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Surgical Technique

Using Computed Tomography-Based Three-dimensional Modeling and Computer Navigation for Minimally Invasive Core Decompression and Adjuvant Orthobiologic Therapy of Femoral Head Avascular Necrosis

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ABSTRACT

Avascular necrosis of the femoral head is a debilitating condition that can lead to femoral head collapse. Core decompression with adjuvant cellular therapies, such as bone marrow aspirate concentrate, delays disease progression and improves outcomes. However, inconsistent results in the literature may be due to limitations in surgical technique and difficulty in targeting the necrotic lesions. Here, we present a surgical technique utilizing computed tomography-based three-dimensional modeling and instrument tracking to guide the therapy to the center of the lesion. This method minimizes the number of attempts to reach the lesion and confirms the three-dimensional positioning of the instrumentation within the lesion. Our technique may improve the outcomes of core decompression and adjuvant therapy and prevent or delay hip collapse in patients with femoral head avascular necrosis.

Introduction

Avascular necrosis (AVN) of the femur, also known as osteonecrosis, is thought to be caused by disruption of subchondral microcirculation in the femoral head [1]. This condition is associated with multiple risk factors, including chronic alcohol use and steroid use [1,2]. Additionally, AVN can occur in the setting of trauma and genetic disorders such as sickle cell hemoglobinopathies [1-3]. There are approximately 10,000 to 20,000 new cases of femoral AVN in the United States each year [1]. Furthermore, a recent rise in reported cases have been attributed to the COVID-19 pandemic [4,5]. It is unclear whether this increase in cases should be attributed to the COVID-19 infection itself or aggressive corticosteroid therapies [6].

At early stages, 50-67 percent of patients with femoral AVN progress to symptomatic disease and/or collapse [7]. Total hip arthroplasty (THA) is the current best treatment for femoral AVN who have experienced femoral head collapse. However, THA in younger patients has an increased risk of mechanical failure due to the higher level of activity and the long-term utilization of the implant [8]. Therefore, there is a need for therapeutic strategies that effectively delay and prevent hip collapse and reduce the likelihood of requiring a THA [9].

There is strong evidence that core decompression can benefit patients with early-stage femoral AVN [10]. Specifically, it can provide immediate pain relief and, in Steinberg stage I femoral AVN, significantly reduce disease progression [10]. Subsequently, multiple studies have explored combining core decompression with adjuvant cellular therapies in order to improve outcomes. For

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instance, bone marrow aspirate concentrate (BMAC) is a potential adjuvant therapy containing growth factors, including platelet-derived growth factor, transforming growth factor-β, bone morphogenetic proteins, and progenitor cells reported to have anabolic and anti-inflammatory effects [11]. Administering BMAC has become an increasingly popular method of augmenting bone and cartilage regeneration [12-15].

Core decompression combined with BMAC was first described in 2002 by Hernigou et al. [16]. In this prospective study, 189 hips across all stages of AVN were analyzed. At the precollapse stages of AVN, Hernigou et al. reported better outcomes when core decompression was combined with BMAC compared to core decompression alone [16].

A systematic review of studies from 2011 to 2020 concluded that core decompression supplemented by BMAC works more efficiently than core decompression alone prior to collapse of femoral head in AVN [17]. Moreover, a 2021 scoping review by Pawar et al. analyzed 612 hips from 11 studies with AVN grade ranging from I to IV [18]. This analysis concluded that core decompression with BMAC in precollapse stages of the disease is beneficial in improving function scores and for reducing the radiological progression of the disease and the need for THA in most cases [18].

However, there are a few studies that report adjuvant bone marrow aspiration may not confer additional benefit [19,20]. We hypothesize that the outcome discrepancy among studies can stem from inconsistency in surgical technique and limitations in finding the best instrument orientation to target the avascular lesions. Notably, such preventative measures are most effective in Steinberg/Association Research Circulation Osseous Classification stages I and II of the disease. However, by definition, there is no X-ray evidence of AVN in stage I, and the radiographic features in stage II can be minor [21]. Therefore, the technique of utilizing two-dimensional fluoroscopy in one or two planes to conduct a core decompression, which is the method of choice for current image-guided surgical techniques, can be inadequate in being able to visualize the necrotic lesions intraoperatively and lead to incorrect spatial delivery of therapies. Furthermore, reaching the optimal central focus of the necrotic lesion with fluoroscopic techniques may require multiple entry and reorientation attempts, which can weaken this already compromised bone structure and increase the risk of fracture. As suggested by previous studies, the heat and forces experienced during excessive drilling can lead to cell death and significantly reduce the potential for bone regeneration [22,23].

