Preoperative Placement of Rigid Markers for the Treatment of Tibial Fractures Using 3D Printed External Repositioning Model Combined With External Fixator

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Research Article

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Abstract

Purpose: To investigate the effectiveness of preoperative placement of a rigid marker 3D printed external repositioning model combined with an external fixation frame in patients with tibial fractures.

Methods: Fifty-five patients with tibial fractures treated from June 2019 to August 2020 were used as study subjects. Patients were divided into a control group and an observation group according to the order of their admission to the hospital. Patients in the control group were treated with conventional surgery, and patients in the observation group were treated with preoperative placement of rigid markers 3D printed external repositioning models combined with external fixators. The treatment results of the two groups were compared.

Results: Patients in the observation group had significantly shorter operative time, hospital stay and fracture healing time than patients in the control group, and intraoperative bleeding was significantly less than that in the control group ($P<0.05$). The pain level decreased in both groups as the time lengthened after surgery. At the same time point, the degree of pain in the observation group was significantly lower than that in the control group ($P<0.05$). The incidence of postoperative complications was 6.66% in the observation group and 36% in the control group, and the incidence of postoperative complications was significantly lower in the observation group than in the control group ($P<0.05$). The excellent rate of fracture healing was 60% in the observation group and 86.67% in the control group, and the difference in the excellent rate of fracture healing between the two groups was significant ($P<0.05$). Patients in both groups gradually recovered their knee and ankle functions after surgery with the extension of time. At the same time point, the HSS and Maryland scores of patients in the observation group were significantly higher than those in the control group ($P<0.05$).

Conclusion：By using preoperative placement of rigid markers 3D printed external repositioning model combined with external fixator treatment. No further incision or fluoroscopic closed reduction is required. This reduces the patient's pain and improves the patient's fracture healing results.

Introduction

Most tibial fractures are caused by high-energy injuries, which can easily lead to serious soft tissue damage. Due to the complex mechanism of injury, the degree of injury to the injured person is serious, which makes treatment and postoperative recovery difficult[1, 2].The medial soft tissue of the tibia is thin, and the anterior medial musculature and blood vessels are few, which can lead to tibial fracture once a high energy impact is delivered[3].The incidence of tibial fractures is higher than the incidence of fractures in other parts of the body, and there is a greater chance of exposure of the tibial fracture site[4].Due to the lack of soft tissue protection and poor skeletal blood circulation, tibial fractures are prone to fracture non-union. Once a tibial fracture does not heal, the continuity of the fracture end cannot be restored, the tibia cannot bear weight and force, and the sequelae remain serious and affect normal life[5].

Currently, tibial fractures are mainly treated surgically with the help of two-dimensional imaging data such as X-rays, CT, and MRI. The patient's fracture condition is judged and the surgical plan is designed. However, due to the problems of overlapping bone blocks and fluoroscopic angles, the imaging is prone to deviations.Therefore, precise data cannot be provided, which increases the risk of surgery[6, 7].Steel plate internal fixation is no longer the main treatment method due to the high trauma and disruption of fracture blood circulation. Intramedullary nail for tibial fractures has improved the fracture healing rate, but it cannot fully achieve satisfactory repositioning, requires a small incision to place the intramedullary pin, and is more traumatic to the medullary cavity. Although the external fixator can promote healing of the fracture break end by means of pressure and traction, it is not possible to completely and accurately place the conventional auxiliary device in the appropriate position intraoperatively due to individual differences and factors such as inflammation and sprain[8].In this study, we analyzed the feasibility of this treatment method by preoperatively placing a 3D printed external repositioning model with rigid markers in combination with an external fixaor in patients with tibial fractures.

Materials And Methods

General information

Fifty-five patients with tibial fractures treated in the orthopedic department of our hospital from June 2019 to August 2020 were divided into a control group (n=25) and an observation group (n=30) according to the order of patient admission. Inclusion criteria: Diagnosis of fresh tibial fracture was confirmed by X-ray , and patients signed an informed consent form. Exclusion criteria: patients with combined hypertension, blood disorders, diabetes mellitus, patients with severe lower extremity vascular or nerve injury, patients who abandoned treatment midway or lost to postoperative follow-up. This study was reviewed and approved by Cangzhou Hospital of integrated traditional Chinese medicine and Western medicine.

