The **Resurgence** of the Silicone MPJ
Vitrium® Bioactive Glass prompts the formation of a Hydroxyapatite (HA) layer to encourage bone formation.

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Red arrows show the host bone integrating throughout and replacing the Vitrium® Wedge vs. growing to the edge in localized areas but not incorporating into the allograft.
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In this Issue of the Podiatry Today Supplement, we use a series of case studies to look at the current state of 1st MTP silicone toe joint preservation. Many may not know that silicone implants were first introduced by Alfred B. Swanson, MD in the 1960’s through Dow Corning Wright (now Wright Medical). The Swanson implant is still on the market today and features a double stemmed straight device with long proximal and distal stems. The device was adopted worldwide as a joint preserving implant by foot and ankle surgeons. To improve durability, grommets were added to the Swanson stem in the 1980’s. Prior to that, Dow Corning Wright introduced a short, straight stem version. Dr. Swanson passed away in April 2016, but his work lives on 50 years after the initial introduction.

In the 1990’s, significant improvements were made by Bruce Lawrence, DPM with the introduction of the Primus Implant (Futura, Nexa, Tomier, Integra). The Primus System incorporated many improvements such as shortened stems with grommets, an improved hinge, a change in the angulation of the stem to better fit the declination of the 1st metatarsal, and increased range of motion.

In late 2016, In2Bones (www.i2b-USA.com) introduced the latest silicone implant for joint preservation of the 1st MTP. The Reference Toe System (RTS) uses the lessons learned from the past 50 years to refine a modern version of the silicone toe. Unlike other systems, the RTS no longer relies on a broaching system for bone preparation. The RTS utilizes a cannulated reamer system over a “single reference” guide wire. This system produces accurate and reproducible preparation of the canal for precise implantation of the silicone implant and grommet. Other features include a robust hinge, straight initial bone cuts, an antirotating feature, and sterile, single use instruments.

When contemplating the silicone implant option, it is important to consider the indications. Middle aged to older patients with the following symptoms may be offered this joint preserving treatment:

- Traumatic Arthritis
- Hallux Rigidus
- Gouty Arthritis
- Geriatric Bunions
- Hallux Rigidus with painful flexible High IM and HAV angles
- Hallux Valgus with Degenerative Joint Disease

Keeping this age group mobile and ambulating is extremely important. This treatment offers a pain relieving, joint sparing, more rapid healing path to recovery.

In the practice of medicine, we as surgeons use our experience to improve. The RTS System by In2Bones builds on lessons learned from past systems and presents a fresh look at a proven treatment method. The following case studies and articles illustrate the design and use of the revolutionary Reference Toe System (RTS).

Comments welcome at "PISupplementcomments@i2b-usa.com"
INTRODUCTION

The patient is an active 78 year old female who presented with the chief complaint of a painful bunion deformity of the right foot. Over the past four years she had been treated conservatively with appropriate shoes, however over time, she experienced increasing deformity and associated pain making it difficult to wear shoes. The patient noted that she had begun to alter her gait and reduce activities due to the painful bunion. Given her degree of deformity, pain, and the associated limits on her lifestyle, the patient requested surgical intervention. Her medical history was non-contributory.

PATIENT

Examination revealed a stage IV hallux abductovalgus deformity of the right foot with a large medial prominence of the first metatarsal head. The first ray was noted to be moderately flexible. Weight bearing x-rays confirmed the stage IV deformity with a significant lateral subluxation of the base of the proximal phalanx on the first metatarsal, and an intermetatarsal angle of 20 degrees (Figure 1). The significant deformity and surgical options were reviewed with the patient. After lengthy discussion, the patient elected surgical correction. Given the patient’s age and active lifestyle, it was important to return her to normal activities as promptly as possible. The plan was to avoid osteotomies and prolonged immobilization. Many of the patients in this category do not have the bone density to provide reliable internal fixation for arthrodesis. Experience suggests, when utilizing arthroplasty with flexible total joint replacement of the 1st MTP, patients are able to return to limited ambulation and activities more rapidly. The implant provides a stable scaffold for surrounding soft tissue healing, providing a comfortable, and functional joint.

PROCEDURE

The patient’s surgery was performed as an outpatient and included bunionectomy with total joint implant utilizing the Reference Toe System (RTS). In this case, a number 2 implant was used. (Figure 2) X-rays taken at the first post-operative visit revealed rectus alignment of the hallux and an intermetatarsal angle of 10 degrees (Figure 3). Post-operatively, these patients are placed in a post-operative surgical shoe for a period of five to six weeks with limited initial ambulation, and then gradually increase activities during the recovery period. Passive range of motion exercises are performed by the patient beginning at two weeks. At five to six weeks, we switch to athletic shoes. By three months, the patient may return to shoes and activities of choice as tolerated.

