Retrospective Analysis of Silastic Implant Arthroplasty of the First Metatarsophalangeal Joint

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The purpose of this study was to evaluate the outcome of implant arthroplasty according to subjective, biomechanic, and radiographic parameters over a long period of time. Implants in 40 feet (27 patients) were analyzed at an average follow-up time of 8.25 years and a mean patient age of 63. The results were consistent with the subjective findings of previous studies that demonstrated that most patients were satisfied with the procedure. Ninety-six percent of the patients in this study confirmed they would undergo the procedure a second time. The radiographic results did not demonstrate a high incidence of implant fracture as previously reported. This review suggests that implants can be effective when used with patients who are carefully selected according to age, activity level, and diagnosis. (The Journal of Foot & Ankle Surgery 37(2):128–134, 1998)

Key words: arthritis, foot, hallux rigidus, implant, Silastic

The development of implants for the first metatarsophalangeal joint began in the 1950s with a metal intramedullary stem implant to replace the metatarsal head (1). In 1967, Swanson introduced a silicone single-stem flexible implant for the proximal phalanx of the great toe. The procedure was considered to be a possible substitute for the Keller bunionectomy which failed in the development and maintenance of an adequate joint space (1).

A high-performance silicone elastomer (Silastic[1]) was developed in 1974, and after favorable clinical trials, the double-stem hinged implant was introduced for general use in 1977 (2). Since 1974, Swanson recommended the use of a double-stem hinged implant in cases of severe arthrosis including: rheumatoid arthritis with a moderate to severe hallux valgus deformity, severe senile hallux valgus deformity, and revision of previous procedures when bony destruction occurs on both sides of the joint (2).

The Silastic double-stem implant has been demonstrated to be an acceptable procedure with successful results when used in the arthritic and geriatic population (2, 3). Swanson et al. advocated using the Silastic implant in severe hallux valgus with destruction on both sides of the joint as observed in patients with rheumatoid arthritis and the elderly (2). Miller et al. recommended the use of the Silastic implants in the geriatric bunion as defined as severe hallux abducto valgus with significant metatarsus primus varus or with an intermetatarsal angle of greater than 14° to 15° (3). Cracchiolo et al. utilized the double-stem implant in 133 cases of rheumatoid arthritis and all patients demonstrated pain relief (4). More recently, press-fit titanium grommets have been developed to shield and improve long-term durability of implants used in arthroplasty (5). The aim of this study was to present a long-term retrospective analysis by reviewing subjective and objective findings of implant arthroplasties used in a patient population that was selected on the basis of age, activity level, and diagnosis.

Materials and Methods

Between 1981 and 1989, 121 double-stem flexible hinged Silastic implant arthroplasties of the first metatarsophalangeal joint were performed in 96 patients. Eleven of the patients were females and 85 were males. Forty patients responded to a subjective questionnaire in which each patient assessed preoperative and postoperative pain at an average of 8.25 years postoperatively (range, 5–12 years). A total of 27 patients (40 feet) fully participated in biomechanical, clinical, and radiographic evaluations. Eight patients were unable to participate in the biomechanical and radiographic studies and the remaining five patients were unable to be contacted.

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The indications for Silastic implant arthroplasty were pain and stiffness of the first metatarsophalangeal joint with little or no response to conservative nonsurgical care. Nonsurgical care involved any one or a combination of custom orthotics, shoe modifications, padding, NSAIDS, and cortical steroid injections. The diagnoses included rheumatoid arthritis, hallux abducto valgus, hallux limitus, hallux rigidus, and geriatric bunion deformity.

Biomechanical and clinical examinations were conducted at an average follow-up of 8.25 years, which included gait analysis, evaluation of hallux purchase, detection of painful lesions, and reoccurrence of deformities. The 27 patients were also placed through range-of-motion measurements that consisted of dorsiflexion, plantarflexion, and hypermobility at the first metatarsophalangeal joint. The measurements were evaluated in degrees.

Standard weightbearing radiographs (dorsoplantar, lateral, and oblique) were obtained. Each foot was assessed for bone density, presence of bony cyst formation, bony regrowth, and residual deformities. The hallux abducto valgus angle and intermetatarsal angle were measured. The integrity of each Silastic implant was also evaluated.