Operative technique

Control group: Patients were treated with conventional surgery. Preoperative X-ray was taken at the fracture site, and the surgical plan was determined according to the imaging results.

Observation group: Patients were treated with preoperative placement of hard markers in 3D-printed fracture models combined with external fixation frames. After admission, a 3.5-mm Kirschner pin was inserted through each side of the fracture under local anesthesia as a stiff marker, and the data of the stiff marker were recorded by CT scan (Fig. 1, A).The image data of the hard markers were transferred to the computer, and the Mimics software was used to preprocess the images, segment the area, select the bone region, and remove excess tissue to simulate the reset fracture end, and obtain a three-dimensional reconstruction model of the reset fracture end, and a four-piece extracorporeal fracture template was designed to closely fit the Kirschner pin with the shape of the major skin contour of the lower leg (Fig.1, B). The fracture ends can be repositioned by template alignment, and a 3D printed fracture reduction model is performed based on the 3D reconstruction model (Fig. 1, C).During surgery, the corresponding four fracture resetting templates are threaded through the positioning holes onto the Kirschner pins of the affected limb and the four templates are docked by traction on the foot of the affected limb. This completes the repositioning of the fracture break end by means of the hard marker repositioning template, and when the fracture break end returns to the normal docking position, all the positioning Kirschner pins are repositioned and both fracture break ends are aligned. The external fixation frame is attached and the repositioning template is retained as an auxiliary fixation to complete the surgical treatment of the tibial fracture (Fig. 1, D).

All data relating to patient parameters, such as gender, age, mechanism of injury,bleeding volume,operation time, hospitalization time,visual analogue pain score(VAS)[9],postoperative complications,Johner Wruhs postoperative evaluation criteria for tibial fractures[10],Hospital for special surgery score(HSS)[11] and Maryland score[12].

Post-operative follow up protocol

Follow up visits were scheduled at six weeks, three and six months post-operatively.During each visit, the patients were evaluated clinically using Johner Wruhs postoperative evaluation criteria for tibial fractures,Hospital for special surgery score(HSS) and Maryland score.

Statistical analysis

Statistical analysis was performed using SPSS 20.0 statistical software. The measurement data were presented as the mean ± standard deviation, and independent-samples t-test was used to compare the data between groups. The counting data were presented as the rate, and the chi-square test was used to compare groups. Differences with $P < 0.05$ were considered statistically significant.

Results

There was no statistically significant difference between the two groups compared to the general data of gender, age, and mechanism of injury ($P > 0.05$)(Tab.1).The operative time, hospital stay and fracture healing time of the patients in the observation group were significantly shorter than those of the patients in the control group. Intraoperative bleeding was significantly less in the observation group than in the control group (Fig. 2). It was demonstrated that the shorter the operative time, the less the hospital stay, and the relatively shorter the fracture healing time for the patients treated by preoperative placement of the 3D printed fracture external repositioning model with rigid markers combined with external fixators.Using the VAS scale scores, it was found that the pain level decreased with increasing time in both groups after surgery. At the same time point, the pain level of patients in the observation group was significantly lower than that of patients in the control group (Fig. 3). This demonstrates that the preoperative placement of a 3D printed fracture model with a rigid marker combined with external fixation can improve the postoperative pain level and psychological status of the patients.The incidence of postoperative complications was 6.66% in the observation group and 36% in the control group. The incidence of postoperative complications in the observation group was significantly lower than that in the control group (Fig. 3). This demonstrates that the patients were better treated by preoperative placement of 3D printed fracture models with rigid markers combined with external fixators, and the postoperative complication rate was lower.The excellent rate of fracture healing was 60% in the observation group and 86.67% in the control group, and the difference between the two groups was significant ($P<0.05$), so the fracture healing in the observation group was significantly better than that in the control group (Fig. 4). This demonstrates that the preoperative placement of 3D printed fracture models with rigid markers combined with external fixators can improve the healing outcome of patients, promote bone formation and growth, accelerate the healing rate, and thus improve the quality of life of patients.Using the HSS scale scores, it was found that patients in both groups gradually recovered knee function as time increased after surgery. At the same time point, the HSS scores of patients in the observation group were significantly higher than those in the control group (Fig.5, A). Using the Maryland scale, it was found that the ankle function gradually recovered with time after surgery in both groups. At the same time, the Maryland score was significantly higher in the observation group than in the control group (Fig.5, B). This demonstrates that preoperative placement of a 3D-printed fracture model with a rigid marker combined with external fixation can improve the functional recovery of the knee and ankle joints after surgery.