In the case of geriatric bunions, careful attention to the soft tissue release is paramount. In order to place the hallux in rectus alignment and avoid angular stress on the implant, the lateral contractures must be addressed in a systematic fashion. Prior to placement of the implant, range of motion is assessed with the grommets and trial sizer in place, and with the foot loaded. (Figure 4D). If during the motion the hallux

FIGURE 1

FIGURE 2

FIGURE 3
deviates laterally, further release must be performed until the lateral forces have been eliminated. This frequency includes partial or total release of the lateral head of the flexor hallucis brevis tendon from its insertion into the base of the proximal phalanx. With adequate soft tissue release and resection of bone, the retrograde force created by the hallux on the first metatarsal is reduced, facilitating reduction of the intermetatarsal angle.

CONCLUSION

Today, there are multiple options when considering a 1st MTP total implant. The advantages of the RTS implant include its innovative stem and grommet design and the elimination of the need for broaching. The osteotomy cuts are straight, so there is no need for the use of cutting guides that may require an extra set of hands in the operating room. (Figure 4A) Easy to use wire guides (Figure 4B) are provided for use with the cannulated reamer (Figure 4C), so accurate placement of the implant stems is consistent. The implants and instruments are provided in individual sterile, single-use disposable trays. (Figure 5). This state of the art feature is appreciated by the surgery facility, as it totally eliminates the need for cleaning, processing and sterilization of instrumentation.

Experience suggests that the use of total joint Implant arthroplasty procedure for correction of the geriatric bunion deformity is a simple, reliable and consistent alternative to other surgical options. The ability to eliminate the deformity while avoiding osteotomies and their associated post-op restrictions, makes the use of implant arthroplasty a common choice for these patients. □

FIGURE 5
**FIGURE 1**

**First MTPJ Implant Arthroplasty**

**Involving Chronic Gouty Arthritis**

Orlando H. Rivera, DPM, FACFAS

**INTRODUCTION**

Gout, also known as gouty arthritis is a form of inflammatory arthritis that develops in some people who have high levels of uric acid in the blood. It occurs in about 4 percent of American adults, but it’s more likely to affect men than women. For many people, the first symptom of gout is excruciating pain and swelling of the big toe, often following illness or injury. Other joints may be involved including the ankle and the knee. Chronic gout develops in people whose uric acid levels remain high over a number of years. Attacks become more frequent and the pain may not subside as normally seen. As a consequence, joint damage may occur which can lead to a loss of mobility.

**PATIENT**

This case report is of a female with chronic gout that damaged her first MTPJ. A 69 year old female presented with a primary concern of painful bilateral 1st MTPJ's for several years, which became worse over the past 9 months. Her Left foot pain was more severe than her right foot. Numerous conservative care modalities were tried, including oral anti-inflammatory medication, (Allopurinol 100 mg once daily), custom molded orthotics and wearing wider shoes. All of these treatments provided minimal relief. Radiographic studies were obtained and revealed a severe Hallux Abducto Valgus deformity with an intermetatarsal angle of 22 degrees and severe degenerative joint changes with juxta-articular erosions and numerous calcified soft tissue atrophy. (Figure 1). Because of the patient’s sedentary lifestyle, age and extensive joint destruction, the Reference Toe System (RTS) was selected as the treatment of choice. Preoperative non-invasive vascular studies were also obtained which showed adequate perfusion to both lower extremities.

**PROCEDURE**

A longitudinal incision was made over the first metatarsophalangeal joint, just medial to the extensive hallucis longest tendon. This incision was deepened down to bone. A dorsal medial capsulotomy was performed and the joint was dissected free on the dorsal and medial sides. At this point, visualization of the joint was accomplished. An extensive amount of gouty tissue was noted and was sharply debrided being careful to preserve as much capsule as possible. All hypertrophic bone around the joint was completely resected with the use of a sagittal saw and all sharp edges were smoothed out. Utilizing a sagittal saw, osteotomies were then performed perpendicular to the weight bearing surface in the distal aspect of the metatarsal head as well as the base of the proximal phalanx. Appropriate implant sizing was performed using the RTS Implant Sizing Guide making sure that the correct thickness, diameter and...
general shape of the implant was observed. (Figure 2). With the use of the Proximal and Distal Wire Guide, both the metatarsal and distal phalanx were prepped, making sure that the guide wire was centered in the canal and parallel to the dorsal surface of the respective bone. (Figure 3). To prevent premature erosion and implant failure, grommets were then firmly compressed into the corresponding bones. A size 3 Reference Toe Implant was then placed in the joint. Implant position was then visualized intra-operatively with fluoroscopy. Closure was made in layers.

