

Are Ankle Implants Worth Another Look?

VOLUME: 16 PUBLICATION DATE: Apr 01 2003

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A Few Thoughts About Ankle Fusion Limitations

Article Reference:

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Issue Number:

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Yes, Mark H. Feldman, MS, DPM, cites technical advances in the devices and promising results from studies.

Diligent study of normal ankle biomechanics and review of previous implant failures has led to the development of a new generation of total ankle replacement (TAR) implants. The newer implants provide a better means of dissipating the rotational forces at the joint surface by using a meniscus-like bearing between the tibial and talar components, while maintaining the integrity and stability of the joint.¹⁻⁴

This improvement, coupled with improved cementless fixation, has led to prosthesis designs that allow for more anatomic ankle motion with decreased rates of implant failure.⁵

A strong understanding of ankle joint biomechanics plays a pivotal role in the design and function of total ankle replacements. Motion and stability of the ankle joint are essential for normal function during gait. The ankle has two degrees of motion and three degrees of stability.⁶ The two degrees of ankle motion are plantar dorsiflexion and internal-external (axial) rotation.⁷⁻¹¹ An inversion-eversion component is also apparent, but Lundberg has described the greater portion of this motion as being associated with the subtalar joint.¹²

The normal ankle joint is stable and constrained from significant motion in three degrees: anterior-posterior, medial-lateral and inversion-eversion. This is accomplished by intrinsic and extrinsic factors. Both the anterior-posterior and inversion-eversion motions of the ankle are constrained by extrinsic ligaments about the ankle. Medial-lateral movement depends upon the intrinsic support of the ankle mortise itself by the medial and lateral malleolus.

Ankle implant devices must take into consideration the above factors of motion and stability in order to provide near-anatomic motion around the joint. Previous devices did not completely allow for the important rotational (axial) forces and failed to totally consider, and design for, the intrinsic and extrinsic anatomic stability of the ankle mortise.

Currently, there are 11 ankle joint prostheses in use around the world. These include the Agility Ankle (DePuy), STAR, Beuchel-Pappas (Endotec), Salto, Alpha OSG, AES, Albatros, Hintermann, Ramses and a ceramic design used in Japan. The Eska ankle is implanted from the lateral side after an osteotomy of the fibula and reflecting it posteriorly. The implant that I've had the most experience with is the Beuchel-Pappas implant, which has been used by surgeons in Europe for over 15 years. The implant has been undergoing FDA clinical investigational trials in the United States since 1998.

A Closer Look At The Beuchel-Pappas (BP) Implant

Frederick Beuchel, MD, and Michael Pappas, PhD, developed and implanted their first ankle design in 1974.¹³ Over the years, they've made several improvements to the device. These improvements included:

- the addition of a second talar fin to reduce the risk of talar necrosis and add stability;
- the deepening of the talar component's tibial sulcus in order to reduce early problems of bearing subluxation;
- an increase of the platform thickness in response to early observation of high stress loads at the tibial component's

Keep in mind that ankle fusions are not without their limitations. The advantages of ankle arthrodesis are limited to pain reduction, stable fixation, an increase in stable ambulation and reduction of severe deformity. However, there are also several reports that described both short- and long-term problems with ankle fusions.²

The common problems described with ankle fusions are: the eventual development of subtalar and metatarsal degenerative joint disease; pain with walking or standing; the need for ambulatory aids; and the need for permanent shoe modifications.

Although the short-term results and complication rates of ankle fusions have been markedly improved by modern techniques of limited periosteal stripping, rigid internal fixation and meticulous attention to alignment/position, the long-term effects of these improved approaches are still unknown.

