

The Use of Cryopreserved Umbilical Cord in Open Reduction and Internal Fixation of Calcaneus Fractures

Christopher M Stewart*

*Baptist Medical Center, Orthopaedic Trauma Surgeon, Little Rock, AR

1. Abstract

Calcaneal fractures are caused by a sudden, high-velocity impact on the heel [1]. The complication rate after open reduction and internal fixation of calcaneal fractures operated on by a lateral extensile approach range from 10 to 20%. Some of the worst perioperative complications associated with calcaneal fractures are tissue or bone infection, and/or wound complications. A retrospective review of 39 consecutive patients treated for calcaneus fracture by open reduction and internal fixation (ORIF) via a lateral extensile approach, was performed on 19 consecutive patients with 20 calcaneus fractures were treated with application of Clarix® cryopreserved umbilical cord (CUC) compared to a control group of 20 consecutive patients. The overall complication rate in the control group was 35%, compared to the cUC group of 10% ($p=0.13$). Additionally, the readmission rate and re-operation rate in the cUC group was lower than the control group (10% vs 30%, respectively; $p=0.24$). The use of cUC directly on the bone and hardware at the time of open reduction and internal fixation can be used as an adjunct to decrease wound complications, re-operations, and infection rates.

2. Introduction

Calcaneal fractures are caused by a sudden, high-velocity impact on the heel [1]. Most intra-articular

fractures occur from a direct axial load [2]. Hansen has described the main functions of the calcaneus: maintenance and support of the lateral foot column, a dynamically stable and accommodative foundation for a patient's body weight, and a lever arm for propulsion of gait through the gastrocnemius-soleus complex [3]. The complication rate after open reduction and internal fixation of calcaneal fractures operated on by a lateral extensile approach range from 10% to 20% [2]. One of the worst perioperative complications associated with calcaneal fractures can be tissue or bone infection, and/or wound complications [3,4]. Li et al. performed a retrospective review of 176 calcaneal fractures, and noted a wound infection rate of 3.977%, and an overall complication rate of 26.704%. They noted that despite developments in surgical fixation of calcaneal fractures, "wound complications still remain inevitable [5]."

Clarix® cryopreserved umbilical cord (Amniox Miami, FL.) has been used in numerous studies for wound coverage and augmentation of healing in

***Corresponding author:** Christopher M Stewart, Orthopaedic Trauma Surgeon, Baptist Medical Center, 9101 Kanis Rd Suite 401, Little Rock, AR 72205, E-mail: orthotraumatmd@hotmail.com

Received Date: October 15, 2019; **Accepted Date:** October 20, 2019; **Published Date:** October 28, 2019

diabetic foot ulcers and complex wounds with osteomyelitis [6-8]. cUC is known for its anti-scarring quality, stimulation of healing, and regenerative capability in wounds [9]. Due to the high complication rate of calcaneus fractures, it was hypothesized that the application of a cUC membrane at the time of primary ORIF of calcaneus fractures would augment soft tissue healing and decrease post-operative wound complications along with re-operation and readmission rates.

3. Materials and Methods

A retrospective review was conducted at a level II trauma center after obtaining institutional review board approval. Patients were identified by CPT code 28415. All patients were treated by a single fellowship-trained orthopedic trauma surgeon. All patients were 18 years of age or greater and were treated for a calcaneus fracture from 2015-2019. Demographics of the patients included: age, BMI, Diabetes, Peripheral Vascular Disease, tobacco use, along with drug and alcohol use/dependence.

A retrospective review of 39 patients treated for calcaneus fracture by ORIF. Nineteen (19) consecutive patients with twenty (20) calcaneus fractures were treated with application of Clarix® cUC (Amniox Miami, FL) at the time of primary ORIF. This was compared to twenty (20) consecutive patients with calcaneus fracture, treated with primary ORIF of their calcaneus prior to the use of cUC. All patients were treated by the same surgeon (CS), at the same hospital, Baptist Medical Center in Little Rock, AR.

All patients were treated with primary open reduction and internal fixation when their soft tissue was ready per surgeon's discretion. The fractures were all fixed with plate and screw constructs, no percutaneous fixation was utilized. All fractures were fixed under a tourniquet at 250 mm Hg. In the patients who received a Clarix® cUC, at the time of closure, either 2.5 x 2.5cm or 4 x 3cm thawed umbilical cord membrane was applied directly



Figure 1: Calcaneus fracture fixation.
over the hardware and bone



Figure 2: Applied Clarix® cUC over hardware and bone.

