EARLY RESULTS OF THE USE OF POROUS TANTALUM OSTEONECROSIS IMPLANT IN STAGE 1 AND STAGE 2 AVN OF FEMORAL HEADS IN ADULTS

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ABSTRACT:

Background: *Osteonecrosis of the femoral head (ONFH) is a debilitating condition responsible for a significant portion of total hip arthroplasties and detrimental functional capacity of patients. Core decompression is the gold standard of treatment for ONFH, however, tantalum rod implantation can provide structural support in the "pre-collapse" stages of ONFH. This study compares the results of tantalum rod implantation to the current literature.*

Aim of the work: *Review the early results of porous tantalum osteonecrosis implant in early stages of AVN of femoral heads in adults.*

Patients and Methods: *A prospective study surveyed patient radiographs, clinical notes, and operating room reports from a level I trauma center with a minimum of 2 years of follow-up. Inclusion criteria were skeletally mature patients with a diagnosis of ONFH with MRI evaluation, and treatment with core decompression with tantalum rod implantation. Primary outcome measures were Harris Hip Score and conversion to total hip arthroplasty (THA). Secondary outcomes measures were operation time and surgical complications.*

Results: *40 patients presented with ONFH were treated with core decompression with tantalum rod implantation. Harris hip scores at 6 months of follow-up had a mean of 97.52, improved from 72.72 at time of presentation. One patient (4%) developed a surgical complication of superficial infection. No other patients had surgical complications. Eight patients underwent conversion to THA. Mean operation time was 38 minutes.*

Conclusion: *Core decompression with tantalum rod implantation can be effective in treating early stage ONFH. For more advanced cases of ONFH, other treatment options may be considered. Increasing length of follow-up time will improve validity of the results.*

Keywords*: Tantalum rod; Osteonecrosis head of femur (ONHF); Trabecular metal implant;*

INTRODUCTION:

Osteonecrosis of the femoral head (ONFH) is a result of decreased blood flow to the femoral head that leads to cellular death, fracture, and collapse of the articular surface.[1] This condition is most prevalent in young, active people between the 3rd and 5th decade of life with an increasing incidence in the United States, with 10,000 to 30,000 new cases diagnosed annually.[1-4] These cases of ONFH result in 10% of the total hip arthroplasty (THA) procedures done annually and can be significantly detrimental to the

functional capacity of the patient population.[1-4]

The etiology of ONFH is undecided in literature, however the two most common risk factors in the United States are alcohol usage (20-40%) and corticosteroid therapy (35-40%).[1] The theorized pathophysiology behind ONFH is a combined effect of metabolic and local factors that lead to vascular damage and increased intraosseous pressure; this leads to hypo perfusion, ischemia, and infarction that results in bone death.[1,5] Trauma can also lead to ONFH through damage of the extra-osseous blood supply. Fractures to the subcapital region of the femoral neck can interrupt the anastomosis between the lateral epiphyseal vessels (branches from the medial femoral circumflex artery) and the artery of the ligamentum teres. This leads to blood flow interruption to the femoral head (FH) and subsequent necrosis of the bone.[1]

The treatment of ONFH is largely undecided in literature, with no established definitive treatment. Non-surgical management options include hyperbaric oxygen therapy, extracorporeal shockwave therapy, prostaglandin analogs, and Low Molecular Weight Heparin. These treatments are largely ineffective, with 80-90% of treatments being unsuccessful. 67% of asymptomatic and 85% of symptomatic patients who remain untreated progress to treatment with total hip arthroplasty.[1,2] Surgical options can be divided into femoral head sparing procedures and femoral head replacement procedures. FH sparing procedures are commonly performed in the pre-collapse stages of ONFH, whereas FH replacement procedures are done in the more advanced post-collapse stages.[1-3,5-8]

