to stabilize a fracture without further injuring soft tissue when other immobilization techniques would be inadequate. It works by balancing the distribution of pressure on the fracture surface and promoting normal healing (Xing, et al, 2020; Lenza, et al., (2019). External fixators come in a variety of subtypes, such as uniplanar, multiplanar, unilateral, bilateral, and circular fixators, and the most common example of circular fixators is Ilizarov fixator (Hadeed, et al., 2022). Furthermore, leg deformity, limb lengthening, open fracture, malunion, nonunion, and bone loss from infection and malignancy are indications for using external fixator (Kozin, 2019).

The external fixator's long-term and intrusive nature will exacerbate the effect of the pins on the surrounding tissues (Bibbo, & Brueggeman, 2010). Serious side effects that can happen are including infection of pin site, osteomyelitis, loosening or failure of frame or pin/wire, soft tissue impalement, non-union, neurovascular injuries, compartment syndrome, and pin-related fracture. Basically, pin site and wound infection may affect major blood vessels and nerves, therefore close monitoring of the color of peripheral skin, temperature and nerve injury postoperatively is required in order to

assure the nonexistence of these abnormalities (Hadeed, et al, 2022; Shah, et al., 2019). Furthermore, external fixation may have a detrimental effect on a patient's social, emotional and physical wellbeing (Xing, et al., 2020).

Self-management is now a widely used concept in health education and is the name attached to many health promotion and patient education programs. Self-management is distinguished from other traditional health promotion and patient education programs through; self-tailoring or using self-management skills and knowledge and applying these to oneself as appropriate (Hassan, et al., 2019). To support and empower patients to improve their health status, the self-management approach also incorporates a number of techniques, including problem solving, action plans, self-monitoring, skills of adaptability, management of stress, sharing experience, coaching, confidence and motivation, positive feedback, and peer role models. To encourage and persuade patients to self-medicate, nurses are crucial and play the most significant role in health education (El-Shishtawy & Mohamed, 2022).

In particular, the prolonged immobilization makes it difficult to provide nursing care for patients with external fixator device (Khoris, et al, 2018; Bader & Atiyah, 2017). As a result, a number of nursing care techniques have been developed, such as individual exercise plans that educate patients and family regarding pin-site care, psychosocial

care and early detection of compartment syndrome (Xing, et al, 2020). Client-nurse conversations should center on elaborating on ways that patients actively participate in the plan of care at home, such as neurovascular integrity assessment, pin site care, protection principles for external fixation devices, management of pain strategy, use of safety precautions, use of energy-saving principles, drug self-administration, exercise practicing, weight loss and techniques of stress management technique (Mohammed, 2017; Linton, 2016; Bahaa, 2015).

Besides various safety precautions to ensure patient safety, promote patient health, increase the success of application of external fixator, and guarantee of recovery of patient with a low incidence of preventable complications, the nurses have significant accountabilities for delivering integral perioperative nursing care to patients receiving external fixation surgeries. Without a doubt, the use of external fixators in conjunction with excellent nursing interventions is substantially connected with positive patient outcomes (Said, et al., 2020)

Patient outcomes are measurable or observed results as a response to interventions of nursing that are documented at specified points during or after care and show that the clients' health state has stabilized or been maintained. Outcomes that are sensitive to nursing are those that are relevant, based on nursing scope and domain of practice and for which there is empirical evidence concerning

nursing inputs and interventions to outcomes (Hanne, et al., 2021). Moreover, the measurement of patient outcomes should include patient or family education, facilitation of self-care, symptom distress management, patient safety and patient satisfaction (Liu, et al., 2014).

Patient satisfaction is the most important indicator of high-quality health care and is used for the assessment and planning of health care (Dzomeku, et al., 2013). Patient satisfaction with nursing care was defined as the patient opinion of the care received from nursing staff during the hospitalization as determined by scaled responses to uniform series of questions designed to elicit patient views regarding satisfaction with key elements of nursing care services (Liu, et al., 2014).

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

External fixation is an important component of the contemporary orthopedic surgeon and is frequently employed in traumatology and reconstructive surgery (Jin, et al., 2022). On the other hand, about 70% of patients with external fixator devices experience a several complications with high incidence rates. Pin site infection and inflammation of the tendon are the most frequent complication of external fixation. (Badr, et al., 2021; Tawfiq, et al., 2016). Moreover, patients with external fixation experienced greater morbidity and mortality after external fixation, as well as deficiencies in self-management when performing

activities of daily life. Additionally, such complications raise the financial expense for both the hospital and the patient and creates additional demands on the time and resources of the hospital's medical and nursing staff (Mohamed, et al., 2020; Xing, et al., 2020).

Nurses employ the concept of self-management as a fundamental component of their profession as an intervention to aid patients in regaining their health, independence and well-being through evaluation and education (Martínez, et al., 2021). Therefore, implementing of the self-management protocol for this research group of patients would improve the patient and family's quality of life while also giving them the knowledge and skills needed for the best possible safe performance and reduced the incidence of complications. Hence, this paper intended to evaluate the effect of the self-management protocol on the early outcomes among patients with lower limb external fixator.

### **The aim of the study:**

This study aimed to evaluate the effect of the self-management protocol on early the outcomes among patients with lower limb external fixator.

### **The research hypotheses:**

It was hypothesized by the current study that:

1. The patients who implemented the self-management protocol will have higher satisfactory level of knowledge, self-reported practices and high level of self-care than those who cared through routine hospital care only.

2. Patients who implemented the self-management protocol will have lower incidence of pin site and wound infection than those who cared through routine hospital care only.
3. The implementation of the self-management protocol has a positive effect on patients' level of satisfaction.

