

Case Report

Revision of a Tronzo Total Hip Arthroplasty

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ABSTRACT

Revision total hip arthroplasty presents many challenges in regards to reconstructing or managing large amounts of bone loss and soft-tissue damage. Modern revision components, as well as techniques, have helped to address these challenges; however, the goal of any surgery is to provide the least amount of surgery with the most successful outcome. This case highlights a 74-year-old man with a Tronzo total hip arthroplasty placed over 50 years prior. He presented with subjective hip instability and radiographs demonstrating disassociation of the modular component. In an attempt to avoid more extensive and costly surgery, a custom-made all-polyethylene femoral head was used. This case illustrates the revision of likely one of the few Tronzo total hips remaining and the utility of obtaining a compassionate-use clearance from the Food and Drug Administration to create a custom piece, to minimize potential morbidity and mortality from extensive hip revision surgery.

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Introduction

Raymond Tronzo, MD, has a legacy of innovation in the field of hip arthroplasty as a surgeon, an author, including the publication of “Surgery of the Hip Joint” in 1972, and an inventor, including the Tronzo total hip [1]. This prosthesis is quite unique in design with an all-polyethylene collared femoral head that freely spins on a metal trunnion (Fig. 1) [2]. His hip design was used for approximately a 10-year time frame starting in 1969. Tronzo used his design in a cemented version and it was the first total hip with biologic ingrowth surfaces as a method of fixation [3]. This was achieved by plasma-spraying stainless steel particles on the implant to allow for bony ingrowth [4]. Tronzo’s patented technology was even at the heart of a multimillion-dollar suit with Biomet [5].

Most modern components have a multitude of modular options making revision surgeries possible with off-the-shelf components; however, this process becomes significantly more complex when unique prostheses are involved. The case that will be presented here is a demonstration of how revision arthroplasty on a uniquely designed

implant put in half a century ago can be achieved with a Food and Drug Administration (FDA) compassionate-use custom implant.

Case history

The patient is a 74-year-old man who sustained a hip fracture and underwent multiple surgeries trying to preserve his native joint when he was in his 20s. Unfortunately, he went on to develop avascular necrosis of the femoral head and underwent a total hip arthroplasty in his late 20s. He states he did very well from this surgery for around 25 years until he underwent a head and liner revision for hip instability and polyethylene wear.

Over the year prior to presentation, he began having feelings of instability, similar to his previous episodes. He was referred to our clinic with a radiology report stating “atypical radiopaque femoral head component not present” (Fig. 2). Interestingly when he was ultimately seen in the clinic for the first time, his hip demonstrated an improvement in alignment (Fig. 3). The patient stated that he could sometimes shift his hip back into a more comfortable position. On examination, he was noted to have a significant leg length discrepancy, which did not bother him and had been present ever since his original hip replacement. An infection workup was performed and was found to be negative. Given operative records were not available, as his original surgeon was deceased years prior, extensive research was undertaken and his components were eventually identified as a Tronzo hip

Investigation was performed at McLaren Orthopedic Hospital, Lansing, Michigan
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Figure 1. Pictures showing the femoral component with its smooth taperless trunnion allowing the all-polyethylene head to freely rotate. The acetabular components shown were available in thick- and thin-walled versions. Both versions had the same central long spike with 3 smaller spikes around the center spike.

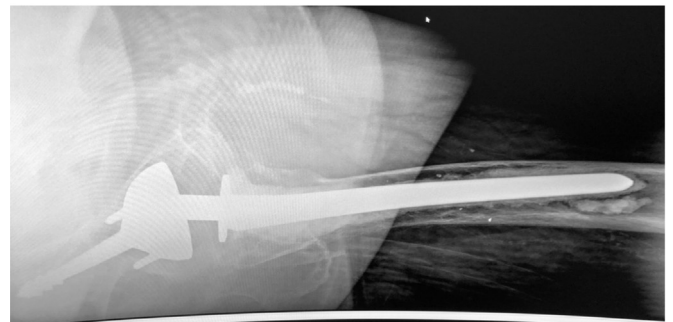


Figure 3. The repeat images taken at the time of his initial visit demonstrating a reduced hip compared with the referral images.



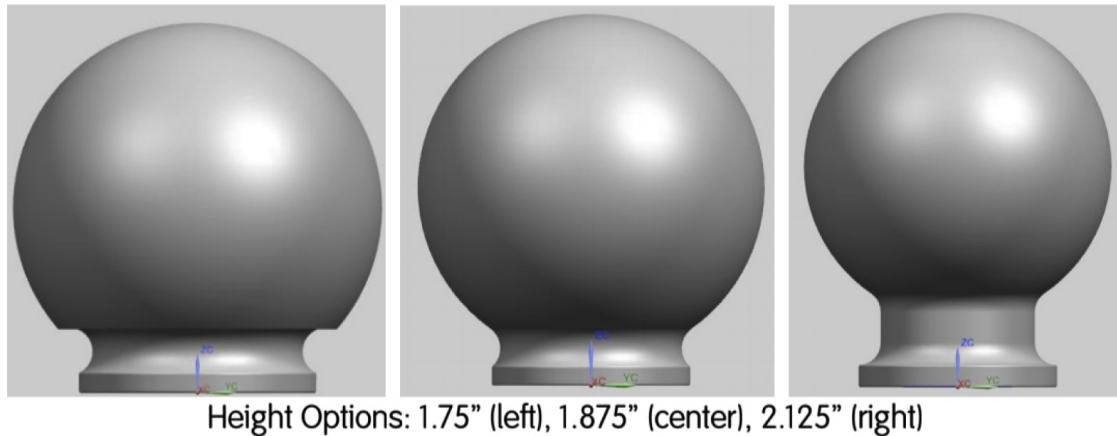
Figure 2. Radiograph of a Tronzo total hip arthroplasty demonstrating well-fixed components with either dislocation of the prosthesis or dissociation of the head from the femoral component.

arthroplasty. Options that were discussed with the patient included revision of all components to modern revision hip systems versus exploring the possibility of a head exchange.