The most common FH sparing procedure is core decompression (CD) of the femoral head, a procedure that reduces intra-osseus pressure and leads to reperfusion of the femoral head.[3] However, this procedure is associated with lack of structural support when done alone, leading to a 13% incidence of intraoperative and immediate post-operative femoral neck fractures.[5] Tantalum rod implantation combined with CD is another option to increase structural support and allow the patient to be weight bearing immediately post operation in early and intermediate stages of FH necrosis.[3,5,8,9] The tantalum rod has a porous and cellular structure that is similar to bone and shows similar flexural rigidity to the human fibula and provides mechanical support to subchondral plate while limiting stress shielding.[3,5] This decreases donor morbidity as it eliminates the microsurgery and graft harvest needed for non-vascularized or vascularized fibula grafting techniques.[2,5] This technique is particularly useful when treating Stage I (normal radiograph, abnormal bone scan and/or MRI), or Stage II (abnormal radiograph showing 'cystic' and sclerotic changes in the femoral head) avascular necrosis.[10,11]

This study evaluates the short-term outcomes following implantation of porous tantalum rods for treatment of pre-collapse stages of ONFH.

AIM OF THE WORK:

Review the early results of porous tantalum osteonecrosis implant in early stages of AVN of femoral heads in adults.

PATIENTS AND METHODS:

An internal review board approved a prospective study on a consecutive series of patients. All patients received an informed consent and treated for ONFH at a level 1 trauma center from were evaluated for participation in this study. Association Research Circulation Osseous (ARCO) internal classification of osteonecrosis was used to classify ONFH. Inclusion criteria were skeletally mature patients, confirmed diagnosis of ONFH with MRI evaluation, and minimum 2 years of follow-up. Exclusion

criteria were complete destruction of the hip joint (ARCO III and IV) and an age greater than 50 years.

40 hips in 40 patients who underwent tantalum rod implantation for treatment of nontraumatic femoral head osteonecrosis were eligible for this study. The study included 16 males and 24 females aged 20 - 48 years old (average age: 35 years old). All 40 cases were unilateral ONFH. No cases were bilateral ONFH. 24 hips were classified as ARCO Stage I. 16 hips were classified as ARCO Stage II. The mean preoperative Harris hip score (HHS) was 72.7. Outcome measures included a preoperative and postoperative limb-specific score (Harris hip score). Postoperative complications were recorded, including the need for conversion to total hip arthroplasty. Survivorship analysis with revision to total hip arthroplasty (THA) was used as the end point in this study.

Surgical Technique:

The direct lateral approach was used for implantation of the tantalum rod. To begin the procedure, the patient is positioned in the lateral decubitus position with the affected hip prepared and draped freely. An incision is made 5 cm proximal to the greater trochanter of the femur. This incision is approximately 8-12 cm in length and continues distally with its center over the greater trochanter. Subcutaneous adipose tissue is dissected to expose the fascia lata underneath. The exposed fascia lata and vastus lateralis muscle are then split in the direction of the fibres.[12]

A guide pin is then inserted with the tip positioned 5 mm from the endosteal surface of the femoral head. The position of the guide pin is confirmed by radiographs in the anteroposterior (AP) and lateral view. Once, the position is confirmed, cannulated reamers are used to progressively ream the core to 10 mm under fluoroscopy. The implant is then threaded into position after final measurements and tapping. The incision is then closed in layers. **Figures (1- 4)**

(a) b)