### **Operational definitions:**

- **Self-management protocol:** It discusses the core skills and information necessary for a patient with an external skeletal fixation to properly care for their pin site, assess neurovascular status and carry out isotonic and isometric exercises.
- **Patients' early outcome:** It deals with preventing the wound and pin site infection, improving patients' knowledge and self-reported practices through encouraging patients to be able to care for their own wound, and pin sites, promoting neurovascular integrity and engaging in isotonic and isometric exercises.
- **Patients' satisfaction:** It speaks to patients' satisfaction with the self-management protocol, which also theoretical content, practical skills, educational booklet, educational methods that are provided and patient's participation and autonomy.

## SUBJECTS AND METHOD

### Research design:

To achieve the goal of this study, a quasi-experimental methodology was used. Quasi experimental research involves the manipulation of an independent variable with the random assignment of participants to conditions or orders of conditions. Among the important types are equivalent groups designs, pretest-posttest, and interrupted time series designs (Baker, (2017)).

### Setting:

The study was carried out in the orthopedic wards and outpatient clinic at Main Mansoura University hospital, Mansoura city, Egypt.

### Subjects:

A sixty purposive sample of adult patients was split randomly into two equal subgroups with 30 individuals for each.

**Control group:** 30 patients who received hospital routine care.

**Study group:** 30 patients received the self-management protocol in addition to hospital routine care.

Patients for this study were chosen from the settings mentioned above based on the following criteria:

**Inclusion Criteria:** Adults aged 18 to 60 years, of both genders, with only lower limb external fixator devices, free from any infection, eager to participate, able to converse, and without prior instruction on the external fixation.

**Exclusion criteria:** Patients have any co-occurring illnesses, such as diabetes mellitus and cancer, as well as mental illnesses or altered levels of consciousness.

**Sample size:** based upon data from literature (Morsy et al., 2021), the following formula can be used in order to calculate the sample size, taking into consideration significance level of 5% and study power of 80% (Charan and Biswas, 2013).

$$n = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 \times p(1-p)}{(d)^2}$$

Where, p = pooled proportion acquired from previous study; d = predictable difference in proportion of events;  $Z_{\alpha/2} = 1.96$  for 5% level of significance and  $Z_{\beta} = 0.84$  for 80% power of study. Therefore,  $n = \frac{2(1.96 + 0.84)^2 \times 0.909(1-0.909)}{(0.667)^2}$

= 29.1

Consequently, the required sample size was 30 in each group (study and control group).

### Tool for data collection:

Data were collected by using the following tool:

**Tool (I) External Fixation Patient's Assessment Sheet:** it was composed of six parts:

**Part (1): Patients' demographic and clinical data:** It was developed by the researchers and written in a simple Arabic language after reviewing the related literature. It was concerned with studied patients' characteristics and clinical health data which included, age, gender, marital status, educational level, occupation, patients' medical diagnosis and type of external fixator.

## **Part (2): Checketts Otterburns Grading System:**

**Checketts, and et al., (2000)** developed this tool for external fixation patients, it was utilized to assess the degree of pin-site infection. Using changes in appearance and the amount of infection-treating therapy required, it assigns an infection a grade from one to six.

**Grade 1:** A pin-tract infection only needs to be treated locally and is characterized by a mild discharge and redness around the pins.

**Grade 2:** Redness of the surrounding skin, soreness in the soft tissues, and occasionally pus discharges from the wound. These infections can be treated locally and with oral antibiotics. medications.

**Grade 3:** In this grade the infection has the similar characteristics to grade 2 infection but fails to improve with intensive local treatment and antibiotics. The infection resolves when the involved pin or pins are removed and relocated, making it safe to resume using the fixator.

**Grade 4:** Severe soft-tissue involvement that affects many pin sites and is resistant to oral antibiotics and local therapy distinguishes infection. The problematic pins must be taken out, and the external fixation device must no longer be used.

**Grade 5:** The infection is identical to that of grade four infection, however radiographic signs of osteomyelitis are present. The problematic pins must be taken out, and the external fixation device must no longer be used.

**Grade 6:** Infection develops after the fixator is removed, and it is defined by the growth of a

chronic sinus and the production of a sequestrum inside the bone.

### **Scoring System:**

Grades 1,2,3 are considered as minor infection while grades 4, 5, and 6 are indicative of major infection.

## **Part (3): External Fixation Patients' Health**

### **Knowledge Questionnaire:**

This part developed by the researchers based on relevant literature (**Morsy, et al, 2021; Xing, et al, 2020; Khorais, et al., 2018**) to assess patients' health knowledge related to external skeletal fixator. It consisted of 30 closed ended questions (MCQ and true or false), which divided into six parts comprised of concept of external fixation device, self-care regarding external fixator, information about medications regimen, nutrition modifications, exercises and information about follow-up plan.

### **Scoring System for Patients' Knowledge:**

Each accurate response received one grade, and the incorrect response or "didn't know" received zero. The following categories were used to categorize overall knowledge:

≥ 60 % was considered the satisfactory level and

< 60% was considered an unsatisfactory level.

## **Part (4): Patients' Self-reported Practices:**

This tool was adopted from (**Morsy, et al., 2021; Khadka, et al., 2012; Perry, et al., 2015**) to assess patients' level of practices regarding external fixator which included three procedures; wound/pin site care (21 steps), assessment of neurovascular integrity (10 steps), and practicing isotonic and isometric exercises

(18 steps).

#### **Scoring system:**

Each correctly completed step received a grade of one, while incorrectly completed or skipped steps received a score of zero. Following are categories for the overall practice score of patients:

$\geq 60\%$  was considered the satisfactory level and  $< 60\%$  was considered an unsatisfactory level.

#### **Part (5) The Exercise of Self-Care Agency Scale (ESCA):**

The Exercise of Self-care Agency tool was developed firstly by (Kearney, & Fleischer, 1979) then modified by (Yamishita, 1998). It was utilized to evaluate the level of self-care agency exercised by patients with external fixator device. There are 43 items on a 5-point Likert scale, with 0 meaning "do not like" and 4 meaning "like very much." The scale is divided into four categories: self-concept (1–8), self-nursing responsibility (9–14), self-care skills (15–26), and level of health knowledge (27–43).