Given the unique design of the Tronzo total hip, the risks of explant would be quite significant. The inner diameter of the acetabulum (44.45 mm) is not compatible with a modern head if we performed an isolated femoral revision, nor is the taperless trunnion compatible to accept any femoral head currently on the market. With both component revision, he would likely have significant additional bone loss in the pelvis given the large spiked component, in addition to the possibility of trochanteric osteotomy to remove the cement and femoral component. He elected to undergo a head exchange as he was very pleased with his last surgery years prior and did not wish to undergo the complexity and



Figure 4. Tronzo implant options with trial heads and cup.



Height Options: 1.75" (left), 1.875" (center), 2.125" (right)

Figure 5. The original blueprints showed 3 options for neck length.

recovery of a full explant and revision. He also was clear that his leg length discrepancy was not a concern or reason for revision.

A replacement polyethylene head on this unique trunnion does not exist as a standard part of any implant company's inventory; therefore, extensive investigation was undertaken to find the original blueprints. The Tronzo hip was being manufactured by Richards before the company was bought by Smith and Nephew. The senior surgeon partnered with Smith and Nephew who was able to locate exact specifications as well as some old trials and components (Fig. 4). Despite creating a custom implant to the original specifications of the original design, the use of modern materials (highly cross-linked polyethylene) with prior designs creates a completely new product, which is not FDA approved. We then proceeded with an FDA compassionate-use approval to allow production and placement of this one-time-use product. This entailed letters from the surgeon and another orthopaedic adult

reconstruction surgeon familiar with the case, written to the FDA explaining the necessity for the implant. We also obtained institutional review board approval with the hospital where his revision surgery was planned, in addition to informed consent stating that this surgery was labeled as experimental, given the nature of the custom implant without a track record.

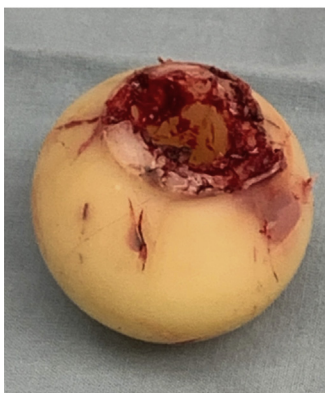


Figure 6. The images show the previous head component after removal in comparison with the new head component that was implanted. Note the significant wear at the base of the old head in addition to the color changes of the polyethylene over time.



Figure 7. Initial postoperative radiograph is shown here demonstrating a properly located hip arthroplasty with increased length and offset because of the use of an increased head length.

The original blueprints showed the inner diameter of the acetabulum to be 44.45 mm (1.75"). Two Tronzo acetabular component options exist, both of which had the same inner diameter but different outer wall thicknesses (Fig. 1). The femoral component has a unique smooth, nontapered trunnion that allows the head to freely spin. There were 3 height options based on the blueprints for the head: 1.75", 1.875", and 2.125" (Fig. 5). Because we did not know the previous size, we elected to have the 2.125" option created, given his significant leg length and offset discrepancy as baseline.

Revision surgery was performed via a posterior approach using one of the multitude of prior incisions, and significant polyethylene wear was immediately identified. The trunnion was disassociated from the head with simple internal rotation of the hip. The head was removed and on inspection was found to have severe wear of the polyethylene skirted portion of the head with significant oxidation present (Fig. 6). The stem and acetabulum were found to be well fixed and the trunnion without damage. There were no trials for this custom case available; therefore, the actual implant was unboxed, slid onto the trunnion, and found to have excellent fit. The hip was reduced and found to be stable. He was discharged home on postoperative day 1 without issue.

He has since followed up for his 4-week visit with radiographs (Fig. 7) and states all his symptoms of instability have fully resolved, and he is very pleased with his outcome as well as avoiding extensive revision.

Discussion

Revision hip arthroplasty can be associated with high morbidity from significant bone loss around the acetabulum and proximal femur from component removal. There are modern components on both the acetabular and femoral sides designed to address these specific concerns to recreate the hip joint, but such surgeries can be associated with higher operative times, blood loss, infection, dislocation, and mortality. In certain circumstances, a custom implant may offer a solution that is the least amount of surgery and associated risk while accomplishing the patient's and surgeon's goal. Comprehensive discussions of risks, benefits, and alternatives regarding all surgical options should occur with shared decision-making.

In unique revision situations, the FDA's expanded access, also called compassionate use, allows patients access to treatment

options outside of what may be considered the normal standard of care when there is no comparable alternative and the benefits outweigh the risks. These treatment pathways cannot interfere with or be related to future clinical trials that would support the devices' approval or marketing.

This case is a rare example of revising a very unique prosthesis, highlighting the significant preoperative planning involved in researching the prosthesis, implant production, and FDA and IRB approval over a 6- to 8-month period. Daunting obstacles to performing the best possible surgery for the patient can sometimes push surgeons to favor nonoperative management as demonstrated by this patient who had to doctor shop for years before getting his revision and relief of his symptoms.

Summary

This case demonstrates a creative revision approach to a very unique hip where components are no longer available in a patient with a long-term well-functioning total hip replacement. In an effort to limit morbidity by minimizing operative time, blood loss, and bone loss through maintaining nonmodular components, a compassionate-use approval through the FDA was obtained and a custom-made all-polyethylene highly cross-linked femoral head was used.

Conflict of interest

The authors declare there are no conflicts of interest.

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