The surgical procedures illustrated in this study were completed prior to 1990. The first metatarsophalangeal joint was exposed by one of the standard bunion approaches. The base of the proximal phalanx was removed approximately 1 to 2 cm from the joint. The cartilaginous cap was removed from the head of the first metatarsal, preserving as much length as possible. A pan metatarsal head resection was performed in some cases of rheumatoid arthritis, and additional bone was resected from the head of the first metatarsal in order to maintain a proper parabola. Tendon lengthening of the extensor halluces longus was performed as needed. Burrs were used to form the medullary canals and grommets were not available at the time of this study. In subsequent years, grommets have been utilized to shield the stem of the implant. Broaches have also since been utilized which have allowed for a better anatomical fit of implants. The patients were maintained in a surgical shoe for a period of 4 to 6 weeks postoperatively, after which the patients were placed in an athletic shoe or an inlay depth shoe.

Results

Forty Silastic double-stem flexible hinged implants in the first metatarsophalangeal joint of 27 patients were evaluated at an average follow-up of 8.25 years (range, 1–21 years) postoperatively. The average age of the preoperative patient population was 63 years (range, 49–79 years); 23 patients (85%) were males and 4 patients (15%) were females. The preoperative diagnoses included 16 patients with geriatric bunion deformity (severe hallux abducto valgus), 7 patients with rheumatoid arthritis, and 4 patients with hallux limitus/rigidus (Figs. 1–3). The Silastic double-stem implants were placed in 13 of the 27 patients bilaterally.

Twenty-seven patients responded to our subjective survey regarding the satisfaction of Silastic implant surgery. Respondents were asked to use their personal opinion to rate subjectively the result of the implant surgery using the following categories: completely satisfied, good, fair, and unsatisfied (Table 1). The survey asked the patients to consider the overall result of the implant surgery using the aforementioned categories at a given postoperative duration. Patients rated the result of implant surgery as "completely satisfied" in 63% (17 of 27 patients), "good" in 26% (7 patients), "fair" in 3.7% (1 patient), and unsatisfied in 7.4% (2 patients) 1 year after surgery. The patient who gave the result as "fair" and one patient who gave an "unsatisfied" rating had their implants removed less

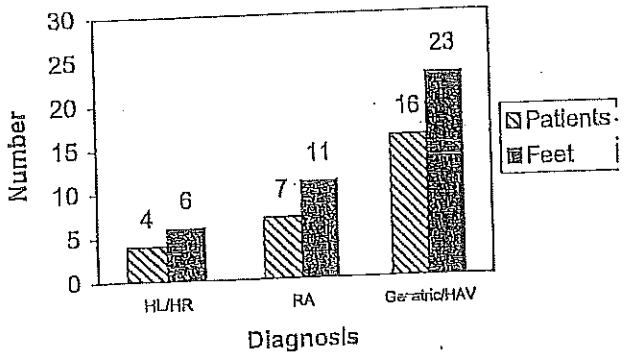

FIGURE 1 Number of patients and feet used in the study on the basis of the diagnosis. HL/HR = hallux limitus/hallux rigidus; RA = rheumatoid arthritis; geriatric/HAV = geriatric bunion deformity/hallux abducto valgus.

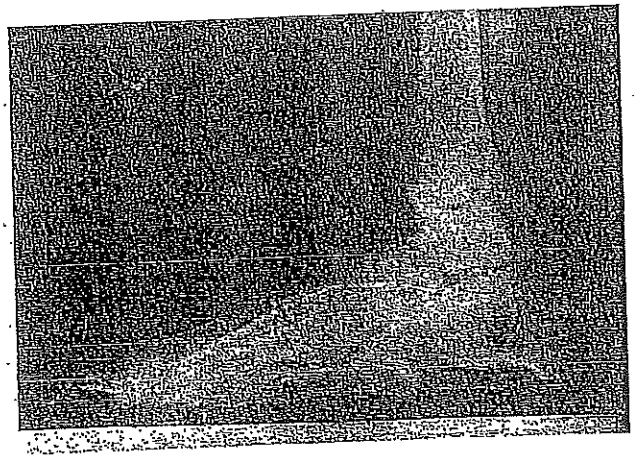

FIGURE 2 Preoperative patient with diagnosis of hallux limitus showing dorsal exostosis at the head of first metatarsal and complete loss of joint space.

FIGURE 3 Preoperative patient with diagnosis of hallux limitus showing dorsal exostosis at the head of first metatarsal and complete loss of joint space.

than 1 year after surgery. The other patient who gave an "unsatisfied" rating did not have the implant removed.