#### **Scoring system:**

The total score, which varies from 0 to 172, is divided into three levels: low (between 0 and 57 points), moderate (between 58 and 115 points), and high (between 116 and 172 points). Patients with higher scores have greater autonomy in self-care.

#### **Part (6): Patient's Satisfaction Scale:**

It was taken from (Dzomeku, et.al., 2013; Larson, et al., 1996) and modified by the researchers based on the related literature reviewing (Badr, et al., 2021; Karaca and Durna, 2019; khoraise, et al, 2018; Custer,

2012). The scale was used to assess the satisfaction of patients regarding self-management protocol subitems, it consisted of 21 statements which were grouped into 4 subtitles: theoretical contents 6 items, practical skills 5 items, methods of teaching 5 items, and awareness of self needs 5 items.

**Scoring system:** The followings are the responses for the items:

Not satisfied = 0, somewhat satisfied = 1 and satisfied = 2. The satisfaction total level is considered as follows:

- Satisfied if score  $\geq 60\%$  of the total score.
- Unsatisfied if score  $< 60\%$  of total score.

#### **Content validity and reliability:**

##### **▪ Validity:**

A group of three experts from the medical surgical nursing department of the Faculty of Nursing at Mansoura University and two specialists in the field of orthopedic surgery from the Faculty of Medicine at the same institution determined the face and content validity, and minor revisions were made.

#### **The Reliability:**

Internal consistency was measured by Cronbach's alpha, which was 0.895 for the External Fixation Patients' Health Knowledge Questionnaire, 0.902 for the Patients' Self-Reported Practices, 0.893 for the Exercise of Self-Care Agency Scale (ESCA), and 0.889 for the Patient's Satisfaction Scale.

### Ethical considerations:

- The researcher got an approval of the study protocol from the Research Ethics Committee in Faculty of Medicine, Kafrelsheikh University.
- Official approval was got to conduct the study from the responsible authorities in Mansoura University Hospital.
- The study's goals and objectives were explained to the participants' patients by the researchers. The privacy and confidentiality of the patients' data are maintained by the researchers. Patients had the option of participating or not, and they were informed that they might leave the research at any moment and without providing a reason.

### Pilot study:

Ten percent of the subjects (6 patients) were used in pilot research to examine the viability and applicability of the created tools as well as the time required to complete them. According to statistical analysis of the pilot study results, minor modifications were done, therefore those subjects were not included in the study.

### Field Work:

The current study's data collecting took place over a period of seven months, from the beginning of November 2021 to the end of May 2022. The study was carried out in two stages (implementation and evaluation phase).

### Implementation phase:

- This phase began at the orthopedic department postoperatively with

interviewing of the studied participants who met the eligibility criteria to explain the goals of the study and obtain their consent before data collection.

- Only routine hospital care was provided to the control group; however, the researchers implemented the self-management protocol for the study group.
- Two days a week, during the morning and afternoon shifts, the researchers were present in the clinical setting and interviewed each patient to collect the baseline data using study tool (part 1, 3, 4, and 5). Each patient's interview lasted between 20 and 30 minutes.
- Create and implement a self-management protocol for the participants in the study group based on their specific needs in addition to the routine hospital care, it was conducted either individually or in small groups of two to three patients.
- Each patient in the study group received a copy of the self-management protocol handout in order to get their attention, inspire them and aid them in home review, it was written in clear Arabic and accompanied with illustrative pictures.
- The protocol was covered in two sessions, with the first session covering the theoretical portion and the final session covering the practical portion as follows:
  - **First session:** during this session, orientation and an explanation of the goals and significance of the self-management protocol, as well as concept of external

fixation, advantage and disadvantage, warning signs and symptoms, complications of external fixator and medications regimen. In addition to, post-operative self-management strategies for the external fixator, dietary changes, follow-up appointments and the kinds and value of physical exercises were explained in this session.

- **The second session** was the "practical portion" where the patient acquired new skills for caring for the wound and the pin site, including how to remove the solid dressing, clean the area and bandage it. This session also included a neurovascular examination and instruction on how to perform isometric and isotonic exercises.
- Each session lasted 20 to 40 minutes and was conducted utilizing the instruction book through lectures, demonstrations, redemonstrations and group discussions. Each session began with a summary of what had been addressed in the previous session and the goals of the new session. It also concluded with a summary and a request for patient input to make sure the patient received the greatest benefit.

#### **Evaluation Phase:**

Evaluation was performed for both groups after one week and one month of follow up in outpatient clinic by using study tool part 2, 3, 4, and 5 as well as the level of patients' satisfaction with the protocol was assessed for the study group using part 6 of the study tool after one month. Comparison was done between two

groups in order to evaluate the effect of the self-management protocol on incidence of infection, the level of patients' knowledge and self-reported practices, self-care, and patients' satisfaction for studied groups.

#### **Data analysis:**

SPSS for Windows version 20.0 was used to conduct all statistical analyses (SPSS, Chicago, IL). When presented as mean and standard deviation, normally distributed continuous data revealed specific trends (SD). Numbers and percentages were used to portray categorical data numerically and statistically. To compare variables with categorical data.

Fischer's exact test or the chi-square test was used, as applicable. Examining the correlations between two variables with continuous data was done using the correlation coefficient test. The reliability (internal consistency) test results for the study's questionnaires were computed. P 0.05 was chosen as the threshold for statistical significance, whereas P 0.01 showed strong significance.

#### **Results:**

**Table (1):** illustrates that the mean age of the study group was  $31.9 \pm 9.9$ , whereas the mean age of the control group was  $35.8 \pm 12.3$ . More than half of both groups (study group and control group) were males (66.7%) and (76.7%) respectively. Regarding to marital status, married patients represented the highest percentage 56.7% and 60% in both study and control group respectively. Concerning to level of education, it was found that less than half of control group

(40%) were diploma degree, however the same percentage of study group were bachelor's degree.