In this paper, we present a surgical technique for guiding the therapy to the center of the necrotic lesion using a computed tomography (CT)-based image-guided tracking system that greatly improves visualization of the avascular necrotic lesion, minimizes the number of attempts to reach the lesion, and confirms the three-dimensional (3D) positioning of the instrumentation within the lesion. By providing the surgeon with a 3D model of the AVN lesion and a 3D image-guided technique to accurately target the lesion, this method may improve the outcomes of core decompression and orthobiologic adjuvant therapy and prevent the need for, or delay, hip collapse.

Surgical technique

Patients underwent general anesthesia with laryngeal mask airway for the duration of this procedure. From the anterior iliac crest, 60 cc of bone marrow aspirate was harvested with an 8-gauge Jamshedi needle. The bone marrow was processed using an automated centrifuge concentrating system (Angel System, Arthrex) in the operating room. This system had an approximate cost of US$1000. The system requires approximately 25 minutes for the centrifugation process and separation of the bone marrow concentrate, which is rich with platelets, nucleated cells, and progenitor cells.

A mobile CT scanner (O-arm, Medtronic, Inc.) and a computer-assisted surgical navigation workstation (Medtronic Stealth Navigation System) were borrowed from the spine surgery service of the hospital. There was a fixed capital equipment cost when the hospital originally acquired this system; the contract details were not shared by the institution. Nursing staff were trained on the use of the navigation system and therefore the presence of paid medical device representative was not required. An orthopedic trauma tray (Medtronic) with a navigated cannulated drill guide and a patient reference frame for registering the femur's 3D position were utilized. Medtronic provides the option to rent the orthopedic trauma tray per use or purchase the tray for approximately US$9000.

While the bone marrow was harvested and concentrated, the patient reference frame, which is proprietary to the navigation system, was secured to the distal femur (Fig. 1). Two percutaneous 3.2 mm Shantz pins were placed into the distal lateral aspect of the femur to support the 3D navigation reference frame. Next, the mobile CT scanner was positioned around the patient. A CT scan was obtained using the mobile scanner and transferred to the computer-assisted surgical navigation workstation.

The navigation system displayed the orientation of a universal drill guide (UDG) overlaid on top of axial, sagittal, and coronal slices of the CT scan. The UDG, which is proprietary to the navigation system, contains a second reference frame that must be visible to the system's camera (Fig. 1). The computer updates the position and orientation of the UDG in the CT-based 3D model in real time. The UDG was placed on the lateral aspect of the femur and adjusted until the optimal drilling trajectory was achieved to pinpoint the central focus on the avascular lesion. The UDG was positioned so that the drill was aimed directly into the center of the osteonecrotic lesion. A 400-mm-long 2.8-mm drill bit-tipped Kirschner wire (Depuy Synthes) was inserted into the UDG (which has an inner cannula diameter of 2.9 mm) and advanced into the bone using a wire driver and advanced into the center of the avascular region.

Next, the UDG was removed, and a 5.0 cannulated drill was utilized to perforate the lateral cortex (Depuy Synthes). To conduct the core decompression and deliver the adjuvant therapy, we utilized Arthrex's Closed Tip Hip IntraOsseos Bioplasty Kit. Subsequently, the outer cannula of a 230-mm-long 8-gauge Jamshidi needle was advanced over the 2.8-mm Kirshner wire until it was positioned in the lesion, as confirmed by fluoroscopy. The Kirshner wire was removed, and a drill with a flip cutter (IOBP decompression device, Arthrex) was advanced through the Jamshidi needle. With the flip cutter activated, a 7-mm core of bone was removed from the avascular region. After achieving the desired decompression, the flip cutter was retracted and removed from the cannula.

Subsequently, the adjuvant therapy was prepared using a ratio of 5 cc of demineralized bone matrix derived from human allograft, 1 cc of contrast dye (350 mgI/mL iohexol), and 2 cc of the BMAC. The approximate cost of bone allograft was US$1000. Depending on the amount of concentrate obtained, we were usually able to prepare approximately 7-10 cc of adjuvant therapy mixture. This biologic mixture was injected via the Jamshidi needle cannula and monitored under fluoroscopy. Lastly, the percutaneous reference pins were removed, and the skin was closed with staples. Local anesthetic was applied. Patients were advised to go home after postoperative clearance by the anesthesia team, and they were cleared to gradually advance to full weight-bearing as tolerated.