Post operatively the patient was placed in a surgical shoe with partial weight bearing allowed. Fluoroscan imaging wa performed one week post operatively and revealed proper position of the implant as well as the grommets. (Figure 4). Sutures were removed 3 weeks post operatively and patient imme-diately started on physical therapy.

CONCLUSION
Total Joint Implant Arthroplasty utilizing silicone implants has been part of the surgical armamentarium since the late 1960’s. Because of the severe deformity encountered at the 1st MTPJ combined with extensive gouty arthritic joint damage, the RTS 1st MTP Implant System was utilized. The “ease of use” cannulated reamers significantly increases accuracy, efficiency and grommet placement/seating. This system allows for consistent reproducible results and is a great improvement to the broach type systems of the past.
INTRODUCTION

Hallux valgus deformity presents as a progressive deformity which is surgically treated with a variety of approaches. Osteotomies, arthrodesis, and total joint implant arthroplasty are among the more common surgical options. The deformity is characterized by an increase in the 1st intermetatarsal angle, increase in the sesamoid position, and varying degrees of great toe joint osseous adaptation and degenerative changes. The geriatric population presenting with symptomatic hallux valgus tend to have more degenerative changes along with a more sedentary lifestyle and increased risk for falls and comorbidities. This case presentation involves a 57 year old female with a moderate hallux valgus deformity and degenerative changes of the great toe joint with decreased range of motion. (Figure 1). The patient previously had a distal 1st metatarsal osteotomy for hallux valgus correction. The hallux valgus has recurred and the joint is painful.

TOTAL IMPLANT ARTHROPLASTY

The surgical treatment involved a total silicone implant arthroplasty of the great toe joint with lateral release of the collateral ligament and adductor tendon along with a medial capsulorrhaphy. The Reference Toe is a new silicone total implant arthroplasty system with disposable instrumentation and redesigned grommets and hinge contour of the implant. The innovative stem of the implant and the grommet design eliminate the need for broaching.

The hinge is anatomically designed to match the 16 degree declination of the 1st metatarsal. (Figure 2). The purpose of this case presentation is to demonstrate the Reference Toe System (RTS) as a viable surgical alternative with simple post op recovery compared to other arthrodesis and osteotomy procedures. Geriatric patients who are at risk for falls and fractures during a non-weight bearing recovery are allowed to ambulate in a walking boot immediately. A hip fracture can be a devastating complication when the geriatric patient falls during a non-weight bearing recovery. Patients who have good bone quality and proprioception are kept non weight bearing for two weeks.

CONCLUSION

Surgical correction of the degenerative hallux valgus (and hallux rigidus) deformities are classically arthrodesis, and osteotomy procedures. In the geriatric population, comorbidities make non weight bearing recovery risky. The silicone total implant arthroplasty with the Reference Toe System provides an excellent alternative that will facilitate immediate weight bearing in a walking boot, which lowers the risk of falls and simplifies the post op course for the patient. (Figure 3) shows the case study at post op week 8. The patient has been weight bearing during the entire recovery with no change in alignment or stability.
The patient was referred by a community orthopedist for evaluation and treatment of functional Hallux Varus and painful 2nd toe. The patient is a 68 year old white female with a history of diabetes and hypertension. She presented for cc of painful left big toe joint and hammertoe deformity of her second toe for more than five years. The patient has failed conservative treatment including shoe gear modification. The deformities became more symptomatic over time. The patient’s main complaint was that she could not wear shoes comfortably because by the end of the day her left big toe deviates medially and shoe rubs against it and causes pain. The patient’s secondary complaint was that her medially deviated hammertoe was painful in shoe gear and ambulation. She stated that she was moderately active and wants to be able to walk without pain.

An examination of her foot revealed a deviated 1st MPJ medially consistent with functional Hallux Varus upon loading the joint. The Intermetatarsal angle was less than 10 degrees and the Hallux Adductus was approximately 30 degrees. Dorsal medial eminence was insignificant (+tracking, -track bound, -crepitus). She also presented with a mildly subluxed 2nd MPJ medially with tender PIPJ. The deformity at the PIPJ and MPJ was reducible. (Figure 1). She was referred for medical clearance before surgical intervention. The patient was given multiple treatment options for the 1st MPJ surgery including fusion, osteotomy, Keller bunionectomy, hemi-implant and total toe implant for 1st MPJ repair. She chose the joint sparing silicone toe implant. She was offered amputation, arthroplasty, and osteotomy for her 2nd toe.

