

A PRELIMINARY ANALYSIS OF A MODIFIED CORE DECOMPRESSION TECHNIQUE FOR THE TREATMENT OF OSTEONECROSIS

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Introduction

Osteonecrosis of the femoral head is a debilitating disease affecting a younger population of individuals in their thirties through fifties.^{1,6,9} Unfortunately, conservative treatments have traditionally yielded poor outcomes with 70% to 80% of non-surgically treated hips clinically progressing¹⁴ to collapse within a short period of time^{3,8,10,13} Since total hip arthroplasty (THA) is not a desirable first step for this young patient population due to their long life expectancy and the finite lifetime expectancy of the implant, bone sparing surgical treatment options, such as core decompression, are attractive.^{5,6,9} Core decompression is a commonly performed procedure for osteonecrosis of the femoral head due to the positive clinical results reported, minimally-invasive approach, and lack of complexity compared to other surgical alternatives.^{6,8} Typically, core decompression techniques are recommended for early stage pre-collapsed osteonecrosis with small to medium size lesions.¹⁰ Although this procedure is commonly performed, there is not a standard method for performing core decompression. The ideal core decompression method would be simple enough to conduct in an outpatient surgery center, utilize a minimally-invasive approach, relieve pain, help restore normal bone growth, and prevent further progression of the disease. The purpose of this paper is to describe a modified core decompression technique and evaluate preliminary results in a series of Ficat Stage I-Stage III hips.

Materials & Methods

Patients were positioned on a standard surgical table in a lateral position. **(Figure 1)** Anteroposterior (AP) and lateral fluoroscopic views were used to confirm position of instruments throughout the procedure. **(Figure 2)** Through a 1.5cm stab incision placed over the lateral aspect of the proximal femur, a 3.2mm fluted guide wire, provided in a self-contained core decompression kit **(Figure 3)**, was advanced under fluoroscopic guidance from an entry site just distal to the greater trochanter up the femoral neck into the necrotic lesion in the femoral head. **(Figure 4)** A tissue protector was inserted to the bony surface over the guide wire and a 9mm cannulated drill bit was used to decompress the necrotic region. **(Figure 5)** The core tract was drilled within 5mm of the subchondral bone. The guide wire and drill bit were removed and replaced by a working cannula, followed by the removal of the tissue protector. A specialized long-handled, narrow-angled curette was used to remove necrotic tissue from the femoral head. After conducting standard debridement, a specialized reamer with an expanding tip (X-REAM™ Percutaneous Expandable Reamer, Wright Medical Technology, Inc, Arlington, TN) **(Figure 3)** was inserted to remove a greater volume of the necrotic lesion. The blade control knob was turned ¼ of a turn clockwise and the entire instrument was rotated one full revolution. The process of expanding and rotating the reamer was repeated until an adequate amount of necrotic material was removed. During this process, the reamer was periodically checked under fluoroscopy using both lateral and AP views to verify the placement and extent of reamer expansion with maximum expansion at 2.1cm. **(Figure 6)** Careful attention was paid to avoid violation of the subchondral plate. After completing the

debridement, the blade control knob was turned counterclockwise until fully collapsed and removed. The debrided material was removed with the specialized curette, and the core tract was thoroughly cleared of reamed materials through repeated irrigation and suction. The core tract was then backfilled with a novel injectable, hard-setting, composite calcium sulfate (CaSO_4)-calcium phosphate (CaPO_4) bone graft substitute (PRO-DENSE™ Injectable Regenerative Graft, Wright Medical Technology, Inc. Arlington, TN). Beginning at the most proximal portion of the defect, graft was sequentially injected as the needle tip and working cannula were correspondingly removed. Adequate placement and complete filling of the graft into the defect were verified using fluoroscopy. **(Figure 7)** If graft placement needed adjustment in the working stage of the material, a tamp was used. The wound was closed in a standard fashion as the graft hardened. After surgery, patients were placed on crutches or a walker for four weeks. After four weeks, patients were gradually allowed to resume full activity as tolerated.



FIGURE 1 | Lateral position for core decompression

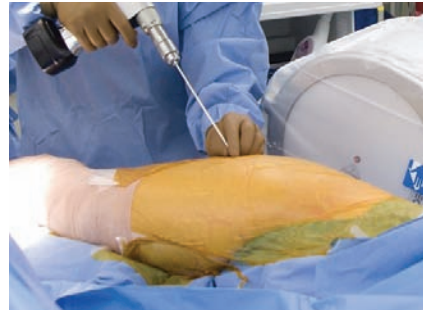


FIGURE 2A |



FIGURE 2B | Anteroposterior (a) and lateral (b) views can be obtained with C-arm and patient position with minimal limb manipulation.