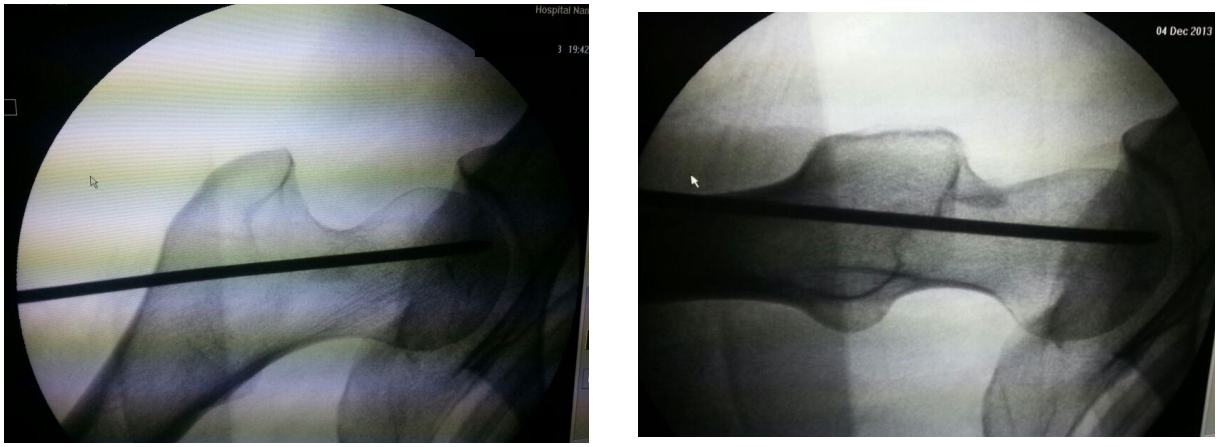

Figure 1: Guide pin in correct position directed to the lesion guided by fluoroscopy in a; AP & b; Lateral views.

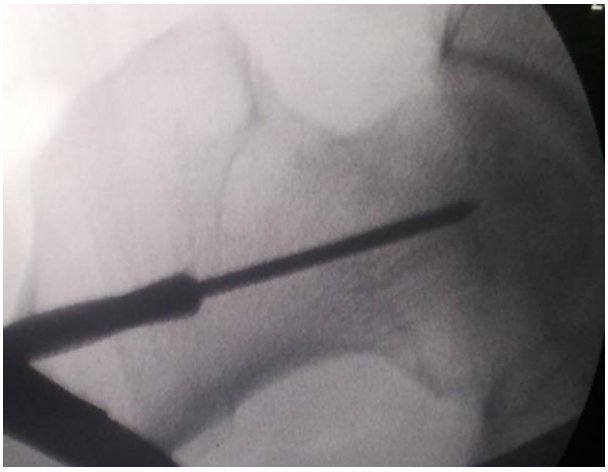

Figure 2: Cannulated reamer was used to ream the core.

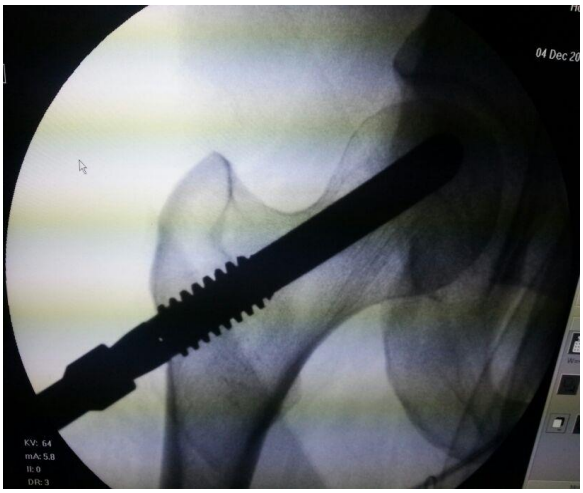

Figure 3: After measuring and tapping, the implant was threaded into the final position.

Figure 4: Instruments used in this technique are shown with the tantalum rod.

Patients were postoperatively managed with instructions to increase weight-bearing on the affected gradually as tolerated. Patients were allowed range of motion of the affected hip. If conversation to total hip arthroplasty (THA) was warranted, this surgical procedure was done through the direct lateral approach. An oscillating saw was able to cut through the implant during the removal of the femoral head. A special core reamer could then be used to remove the

remainder of the implant without incurring major bone loss.

