Umbrella-shaped, memory alloy femoral head support device for treatment of avascular osteonecrosis of the femoral head

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Abstract

Purpose Avascular necrosis (AVN) of the femoral head is a common orthopaedic disease that is difficult to treat. The purpose of this study was to explore the preliminary efficacy of a self-designed umbrella-shaped memory alloy femoral head support device in the treatment of adult patients with avascular osteonecrosis of the femoral head.

Methods The minimally-invasive approach involved curettage of the necrotic tissue of the femoral head, and a self-designed umbrella-shaped, memory alloy femoral head support device was implanted into the collapsed necrotic area to support the collapsed femoral head. Autologous iliac bone and artificial bone were implanted into the support device for the treatment of adult patients with avascular osteonecrosis of the femoral head.

Results The clinical device was used in ten patients and 18 hip joints. The support device failed in one hip joint, which subsequently underwent joint replacement surgery, and the remaining 17 implanted devices were followed up for four to 19 months. The 17 postoperative hip joints were evaluated using the percent-efficacy evaluation method for avascular osteonecrosis of the femoral head in adult patients, and the efficacy rate was 82.35 %.

Conclusion The umbrella-shaped femoral head support device can be used in Ficat stage I, stage II, and stage III adult patients with avascular osteonecrosis of the femoral head.

Introduction

Avascular necrosis (AVN) of the femoral head is a common orthopaedic disease that is difficult to treat and is prone to occur in young patients [1–3]. If the condition is not effectively treated, 80 % of these patients will experience femoral head collapse and osteoarthritis [4–6], which has a serious impact on the quality of life [7–9]. In addition, joint replacement will ultimately be necessary, which poses a heavy burden on the patients' families and society [10–12]. Therefore, early treatment is essential to prevent femoral head collapse [13, 14].

Commonly used treatment methods for early osteonecrosis of the femoral head include the following: core decompression [15], free fibular grafting [16], and osteotomy [17]. The mechanism for the development of osteonecrosis of the femoral head is believed to be related to the stress generated from the formation of a hollow space after necrosis and the lack of mechanical support of the subchondral bone [18–20]. Therefore, based on this principle, researchers have designed a variety of support devices to mechanically support the femoral head and have achieved certain effects from devices such as the tantalum rod [21] and the titanium alloy support device [22].

These support devices were implanted into the femoral head via its decompression channel during minimally-invasive surgery [23, 24]. However, all of these devices had certain limitations because the support area was too small. Wang et al. designed the nickel-titanium (Ni-Ti) memory alloy tennis device that was woven with a metal wire [25]. Although the support area was relatively large, the support rendered by the device was relatively weak.

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Furthermore, the use of this metal tennis device required open surgery on the femoral head, resulting in significant trauma.

In view of the above-mentioned limitations, we designed an umbrella-shaped memory alloy femoral head support device (China new practical device patent number: ZL 2010 2 0641438.5). Using a minimally invasive approach, this support device was implanted into a collapsed femoral head via its decompression channel and was then expanded. Subsequently, the patient's iliac bone and artificial bones were implanted into the cavity that was expanded by the device to support the femoral head and prevent its collapse. Since 2009, this method has been used on ten adult patients with osteonecrosis of the femoral head and on 17 affected hip joints, and the preliminary results have revealed that this support device has excellent mechanical properties and that its efficacy is satisfactory, as described below.

Methods

The umbrella-shaped memory alloy femoral head support device consisted of two components: the sleeve and the umbrella-shaped frame. The sleeve of the umbrella-shaped memory alloy femoral head support device was a 1 mm-thick Ni-Ti alloy plate (the atomic ratio of Ni and Ti was 1:1) cut into a 20×30 mm rectangular plate (height 20 mm; width 30 mm) and pierced as shown in Fig. 1a. The circular hole was the blood-supply hole (diameter 3 mm), and the V-shaped hole was the non-slip barb hole (the length of the V-shaped hole was 4 mm, and the base length was 3 mm. The bottom edge was fixed, and the tip was bent at a downward acute angle of 45° and a height of approximately 1.5 mm).