FIGURE 3 | Components from a self-contained core decompression kit **(A)** and X-REAM™ Percutaneous Expandable Reamer **(B)** available from the manufacturer are the only specialized instruments required for this procedure.

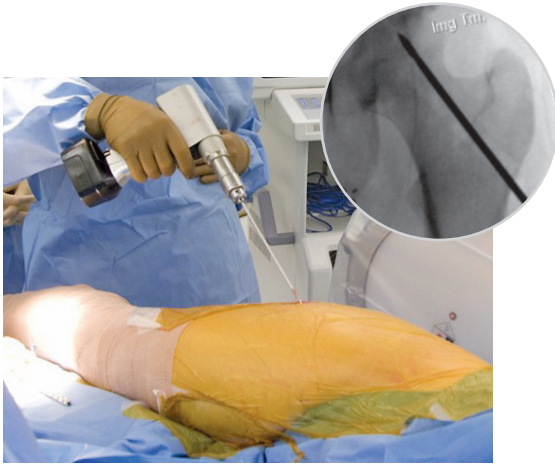


FIGURE 4 | The guide wire is advanced under fluoroscopic guidance into the necrotic lesion in the femoral head.

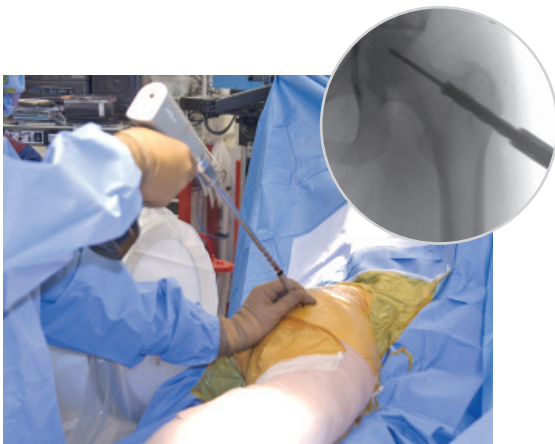


FIGURE 5 | After inserting a tissue protector over the guide wire, the necrotic region is decompressed using a 9mm cannulated drill bit.

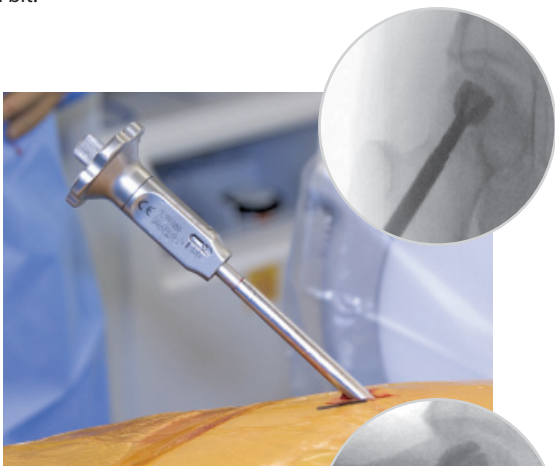


FIGURE 6 | The X-REAM™ Percutaneous Expandable Reamer is used to further debride the necrotic region after conducting standard debridement.

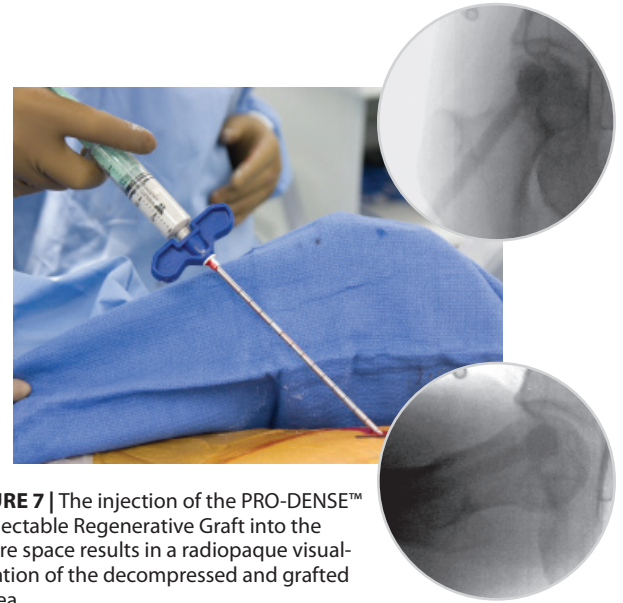


FIGURE 7 | The injection of the PRO-DENSE™ Injectible Regenerative Graft into the core space results in a radiopaque visualization of the decompressed and grafted area.

A preliminary analysis was conducted on patients with Ficat Stage I through Ficat Stage III hips treated with this modified core decompression procedure by two surgeons at two institutions between April 2006 and April 2007. Patients were assessed based on post-operative pain and radiographic evidence of progression. Total hip arthroplasties and resurfacing revisions were also recorded.