According to the follow-up survey, 51.9% (14 of 27 patients) rated the result as "completely satisfied," 33.3% rated as "good," and 14.8% rated as "fair," including the two patients who had the implant removed. One patient gave no response. To date, 3 of 40 (7.5%) implants have been removed. Chronic ulceration with intractable pain and postoperative infection were the causes for the two implants' removal in the first year. One patient who rated his satisfaction as good had the implant removed due to chronic gout beyond 1 year postoperative.

The patients were also asked whether or not they experienced pre- and postoperative bunion pain (Table 1). Ninety-three percent (25 of 27) of the patients indicated they experienced bunion pain preoperatively. Bunion pain persisted in 19% of the 27 patients postoperatively. Two patients who reported no bunion pain preoperatively remained pain free after surgery. Twenty-six of 27 patients (96%) said they would repeat the implant procedure. The patient responding he would not repeat the procedure experienced a postoperative infection and had the implant removed less than 1 year after surgery.

TABLE 1 Questionaire data

	Age		Implant	Foot		Bunion Pain		Satisfaction			Implant	Repeat
Patient	Surgery	Follow-up	Year	Right/Left	Diagnosis	Preoperative	Postoperative	One Year	To Date	Sex	Removed	Procedure
1	64	73	85	Right	G	Yes	No	Good	Good	Male	No	Yes
2	54	62	86	Right	RA	Yes	No	CS	CS	Male	No	Yes
3	51	64	81	Bilateral	RA	Yes	No	CS	CS	Male	No	Yes
4	68	73	88	Bilateral	G	Yes	No	CS	Good	Male	No	Yes
5	66	73	86	Right	G	Yes	No	CS	Good	Male	No	Yes
6	61	71	83	Right	HL	Yes	Yes	Good	Fair	Male	No	Yes
7	49	54	88	Bilateral	*	Yes	No	CS	CS	Male	No	Yes
8	62	71	84	Bilateral	HR	Yes	No	Good	Good	Male	Yes(Gout)	Yes
9	65	72	86	Right	G	Yes	No	CS	CS	Male	No	Yes
10	63	70	86	Left	RA	No	No	CS	CS	Male	No	Yes
11	62	69	86	Bilateral	RA	Yes	No	Good	Good	Male	No	Yes
12	62	74	*	Bilateral	RA	Yes	No	CS	CS	Male	No	Yes
13	69	70	85	Bilateral	HAV	Yes	No	CS	CS	Male	No	Yes
14	50	79	83	Bilateral	HAV	Yes	No	Good	Good	Male	No	Yes
15	55	67	88	Bilateral	RA	Yes	No	CS	CS	Male	No	Yes
16	69	77	83	Left	HAV	No	No	CS	CS	Male	No	Yes
17	57	78	84	Right	HAV	Yes	Yes	Good	Good	Male	No	Yes
18	65	67	85	Left	G/HAV	Yes	No	Good	Good	Male	No	Yes
19	58	72	88	Bilateral	HAV	Yes	No	CS	Good	Male	No	Yes
20	62	70	82	Bilateral	G	Yes	No	CS	CS	Male	No	Yes
21	69	70	86	Bilateral	HL	Yes	No	CS	CS	Female	No	Yes
22	67	77	86	Left	HAV	Yes	No	CS	CS	Female	No	Yes
23	61	74	86	Bilateral	HAV	Yes	No	CS	CS	Female	No	Yes
24	65	67	87	Left	HR	Yes	No	CS	CS	Male	No	Yes
25	60	67	86	Left	HAV	Yes	Yes	U	Fair	Male	No	Yes
26	66	72	87	Right	RA	Yes	Yes	Fair	Fair	Female	Yes(Pain)	Yes
27	75	79	89	Right	HAV	Yes	Yes	U	Fair	Male	Yes(Infect)	No

HL = hallux limitus; HR = hallux rigidus; RA = rheumatoid arthritis; HAV = hallux abductor valgus; G = geriatric bunion; CS = completely satisfied; U = unsatisfied; F = Fair; * = no response to questions.

There was no apparent evidence of detritic synovitis clinically or radiographically in our study. Radiographs revealed a fracture in one implant, which was an incidental finding and was asymptomatic. Radiographs showed minor radiolucent areas and bone hypertrophy around the implantation sites. Twenty of 40 cases (50%) demonstrated evidence of bony regrowth at the distal aspect of the first metatarsal or the base of the proximal phalanx (Table 2, Fig. 4). No bony overlap was noted radiographically or clinically at the hinge of the implant. Nine of 40 cases had cystic changes at the subchondral level of the metatarsal and proximal phalanx (Fig. 5).