Working status showed that more than half of control group (56.7%) were working, whilst the high percentage of participants in the study group (60%) were not working. Concerning to occupation type, it was found that the highest percentage of worked patients in both groups had manual work (82.4% for control group) and (66.7% for study group). In respect to the patient's orthopedic diagnosis, it was found that more than half of the study group (53.3%) had fracture limb, whereas the half of the control group (50%) used fixator for lengthening. Over that, all of the studied subjects in both groups (100.0%) using Ilizarov fixator.

This table also revealed no statistically differences between studied groups regarding patients' demographic and clinical data which include age, gender, marital status, education level, occupation type, patient's orthopedic diagnosis, as well as type of external fixator among other demographic and clinical characteristics.

As observed in **Table (2)**: 73.3% of the study group had no infection with grade 0 compared to 40% of the control group post implementation of the self-management protocol. In the follow-up phase, 90% of the study group were free from infection and only 10% had infection grade 1, while, 46.7% of the participants in the control group had no infection with grade 0 and 33.3% of them had infection grade 1, with

statistically significant difference was found at post and follow up phase after implantation of the self-management protocol between both groups where  $p=0.031^*$ ;  $p<0.001^{**}$  respectively.

**Table (3)**: Reveals comparison of knowledge subitem scores between the study group and the control group; statistically significant differences were found for all knowledge subitems, including "concept of external fixation device, self-management regarding external fixator, information about medications regimen, nutrition modifications, exercises, and information about follow-up plan" in post and follow up phase after implementation of the self-management protocol.

**Table (4)**: Shows comparison between the control and the study group according to their total knowledge scores; the high percentages of the studied groups 70% of the control group and 80% of the study group have unsatisfactory knowledge pre implementation of the self-management protocol. In comparison to follow-up phase, this table shows that 63.3% of the control group and 86.7% of the study group have satisfactory level of knowledge with statistically significant differences between both groups in post and follow-up phase  $p \leq 0.05$ .

**Table (5)**: Illustrates that there were statistically significant differences regarding all items of self-reported practices scores which included wound care, neurovascular assessment of the lower extremities, practicing exercises in

post and follow-up phase after implementation the self-management protocol  $p \leq 0.05$ .

**Table (6):** Shows that, more than two third of both the control and the study groups (76.7% & 70%) respectively had unsatisfactory level of practice in the pre-implementation phase. Then, 83.3% of the study group had a satisfactory level of practice compared with only 56.7% of the control group in the follow-up phase after implementation of the self-management protocol with statistically significant differences between studied groups.

**Table (7):** Clarifies comparison between the control and study groups based on ESCA scores; revealed that statistically significant improvements for all items of self-care agency scores including self-concept, self-nursing responsibility, self-care skills, and level of health knowledge in the post- and follow-up phase following the implementation of the self-management protocol ( $p \leq 0.05$ ).

**Table (8):** According to the comparison of the ESCA total scores between the studied groups, this table shows that (80%) of the control

group and (70%) of the study group had low level of self-care in pre implementation phase while in the follow-up phase 66.7% of the participants in the study group compared with 30% of the control group had high level of self-care with significant differences between both groups  $p \leq 0.05$ .

**Table (9):** Shows that highest satisfaction percentage 76.7% was in favour of practical part followed by 73.3% for methods of teaching and 70% were satisfied with the theoretical part. Additionally, 66.7% were satisfied with their awareness of self needs part.

**Figure (1):** Illustrates that 73.3% of the study group were satisfied with the self-management protocol, while 26.7% of them were unsatisfied after implementation of the self-management protocol.

**Table (10):** Shows that there was an inverse correlation between the infection grading with patients' knowledge, self-reported practices and the exercise of self-care agency scores for the study group with a highly statistically significant at  $p < 0.001$ .

**Table (1): Comparison Between the Control Group and the Study Group in Accordance with Patients' Demographic and Clinical Data (n=60)**

Patients' demographic and clinical data	Control (n=30)		Study (n=30)		Chi-Square / Fisher's Exact Test	
	N	%	N	%	X <sup>2</sup>	P
<b>Age (Years)</b>						
20 – 25	4	13.3	6	20.0		
25 – 35	11	36.7	16	53.3		
35 – 50	7	23.3	6	20.0		
50 – 60	8	26.7	2	6.7	5.003	FET (0.172)
<b>Mean ±SD</b>	35.8 ±12.3		31.9 ±9.9		1.352	0.181
<b>Gender</b>						
Male	23	76.7	20	66.7		
Female	7	23.3	10	33.3	0.739	FET 0.390
<b>Marital Status</b>						
Single	5	16.7	8	26.7		
Married	18	60.0	17	56.7		
Widow	7	23.3	5	16.7	1.054	0.590
<b>Educational level</b>						
Basic	8	26.7	7	23.3		
Diploma	12	40.0	11	36.7		
Bachelor's degree	10	33.3	12	40.0	0.292	FET (0.864)
<b>Occupation</b>						
Work	17	56.7	12	40.0		
Don't work	13	43.3	18	60.0	1.669	0.196
<b>Occupation Type</b>	<b>(n=17)</b>		<b>(n=12)</b>			
Office work	3	17.6	4	33.3		
Manual work	14	82.4	8	66.7	0.945	0.331
<b>Patients' diagnosis</b>						
Fracture Limb	13	43.3	16	53.3		
Lengthening	15	50.0	10	33.3		
Angulation correction	2	6.7	4	13.3	1.977	FET (0.372)
<b>Type of External fixator</b>						
Illizarov	30	100.0	30	100.0	0.000	1.000

$\chi^2$ : Chi square test

FET: Fisher's exact test

SD: standard deviation

p: p value for comparing between the studied groups

\*: Statistically significant at  $p \leq 0.05$ .