All patients were closed with full thickness vicryl sutures, Donati-Allgower nylon sutures on the skin, and a deep suction drain



Figure 3: Final skin closure after ORIF. All patients received the same initial hospital post-operative day 2, and discharge home with home physical therapy. All patients remained non-weight bearing (NWB) for 6 weeks, and then began progressive weight bearing as tolerated (WBAT). All patients were seen at regular interval of three weeks, six weeks, twelve weeks, and six months postoperatively. All patients were reviewed for: need for any local wound care,

need for oral antibiotics, readmission for infection and/or wound complications, any surgical site re-operation, established FRI and osteomyelitis, and overall union rates. We specifically evaluated need for re-operation, or lack thereof, within six months post-operatively as a surrogate for wound healing. We defined Fracture Related Infection (FRI): fistulas or sinus tracts that communicate directly with the bone or hardware, wound breakdown with exposed bone or hardware, purulent drainage from the wound, or two positive intra-operative cultures obtained at the time of surgical intervention. Clinical signs suggestive of infection included: local redness/swelling, increased local tissue temperature, oral fever of $>38.3^{\circ}\text{C}$ (101°F), radiographic bone signs of osteolysis, implant loosening, sequestration, periosteal bone formation, and failure of progression of bone healing (nonunion). Demographics of the patients collected included: age, BMI, Diabetes, Peripheral Vascular Disease, tobacco use, along with drug and alcohol use/dependence. Statistical analysis was performed using Chi square and Fischer exact test, with significance defined as $p<0.05$ (IBM SPSS version 20.0).

4. Results

The average age of the patients receiving the cUC at the time of ORIF was 39.5 ± 15.2 , with a BMI= 27.7 ± 5.5 . The average age of the patients who didn't receive the umbilical cord was 52.0 ± 13.3 with a BMI= 26.9 ± 4.6 .

Table 1

n=20	No Clarix®	With Clarix®	P value
Wound care	7 (35%)	2 (10%)	0.13
Antibiotics	6 (30%)	2 (10%)	0.24
Readmission	6 (30%)	2 (10%)	0.24
Re-operation	6 (30%)	2 (10%)	0.24
Infection	5 (25%)	2 (10%)	0.41

Nonunion	1 (5%)	0	1
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It lists the study group's demographics with patient's age, BMI, Diabetes Mellitis, nicotine use, alcohol and drug use, closed and open fractures, along with p values. In the group that didn't receive the cUC, the following medical comorbidities existed: Diabetes (10%), Tobacco dependence (35%), Drug/Alcohol dependence (5%), Peripheral Vascular Disease (0%). There were seventeen (17) closed calcaneus fractures, and three (3) open fractures. In the group that did receive the cUC, the following medical comorbidities existed: Diabetes (0%), Tobacco dependence (32%), Drug/Alcohol dependence (5%), Peripheral Vascular Disease (0%). All twenty (20) calcaneus fractures were closed, one patient had bilateral fractures.

In the group that didn't receive the umbilical cord, the following complications were seen: seven (7) patients required wound care postoperatively, along with six (6) of these also requiring oral antibiotics. Six (6) patients required readmission, with all six requiring re-operation for wound complications and infection. Five patients had confirmed FRI with positive intraoperative cultures. One patient went on to nonunion (5%).

In the group that did receive the cUC, the following complications were seen: two (2) patients required wound care postoperatively, along with both of these patients also requiring oral antibiotics. Two (2) patients required readmission, with both requiring re-operation for wound complications and infection. These two patients had confirmed FRI with positive intraoperative cultures. No patients went on to nonunion.

The wound complication rate requiring intervention was 35% in the patients who didn't receive the cUC and was 10% in the patients who did ($p=0.13$). The readmission and re-operation rates were 30% in the group who didn't receive the cUC and was 10% in the group who did ($p=0.24$). It lists the rates of wound complications, need for antibiotics, readmissions,

Table 2

n=20	No Clarix®	With Clarix®	P value
Wound care	7 (35%)	2 (10%)	0.13
Antibiotics	6 (30%)	2 (10%)	0.24
Readmission	6 (30%)	2 (10%)	0.24
Re- operation	6 (30%)	2 (10%)	0.24
Infection	5 (25%)	2 (10%)	0.41
Nonunion	1 (5%)	0	1

re-operations, infections, and nonunion, along with p values. None of these parameters reached statistical significance.