The entire plate was pierced through three layers. The first layer and the third layer had a semi-circular hole, a V-shaped hole, a round hole, another V-shaped hole, and another semi-circular hole. The second layer had a semi-circular hole, three round holes, and another semi-circular hole. The horizontal distance between the holes was 2 mm, and the vertical distance was 3 mm (Fig. 1a). Finally, the rectangular plate was rolled into the cylindrical sleeve of the support device. The closed diameter of the sleeve was 9 mm. The diameter of the memory status was 12 mm (i.e., when the temperature was 37°C and above, the sleeve kept the expansion at a diameter of 12 mm). The six semi-circular holes formed three round blood-supply holes, that is, a total of eight blood supply holes and four V-shaped, non-slip barb holes (Fig. 1b, c).

The role of the blood-supply holes was to allow contact between the bone graft within the sleeve and the cancellous bone on the inner wall of the femoral decompression channel, thus promoting bone ingrowth. The role of the non-slip barb holes was to prevent the sleeve from sliding out of the femoral decompression channel.

The umbrella-shaped frame of the memory alloy femoral head support device comprised a 1-mm-thick Ni-Ti alloy plate cut into a square shape with a width of 70–81 mm. A 4.5-mm round hole was cut into the centre of the plate, and eight strips of 1.2-mm-wide umbrella-shaped arms were then evenly cut around the round hole to form the roughcast of the umbrella-shaped frame (Fig. 1d). The roughcast was heated using an acetylene gun (based on the manufacturing process requirements) and was moulded when it turned red. The top of the umbrella-shaped frame mold was used to support the centre of the roughcast, and tools were then used

Fig. 1 Umbrella-shaped femoral head support device. **a** Roughcast of the umbrella frame and sleeve of the femoral head support device. **b** Lateral view of the moulded sleeve of the support device. The round hole is the blood supply hole. **c** Frontal view of the moulded sleeve of the support device; the V-shaped hole is the non-slip barb hole. **d** The umbrella shape of the support device. **e** The shape of the moulded umbrella-shaped frame of the femoral head support device. **f** The final state of the support device

to sequentially mold each umbrella arm and to form the final shape of the umbrella top, which had a diameter of approximately 25–32 mm and a height of approximately 15–18 mm. The eight umbrella arms at the tail end were pulled back into a cylinder with a diameter of 8 mm, and 1 mm of the end portion was tilted outward (Fig. 1e). The role of the outwardly tilted end was such that eight outwardly tilted arms hooked onto the wall of the sleeve bottom to prevent the umbrella frame from sliding out of the sleeve.

Based on the pre-operative pelvic X-ray findings regarding the location and extent of osteonecrosis of the femoral head, a support device with the appropriate specifications was selected (expansion diameter > the diameter of the necrotic area + 4 mm).

First, the sleeve and umbrella frame of the support device were placed into ice-cold saline at 0 °C to change the umbrella shape of the frame into a cylindrical shape with a diameter of 8 mm. Next, the sleeve was spread apart at the opening to wrap the lower portion of the cylindrical frame so that the eight outwardly tilted arms were outside the lower portion of the cylindrical frame (the sleeve diameter was 9 mm when closed). Finally, hot saline at 50 °C was injected into the support device to restore it to the original memory state (Fig. 1f).

This study enrolled ten patients with avascular osteonecrosis of the femoral head with a total of 18 hip joints. There were seven males (12 hip joints) and three females (six hip joints). The patients were between 21 and 53 years of age. Seven patients had hormone-related osteonecrosis of the femoral head (bilateral), one patient had alcohol-related osteonecrosis of the femoral head (bilateral), and two patients had traumatic osteonecrosis of the femoral head (unilateral). The duration of the disease was one to five years. Based on the Ficat classification, ten hip joints were at stage II, six were at stage III, and two were at stage IV (young patients, all <30 years of age).

Each patient was placed in the supine position (with the ipsilateral buttock slightly padded and raised) and was anaesthetized using continuous epidural anaesthesia. Under C-arm X-ray fluoroscopy, a Kirschner needle was used to mark the body surface from 1–3 cm below the greater trochanter to the central necrotic area of the femoral head.