Several orthopedic surgeons believe the rates of problems related to arthrodesis are unacceptably high and have continued to search for a workable ankle arthroplasty for selected circumstances.

platform edges;

- the use of titanium alloy and ceramic coating technology, which reduced contact wear; and
- the application of an improved porous coating at the bone contact area for better bony ingrowth, which facilitated a more solid fixation surface.^{14,15}

As described above, the current Beuchel-Pappas device is a three-piece mobile implant. The current design of the articulating surface of the tibial component consists of a flat loading plate with a single fixation stem at a seven-degree anterior incline. The articular surface of the talar component has a convex surface with a central trochlear groove. The talar fixation surface has two anchoring stems, which allow for minimal talar resection and decreased risk of talar avascular necrosis.

You may also implant a thick talar component in cases of talar AVN or when the talar bone stock has been previously reduced or is absent. In cases where the talus is absent, the thick talar component is seated directly on the calcaneus.

The meniscal bearing articulates congruently with both components matching the flat tibial surface and the trochlear talar surface. The tibial and talar components are made of titanium alloy with a titanium nitride ceramic coating. The tibial and talar components have a titanium porous coating at the implant-bone interface. Fixation of both the tibial and talar components is done via the titanium nitride coated porous beads. Bony ingrowth is complete in six weeks. The current Beuchel-Pappas device provides mobility with congruency, avoiding many problems of the past.

What One Study Reveals About The Mobile-Bearing Total Ankle Replacement

In an effort to evaluate the mobile-bearing implanted ankle, a study by Komistek, et. al., confirmed anatomic observations of axial rotation about the ankle joint. They evaluated the ankle range of motion of patients who underwent unilateral mobile-bearing TAR.¹⁶ The study included evaluation of translation and rotational motions of the distal tibia relative to the talus in the sagittal and frontal planes. They studied 10 subjects, each of whom had a normal ankle and a Beuchel-Pappas TAR.

The researchers concluded that at maximum dorsiflexion, both the normal and implanted ankles had similar midline talar contact positions. However, with plantarflexion, the implanted ankles had increased posterior talar contact. They also reported that the implanted ankles experienced rotational and translational motions similar to the patients' normal ankle joint. The authors noted that the increased posterior talar contact might have been due to surgical positioning of the implant or alterations of ligamentous tension.

An Early Glimpse Of Follow-Up Results

In our own ongoing study, the current data appears very promising. As of this writing, I implanted the BP prosthesis in 74 patients over a 39-month period in the U.S. (Of the 74 patients, 11 received the Doets-Feldman modified tibial component and were excluded from the study, as was one patient who had bilateral implants. In addition, four patients were excluded due to incomplete data and two were lost to follow-up.)

Pursuant to the required FDA timetable, we reported on 57 patients at three-, six-, 12- and 24-month postoperative periods. The 57 patients included 42 (74 percent) males and 15 (26 percent) females. The average age was 55, with patients ranging from 15 to 83 years old. Forty-seven of 57 (82 percent) had one or more prior surgical procedures on the implanted ankle. The patients were originally diagnosed with posttraumatic osteoarthritis (68 percent), degenerative osteoarthritis (25 percent) and rheumatoid arthritis (7 percent). Two of the patients underwent a "take down" of a previous ankle fusion.

Twelve months out, 85 percent of the patients achieved "good to excellent" results, 10 percent achieved "fair" results and 5 percent had "poor" results. Two years postoperatively, 88 percent of the patients reported "good to excellent" results and 12 percent reported "fair" results.

Final Notes

The reported Beuchel-Pappas TAR studies published since 1988 lead to the conclusion that the procedure is a good to excellent alternative to fusion for the long-term viability and function in more than 80 percent of patients. Unfortunately, TAR failures in the 1970s and 1980s have caused many surgeons in America to discount the reported results and refuse to reconsider the procedure. Even more unfortunate is the fact that, in most cases, patients are not informed of the availability of TAR so that it might be considered. Clearly, general availability of the procedure in the future will help to solve this problem. As in the past, this exceedingly complex procedure should be performed on a regular basis rather than infrequently, lest failure be blamed on the prosthesis rather than surgical infrequency.