5. Discussion

The complication rate after ORIF of calcaneal fractures operated on by a lateral extensile approach is approximately 10-30%. Some of the most devastating complications include wound complications, need for return to operating room, and deep surgical infection and/or osteomyelitis. In this study, a consecutive series of patients treated for calcaneus fractures by ORIF augmented with the application of Clarix® cUC was compared to a consecutive series of patients prior to the use of cUC. Results showed the wound complication rate, along with readmission and re-operation rates was decreased in the group that received the cUC at the time of initial ORIF. We also noted one nonunion in the group that didn't receive cUC, but none in the group that did.

Ding, et al. showed that diabetes mellitus, Sanders classification, and smoking were the greatest risk factors for a wound complication following ORIF of a closed calcaneal fracture [10]. We had a low rate of medical comorbidities in our study, except smoking. A total of 32% and 35% of patients used nicotine in the group that didn't receive cUC and did receive cUC, respectively. All patients are counseled on how

this is a significant risk factor, but ultimately must decide the risks and benefits of surgery for themselves. Furthermore, the use of Clarix® implantation at the time of surgical fixation was implemented in order to minimize complications in operatively treated calcaneal fractures.

Even though the complication rate is high for operatively treated calcaneal fractures, patients report functional scores higher after fixation. In a retrospective review, DeBoer showed that patients with ORIF and percutaneous fixation reported better functional outcome scores (Foot Function Index and AOFAS hindfoot scale) than patients who had nonoperative treatment [11]. A meta-analysis of eight randomized trials by Meena et al. showed that patients who had operative treatment of their calcaneus fracture were more likely to resume pre-injury work, had fewer shoe wear problems, and a higher physical component summary score of SF-36 [12].

Results are consistent with prior studies. Folk et al. reported a 25% wound complication rate for operatively treated calcaneal fractures. Of those patients, 83% required surgical treatment [13]. Li et al. performed a prospective randomized trial that compared complication rates in displaced intra-articular calcaneal fractures treated with sinus tarsi approach versus the lateral extensile approach. They had an overall wound complication rates of 6.3% and 31.2% in the sinus tarsi and extended lateral approaches, respectively [14]. However, Benirschke conducted a chart review of 341 closed calcaneal fractures and 39 open calcaneal fractures. A total of 1.8% of closed fractures and 7.7% of open fractures required intervention beyond oral antibiotics. All of the fractures and incisions eventually healed [15]. Unfortunately, our studies' complication rate was much higher than this reported rate by Benirschke. Yet, the use of cryopreserved umbilical cord made a reduction in all wound complications, readmission, and re-operation rates compared to our control group. Howard et al. performed a prospective, randomized,

multi-center study at four Level I trauma centers. There were 226 displaced intra-articular calcaneal fractures (206 patients) who received ORIF. 57 of 206 patients (28%) had at least 1 major complication. Howard et al. showed that complications occur regardless of the treatment strategy, and despite treatment by experienced surgeons [16].

There were numerous strengths to this study. All patients underwent the same surgical procedure by one surgeon (CS). All procedures were performed at the same institution, and preoperative and postoperative care was standardized. The patients all received the same: anesthesia, surgical approach and closure, fixation strategy utilizing plates and screw constructs, identical rehabilitation protocols, pain management, preoperative antibiotics, weight restriction, time to weight bearing, and time to suture removal. This removed the influence of many confounding variables that could affect the results. So, the differences between the groups as it relates to postoperative wound complications and re-operation should solely be attributed to the Clarix® cryopreserved umbilical cord membrane.

There are several drawbacks to our study. First, it is only a retrospective review of cases performed, and hence there is no randomization. Also, there is a small sample size of both groups, which magnifies the differences in the two groups. Perhaps a larger sample size would have allowed for greater statistical significance. Also, all patients were post-operatively followed by the primary surgeon, which could create bias against identifying and treating infection. Regardless, we were able to eliminate some bias, as this study used a consecutive series of patients treated with or without the cUC. No patients in either consecutive series was eliminated.

6. Conclusion

The use of cryopreserved umbilical cord application directly on the bone and hardware at the time of open reduction and internal fixation of calcaneal fractures can decrease wound complications, re-operation rates,

and infection rates.

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Citation: Christopher M Stewart. The Use of Cryopreserved Umbilical Cord in Open Reduction and Internal Fixation of Calcaneus Fractures. SunKrist J Trauma Emerg Med Acute Care. 2019; 1: 1001.

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