**Table (2): Comparison between Studied Groups in Accordance with Checketts- Otterburns Grading System for Pin Site Infection (N=60).**

Checketts- Otterburns Grading System for pin site infection	Control (n=30)		Study (n=30)		Chi-Square / Fisher's Exact Test	
	N	%	N	%	X <sup>2</sup>	P
<b>Post</b>						
Grade 0	12	40.0	22	73.3		
Grade 1	12	40.0	6	20.0		
Grade 2	6	20.0	2	6.7	6.941	FET (0.031*)
<b>Follow – Up</b>						
Grade 0	14	46.7	27	90.0		
Grade 1	10	33.3	3	10.0		
Grade 2	6	20.0	0	0.0	13.891	<0.001*

$\chi^2$ : Chi square test

p: p value for comparing between the studied groups

FET: Fisher's exact test

\*: Statistically significant at  $p \leq 0.05$ .

**Table (3): Comparison between the Control Group and the Study Group in Accordance with their Knowledge Subitems Scores (N=60).**

knowledge sub-items	Control (n=30)				Study (n=30)				Chi-Square / Fisher's Exact Test	
	Unsatisfactory knowledge		Satisfactory knowledge		Unsatisfactory knowledge		Satisfactory knowledge		X <sup>2</sup>	P
	N	%	N	%	N	%	n	%		
<b>Concept of external fixation</b>										
Pre	19	63.3	11	36.7	24	80.0	6	20.0	2.051	0.152
Post	18	60.0	12	40.0	9	30.0	21	70.0	5.454	0.019*
Follow – Up	11	36.7	19	63.3	4	13.3	26	86.7	4.356	0.036*
<b>Self-management regarding external fixator</b>										
Pre	20	66.7	10	33.3	21	70.0	9	30.0	0.077	0.781
post	18	60.0	12	40.0	10	33.3	20	66.7	4.285	FET 0.038*
Follow – Up	13	43.3	17	56.7	5	16.7	25	83.3	5.079	0.024*
<b>Information about medications</b>										
Pre	23	76.7	7	23.3	25	83.3	5	16.7	0.416	0.518
post	18	60.0	12	40.0	10	33.3	20	66.7	4.285	0.038*
Follow – Up	13	43.3	17	56.7	5	16.7	25	83.3	5.079	0.024*
<b>Information about nutrition</b>										
Pre	24	80.0	6	20.0	26	86.7	4	13.3	0.480	0.488
Post	19	63.3	11	36.7	10	33.3	20	66.7	5.406	FET 0.020*
Follow – Up	10	33.3	20	66.7	3	10.0	27	90.0	4.811	0.028*
<b>Information about exercises</b>										
Pre	20	66.7	10	33.3	23	33.3	7	23.3	0.738	0.390
Post	19	63.3	11	36.7	20	66.7	10	33.3	5.406	0.020*
Follow – Up	12	36.7	18	60.0	4	73.3	26	86.7	5.454	0.019*
<b>Information about Follow-up</b>										
Pre	24	80.0	6	20.0	25	83.3	5	16.7	0.111	FET (0.738)
Post	19	63.3	11	36.7	11	36.7	19	63.3	4.266	0.038*
Follow – Up	12	40.0	18	60.0	3	10.0	27	90.0	7.200	0.007*

$\chi^2$ : Chi square test

p: p value for comparing between the studied groups \*.

FET: Fisher's exact test

Statistically significant at  $p \leq 0.05$

**Table (4): Comparison between the Control Group and Study Group in Accordance with their Total Knowledge Score (n=60).**

	Control (n=30)				Study (n=30)				Chi-Square / Fisher's Exact Test	
	Unsatisfactory knowledge		Satisfactory knowledge		Unsatisfactory knowledge		Satisfactory knowledge		X <sup>2</sup>	P
	N	%	N	%	n	%	n	%		
<b>Pre</b>	21	70.0	9	30.0	24	80.0	6	20.0	0.800	0.371
<b>Post</b>	18	60.0	12	40.0	10	33.3	20	66.7	4.285	0.038*
<b>Follow – Up</b>	11	36.7	19	63.3	4	13.3	26	86.7	4.356	FET 0.036*

 $\chi^2$ : Chi square test

FET: Fisher's exact test

p: Statistically significant at p 0.05 when comparing the study groups.

**Table (5): Comparison between the Control Group and the Study Group in Accordance with their Self-Reported Practices Scores (n=60).**

Self-reported practices sub-items	Control (n=30)				Study (n=30)				Chi-Square / Fisher's Exact Test	
	Unsatisfactory knowledge		Satisfactory knowledge		Unsatisfactory knowledge		Satisfactory knowledge		X <sup>2</sup>	P
	N	%	N	%	N	%	n	%		
<b>Wound care</b>										
Pre	24	80.0	6	20.0	19	63.3	11	36.7	2.051	FET 0.152
Post	19	63.3	11	36.7	10	33.3	20	66.7	5.406	0.020*
Follow – Up	16	53.3	14	46.7	6	20.0	24	80.0	7.177	0.007*
<b>Neurovascular assessment of the lower extremities</b>										
Pre	23	76.7	7	23.3	22	73.3	8	26.7	0.088	0.765
Post	19	63.3	11	36.7	11	36.7	19	63.3	4.267	FET 0.038*
Follow – Up	13	43.3	17	56.7	5	16.7	25	83.3	5.079	0.024*
<b>Practicing exercises</b>										
Pre	22	73.3	8	26.7	21	70.0	9	30.0	0.082	FET 0.774
Post	18	60.0	12	40.0	9	30.0	21	70.0	5.454	0.019*
Follow – Up	14	46.7	16	53.3	6	20.0	24	80.0	4.800	0.028*

 $\chi^2$ : Chi square test

FET: Fisher's exact test

p: p value for comparing between the studied groups \*: Statistically significant at p  $\leq$  0.05.**Table (6): Comparison between the Control Group and the Study Group in Accordance with their Total Score of the Self-Reported Practices (N=60).**