The skin was disinfected, and surgical towels and sheets were laid out according to routine procedures. Based on the mark on the body surface below the greater trochanter, a Kirschner needle was used to drill the tissue until it reached the necrotic area of the femoral head via the central femoral neck. The Kirschner needle was positioned as vertically as possible to the borderline between the necrotic area of the femoral head and the normal area. Subsequently, the Kirschner needle was used to make a straight, 3 cm-long incision along the lateral femur. Next, a hollow drill with a diameter of 9 mm was used to access the necrotic area of the femoral head along the Kirschner needle and through the

femoral neck, forming a 9-mm-diameter decompression channel. Under X-ray fluoroscopy, an elbow patula and a specific reamer were used to completely curette the necrotic tissue of the femoral head through the decompression channel, including 1–1.5-mm below the subchondral bone in the direction of the articular surface and 1–2 mm into the normal cancellous bone for the remaining area.

Two criteria were used to determine the extent of curettage. The necrotic bones were mostly hard in texture. Some had a soft texture (in patients with a shorter duration of the disease). Therefore, during scraping with the spatula, a sudden drop in the required force and the morphology of the scraped cancellous bone could be used to judge whether the necrotic bones had been completely removed. Furthermore, the tissue was observed under fluoroscopy for the analysis.

A femoral head support device that was larger than the 4-mm necrotic area (or larger than the 2-mm scraped cavity) was placed into ice-cold saline at 0 °C and assembled. A hollow guide rod was used to push the support device along the decompression channel into the scraped cavity.

If the femoral head collapsed, then the top of the support device was used to support the collapsed area. This was accomplished by hammering the end of the guide rod so that the support device could withstand the collapsed femoral head. Next, hot saline (50 °C) was injected into the hollow hole at the end of the guide rod, and under fluoroscopy, the cylindrical umbrella frame of the support device was observed to verify that it reverted to the original memory state to support the cartilage surface and occupy the entire cavity. Meanwhile, the sleeve of the support device was observed to verify that it expanded into the surrounding area and that the non-slip barbs pierced into the decompression channel. Next, through the hollow hole of the guide rod, the pre-acquired 2 cm³ of autogenous iliac bone and 2–3 g of allogeneic bone (Shanxi Aorui Biological Material Co., Ltd, Taiyuan, China), which were made into 5-mm-diameter particles, were mixed with the normal bone powder that had been removed during drilling. This mixture was subsequently implanted and filled the umbrella frame and sleeve of the support device. The guide rod was withdrawn after the bone mixture was compacted.

A cylinder-like allogeneic bone (Shanxi Aorui Biological Material Co., Ltd, Taiyuan, China) with a diameter of 10 mm was selected to fill the decompression channel and was embedded into the lower portion of the support device to further prevent the downward sliding of the support device.

The incision was closed, and skin traction was applied to the surgically-treated limb for three weeks. After an additional three weeks, patients began continuous passive motion (CPM) function exercises of the lower limb. X-ray or computed topography (CT) was conducted each month after the operation to evaluate the condition of the femoral head

collapse and healing of the bone as well as to design the rehabilitation program. Most of the patients gradually walked with crutches within two to three months after the operation.

Results

This study enrolled ten patients with 18 affected hip joints. During the surgical operation of one hip joint, the femoral neck bone channel was made in the wrong direction, causing the femoral head support device to be placed outside the femoral head (Fig. 2b). The patient underwent artificial hip replacement for that joint ten days later (Fig. 2c). However, all of the other operations progressed smoothly. The average operation time on one limb was 67.4 ± 20.3 min, and the average blood loss was approximately 46 ± 18 ml. All ten patients and 17 hip joints were followed up. The average follow-up time was four to 19 months. Based on a published study [26], the patients were evaluated using the percentage-efficacy method. In this analysis, the clinical evaluation accounted for 60 points, and the X-ray evaluation (based on the Ficat classification) accounted for 40 points. The following categories comprised the standards of the efficacy evaluation: “excellent,” > 90 points; “good,” 75–89 points; “fair,” 60–74 points; and “poor,” < 60 points. In this study, five cases were rated as “excellent” (four stage II cases and one stage III case), nine cases were rated as “good” (five stage

II cases and four stage III cases), two cases were rated as “fair” (one stage III case and one stage IV case), and one case (stage IV) was rated as “poor”. The efficacy rate was 82.35 %. The representative pre-operative and postoperative X-rays are displayed in Fig. 3.

