Flexible hinge silicone implant with or without titanium grommets for arthroplasty of the first metatarsophalangeal joint

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ABSTRACT

Purpose. To review outcomes of 37 patients who underwent arthroplasty of the first metatarsophalangeal joint using flexible hinge silicone implants with or without titanium grommets.

Methods. 36 women and one man (63 feet) underwent arthroplasty of the first metatarsophalangeal joint for rheumatoid arthritis (RA) using Swanson flexible hinge silicone toe implants with or without titanium grommets. 20 women (35 feet) aged 31 to 72 (mean, 52) years with Steinbrocker grade II (n=4), grade III (n=6), and grade IV (n=10) RA of the feet were treated with the implant without grommets, whereas 16 women and one man (28 feet) aged 48 to 73 (mean, 60) years with Steinbrocker grade III (n=4) and grade IV (n=13) RA of the feet were treated with the implant with grommets. Pain levels were self-rated. Degenerative changes and the presence of osteophytes or deformity were recorded, as were breakage or deformation of the implants, radiolucencies around the implant, implant loosening, silicone-induced synovitis, and sclerosis around the implant.

Results. All patients reported pain relief from severe to mild or moderate. Respectively for the feet with and without grommets, the rates of implant deformation were 25% and 63% (p=0.031), whereas the rates of moderate-to-severe radiolucencies (>2 mm) were 4% and 34% (p=0.004). Sclerosis developed around the implant in all feet.

Conclusion. Titanium grommets appear to protect the implant and improve clinical outcomes.

Key words: arthritis, rheumatoid; arthroplasty, replacement; metatarsalgia

INTRODUCTION

In patients with rheumatoid arthritis (RA), deformities of the forefoot often cause pain and disability. Initial treatment usually involves non-steroidal anti-inflammatory drugs, modification of shoes, and orthotic devices. Surgical treatments for the arthritic hallux metatarsophalangeal joint include resection arthroplasty, arthrodesis, and implant...
arthroplasty. Resection arthroplasty results in a shortened hallux and a decrease in push-off power, whereas arthrodesis requires accurate surgical technique and internal fixation to facilitate fusion.\(^1\,^4\) Arthroplasty of the first metatarsophalangeal joint using a flexible hinge silicone implant enables faster recovery and restoration of the normal biomechanics of the joint.\(^3\,^5\) However, sharp bony edges and shearing forces may tear the implant midsection and lead to implant failures.\(^6\,^7\) Thus, titanium grommets are added to the flexible hinge silicone implants.\(^6\,^9\)

We reviewed outcomes of 37 patients who underwent arthroplasty of the first metatarsophalangeal joint using flexible hinge silicone implants with or without titanium grommets.

**MATERIALS AND METHODS**

36 women and one man (63 feet) underwent total replacement of the first metatarsophalangeal joint for RA using Swanson flexible hinge silicone toe implants (Wright Medical Technology, Arlington [TN], USA) with or without titanium grommets by senior surgeons in our hospital. Between 1982 and 1992, 20 women (35 feet) aged 31 to 72 (mean, 52) years with Steinbrocker grade II (n=4), grade III (n=6), and grade IV (n=10) RA of the feet were treated with the implant without grommets and followed up for a mean of 7.8 (range, 5–11) years. Between 1993 and 2001, 16 women and one man (28 feet) aged 48 to 73 (mean, 60) years with Steinbrocker grade III (n=4) and grade IV (n=13) RA of the feet were treated with the implant with grommets and followed up for a mean of 5 (range, 3–8) years.

Surgery was undertaken under general or lumbar anaesthesia, and a tourniquet was used. A dorsomedial incision was made, and the capsular incision was made longitudinal to the metatarsophalangeal joint of the great toe. A portion of the metatarsal head was excised first to improve the exposure and to facilitate soft-tissue release. The capsule was release laterally, as were the adductor halluces and the attachment of the transverse intermetatarsal ligament to the proximal phalanx and the lateral sesamoid. The intramedullary canals were enlarged to accept the implant stem, and the ends of the bone were smoothed to avoid damage to the implant. After a preliminary reduction with a trial implant, the optimal implant was placed in the canals, and the medial part of the capsule was closed in the correct position. For the lesser toes, a longitudinal dorsal approach was used. Extensor tendons were cut and the metatarsal heads were resected. Hammer toe deformity was corrected and Kirschner wires were inserted to maintain the corrected position.

At postoperative week 3, casting and all Kirschner wires were removed, and walking with arch support orthotics was allowed, and the great toe could move freely. Patients were advised to wear wide box-toe shoes and avoid narrow or high-heeled shoes for 6 months.

Pain levels were self-rated as minimum, mild, moderate, or severe. The hallux valgus angle (HVA) and the first intermetatarsal angle (IMA) were measured on radiographs. Degenerative changes in the first metatarsophalangeal joint and the presence of osteophytes or deformity were recorded.\(^5\,^10\) Breakage or deformation of the implants was classified as grade 0 (no evidence of deformation or fracture), grade 1 (slight deformation or fracture of the stem or the hinge), and grade 2 (complete deformation of the implant) [Fig.].\(^10\) Radiolucencies around the implant were classified as slight (<2 mm), moderate (2–4 mm), and severe (>4 mm).\(^3\) Implant loosening and silicone-induced synovitis were also assessed. Sclerosis around the implant was classified as slight (small but detectable formation of spur only), moderate (<50% encroachment on the cartilage), severe (≥50% encroachment), and complete osseous bridging.\(^5\)

The Fisher’s exact test was used to compare patients treated with implants with or without grommets. A p value of <0.05 was considered statistically significant.