	Control (n=30)				Study (n=30)				Chi-Square / Fisher's Exact Test	
	Unsatisfactory score		Satisfactory score		Unsatisfactory score		Satisfactory score		X <sup>2</sup>	P
	N	%	N	%	N	%	N	%		
<b>Pre – Intervention</b>	23	76.7	7	23.3	21	70.0	9	30.0	0.341	0.559
<b>Post – Intervention</b>	19	63.3	11	36.7	10	33.3	20	66.7	5.406	FET 0.020*
<b>Follow – Up</b>	13	43.3	17	56.7	5	16.7	25	83.3	5.079	0.024*

 $\chi^2$ : Chi square test

FET: Fisher's exact test

p: p value for comparing between the studied groups \*: Statistically significant at p  $\leq$  0.05

**Table (7): Comparison between the Control Group and the Study Group in Accordance with their Exercise of Self-Care Agency (ESCA) Scores (N=60).**

Exercise of Self-Care Agency sub-items	Control (n=30)						Study (n=30)						Chi-Square / Fisher's Exact Test	
	Low self-care		Moderate self-care		High self-care		Low self-care		Moderate self-care		High self-care		X <sup>2</sup>	P
	N	%	N	%	N	%	N	%	n	%	n	%		
<b>Self-concept</b>														
Pre	23	76.7	5	16.7	2	6.7	20	66.7	6	20.0	4	13.3	0.966	0.616
Post	18	60.0	7	23.3	5	16.7	8	26.7	13	43.3	9	30.0	6.789	0.033*
Follow – Up	9	30.0	11	36.7	10	33.3	3	10.0	8	26.7	19	63.3	6.266	0.043*
<b>Self-nursing responsibility</b>														
Pre	24	80.0	5	16.7	1	3.3	20	66.7	7	23.3	3	10.0	1.696	FET 0.428
Post	17	56.7	8	26.7	5	16.7	7	23.3	14	46.7	9	30.0	6.945	0.031*
Follow – Up	13	43.3	9	30.0	8	26.7	4	13.3	8	26.7	18	60.0	8.669	0.013*
<b>Self-care skills</b>														
Pre	21	70.0	7	23.3	2	6.7	21	70.0	6	20.0	3	10.0	0.276	0.871
Post	17	56.7	8	26.7	5	16.7	7	23.3	13	43.3	10	33.3	7.024	FET 0.029*
Follow – Up	12	40.0	10	33.3	8	26.7	3	10.0	8	26.7	19	63.3	10.103	0.006*
<b>Health knowledge level</b>														
Pre	23	76.7	6	20.0	1	3.3	22	73.3	5	16.7	3	10.0	1.113	0.573
Post	15	50.0	8	26.7	7	23.3	6	20.0	9	30.0	15	50.0	6.825	0.032*
Follow – Up	9	30.0	10	33.3	11	36.7	3	10.0	7	23.3	20	66.7	6.142	FET 0.046*

$\chi^2$ : Chi square test

FET: Fisher's exact test

p: p value for comparing between the studied groups \*: Statistically significant at  $p \leq 0.05$

**Table (8): Comparison between the Control Group and the Study Group in Accordance with their Total Scores of the ESCA (N=60).**

	Control (n=30)						Study (n=30)						Chi-Square / Fisher's Exact Test	
	Low self-care		Moderate self-care		High self-care		Low self-care		Moderate self-care		High self-care		X <sup>2</sup>	P
	N	%	N	%	N	%	N	%	N	%	n	%		
<b>Pre</b>	24	80.0	6	20.0	0	0.0	21	70.0	6	20.0	3	10.0	3.200	0.201
<b>Post</b>	18	60.0	7	23.3	5	16.7	8	26.7	13	43.3	9	30.0	6.789	FET 0.033*
<b>Follow – Up</b>	11	36.7	10	33.3	9	30.0	2	6.7	8	26.7	20	66.7	10.625	0.004*

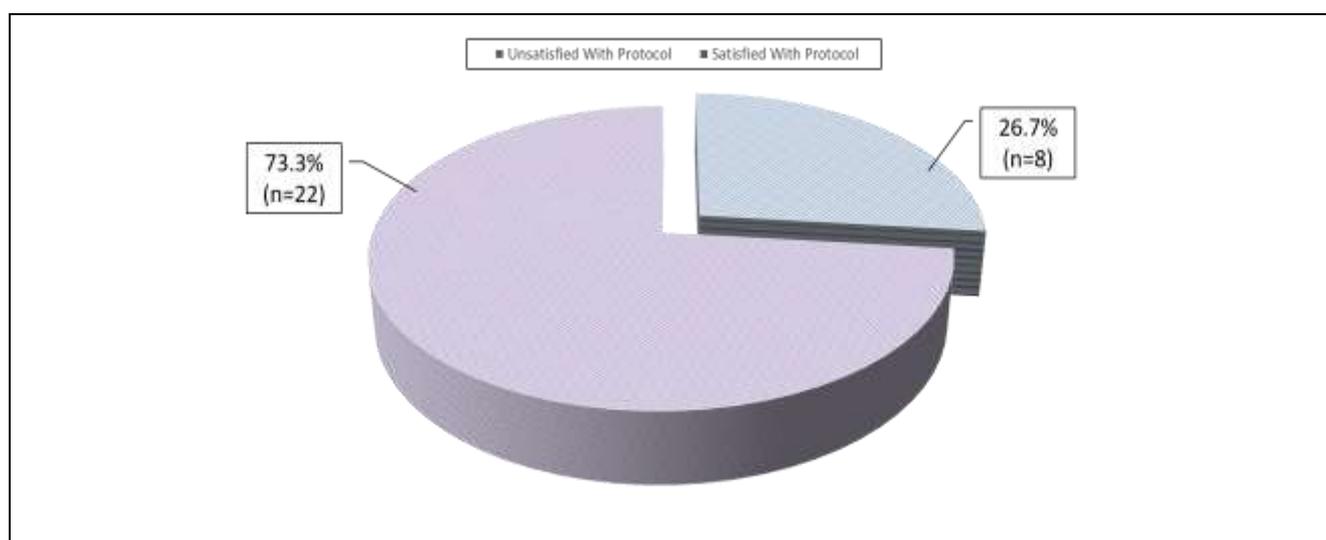
$\chi^2$ : Chi square test

FET: Fisher's exact test

p: p value for comparing between the studied groups \* : Statistically significant at  $p \leq 0.05$ .