Discussion

Currently, most tibial fractures are treated surgically. Although the traditional surgical treatment is more effective, the soft tissues at the fracture site need to be stripped during the surgery, which causes soft tissue damage and affects the blood circulation at the fracture site, thus increasing the incidence of postoperative complications in patients[13, 14].

In recent years, 3D printing technology has been widely used in the field of orthopaedic trauma, and this technology can transform two-dimensional images into solid models[15].3D images allow for more accurate pre-operative planning, simulation of surgery, and other operations, leading to a complete and personalized surgical plan[16, 17].By creating a 3D model, the surgeon has a clearer understanding of the patient's fracture, which provides a basis for the selection and placement of fixation and increases the likelihood of fracture reduction[18].Xie and Shen compared 3D printing with incisional internal fixation in the treatment of tibial plateau fractures, and showed that 3D printing shortened operative time and fracture site healing time, and reduced operative bleeding[19, 20].Ren, Jian et al. tested a common plate and a new anatomically locked plate by 3D printing technology, respectively, and the newly designed fixation material is stable and reliable, and more suitable for clinical application[21, 22].However, there are no reports on the use of 3D printed fracture external repositioning models with preoperative placement of rigid markers.

In this study, patients in the observation group were treated with a 3D printed fracture model with rigid markers combined with an external fixator. The 3D printed fracture model was used to reset the fracture ends without incision or X-rays, and then an external fixator was applied. After treatment, all the observed indexes of the patients were reduced compared with the control group. The postoperative pain level was significantly reduced, the complication rate was reduced, the healing of the fracture site was significantly improved, and the function of the knee and ankle joint was basically restored about 6 months after surgery, which improved the prognosis of the patients.

In this study, we introduced a rigid marker by inserting a locating Kirschner pin on both sides of the fracture, and then performed a CT scan to collect data, input the data into the computer, simulate the repositioning and design a repositioning model to fit the marker. The 3D-printed model was used to determine the position of the pins outside the patient's body during surgery, and the tibial fracture was then repositioned. The disadvantages are as follows: (1) The 3D printing modeling relies on preoperative imaging data, but there are also modeling errors due to muscle pulling at the fracture site and bone block occlusion. (2) 3D printing modeling is time-consuming and cannot be used in emergency surgery. To address these shortcomings, the next step is to investigate more convenient and efficient 3D modeling methods to provide a detailed theoretical basis for the accurate repositioning treatment of more tibial fracture patients.

Conclusion

Preoperative placement of a 3D-printed fracture model with a rigid marker combined with an external fixator in patients with tibial fractures allows for minimally invasive repositioning that is easy for the surgeon to perform. This treatment can reduce the pain of patients and improve the healing of fracture ends, which is of clinical significance.

Declarations

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Authors’ contributions

GLL designed this study, prepared the manuscript, tables and figures and have read and approved the final manuscript.JYZ,YDZ,XYW,QILINLIU collected and/or rated the data, read and approved the final manuscript.

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None

Availability of data and materials

The patients’ dataset are confidential and are privately held for patients confidentiality safeguard. As such, the datasets generated and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study was approved by the medical ethics review board of Cangzhou Hospital of integrated traditional Chinese medicine and Western medicine.

All methods in the study were carried out in accordance with the Helsinki guidelines and declaration.