**PROCEDURE**

The patient’s surgery was done in a community hospital under local anesthesia with sedation. The chosen procedure was a total implant in the 1st MPJ using the Reference Toe System (RTS). In this case, a size 2 Implant was used. An x-ray performed post operatively revealed rectus alignment of the Hallux and IM within normal limits. (Figure 2). Post operatively the patient was placed in a post op shoe for 3-5 weeks then sneakers. Limited ambulation was recommended during the first week with gradual increases in activity after. After two months, the patient returned to regular shoes.

When using a total toe implant in any population, the most important decision is proper patient selection for the proposed procedure. Also it is important to make sure that the implant is properly implanted. The RTS System is cannulated and all instrument reaming is performed over a single guide wire. This single reference point helps assure reproducible implantation results. Range of motion is assessed with the grommets and trial sizer in place while loading the foot. If a deviation exists or the joint space seems too tight, these must be addressed by doing the appropriate soft tissue dissection and bone resection. If the joint has adequate range of motion and is rectus, the permanent implant is secured into place and the capsule is re-approximated. The incision is closed in layers in the normal manner.

**CONCLUSION**

There are many different procedures and implants available to treat 1st MPJ deformities. The RTS implant is an excellent choice in the right patient for correction of these deformities. It is simple to use and allows for excellent pain free motion. **Comments welcome at “PISuplementtocomments @i2b-usa.com”**
Silicone toe implant technology has not advanced for over a decade. The core technology from Wright Medical dates back to the 1960’s. With the revolution of sterile packaged, single-use disposable product solutions, comes the In2Bones Reference Toe System (RTS). The RTS advances the science by incorporating modern joint replacement with state-of-the-art instrumentation. This is the first MPJ replacement system with single-use instruments. The RTS implant design marries the complexity of computer modeling and finite element optimization with a reimagined instrument set that produces repeatable results in the simplest way. The RTS Silicone Toe offers the next generation flexible joint replacement solution for today’s demands.

**OVERVIEW**

The RTS implant is equivalent in strength to leading implants currently on the market. Finite element computer models were created of the RTS and two competitive implants. A FEA analysis comparing its resulting stress from a given displacement of two different competitive designs was performed. The stress output results showed equivalent strength to the competitive implants when subjected to an equal displacement load. Figure 1 below is a stress color plot of the RTS three-dimensional finite element model where red is designated as the highest stress locations and dark blue is designated as the lowest stress areas. (Figure 1).

**STRENGTH ANALYSIS**

The RTS implant is equivalent in strength to leading implants currently on the market. Finite element computer models were created of the RTS and two competitive implants. A FEA analysis comparing its resulting stress from a given displacement of two different competitive designs was performed. The stress output results showed equivalent strength to the competitive implants when subjected to an equal displacement load. Figure 1 below is a stress color plot of the RTS three-dimensional finite element model where red is designated as the highest stress locations and dark blue is designated as the lowest stress areas. (Figure 1).

**IMPLANT DESIGN**

- Implant available in 4 sizes to cover the anatomic range of the patient population.
- Anatomically angled proximal stem at 16° to match natural declination angle of the 1st metatarsal. (Figure 2)
- Hourglass body shape to facilitate medial/lateral flexion for fit into shoes while maintaining a high strength hinge in the sagittal plane for GAIT.
- Hinge design provides excellent strength while still allowing for good range of motion.
- Implants are composed of medical grade ultra high performance, high consistency silicone elastomer designed, manufactured and purified to meet the strictest needs of the healthcare industry.
- Titanium grommets are 100% precision machined to tight tolerances and high polished which results in a consistent, repeatable fit with both the implant and bone interfaces reduces the risk of silicone wear.
- Grommet shape and fit with implant helps resist implant rotation. Press-fit and shape provides a secure fit with the bone. (Figure 3).
INSTRUMENT SET DESIGN

Fully disposable single-use instrumentation for ease of use and reduction of patient risk from recleaning, resterilization procedures [Patent Pending]. Patient labels and lot coding enables full traceability to each implantation.