RESULTS:

No patients in this study were lost to follow-up. Evaluation of 40 patients (16 men and 24 women) with 40 cases of ONFH were completed with regards to clinical and radiological outcome after implantation of an osteonecrosis intervention rod. The mean operative time was 38 minutes. Primary healing of the incision was achieved in all patients. 1 patient developed a superficial surgical site infection (4%); this was treated with oral antibiotics without further complications. Patients completed an average of 26 months of follow-up (range: 24 to 36 months). None of the patients experienced additional surgical complications, required reoperation. Eight patients showed clinical and radiographic deterioration and underwent conversion to THA.

The postoperative Harris hip score at a follow-up time of 6 months was 97.5 ± 3.5. 23 patients had excellent outcomes.

DISCUSSION:

Osteonecrosis of the femoral head (ONFH) usually progresses to destruction of the hip joint within a few years, leading to necessary total hip arthroplasty. Treatment of this condition varies widely in literature and no definitive algorithm exists for management. Several conservative management strategies for early-stage ONFH have been described, including magnetic field therapy, shock wave therapy, hyperbaric oxygenation, and pharmacotherapeutic treatments. None of these conservative measures have demonstrated clear evidence of successful long-term outcomes.

Current treatment for ONFH is aimed at restoring blood flow to the necrotic region and providing structural support to prevent advanced collapse and the need for total hip arthroplasty. Core decompression is a common surgical technique that relieves pressure on the femoral head and allows reperfusion. A study by Ficat et al. suggested good long-term results with core decompression. 133 patients with ONFH (without destruction of femoral head) were evaluated 9.5 years after core decompression. Radiologic failure occurred in 13.4% of patients with Ficat stage I and 33.3% of patients with stage II ONFH.[13] Tooke et al. confirmed that the outcome of core decompression is dependent on the stage of ONFH. Their study examined patients 3 years after core decompression and showed no instances of radiologic failure in Ficat stage I, 42% failure in stage II, and 56% failure in stage III.[14] Camp et al., however, published a less favorable study in regards to core decompression outcomes. Their study indicates 60% clinical and radiologic failure 18 months after core decompression. This study, however, did not differentiate between preoperative stages of ONFH.[15]

Core decompression in the early stages of ONFH is further supported in literature by a meta-analysis conducted by Mont et al. This meta-analysis included 24 studies and 1,206 hips, leading to good outcomes in 84% of patients with Ficat stage I and 65% of patients with stage II.[16] Another meta-analysis compared core decompression with nonoperative treatment, defining "success" as no further surgical intervention. Further surgical intervention was necessary in 39% of Steinberg stage I patients, 41% of stage II, and 75% of stage III that were treated nonoperatively. This was compared to further surgical intervention in 16% of Steinberg stage I, 37% of stage II, and 71% of stage III that were treated with core decompression.[17]

Our study employed a treatment modality of core decompression with tantalum rods in pre-collapse (stage I and stage II) stages of ONFH. No patients had major surgical complications. One patient developed a superficial surgical site infection

that was treated with oral antibiotics and resolved without further complications or need for surgical intervention. Thirty two patients met criteria for a successful outcome based on the Harris Hip Score, with a mean increase in HHS of 24.8 from the preoperative assessment to the 6-month follow-up visit. [19,20]

The results of this study showed that there was no significant progression of femoral head collapse in ARCO stage one cases. However, eight cases of ARCO stage 2 showed significant progression of femoral head collapse, and all of them received total hip replacement.

Our findings are compatible with the previous studies of tantalum rods in adult patients. Aldeghrie et al studied the results in 10 cases and found marked clinical improvement with no further progression in 9/10 patients. [21]

Similarly in another study of 26 patients, significant clinical improvement has been shown in all cases with 50% of them had no radiographic progression of collapse. Also, in a recent systematic review that included 550 cases across 10 studies, 77.9% of patients had shown stable lesions with no radiographic progression after a mean follow up of 3.1 years.