All procedures were undertaken by the senior author after obtaining informed consent for all patients.

Consent for publication

Participate in our study involving human subjects,signed informed consent was obtained from all participants.

Competing interests

No competing interest to report.

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Tables

Due to technical limitations, table 1-2 is only available as a download in the Supplemental Files section.

Figures

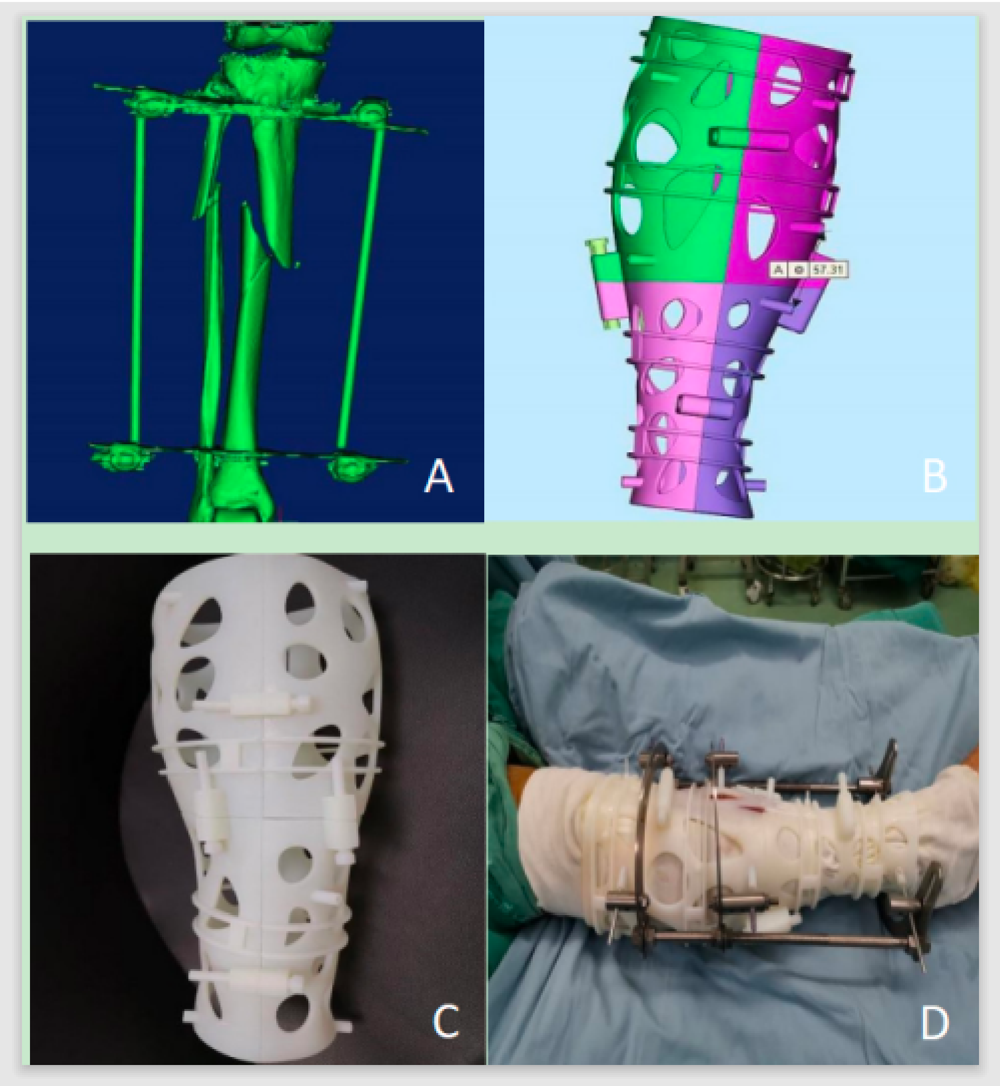

Figure 1

CT scan of the fracture site and rigid markers location in the observation group (A). 3D reconstructed model by Mimics software (B). 3D printed object (C). State of the patient after fixation at the fracture (D).