Results

Overall, 35 hips were treated in 24 patients using this technique. The population was composed of 18 males and 6 females with an average age of 38 years (range: 16-63 years). Eleven patients had bilateral procedures performed. The treated hips consisted of 1 Ficat Stage I, 23 Stage II, and 11 Stage III hips, 31 of which were symptomatic at time of treatment. The average follow time for this population is 8 months (range: 2-18 months). Pain has partially or completely subsided in 27 hips while 8 continue to experience pain or have been surgically treated. Four asymptomatic hips at time of treatment have

Table 1: Status Grouped by Stage of Osteonecrosis

	Symptomatic	Total	Radiographic Progression	% Radiographic Progression	Pain Relief*	% Pain Relief*	THA or Resurfacing	Survival Rate
Stage I	0	1	0	0%	1	100%	0	100%
Stage II	20	23	1	4%	20	87%	2	91%
Stage III	11	11	5	45%	6	55%	5	55%
Total	31	35	6	17%	27	77%	7	80%

*Absence or improvement of pain. Includes 4 asymptomatic hips that have remained pain free.

not developed any pain. Two stage III hips were treated with femoral head resurfacing and 3 stage III hips were treated with THA due to persistent pain as well as radiographic progression of the disease. Two stage II hips were revised to a THA due to persistent pain despite lack of radiographic progression. On average, the time to intervention was 6 months (range: 2-11 months). In the pre-collapse subset of 24 Ficat stage I and stage II hips, 88% experienced pain relief with a 92% survival rate. The radiographic progression within pre-collapse hips was low with 1 hip, or 4%, progressing. As expected, the results within the post-collapse Ficat stage III subset were not as dramatic as the pre-collapse group; nevertheless, pain relief and survival were seen in 55% of the 11 hips and radiographic progression in 45% of this group. (Table 1)

Case Example:

A 42 year-old female presented with bilateral groin pain. Radiographic and MRI evaluation (Figure 8) revealed idiopathic Stage II osteonecrosis of the femoral head in both hips. The patient was treated with staged bilateral core decompression with bone grafting using the surgical technique described herein. The surgical procedures were uneventful. Post-operatively the patient was instructed to remain touchdown weight-bearing for 4 weeks on the treated hip after each procedure. Consecutive radiographs (Figure 9) denote consolidation of the graft marked by slow material resorption and reconstitution with dense, cancellous bone. At one year, radiographs depict apparent normal bony architecture in the region of the core decompression defect. The patient is not experiencing pain in either hip and has full range of motion.

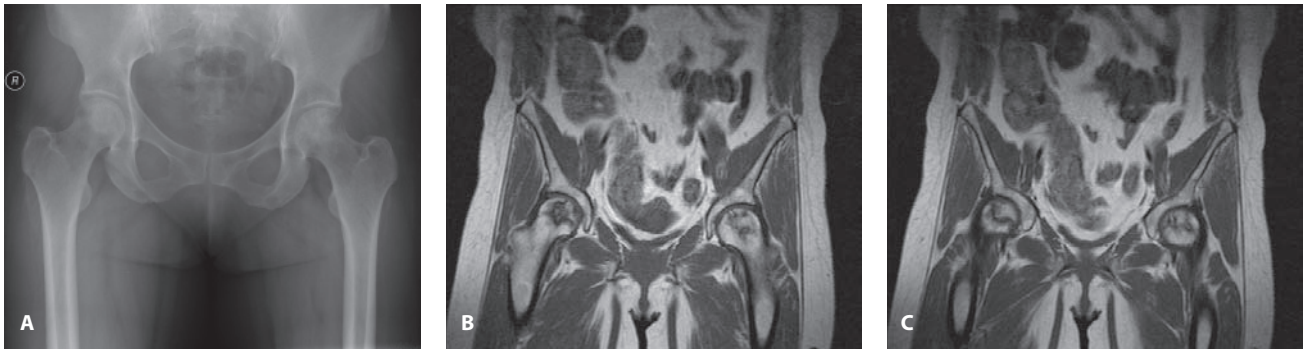


FIGURE 8 | Pre-operative radiograph (A) and MRI images (B, C) of bilateral Stage II osteonecrosis of the femoral head.



FIGURE 9 | Post-operative radiographs of the right hip immediately after surgery (A), at 10 weeks (B), and 14 months (C). Post-operative radiographs of the contralateral left hip immediately after surgery (B) and at 11 months (C).