Discussion

The main treatment goal for AVN of the femoral head is to prevent subchondral bone collapse and to halt or delay the joint degeneration process, and researchers worldwide have performed many studies on this topic [27, 28]. AVN treatment methods can be summarized and divided into three categories: non-surgical treatment, palliative surgical treatment, and artificial hip replacement. Nonsurgical treatment includes various measures that reduce or avoid weight bearing with the goal of facilitating self-repair of the femoral head; however, the results are usually poor. A study that compiled the follow-up results of 21 hospitals and 182 hip joints revealed that the improvement rate determined by clinical observation was only 22 %, while the improvement rate observed by X-ray was 35 % for stage I, 31 % for stage II, and 13 % for stage III [29].

Palliative surgical treatment includes core decompression, vascular bundle implantation, and the use of vascularized or non-vascularized bone grafts. Some authors have reported that

Fig. 2 A 34-year-old male patient was admitted due to “hormone-induced femoral head necrosis”. **a** The necrosis was in stage II in the left femoral head and phase III in the right femoral head. **b** One week after surgery, pelvic plain films indicated that the brace on the right side was satisfactorily placed, with definite bone filling; meanwhile, the brace on the left side broke through the cartilage and entered the joint. **c** Pelvis X-ray nine months after surgery indicated that the necrotic bone

on the right side had completely been replaced by new bone, and no continuous collapse of cartilage was found. The location of the prosthesis was ideal after the total hip arthroplasty was performed on the left side. **d** After nine months, as shown by the function diagram, function of the bilateral hip joints was satisfactorily recovered in the patient, without pain or lameness

Fig. 3 A 38-year-old male patient was admitted due to “hormone-induced femoral head necrosis”. **a** The necrosis was in stage II in the left femoral head and phase III in the right femoral head. **b** Pelvis plain film one year after surgery showed that the brace was satisfactorily placed, with definite bone filling. **c** Pelvis X-ray 1.5 years after surgery indicated that the necrotic bone had completely been replaced by new bone, and no continuous collapse of cartilage was found. **d** After 1.5 years, as shown by the function diagram, function was satisfactorily recovered in the patient, without pain or lameness

the effective rate of core decompression in the treatment of early AVN can reach 80 % [30, 31]. However, other researchers have not determined such a high efficacy for this method [32, 33]. Moreover, it is generally held that this surgical technique can accelerate the collapse of the femoral head. This collapse could occur because during the repair of femoral head osteonecrosis and the reconstruction of the blood supply, the rate of bone break down and resorption is often faster than that of the formation of new bone. Core decompression can further compromise the already weakened mechanical support of the subchondral bone. Notably, in cases of AVN that are triggered by steroid hormones (accompanied by significant osteoporosis of the femoral head), core decompression will cause the concentration of stress and accelerate the collapse of the femoral head.

Zhang used a vascularized fibular graft to treat 48 patients (56 hip joints) with AVN. After an average of 16 months follow-up, 39 hips (69.6 %) showed improvement [34]. The advantage of this surgical method is that the graft can support the femoral head and prevent its further collapse. However, the disadvantage is that the surgery is more complex, requiring two incisions and a vascular anastomosis [35]. Vascularized bone transfer is an effective, established treatment for avascular necrosis and atrophic or infected nonunions. However, limited donor sites and technical difficulty limit its application. Vascular bundle transplantation may provide an alternative; effective revascularization of bone could be seen when a simple vascular bundle was introduced into a segment of bone deprived of its normal blood supply [36].

Total hip arthroplasty is mainly used for patients with advanced AVN and secondary hip osteoarthritis [37, 38]. Approximately 5–12 % of hip-replacement patients exhibit AVN. In fact, the failure rate of total hip arthroplasty is higher in AVN patients than in other patients [39]. AVN

often occurs in patients within the 30–50-year age group, and the rate of postoperative joint loosening is higher due to their postoperative increase in body weight and higher mobility [40]. For these reasons, prior to artificial hip-joint replacement, a palliative surgical procedure that retains the femoral head is usually selected to delay or prevent hip replacement.

AVN of the femoral head is caused by obstructed blood circulation in the femoral head, which results from a variety of factors (i.e., arterial hypoperfusion and obstruction of venous backflow) that lead to increased intraosseous pressure and osteonecrosis. Subsequently, weight bearing precipitates collapse of the femoral head and osteoarthritis. Many studies using radiological, histological, and nuclear medicine approaches have revealed that collapse of the femoral head occurs during the repair of necrosis, rather than during the early stages of ischemic necrosis.