It is my position that current implants and the reported worldwide results are sufficient to endorse TAR as a viable treatment choice in patients with end-stage rheumatoid and osteoarthritic disease. At the very least, patients should be given the choice of fusion or implantation with sufficient references to both procedures so they can make an informed decision. If fusions are performed, the fibula should be left intact. This allows a "takedown" to be performed years later if the patient chooses this option. The success of the Beuchel-Pappas device and similar prostheses will endure as long as we ensure proper patient selection and adequate training of those surgeons who are performing the procedure.

Further studies with longer-term results are necessary to determine the limiting factors for the current prostheses in use around the world. The overall results of our study thus far are promising. It is obvious that this current design is far superior to the ankle implants of the past. Clearly, the results of the reported Beuchel-Pappas implants in Europe have been duplicated in the U.S.¹⁷ As this issue went to press, the FDA is currently evaluating the results of the clinical trials that were conducted in November 1998 through November 2001.

Dr. Feldman has surgical experience with six of the aforementioned implants and has performed over 100 total ankle replacement procedures in the United States and six European countries. He has a private practice in Miami, Fla., and is on the faculty of the Podiatry Institute.

Editor's Note: This article was adapted with permission from a previously published article in Update 2002: The Proceedings of the Annual Meeting of the Podiatry Institute.

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Yes, John Grady, DPM, praises current implants but emphasizes a strong awareness of potential complications and appropriate patient selection for this technically demanding procedure.

There is no question that ankle joint implants have been proven to reduce pain, increase motion and ambulation, restore joint motion, protect adjacent joints from excessive arthritis, and allow for more activity and mobility for patients.¹ In addition to these advantages, the ankle arthroplasty can also be revised to an arthrodesis later, sometimes simply as a graft with fusion.

Nevertheless, there are circumstances when an ankle implant produces a less desirable result than fusion. I think it is in the reduction of deformity that we will find that ankle implants have the opportunity to fail.

Back in the 1980s, I performed a handful of Oregon ankle implants and was firmly convinced that ankle joint replacement should not be performed and that there was no successful ankle joint replacement between the knee and first metatarsal phalangeal joint. However, with the advent of several new and effective ankle joint replacement options, I was convinced to change my mind.

The current class of ankle prosthesis includes: the Agility Ankle (DePuy, Inc., FDA Class II), the Howmedica Ankle (Howmedica, Inc., FDA Class II), the TNK Ankle, the Beuchel-Pappas Ultra Total Ankle Replacement (FDA Class III), the New Jersey Total LCS Total Ankle, the Scandanavian Total Ankle Replacement (STAR) (FDA Class III) and the Hinterga Implant Replacement System, among others.

There are certainly many limitations with current implants that are available. All of these but the Hinterga (the newest of the group) were reviewed recently in an article by Saltzman.³ He reached the conclusion that, "As yet, the ideal total ankle patient remains to be defined." While I fundamentally agree with this quote, I also believe that the ideal total ankle joint system has yet to be developed.

Reducing Pain: What One Study Of The Agility Ankle Reveals

Nevertheless, current ankle implant systems are not only successful but superior to ankle arthrodesis when it comes to preserving joints of the rest of the extremity from degenerative arthritis. Ankle replacement should be considered the primary treatment for arthritis with arthrodesis being reserved for patients who have severe structural deformity. Currently, the only FDA-approved model used in the United States is the Agility Ankle. One study focused on 100 patients who underwent total ankle arthroplasty with an Agility Ankle.¹ Out of those 100 patients, 45 were diagnosed with posttraumatic degenerative joint disease, 26 had a diagnosis of primary osteoarthritis, 26 had rheumatoid arthritis, two had septic arthritis and one had psoriatic arthritis.