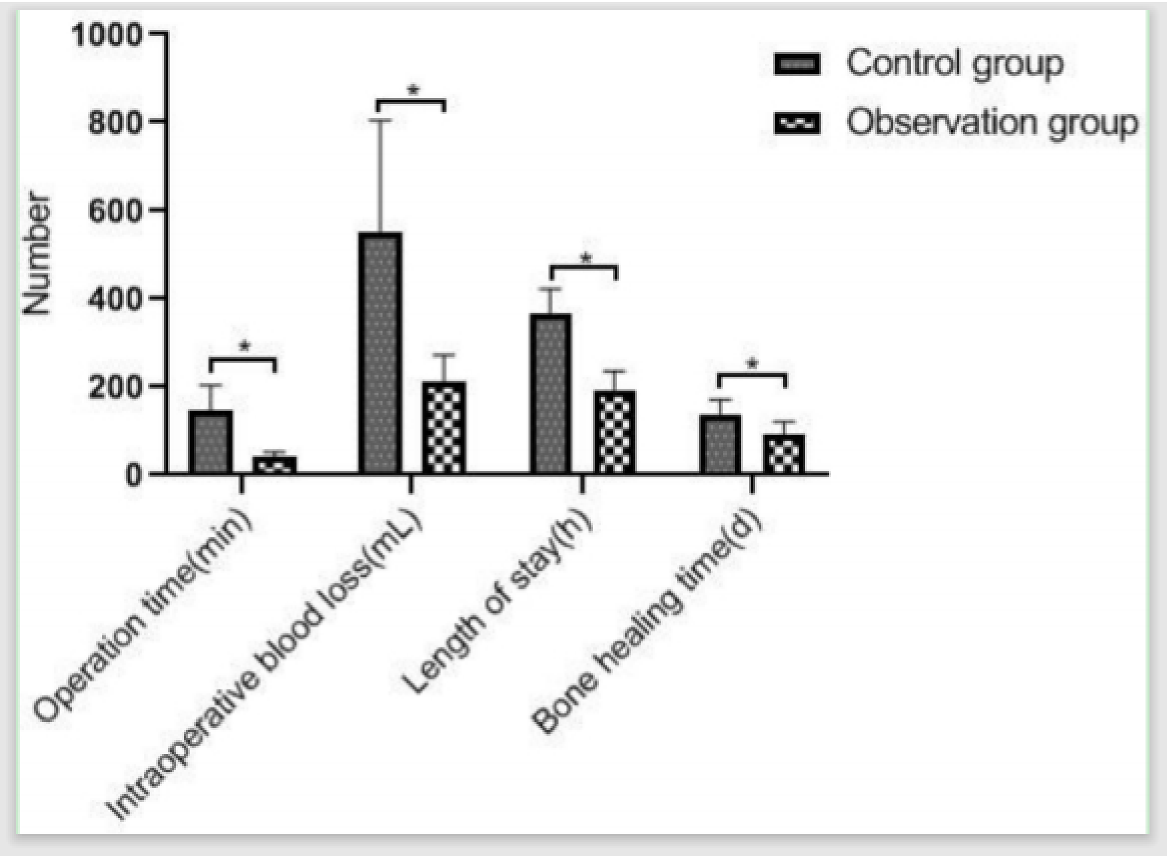

Figure 2

Comparison of perioperative indicators between two groups of patients.