Brown et al. conducted a mechanical study of femoral head necrosis, and the results indicated that the mechanical properties of cancellous bone from the collapsed human femoral head are significantly impaired [18]. Ueo et al. used the finite element method to analyse mechanical changes during femoral head necrosis and determined that the increased stress surrounding the necrotic bone is the main reason for progression of the disease [41]. Increased stress can result in fracture of the femoral head, which not only affects the local mechanic properties but also obstructs repair of the necrotic tissue, making it difficult to achieve repair of the subchondral bone in the weight-bearing area. Kim et al. conducted mechanical measurements of subchondral bone and central cancellous bone in the necrotic femoral head and demonstrated that the decline in the mechanical properties of the subchondral bone in the weight-bearing area is directly associated with the collapse of the femoral head [42].

With the decline of the mechanical properties of the subchondral bone plate, the femoral head is subject to greater stress and subsequently collapses after fracture. The repair of femoral head necrosis has dual effects. The positive effect is reconstruction of the necrotic area; the negative effect is that during the repair process, there may be changes in the bone structure and a decline in the mechanical properties with the latter as the most direct cause for collapse of the femoral head. Brown et al. also reported that core decompression removes the structural bone and that the ratio of the maximum stress to the strength will generally increase [18]. Bone grafts inserted through a core decompression channel can change the load distribution. These authors stressed that an optimal bone graft should be cylindrical, as is the decompression channel, to ensure maximum contact with the surrounding bones; concurrently, the proximal end of the bone graft and subchondral bone should be matched. If the bone graft is in maximum contact with the subchondral bone, then the ratio of the maximum stress to the strength will be significantly reduced, thereby reducing the possibility of femoral head collapse. Currently, the commonly used bone grafting methods for improving the biomechanical strength of the femoral head include vascularized or free fibular grafts and a variety of cortical bone implants. In this type of bone graft, fixation is obtained using as much extrusion as possible; however, contact with the bone graft area is still discrete, with a limited ability to prevent collapse.

For these reasons, we took advantage of the super-elastic Ni-Ti memory alloy and its shape-memory effect [16, 43] to design and manufacture a femoral head support device for the treatment of adult patients with AVN of the femoral head. Ni-Ti alloys are composed of a specific percentage of Ni and Ti. This new alloy, composed of Ni and Ti in anatomic ratio of 1:1, is lighter than the usual alloy by 25 %, with the same corrosion resistance as the Ti material and no metal allergenicity. The weight percent (wt%) of Ni is ≤ 54.5 –57.0 %, and the remaining weight consists of Ti and other trace elements. The Ni-Ti alloy, which is a rare, new bioengineered material, has a stable shape memory and the characteristics of superelasticity, low magnetism, fatigue resistance, resistance to wear-and-tear, resistance to corrosion, and biocompatibility. In addition to the stable shape memory, the alloy exhibits a so-called superelasticity, which differs from the elasticity caused by a change in atomic positions. The elastic deformation of the usual elastic materials, such as stainless steel wire and copper alloy spring wire, does not exceed 0.5 %, whereas the elastic deformation of the Ni-Ti alloy exceeds that of the usual materials by more than ten times—or even dozens of times. The phase-transition point of the selected Ni-Ti alloy in this study was chosen to match the body temperature of 37 °C. The alloy plate was cut and moulded into a shape that had eight supporting umbrella arms, which were subsequently bent