The mean age at surgery was 63 years old, with the patients ranging in age between 28 to 81. The average length of follow-up was 4.8 years. Two patients died within two years, leaving 98 ankles to review. Twelve patients were deceased at the time of the study, thus leaving 83 patients with 86 ankles to review.¹

There were five complications in the initial series, involving three talar component revisions, one tibial component revision and one total ankle resection with arthrodesis. There were two superficial wound infections and no deep infections. At follow-up, 54 percent of the patients had no pain, 29 percent had mild pain, 16 percent had moderate pain and no patients had severe pain. Most patients were satisfied with the results as 79 percent rated their satisfaction level as "extremely satisfied." As for the other patients, 13 percent said they were "satisfied" and 8 percent said they were "indifferent" or "disappointed."¹

Seventy-two percent of the patients noted an increase in their level of function, 10 percent had a noticeable limp, 6 percent used a cane regularly and 4 percent needed an ankle/foot orthosis to control valgus deformity. Postoperatively, the mean range of dorsiflexion/plantar flexion at follow-up was 36 percent, with a range between 10 to 64 percent. Fifty percent of patients had a plantar flexion contracture averaging 70 percent and 67 percent felt more comfortable walking in a shoe with a slight heel.¹

Addressing Concerns And Complications

One of the biggest problems with ankle joint replacement is failure of syndesmotic fusion. In this study, 29 percent had delayed union.¹ Researchers identified "delayed" union as a nonunion that took longer than six months to occur while 9 percent overall had a nonunion. There were 19 cases of component migration with 12 tibial components and seven talar components. Sixty-seven percent of the ankles associated with tibial component migration were associated with a later nonunion of the syndesmosis. The tibial component migration was independent of syndesmotic fusion.

In addition to these complications, be aware that some type of inadvertent malleolar fracture occurs either intraoperatively or postoperatively almost one-third of the time. While these can be fixated, keep in mind that fractures that occur postoperatively can be associated with ankle implant migration and may also become symptomatic as well.

In our own study, we have also noticed that a wound dehiscence occurs in four percent of patients. While we have changed our technique of closing to compensate for this, wound dehiscence continues to be a problem. It seems to occur anteriorly where there is much tension in the wound after joint replacement, especially because it is done under distraction technique. In addition to that concern, there is always the fear, as with any implant of ectopic bone formation, of restricting motion.

In addition to these factors, the distraction can cause vasoconstriction and the titanium implant does not seem to aggressively incorporate in the ankle as it does in the knee and hip so far. This allows slightly higher incidence of the aforementioned migration of the implant.

Another problem with the implant, as with any implant, is that it will unmask deformities. For instance, if a patient has more than 15 degrees of valgus deformity, it is likely that he or she has either deltoid ligament dysfunction coupled with tibialis posterior dysfunction (or at least significant tibialis posterior dysfunction), and this will be difficult to correct with an implant. Rather, it will actually be challenged more with ankle motion than it would be with an ankylosing joint or with arthrodesis.

Other Key Issues

It's also important to keep in mind that we still do not exactly know the life of the implant. Many of the implants that were first implanted are still intact, but some have not been tested to their full extent.

The ankle implant procedure is also very technically demanding. The procedure averages about three and a half hours, and certainly has a large learning curve. If these problems are not enough, implants still are not available to all surgeons nor would everyone have the technical ability to handle the complications that occur both intraoperatively and postoperatively.

Final Notes

With all of these factors to consider, one might consider that there are instances when arthrodesis would certainly be superior to ankle joint replacement. Nevertheless, ankle joint replacement can frequently be revised to an arthrodesis. It is more difficult to revise an arthrodesis to an ankle joint replacement, particularly if the fibula is sacrificed during the arthrodesis procedure.

For all of those reasons, I think we still must be discretionary in our use of the ankle joint replacement. Nevertheless, I feel that in defined specific circumstances, it is superior to ankle arthrodesis.

Dr. Grady has performed 48 ankle implant procedures. He has a private practice in Oak Lawn, Illinois.

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