Discussion

Despite having common physiological goals of pain relief and prevention of disease progression, core decompression methods are similar but far from standardized, indicating a need for improvement.⁶ In most cases, core decompression implies a single centralized core tract from the lateral aspect of the femur to the area of necrosis within the femoral head. The width of the tract, number of tracts, and extent of necrotic tissue debridement may vary. Although some debridement can occur using conventional curettes, the angles of these instruments as well as the size of the lesion may prohibit the removal of all necrotic bone.¹² For this reason, some investigators have turned to modified trap-door and light-bulb methods in an effort to more effectively remove the necrotic tissue.¹² Although, these methods may allow for increased access and removal of the lesion, they are more invasive in nature. The use of this core decompression technique offers a number of advantages over traditional core decompression methods, including the simplicity of the technique, the minimally-invasive approach, and broader capabilities in debriding the necrotic lesion percutaneously. Lateral patient positioning allows use of a standard surgical table rather than a fracture table. All components and specialized instruments required for a core decompression are provided in self-contained disposable kits. The X-REAM™ Percutaneous Expandable Reamer is a reusable device. The lack of specialized equipment required by the facility for this method improve the chances that this procedure could be conducted in an outpatient surgery center, thereby reducing patient expense and scheduling logistics.

The minimally-invasive nature of this procedure and the maintenance of the natural hip anatomy with this modified core decompression technique maintains all future surgical options in the hip should they be required. The novel, percutaneous, expanding reamer used in this application increases

the volume and extent of lesion debridement achievable with a traditional lateral approach. This allows for percutaneous debridement through a small incision and prevents the need for an open approach required for trap-door or light-bulb procedures. Backfilling the defect with an injectable, synthetic bone graft substitute also helps reduce patient morbidity since an autogenous graft harvest is not required. The use of this material in pre-clinical studies has been shown to produce stronger bone regenerate than both autograft and CaSO₄ alone at 13 weeks in a critical-sized defect in the canine proximal humerus.^{16,17} If these bone growth capabilities were clinically exhibited in surgically created core decompression defects, the normal femoral head architecture might be restored to help prevent further progression of the disease. If more normal bone architecture and resorption patterns could be established in a previously necrotic area, the need for a THA might be delayed or prevented in the young patient. Further study is required to determine if normal bone architecture and resorption patterns are achieved clinically in this indication.

Due to the etiological factors associated with osteonecrosis, such as corticosteroid use, it is not unusual for persons with osteonecrosis of the femoral head to be affected bilaterally with different progressive stages in each hip.⁴ In a study by Israelite *et al.*, core decompression conducted bilaterally was found to be equally safe and more clinically effective than core decompression procedures conducted unilaterally. The improvement in bilateral results may be attributed to the earlier surgical treatment of early osteonecrotic stages treated simultaneously with the symptomatic, more advanced, contralateral hip.⁴ Using this modified technique, the simplicity of the procedure allows for the treatment of hips bilaterally if both display signs of osteonecrosis. Caution must be exercised, however, since the performance of bilateral procedures at a single surgical setting might increase the risk of post-operative fracture since

protected weightbearing will be much more difficult. The bilateral procedures can also be conducted in a staged fashion with a short period between procedures. Use of the injectable, synthetic bone substitute eliminates concerns regarding the quantity of bone graft required in bilateral situations since the volume constraints inherent to autologous bone graft sources are absent.

The results seen in this preliminary series are promising. It is appropriate to examine the effects of this technique in the early post-operative period since the majority of core decompression revisions to THA occur within the first 24 months.¹⁵ The quick progression of those hips that fail may be linked to the rapid progression of the disease overall. Approximately 70-80% of non-treated hips will progress and collapse within a 1-5 year period.^{3,8,10} The review of such hips in early timepoints may, therefore, be an important indicator for overall success. Based on the radiographic evidence from this series, use of the injectable graft helps restore bone within the decompression defect in the average eight month timeframe. Although it is suggestive that the treated bone returns to a more normal state, it is unknown how this bone will change over time. This ambiguity in progression is somewhat related to the mysterious etiology and overall effects of osteonecrosis.

Conclusions

The use of a simplified core decompression technique with advanced debridement and synthetic bone grafting is a technically feasible procedure that can be conducted in most surgical centers without specialized equipment required of the facility. The use of the percutaneous expanding reamer allows for increased debridement of the necrotic lesion while maintaining a minimally-invasive lateral approach. Early experience with backfilling of the core defect with an injectable synthetic graft suggests an opportunity for bony restoration in the femoral head defect. Since the natural hip anatomy is main-

tained in this procedure, utilizing this technique will not prevent further hip surgery options should they be required. In a preliminary analysis of 35 hips treated with this method, the reduction in pain and lack of radiographic progression overall have been encouraging. A long term, prospective, randomized study is recommended to fully understand the effectiveness and possible benefits of this technique compared to core decompression alone.

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