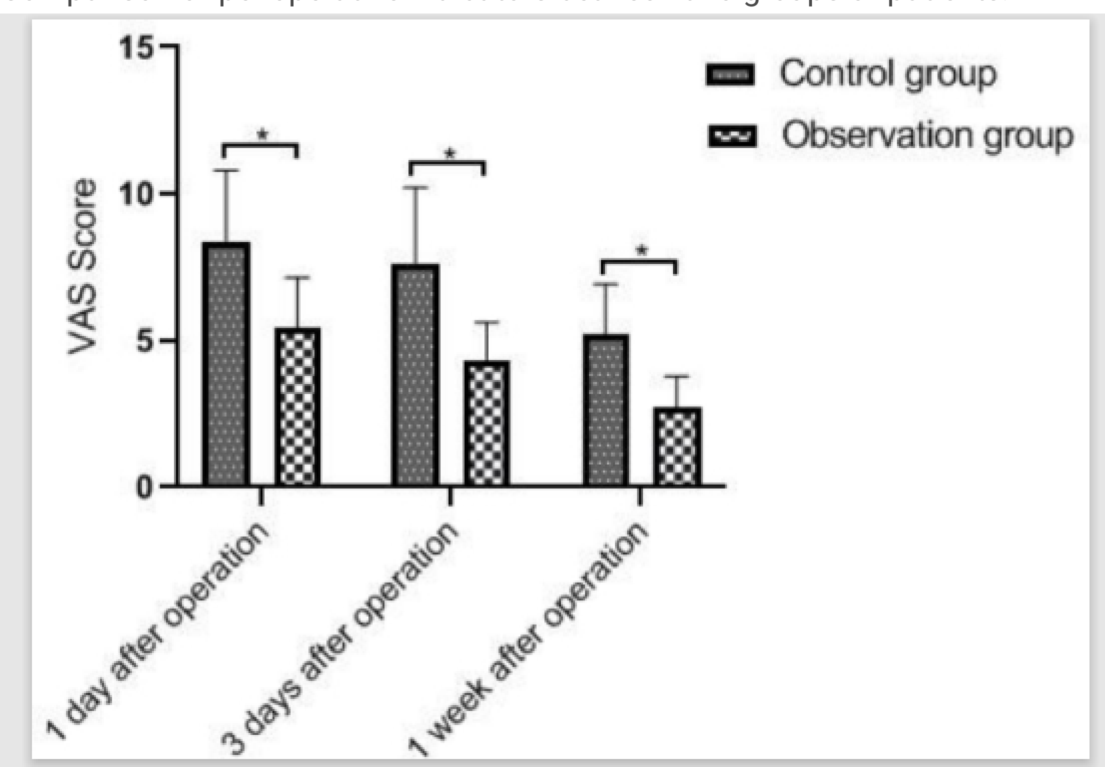

Figure 3

Comparison of postoperative pain between two groups of patients.