into an umbrella shape to form the umbrella-shaped support device, and the sleeve was socketed at the tail end of the support device. Specific memory shapes were formed, and the umbrella-shaped support devices were made with various specifications and could be applied to the cleared areas of necrosis based on their different sizes. The elasticity and strength of the material decreases below 37 °C; thus, we could easily change its shape in ice-cold water (0 °C), moulding it into a 9-mm-diameter cylinder using special tools. Subsequently, the support device could be inserted into the femoral head through the preformed bone channel to achieve the goal of minimally invasive treatment. When hot water was injected into the support device, the cylindrical Ni-Ti alloy was quickly restored to the original memory state to form the umbrella-shaped support device. Femoral head necrosis is mainly concentrated in the weight-bearing region with an umbrella-shaped distribution that involves a large area. The area supported by the tantalum rod and fibula is limited, and the maximum diameter does not exceed 10 mm. However, the diameter of the adult femoral head exceeds 40 mm, and its weight-bearing area is approximately 35 mm in diameter. The umbrella shape of this support device is identical to that of the necrotic area of the femoral head, and the arc of the umbrella matches that of the weight-bearing area of the femoral head. The maximum diameter of the final shape of the umbrella top can reach 32 mm; therefore, the support device completely fills the necrotic area of the femoral head and resembles the cartilage of the femoral head, which confirms the mechanical advantages. After the tail ends of the umbrella arms are fixed to the sleeve, the support device can withstand a relatively high pressure. Meanwhile, there are blood-supply holes on the sleeve, so the bone graft inside the sleeve and the cancellous bone along the decompression channel heal as one unit, enhancing the stability of the support device. The support device can withstand high pressure on its own. The implantation of autologous bone and artificial bone inside the support device increases its strength and stability and reduces its deformation. Over time, the cavity heals, and the strength of support increases. Furthermore, the shape of the support device matches that of the femoral head. With restoration of the collapsed femoral head by hammering and expansion, the support device can restore the concentric circles in the femoral head, increase the force-bearing area, and uniformly distribute the pressure while eliminating the stress concentration on the weight-bearing area of the femoral head. Consequently, the force acting on the weight-bearing area of the femoral head is first borne by the cartilage and the subchondral bone, which subsequently deform to transfer the pressure to the support device beneath the subchondral bone. The support device diffuses the load along the umbrella surface; the force that is transferred from the surface of the umbrella is then absorbed by the gap

between the metal arms of the umbrella support device, thus providing significant mechanical support. Moreover, when the necrotic tissue of the femoral head is removed, the shape of the formed cavity is precisely the shape of an umbrella. The decompression channel through the femoral neck matches the shape of our self-designed support device; therefore, after expansion, the support device adheres to the cavity of the necrotic area and does not easily slide downward. In addition, our selected support device is larger than the cleared cavity and always retains its superelastic expansion state at body temperatures greater than or equal to 37 °C. At the bottom, the non-slip barbs and compacted bone grafts generate great tension on the support device, which is sufficient to ensure a supporting force for the femoral head and to create conditions conducive to self-repair of the femoral head. The cancellous bone inside the support device fuses with the bone outside the support device, resembling reinforced concrete. Consequently, the above-mentioned factors favourably ensure the repair and reconstruction of the necrotic area of the femoral head by the cancellous bone that is implanted within the support device.

In the present study, this method was clinically applied to ten cases and 18 hip joints. The operation on one hip joint was unsuccessful, confirming the possibility of failure of this surgical technique. Therefore, intra-operative fluoroscopy would be necessary to determine the decompression and placement locations and thus to minimize the chance of failure. The efficacy rate in the remaining 17 cases was 82.35 %, suggesting that the efficacy of this treatment method was satisfactory. Moreover, the operation was brief and caused minimal trauma. Consequently, this method can be applied in clinical practice. Furthermore, in this study, there were two young patients exhibiting Ficat stage IV. Because they were younger than 30 years of age and not suitable for joint replacement, we attempted to use this surgical technique on them. The results revealed one case rated as “fair” and the other case rated as “poor,” but both patients could conduct everyday activities and did not require joint replacement during the follow-up period. Therefore, we believe that this method can be used to treat young patients, even those exhibiting Ficat stages IV. However, there are certain limitations of this study. For instance, the number of cases was relatively small, the follow-up period was short, and further observation of the long-term efficacy is still necessary. Moreover, there exists a slip phenomenon, in which the support device is inserted into the sleeve of the femoral head, making it difficult to perform the surgical procedures. Therefore, we plan to design a conjoined support device to simplify this operation.

In conclusion, the use of an umbrella-shaped femoral head support device for the treatment of adult patients with avascular osteonecrosis of the femoral head poses the

following advantages: complete removal of the sequestrum and core decompression and increased mechanical support of the subchondral bone in the weight-bearing area of the femoral head, which reduces the local stress and is thus conducive to the restoration and reconstruction of the necrotic femoral head. This surgical method is indicated for Ficat stage I, stage II, and stage III patients with osteonecrosis of the femoral head. It can also be used to treat certain young stage IV patients and advanced cases that are not suitable for joint replacement.

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