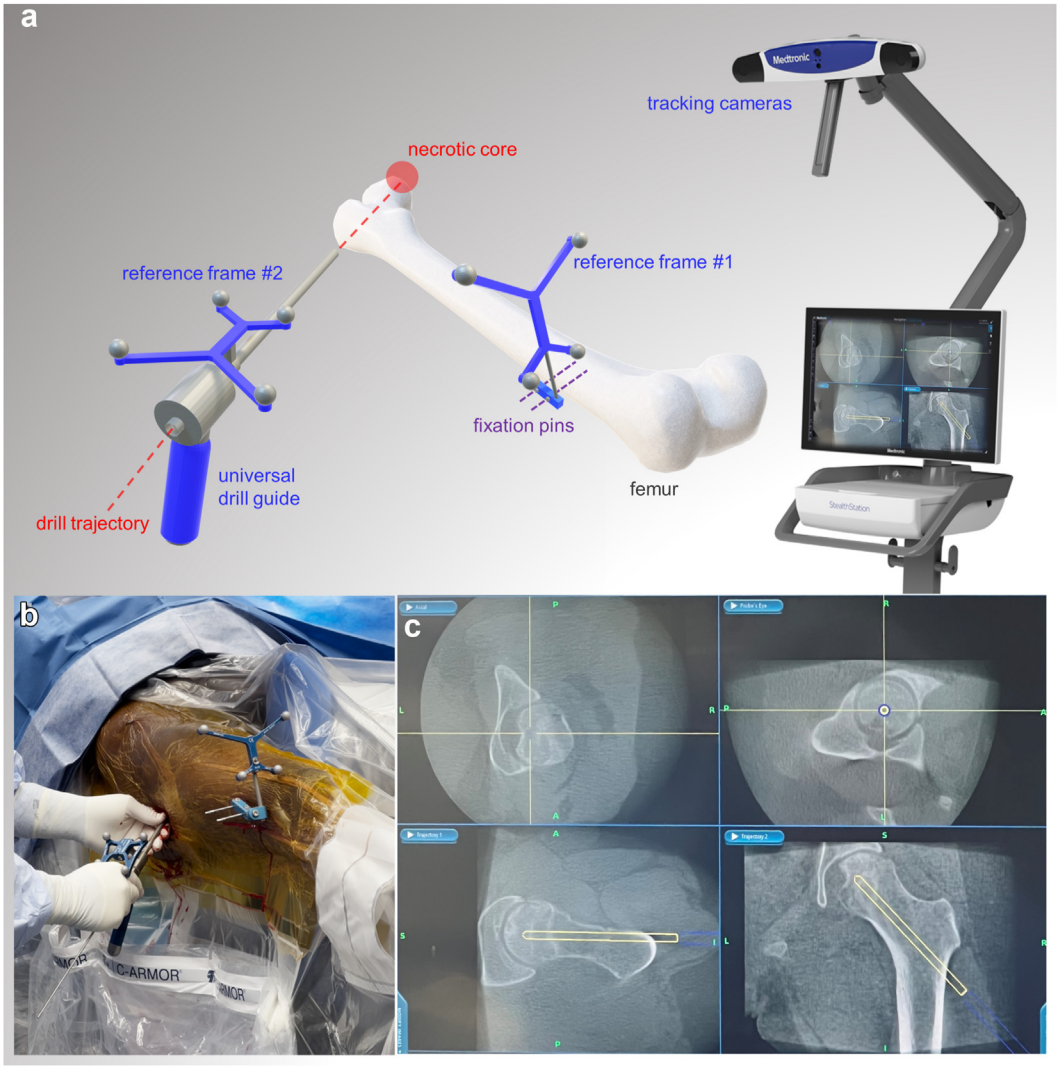

Figure 1. Imaging system along with device tracking software were used for core decompression and autologous bone marrow concentrate administration. (a and b) A reference frame (#1) is fixed on the distal lateral side of the femur. The navigation system's tracking camera identifies the position of reference frames. (c) A computed tomography scan of the patient's hip was obtained intraoperatively. The drill trajectory is tracked using reference frame #2 and registered with the imaging in real-time.

Discussion

Thirty-one patients were treated with computer-assisted core decompression and BMAC. The intraoperative fluoroscopy images confirmed the correct positioning of the needle tip in the necrotic region. The first patient required 2 needle entry attempts due to a slight deviation of the needle at the soft-tissue and bone boundary, which can be corrected by minimizing the drill revolutions per minute at this interface. The subsequent 20 patients required a single needle entry attempt to reach the necrotic core. The procedures took approximately an hour to complete. Fifteen minutes of this time were spent preparing the patient and setting up the imaging system. The remaining time was spent performing the core decompression and administering the bone marrow concentrate.