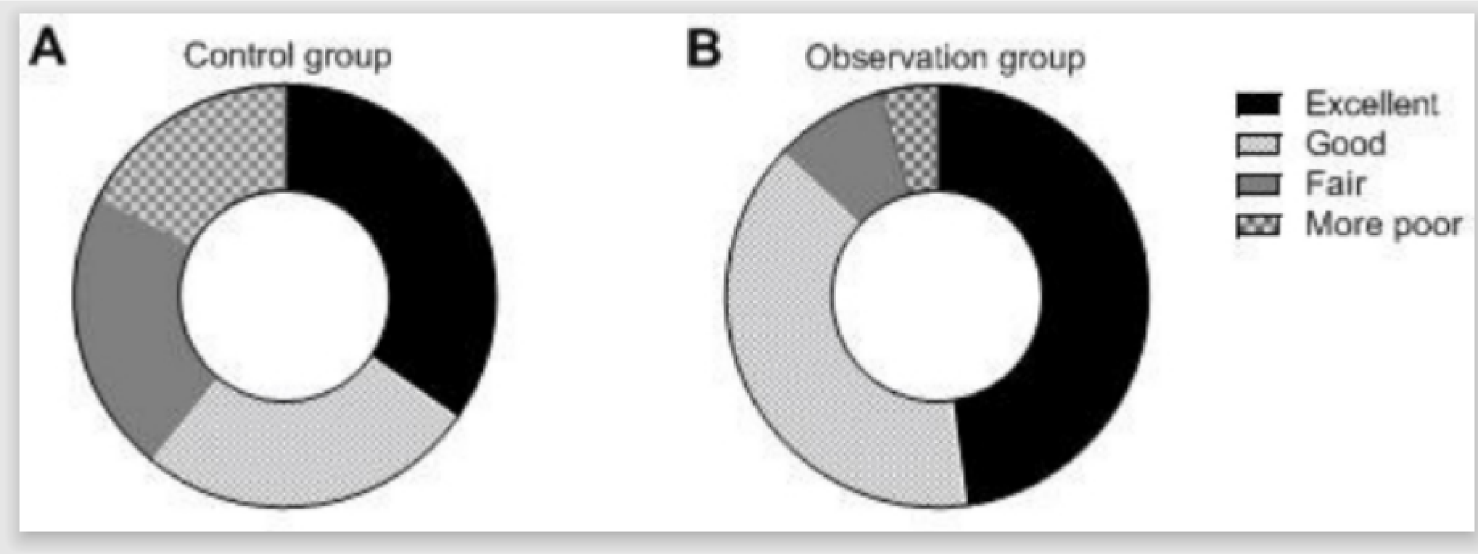

Figure 4

Comparison of fracture healing in the two groups.

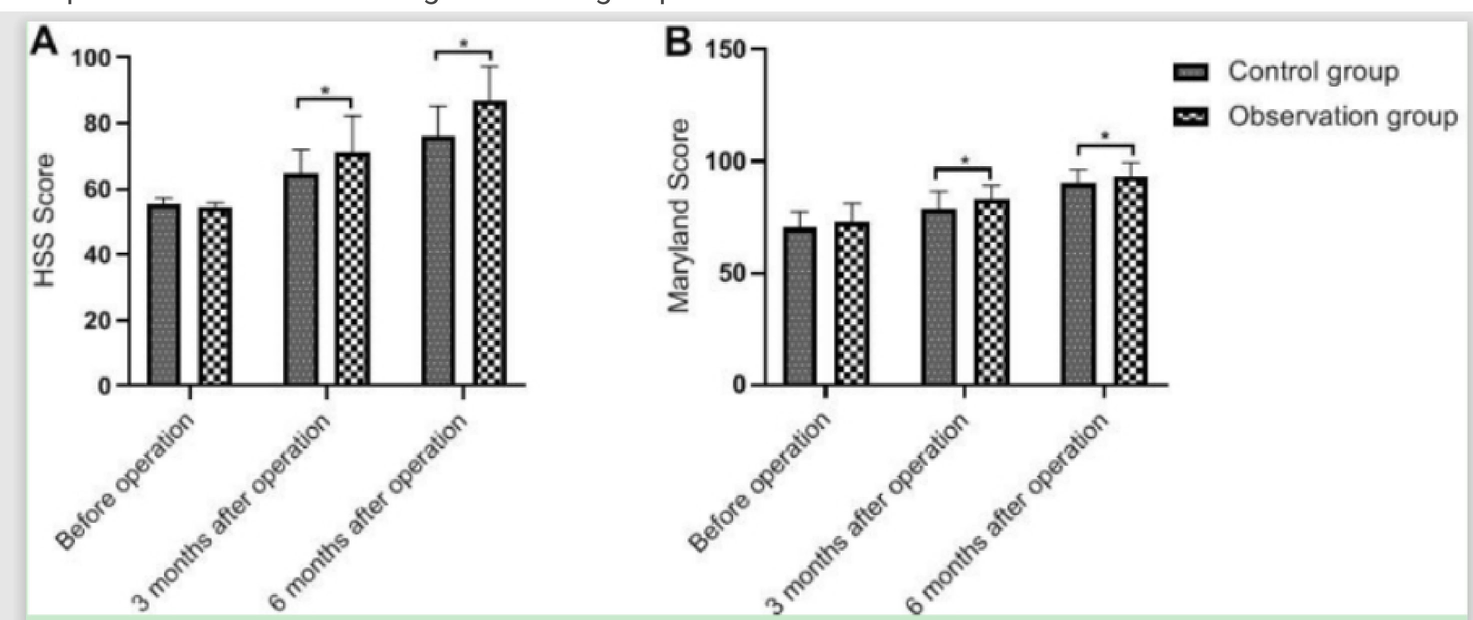

Figure 5

Comparison of functional recovery of knee and ankle joints between two groups.

Supplementary Files

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- Table1.pdf
- Table2.pdf