**Table (9): Distribution of the Study Group According to their Level of Satisfaction regarding Self-Management Protocol Subitems (N=30).**

Self-management protocol subitems	Not Satisfied		Somewhat Satisfied		Satisfied	
	N	%	N	%	N	%
Theoretical part	3	10.0	6	20.0	21	70.0
Practical part	3	10.0	4	13.3	23	76.7
Methods of teaching	2	6.7	6	20.0	22	73.3
Awareness of self needs	3	10.0	7	23.3	20	66.7
<b>Total Score</b>	3	10.0	5	16.7	22	73.3

**Figure (1): Distribution of the Study Group according to their Total Satisfaction with the Self-Management Protocol (N=30).**

**Table (10): Correlation between Checketts Otterburns Grading System with Total Knowledge Scores, Total Self-Reported Practices Scores and Total Exercise of Self-Care Agency Score for the Study Group (No= 30).**

Checketts- Otterburns grading system for infection grading						
Items	Pre		Post		Follow – Up	
	R	P	R	P	R	P
Knowledge Scores	0.131	0.489	-0.442	0.015*	- 0.538	0.002*
Self-reported Practices Scores	-0.116	0.543	-0.618	<0.001**	- 0.672	<0.001**
Self-Care Agency Exercise Scores	0.197	0.296	-0.444	0.014*	- 0.720	<0.001**

r: Pearson coefficient, (+) sign indicates direct correlation and (-) sign indicates inverse correlation.

No significant at  $p > 0.05$ , \*Significant at  $p \leq 0.05$ , \*\*Highly significant at  $p < 0.001$ .

## Discussion:

External skeletal fixation is one of the management modalities of complex fracture; it is utilized for limb restoration and deformity correction. Patients will need to deal with the external fixator and demonstrate awareness of the accepted practices for pin site care, because the external fixation can be in place for a long period **Gouda, (2017)**. The measurement of patient satisfaction provides vital data on the performance, therefore contributing to total quality management **Goh, et al., (2016)**.

Thus, the present study was conducted to evaluate effect of the self-management protocol on early outcomes among patients with lower limb external fixator. The current study results showed significant improvement in the incidence of pin-site infection, increasing level of the knowledge and self-reported practices, and patient's satisfaction after implementation of the self-management protocol. The findings lead to achieving the set hypotheses, with confirmation of the effectiveness of the established protocol.

Based on the finding of the current study it was found the mean age of the studied groups was  $31.9 \pm 9.9$ ,  $35.8 \pm 12.3$  for study and control group respectively, also about two thirds of the patients in the study group and nearly three-quarters of the patients in the control group were males. This finding may due to young males are risk for accidents and fracture more than females due to frequent exposure to street and high level of activity-related injuries. According to **WHO, (2021)**, trauma typically affects the young, healthy, and productive population and more than 50% of traumatic injury-related deaths occur in those under the age of 45. This is consistent with, **Morsy, et al., (2021)** who mentioned that men were considered the majority of the participants among the studied subjects.

This result concurs with **Khorais, et al., (2018)** who reported that the mean age of the patients under the study was  $(30.9 \pm 8.43)$ . These results are consistent with another study by **Babis et al., (2011)**, who discovered that more than half of the patients under examination were men. While a study by **Mohamed, et. al, (2015)** who

demonstrated that the mean age of the patients with external fixator was (40±13.89), this result is incongruent with this finding. On the other side, this result disagreed with **Xing et al. (2020)**, who claimed that more than half of patients were females. In addition to, **Modin et al. (2009)**, in their study they found that, the majority of the studied patients were female.

Concerning to level of the education of the participant, it was noticed that no one in both groups was illiterate, while the study group's percentage of bachelor's degree holders was equal to the diploma degree holders in the control group at less than half of the participants. whereas the other percentage had a different level of education. This reflects increasing the awareness regarding the importance of education in our society. In contrast with this finding the conducted study by **Khorais, et al., (2018)** showed that nearly a third of the studied patients were illiterate. This finding also contrasted with that of **Wong, et al., (2010)** who found that the majority (96%) of patients with external fixation devices have basic and secondary educational levels.

According to occupation type, manual work accounted for the highest proportion of patients who were employed in both groups. This can be a result of the nature of their profession, which leaves them more vulnerable to accidents and various fractures. This finding is in accordance with a study conducted by **Morsy, et al., (2021); Sayed et al., (2019)** who found that two thirds of the patients were manual workers in regards of occupation. On the other hand, this

conclusion was refuted by **Xing et al. (2020)** who found that more than half of participants engaged in employment with that little physical exercise.

This study also revealed that there were no statistically differences between the studied groups regarding patients' demographic and clinical data which includes; age, gender, marital status, education level, occupation type, patient's orthopedic diagnosis, as well as the type of external fixator. These results revealed that the study and control groups were homogenous and exclude the extraneous variables that might confusion the effect of self-management protocol on early outcomes among patients with lower limb external fixation.

The result showed that all of the studied subjects in both groups (100.0%) using Ilizarov fixator, and in relation to infection grade, the finding of the current study reported that, nearly three-quarters of the study group have no infection with grade 0 compared to two fifth of the control group post implementation of the self-management protocol. But in the follow-up phase; the majority of the study group were free from infection and only 10% has grade 1 infection, while, less than half of the participants in the control group have no infection and one third of them has grade 1 infection with statistically significant difference was found at post and follow up phase after implantation of the self-management protocol.