The goal of the minimally invasive procedure described here is to improve outcomes of core decompression and BMAC therapy in patients with early-stage disease by standardizing how lesions are targeted in 3D. Given that the majority of patients with femoral AVN experience disease progression, such developments are crucial in preventing hip collapse and surgery. Furthermore, because younger patients have a higher risk for prosthetic failure and requiring partial or complete replacement, delaying arthroplasty in this patient population can help reduce the likelihood of requiring revision surgery.

Conventional core decompression techniques utilize freehand drilling under fluoroscopic guidance. However, navigating under two-dimensional imaging limits the ability to accurately guide therapeutics to the necrotic core. In addition, fluoroscopic guidance may be limited in its ability to identify the necrotic region. This limited accuracy sometimes leads to multiple drill attempts or blindly drilling into the femoral head, which is detrimental to the healing process and increases the risk of fracture.

Using computer navigation, we were able to visualize the lesion in 3D and focus the therapy exactly in the center of the lesion with minimal needle entry attempts. Less drilling can help the healing process and shorten the procedure time. Moreover, consistency and standardization across cases allows for a more robust assessment of long-term procedural outcomes.

We recommend utilizing fluoroscopic guidance to confirm the accuracy of the computer navigation system in the first few cases.

However, fluoroscopic monitoring can potentially be eliminated from the protocol once confidence in the 3D navigation system and the surgical technique is achieved.

One of the limitations of this study is the radiation exposure from the intraoperative CT scan. In the initial stages of developing this methodology, we used foam models of a femur to optimize the scan parameters. In these experiments, low-dose CT protocols resulted in high levels of artifacts from the operative table. We opted to use standard dose CT parameters using the Medtronic O-arm, which could have an effective dose between 3 and 6.4 mSv [24]. Better reporting of dose profile for this procedure should be conducted in the future. Furthermore, we may attempt navigation devices that spatially register intraoperative ultrasound or fluoroscopic imaging with preoperative magnetic resonance imaging/CT in order to reduce procedure time and radiation. Additionally, existing universal needle navigation devices that work with conventional CT scanners may be utilized to improve efficiency and reduce cost.

Another limitation of this study and the core decompression procedure in general is the one-size-fits-all approach to choosing the appropriate canal size. We used a 7-mm core decompression device for all patients. Traditionally, core decompression is performed by opening an 8-10-mm-wide canal [25]. Although 3D navigation improves accuracy of the placement of the canal, which may mitigate the need for larger canals, future studies may allow for personalized selection of core decompression size based on preoperative 3D models. Furthermore, given our concern that the 7-mm device is not large enough for some lesions, we are developing a technique to use a larger flip cutter, the Arthrex AVN Expandable Reamer, which has a 5 mm shaft with a flip cutter that can expand to 18 mm.

In conclusion, the technique outlined here optimizes the drilling trajectory for core decompression of the femoral head and potentially maximizes the efficacy of decompression and adjuvant cellular therapy of necrotic tissue. Such advancements in intraoperative navigation technology may improve clinical outcomes for patients with early-onset femoral AVN.

Summary

Femoral AVN is a debilitating condition associated with compromised blood supply to the proximal femur. The treatment of AVN using core decompression and concentrated bone marrow aspirate has been shown to reduce pain and hip collapse in the early stages of the disease; however, current surgical techniques lack the ability to consistently direct treatment to the primary necrotic region. Current techniques can lead to decompression and adjuvant treatment of an incorrect region of the femoral head, as well as multiple attempts at correcting the instrument trajectory, thereby increasing the risk of iatrogenic fracture and compromising the healing process. Here, we demonstrate a minimally invasive, real-time 3D image-guided approach for delivering personalized treatment to the optimal location in the femoral head. For 31 patients, autologous bone marrow aspirate was obtained from the iliac crest and concentrated using a bone marrow processing system. An intraoperative CT scan was used to create a 3D model of the hip and identify the necrotic region. Next, computer navigation was used to orient instruments and deliver the BMAC to the central location of the necrotic region. This approach yielded an estimated operative time of 1 hour. We successfully reached the necrotic region without instrument reorientation in 30 of 31 patients. This technique may improve clinical outcomes for patients with early-onset femoral head AVN by precisely targeting necrotic regions. Furthermore, it may allow better comparison between therapies by standardizing treatment protocols.

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Conflicts of interest

D. Wiznia is a paid consultant for Globus Orthopedics and Materialize and receives research support from Stryker Orthopedics-MAKO Robotics. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

Alborz Feizi: Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Cameron Ellison Bell:** Investigation, Methodology. **Gregory Ronald Roytman:** Investigation. **Nancy Park:** Visualization. **Annie Wang:** Supervision, Writing – review & editing. **Steven Tommasini:** Supervision, Resources. **Daniel Wiznia:** Conceptualization, Investigation, Resources, Supervision, Writing – review & editing.

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