A. Colored silicone trials provided for final size selection and ROM confirmation
B. Disposable sizing instrument provides an easy size and resection width determination. Patent pending
C. Ergonomic wireguide with placement assistance features for easy wire insertion
D. Fully cannulated power reamers with standard small AO quick connection for quick bone preparation
E. Depth-limiting sleeve for accurate repeatable reaming depth and grommet fit (patent pending)
F. Purposefully designed Grommet Placer for controlled and confident grommet placement and a self-retaining feature for ease of insertion.
G. A dedicated grommet impactor to fully seat the grommets in the case of hard bone

No need for broaching or hand-preparing bones to accept the grommets.

TECHNIQUE INNOVATIONS

- Bone joint resections are straight, parallel and aligned with weight bearing so no need for cutting guides. (Figure 4).
- The wireguide creates a single point of reference from which the subsequent instruments locate.
- Fast-cutting cannulated reamers with depth stops replace broaching to provide precise grommet fit and reproducible results.
- Trials are provided for final ROM assessment prior to final implant placement.

FIGURE 4
INTRODUCTION

Hammertoe deformity is one of the most common ailments that is seen in the physician’s office. It is primarily a sagittal plane deformity, however it can also have components of transverse plane and frontal plane abnormality. Typically, the patient presents with discomfort from either their shoe rubbing on the toe, or from the thick and inflamed corn which is a secondary effect of the tight shoe.

It is the rigid hammertoe which usually requires surgical intervention. In the majority of these cases, either an arthroplasty, or an arthrodesis is performed. It is a belief which has evolved over the past 25 years, that the fusion of the toe provides a more predictable and reproducible result. In addition, when multiple toes are involved, the arthrodesis provides a more stable walking platform, as well as a more aesthetically appealing foot.

CASE HISTORY

This patient presented to the office with a complaint of pain at the bunion site and discomfort from a long 2nd toe which had become a chronic problem. Most of her shoes which used to be comfortable, were no longer fitting well and had become very uncomfortable. In addition, her daily exercise routine was affected as well since her sneakers were now problematic. (Figure 1)

Initially, non-operative care was provided including padding, shoe style change recommendations, anti-inflammatory medications, and offer of an injection into the bunion in an attempt to reduce the inflammation and discomfort. After some thought, the patient decided to schedule surgery to correct the bunion and the 2nd toe hammertoe.

THE PROCEDURE

For purposes of this discussion, we will focus our attention to the hammertoe surgery.

A 1.5cm midline dorsal incision was made on the 2nd toe. The dissection was carried down to the level of the subcutaneous tissue and the EDL tendon. At the PIPJ level, the tendon was transected and reflected proximally to the neck of the proximal phalanx. The next step was to sever the collateral ligaments on the medial and lateral sides of the head of the phalanx, and deliver the phalanx into the operative site. Utilizing a sagittal saw (sagittal or oscillating work well), the head was resected at exactly the point of the flair on the bone where it meets with the head. The head was dissected free and removed from the wound.

The next step was to remove the articular cartilage on the base of the middle phalanx. The same saw was used to accomplish that. The appropriate size drill bit was used to create a channel for the bone allograft to slide into. There are proximal and distal depth lines etched onto the drill bit. Once the drill holes are created, the AlloAid PIP allograft was removed from its sterile packaging. The allograft comes packaged sterile in a small vial with saline therefore no hydration is required. The AlloAid PIP...
Allograft is offered in 2.5mm and 2.9mm diameters and both straight and 10 degree angled options. (Figure 2). In this patient, a 2.9mm x 19mm angled implant was used.

In the majority of cases, the implant is inserted into the proximal phalanx first. The implant is held by the forceps at the transition point between the proximal and distal keels which prevents the implant from being placed too deeply into the drill holes. (Figure 3). Once the implant is positioned proximally, the distal portion of the toe is placed onto the allograft which is protruding from the proximal phalanx. It is positioned directly onto the implant and compressed until the two cut surfaces of bone (proximal and middle phalanx) are opposed. Once the two bones are positioned correctly, the wound is irrigated and the tendon is re-approximated in any fashion desired by the surgeon. (Figure 4).

**DISCUSSION**

Biomechanically, the fusion of the toe provides a rigid lever arm for propulsion as well as a mechanism whereby the flexors stabilize the MTPJ. With the sterile AlloAid PIP bone allograft, there are several advantages over metallic implants, and K-wires.
1. This allograft implant provides an environment for both osteoconduction and osteoinduction.
2. The cancellous nature of the bone, with its porosity provides “scaffolding” for the new bone to be laid down into by the osteogenic precursor cells.
3. Regarding osteoinduction, the undifferentiated mesenchymal stem cells become “active and awakened” to create the pathway for new bone to develop.
4. This implant provides excellent fixation and fully resorbs into the bone over time resulting in successful surgical outcomes.

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