This improvement of pin site infection attributed to positive consequence of implementation of self-management protocol which emphasized on important knowledge and

practices about pin site care. Harmonious with these point of view **Jennison, et al., (2014)** stated that in order to prevent infection, pin site care is still is the most important concern.

Similar results were reported by **Badr, et al., (2021)** who discovered that after the implementation of a safety measures educational program, a statistically significant difference was observed in connection to pin site infection among the tested groups. This result is in the line with the findings of **Hossny, et al., (2020)** who noted that grade (I) represented (6.7%) of the study group, while grades I, II, and III (6.7, 20.0, and 6.7%, respectively) were developed in the control group following the provision of preventive nursing care.

The finding of this study stated that studied subjects who received self-management protocol had higher levels of knowledge throughout the study phases than the control group who just got the routine hospital intervention, with statistically significant differences between both groups. In the pre implementation phase, the highest percentage among the studied groups had unsatisfactory knowledge, nevertheless in the follow-up phase, the majority of the patients in the study group have satisfactory level of knowledge, and less than two thirds of the control group with statistically significant differences between both groups in the post and follow-up phases.

These results proved the positive benefit of self-management protocol in enhancing the knowledge among the subjects in the study group along the study period. This result was supported

by **Ahmed & Abd-El mohsen (2018)**, who found that orthopedic patients in the study group had improved their level of knowledge at the time of discharge compared to the control group following the education program. This finding was corroborated by **Khorais et al., (2018)** they noted that after implementation of the self-management program, they observed statistically significant differences among the investigated patients regarding their level of the knowledge.

Concerning the level of patients' self-reported practices, there was a noticeable improvement in all items of self-reported practices scores in post and follow-up phases after implementation the self-management protocol. Moreover, more than two third of both groups have unsatisfactory level of practice during the pre- implementation phase. However, the majority of patients in the study group in contrast to just over the half of the control group show satisfactory levels of practice in the follow-up period, with statistically significant differences between the both groups. These acceptable results reflect the positive effect of the implemented self-management protocol in improving the skills of self-management among the study group.

In the same line, the findings of the current study were consistent with a study by **Brereton (2016)**, who established that following education of patients with external fixation, the practices improved in terms of the pin site and wound care. Additionally, the results of the current study were supported by **Khorais et al., (2018)** who observed that that there are statistically significant differences among studied

group regard to the overall satisfactory level of practices at immediately post and follow up after self-care program implementation. Also, the similar finding was noticed by **Morsy et al., (2021)** who asserted that highly significant differences regarding patients' reported practices of external skeletal fixation (pin site and wound care) among studied group after conduction of nursing guidelines for patients with external fixation.

In reference to ESCA, the highest percentage of the participants in the control group and the study group have low level of the self-care in the pre implementation phase. In comparison to the follow-up phase, there were more than one quarter of the patients in the control group had high self-care, whilst more than two quarters of the participants in the study group had high self-care with statistically significant improvement regarding all items of self-care agency scores including self-concept, self-nursing responsibility, self-care skills, and health knowledge level. The preceding findings may have been a result of the study group's patients' motivation to use the self-management protocol's content and application to adapt to their physical limits and develop their self-care skills.

Harmonious with this finding **Xing, et al., (2020)**, reported that two-thirds of the outpatients with external fixation had total mean of the ESCA score underneath the "high" category in their descriptive study. Over that, **Walker, (2018)** stated that, a well-structured educating and plan of care can advance most extreme self-care for the patients with external fixator devices and will

reduce dissatisfaction with mobilization. Furthermore, the nursing protocols progresses their performance of exercises, quality of life, capacity to self-management their state and patients' satisfaction

Regarding the level of satisfaction, the current study clarified that most of the participants in the study group were satisfied with the self-management protocol elements that include practical part, method of teaching, theoretical part and awareness of self needs. In reference to the total satisfaction level, more than two thirds of the study group reported feeling satisfied overall following the implementation of the self-management protocol. This conclusion might be connected to the fact that when the nurse tells patients about each application, procedure, and essential clarifications concerning illness, diagnosis, and therapy this leads to ensure patients' satisfaction and delivery of high-quality nursing care **Karaca, & Durna, (2019)**. In the same line, **Abdel Maqsood et al., (2012)** stated that providing education and information are significant elements influencing patient satisfaction. This is in line with the findings of **Badr, et al., (2021)** who reported that, most of the studied participants were satisfied with the teaching program and its components, including the knowledge and practices required for maintaining an external fixation device, the educational booklet, and the educational techniques. Additionally, this finding was in the same line with **Ahmed & Abd-El Mohsen (2018)** who claimed that the introduction of a

structured teaching program raised patients' levels of satisfaction.

As well, the present study found that there was inverse correlation between infection grading with patients' knowledge, self-reported practices and the self-care agency scores among study group, this finding confirmed the positive effect of implementation of the self-management protocol which improve the patient knowledge, practice and use ideal technique for selfcare and therefore reduce the incidence of pit site infection. This finding is in the line with a study by **Sayed, et al., (2019)**, who indicated that negative correlations had been established between pin site infection and patients' knowledge, indicating that the percentage of pin site infection decreases as patient knowledge increases.

### Conclusion:

Self-management protocol has a positive effect on external fixation patients' regarding reduce the incidence of wound and pin site infection, increase level of knowledge and self-reported practices, in addition to self-care agency. Moreover, the majority of patients of the study group expressed satisfaction with the self-management protocol which refers to the acceptance and prove of the research hypotheses.

### Recommendations:

- Engage the self-management protocol as a guidance when providing routine nursing care for patients with external fixator.
- To ensure that the results are generalizable and that the self-

management technique is used more widely, it is advised that the study be replicated over a longer time period and with a bigger probability sample.

- It is advised to conduct additional research to identify the variables influencing the early and late health outcomes for patients with external fixation.

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