Reference Toe System: For Revision of Failed Synthetic Cartilage Implant (SCI)

Figure 11

post-operative visit, I tell them to return in one month if they have problems other than mild swelling.

DISCUSSION

To date, the author has performed six revisions in this manner. Four of the six patients called and said they were happy and did not need to come in. The other two were pleased but had questions about activity levels.

All are satisfied that they have minimal to zero post-operative pain, have motion, and are able to wear “desirable shoes.”

The intraoperative bone and soft tissue findings vary tremendously with SCI, as does the degree of subsidence. As seen in Figure 7 an extra-articular inflammatory exudate can occur. Figure 8 shows marked bone erosion and dorsal mini fracture. Figure 9 and Figure 10 show abundant soft tissue reaction in comparison to Figure 11 in which the patient presented with pain but relatively mild intraoperative changes other than the subsidence.

Cassinelli and An showed with an MRI study of 18 symptomatic SCI patients radiographic loss of MTP joint space, the progression of arthritis, soft tissue and bone edema and peri-implant fluid suggesting instability at the implant-bone interface. This is consistent with my intraoperative findings.

CONCLUSION

The first two RTS procedures that I performed were SCI revisions in patients who refused to have MTP fusions. My longest follow-ups are at three years with high patient satisfaction relative to their pre-operative status. Because of this success, I began to explore the usage of RTS in stage 3 and 4 Hallux rigidus (without any hallux valgus) as an option for patients who refuse fusion. After considerable literature review, in low demand patients, 3rd generation double stemmed implants have a failure rate of only 3.6% at seven years, an overall average improvement in pain of 77% and an average patient satisfaction rate of 84%.

This has led me to the belief that in patients over 55 years of age with severe hallux rigidus (no hallux valgus) and a relatively sedentary lifestyle, the Reference Toe implant should be considered if the patient desires MTP motion. Currently, the literature lacks a significant number of long-term outcome studies with 3rd generation double stemmed prostheses with titanium grommets. Further research is needed.

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Reference Toe System For Revision of Failed Synthetic Cartilage Implant (SCI)

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ABSTRACT
There is considerable debate in the foot and ankle literature about early and long-term outcomes of polyvinyl alcohol hydrogel derived Synthetic Cartilage Implants (SCI). Multicenter, prospective, randomized studies have shown an 80% plus survival rate at two years with a 93% reduction of pain1,2,3. Other randomized studies have shown an average improvement in pain post-operatively but failed, patients are usually recommended and conversion to MTP joint arthroplasty. The following case study describes successful SCI conversion to a Reference Toe System (RTS) Implant.

INTRODUCTION
Motion sparing options in painful Hallux Rigidus continue to plague the orthopedic and podiatric community. Early SCI reviews were promising; however, there is now a growing concern about their potential survival rates. There is no question about the successful long-term results of MTP fusions; however, some patients simply want motion. These patients are typically steered away from arthroplasty and led to SCI when indicated. When it fails, patients are usually recommended for a revision with the replacement of the prosthesis or to a MTP fusion, of which the patient most likely didn’t want in the first place. This paper offers a successful revision option for patients who are adamant about maintaining first MTP motion.

CASE
This is the case of a 56-year-old healthy female with hallux rigidus who was conservatively managed by another local surgeon successfully for a number of years. Subsequently, she went on to present with constant pain and ultimately underwent SCI implantation by her previous surgeon. She had mild reduction of pain post-operatively but not to her satisfaction. Her pain continued for seven months, accompanied with swelling and stiffness. She was encouraged to be patient with her procedure, but her patience grew weary. She presented to my office with pain, swelling, stiffness, and a strong desire to have motion and wear what she called “desirable shoes.” AP and Lateral radiographs demonstrated bone on bone degenerative joint disease with subsidence of the prosthesis. (Figure 1)

and 2: A discussion about giving this procedure more time occurred but she refused. The benefits and success of MTP fusion, in general, were also discussed but the patient was adamant about preserving motion. We talked about metallic implants and the subsequent failure rates and the resurgence of third-generation Silastic implants, the Reference Toe System (RTS). The patient chose the RTS implant. She was informed about the possibility of mild residual pain and the potential need for possible revision surgery in 15-20 years. Her response was, “Doctor, if it doesn’t work, then fuse me!”

The patient had a previous dorsal incision, which was used (Figure 3). A longitudinal capsulotomy medial to the EHL tendon was performed. Immediately, an abundance of synovial fluid was encountered with surrounding inflammatory tissue. The prosthesis was partially covered with fibrinous scar tissue with moderate bone erosion around the periphery of the prosthesis (Figure 4). The size 10 mm prosthesis itself was very loose and popped out with little resistance.

Minimal excision bone cuts perpendicular to the metatarsal head, and base of the proximal phalanx were performed. The resected surfaces measured to a size 3 RTS prosthesis. Curettage of the metatarsal head implant hole was done to remove debris. The canals were then reamed with the intramedullary system in preparation for the prosthesis. At this time, it was evident that the SCI hole enlargement was larger than the inner diameter of the grommet and therefore bone void filler was used to stabilize the metatarsal head grommet. (Author’s note, size 10 mm SCI implants usually require bone void fillers, but size 8 mm implants typically do not).

The bone void filler was placed around the inner base of the grommet and some in the front of the canal. As the filler was beginning to take shape, the titanium grommets were introduced. All excess bone void filler was removed from the canal and the periphery, and the RTS prosthesis was inserted. This allowed the grommets to seat in the bone on both sides, particularly the metatarsal head side. The surgeon must be patient at this point to allow the bone void filler and prosthesis to settle. The immediate post-operative x-rays are seen in Figure 5 and Figure 6.

After copious irrigation, deep tissues are closed with 0 vycril, subcutaneous tissues with 2.0 vycril and the skin with regular staples.

Post-operative management consists of heel weight-bearing with a Darco heel weight-bearing shoe or partial weight-bearing in a short walking boot. They are progressed to full weight-bearing as tolerated after skin staple removal at 10 to 12 days. Patients are allowed to move the great toe as tolerated and are put into a stiff-soled wide tennis shoe at four-five weeks. Typically, at the eight-week...
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There is considerable debate in the foot and ankle literature about early and long-term outcomes of polyvinyl alcohol hydrogel derived Synthetic Cartilage Implants (SCI). Multicenter, prospective, randomized studies have shown an 80% plus survival rate at two years with a 93% reduction of pain. Other studies, however, show a 38% dissatisfaction rate at 18 months. Revision options after failure include MTP fusion, followed by reimplantation of the implant, and conversion to MTP joint arthroplasty. The following case study describes successful SCI conversion to a Reference Toe System (RTS) Implant.

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