On the other hand, in a study of 104 cases of combined iliac autologous bone grafting and tantalum rods insertion, MA et al showed that this technique is not a viable option for femoral head AVN due to significant radiographic and clinical worsening in most of the cases [22]. This has been similar to our results in ARCO stage two cases.

As regards to comparison between tantalum rod insertion and other treatment methods of AVN, Zhang et al found that tantalum rod insertion improved clinical scores and radiographic outcomes significantly more than bone grafting whether vascularized or no vascularized [23]. Compared to core decompression, Miao et al found in a prospective RCT, no significant difference in the clinical and radiological outcomes between the gold standard CD technique and tantalum rod insertion. Hence, in our opinion, the cost benefit of tantalum rod technique has to be justified in further randomized controlled studies. [24]

As for the results of THR after tantalum rod insertion, Olsen et al found no significant difference in Harris hip score nor the wear rates between the two groups in his study. They were divided into patients who received THR after tantalum rod insertion, and the other group received THR after CD.[25]

Our study is not without limitations. Our study reports only short-term outcomes, with our follow-up periods between 24 and 36 months. It is possible that a longer follow-up term may demonstrate a higher failure rate than is seen in our patients. Continued research with longer follow-up periods is encouraged to further validate the results of this study.

Conclusion:

Tantalum rod is one of the recognized treatment options that aimed at hindering or delaying femoral head collapse. It can achieve favorable clinical and radiological outcomes in early stages of AVN, before the occurrence of femoral head collapse. In light of the close outcomes with the use of less expensive/ more feasible treatment options, and with exclusion of the industry pushed studies, we think that this technique offers no obvious advantages over the other treatment options, such as core decompression, with or without bone grafting. Future studies should consider more the use of biological interventions and focus on the early detection of femoral head AVN in high risk groups.

Conflict of interest:

The authors declare that they have no conflict of interest.

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النتائج الأولية لإستخدام التنتالوم المسامي في المرحلة الأولى و الثانية لتنخر العظام في رأس عظمة الفخذ

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الخلفيه: يعتبر التأكل النكروزي لرأس عظمة الفخذ احد المشاكل الصعبه التي قد تتسبب في استبدال مفصل الورك. وعلي الرغم من ان جراحة التثقيب هي العلاج المتعارف عليه في حالات التاكل النكروزي، الا ان مسمار التنتالوم المجوف هو طريقه جراحيه حديثه نسبيا يمكن استخدامها في حالات التاكل النكروزي البسيطه

الهدف من الدراسه: مراجعة النتائج المبدئية لاستخدام مسمار التنتالوم المجوف في حالات التاكل النكروزي البسيطه لرأس عظمة الفخذ

المرضي و طرق العلاج: تم اجراء الدراسه علي ٤٠ مريض في دراسه استباقية. تم دراسة النتائج الاوليه من خلال التحسن في الحاله الوظيفيه لمفصل الورك و نسبة الاحتياج لاجراء جراحة استبدال مفصل الورك. النتائج الثانويه تمت دراستها عن طريق ملاحظة الوقت اللازم للجراحه و نسبة عواقب الجراحه

النتائج: تم تحسن الحاله الوظيفيه العامه لمفصل الفخذ في الحالات التي تضمنتها الدراسه و لوحظ ذلك عن طريق تحسن نتيجة استبيان هاريس لمفصل الورك. حالة واحده حدث لها التهاب ميكروبي سطحي و ثمانية حالات احتاجو استبدال مفصل الورك بمفصل صناعي كامل

الملخص: يعتبر استخدام مسمار التنتالوم المجوف علاج فعال في حالات التأكل النكروزي البسيطه لرأس عظمة الفخذ. في الحالات المتقدمه يفضل استخدام وسيله علاجيه اخري. يتطلب الحصول علي نتائج امثل زيادة وقت الدراسه