**Figure** Arthroplasty of the first metatarsophalangeal joint using a flexible hinge silicone implant showing (a) a fracture in the medial shoulder (arrow) and radiolucencies around the distal stem (arrowheads) of the flexible hinge silicone implant and (b) sclerotic change around the implant (arrowheads). (c) The implant with titanium grommets.
RESULTS

All patients reported pain relief from severe to mild or moderate. Of 35 feet without grommets, pain was mild in 31 and moderate in 4. The mean HVA improved from 31º to 19º, and the first IMA improved from 10º to 11º. Of 28 feet with grommets, pain was mild in 26 and moderate in 2. The respective mean HVA and first IMA improved from 48º to 20º and from 14º to 12º. The preoperative mean HVA was significantly higher in feet with grommets (p=0.008, unpaired t-test).

Respectively 13, 18, and 4 feet without grommets and 21, 7, and 0 feet with grommets developed implant deformation of grades 0, 1, and 2. The rates of implant deformation were 63% and 25%, respectively (p=0.031, Fisher’s exact test). Titanium grommets appeared to protect the silicone implants.

Respectively 9, 9, and 3 feet without grommets and 15, 1, and 0 feet with grommets had slight, moderate, and severe radioluencies around the implant. The rates of moderate-to-severe radioluencies (>2 mm) were 34% and 4%, respectively (p=0.004, Fisher’s exact test). Titanium grommets appeared to prevent implant loosening.

Respectively 7, 16, and 11 feet without grommets (one had complete osseous bridging) and 6, 15, and 7 feet with grommets had slight, moderate, and severe sclerosis around the implant. All feet had sclerotic reaction around the implant.

DISCUSSION

Resection of the diseased metatarsophalangeal joints is the mainstay treatment for metatarsalgia and deformities of the rheumatoid forefoot. In one study, 76% of patients with RA achieved satisfactory results after Keller resection arthroplasty; unsatisfactory results were mainly due to recurrent hallux valgus, which occurred in 53% of patients. Arthrodesis of the first metatarsophalangeal joint is advocated to maintain alignment and re-establish weight-bearing function. In another study, 16 of 18 patients with RA achieved good or excellent results after arthrodesis, but arthrodesis caused increased stress and possible degenerative changes in the joints proximal and distal to the fusion.

In 94 arthroplasties of the first metatarsophalangeal joint using a double-stemmed implant, all patients were pain-free, and the mean HVA improved from 44º to 11º at postoperative month 30. One implant was removed because of infection; there was no implant fracture or absorption or production of bone around the implant. In 40 arthroplasties of the first metatarsophalangeal joint using silicone-rubber implants and a basal osteotomy to correct metatarsus primus varus, all patients were satisfied with the results, and there was no implant-related complication after 3 to 5 years. The silicone-rubber implant was reported to provide excellent stability and power. However, sharp bony edges and shearing forces have been reported to tear the implant midsection and lead to implant failure and reaction. Thus, Swanson introduced the High Performance Silicone Elastomer (Dow Corning Wright, Arlington [TN], USA), with press-fit titanium grommets to shield the implants.

In the present study, no evidence of silicone synovitis or mechanical failure was noted. The sclerotic lines were probably a bony response to the implant. Some sclerotic reaction around the implant was noted in all feet: 13 feet had slight spurps, 31 feet had moderate osteophytes which were not detrimental to the function of the implant, 18 feet had severe sclerosis around the implant, and one foot had complete osseous bridging. Slight, non-progressive radioluencies were noted in 24 feet. Subsidence was noted in 15 of the implants, but in 13 this was mild (<2 mm) and not progressive. Subsidence occurred on the proximal phalanx side in feet without grommets, in contrast to the metatarsal side in feet with grommets. This may be because the diameter of the proximal phalanx is smaller than the metatarsal side, and therefore the grommet usually rests on cortical bone. The metatarsal grommet is the same size as the phalangeal grommet and is usually supported by cancellous bone only. This may have implications for future design. The grommets appeared to protect the implant from the surrounding bone, stabilising it and lessening the formation of small amounts of silicone wear debris.

A study using a hinged silicone prosthesis reported a 29% mechanical failure rate and a 53% osteophyte formation rate. Most of the patients underwent revision arthroplasty for failed procedures; only 20% of the patients answered questionnaires, and there was no other clinical or radiographic follow-up. The implant was disused owing to radiographic changes. In 67 double-stem implants (without titanium grommets) followed up for 6 years, 87% achieved excellent and good results. Implant fracture occurred in 7 feet and radioluencies in 6. In 86 double-stem implants (only 2 with titanium grommets) followed up for 6.8 years, results were excellent. Bone production was noted in the hinge portion in 62% (severe in only 3 feet), implant fracture was noted in 8 feet, radioluencies in 39%, and patient...
dissatisfaction was reported by 9% (usually younger patients who had failed previous bunion surgery). In a study using implants with or without titanium grommets, results were excellent in 90 feet (66 had RA) after a mean of 29 months. There was no evidence of silicone synovitis, bone resorption, or implant fracture; only 2 implants rotated and required revision.

In a case report examining the bone/implant interfaces, silicone particles within the fibrous tissue, and a tear and severe scuffing of the implant surface were detected in the joint without grommets (but not in the joint with grommets). Grommets may improve implant durability and prevent particulate synovitis.

Patient selection remains the most important factor for achieving good outcomes. Implants should be used only in patients with reduced activity levels, such as those with RA. Arthrodesis is recommended for younger or highly active patients with joint destruction.

CONCLUSION

Titanium grommets appeared to protect the flexible hinge silicone implant and improve the clinical outcome. Nonetheless, the implant failure rate was relatively high (25%). Long-term follow-up is needed to determine whether radiolucencies lead to future loosening and/or dislocation.

DISCLOSURE

No conflicts of interest were declared by the authors.

REFERENCES