The average postoperative intermetatarsal angle was 10° (range, 5°–21°) and the average hallux valgus angle was

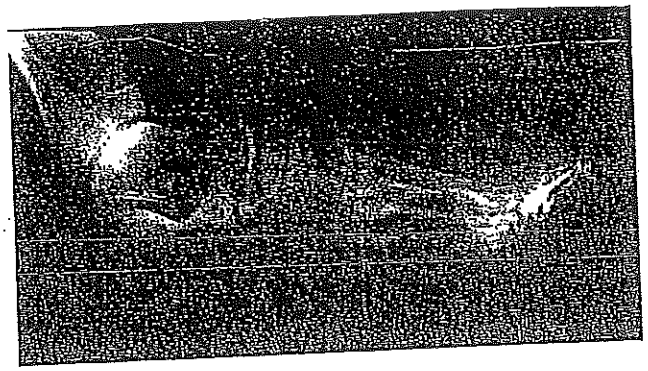

FIGURE 4 Eight-year postoperative radiograph of bony regrowth at base of proximal phalanx.

TABLE 2 Biomechanical, clinical, and radiographic data

Foot	Side-Patient#	Gait	Second Metatarsalgia	Hallux (Deg) DF	PF	Total ROM	Purchase	Bony Regrowth	Cyst	IM Angle	HAA
1	Right-1	N	No	30	20	50	Yes	Yes	No	10	20
2	Right-2	AN	No	20	38	58	No	Yes	No	12	28
3	Right-3	N	No	10	13	23	No	No	No	18	40
4	Left-3	N	No	24	30	54	No	Yes	Yes	12	34
5	Right-4	N	No	15	12	27	Yes	No	No	10	20
6	Left-4	N	No	16	20	36	Yes	Yes	No	8	12
7	Right-5	N	No	32	20	52	Yes	No	Yes	10	18
8	Right-6	N	No	25	35	60	Yes	Yes	Yes	6	1
9	Right-7	N	Yes	15	10	25	Yes	No	Yes	10	11
10	Left-7	N	Yes	20	15	35	Yes	No	Yes	6	5
11	Right-8	N	No	10	10	20	Yes	Yes	No	5	15
12	Left-8	N	No	10	0	10	No	Yes	No	10	5
13	Right-9	N	Yes	25	10	35	No	No	No	5	18
14	Left-10	N	Yes	25	10	35	Yes	No	Yes	11	9
15	Right-11	AP	No	25	15	40	Yes	Yes	No	20	45
16	Left-11	AP	No	10	10	20	Yes	Yes	No	21	50
17	Right-12	N	No	10	15	25	No	No	No	6	15
18	Left-12	N	Yes	20	22	44	No	No	No	8	17
19	Right-13	N	No	50	10	60	Yes	Yes	No	8	11
20	Left-13	N	No	30	0	30	Yes	Yes	No	5	7
21	Right-14	AN	No	5	10	15	No	Yes	No	10	17
22	Left-14	AN	No	15	10	25	No	Yes	No	8	16
23	Right-15	N	No	15	10	25	Yes	Yes	No	5	18
24	Left-15	N	Yes	20	15	35	No	No	No	8	33
25	Left-16	N	No	5	5	10	No	No	No	12	14
26	Right-17	N	No	25	20	45	No	No	No	16	25
27	Left-18	N	Yes	30	15	45	No	Yes	No	4	21
28	Right-19	N	Yes	10	7	17	No	No	No	7	15
29	Left-19	N	No	18	15	33	No	No	No	9	15
30	Right-20	N	No	10	20	30	Yes	Yes	No	15	18
31	Left-20	N	No	25	20	45	No	Yes	No	19	28
32	Right-21	N	No	7	5	12	Yes	No	No	7	12
33	Left-21	N	No	11	5	16	No	No	Yes	11	15
34	Left-22	N	No	45	20	65	Yes	No	No	8	0
35	Right-23	N	No	20	18	38	No	No	No	10	12
36	Left-23	N	No	25	20	45	No	No	No	12	27
37	Left-24	N	No	13	20	33	Yes	Yes	Yes	10	5
38	Left-25	N	No	15	15	30	Yes	Yes	No	10	8
39	Right-26	N	No	0	0	0	No	Yes	Yes	8	0
40	Right-27	AN/AS	Yes	0	0	0	No	No	No	16	12

AP = apropulsive; N = normal gait; AN = antalgic; AS = assisted.

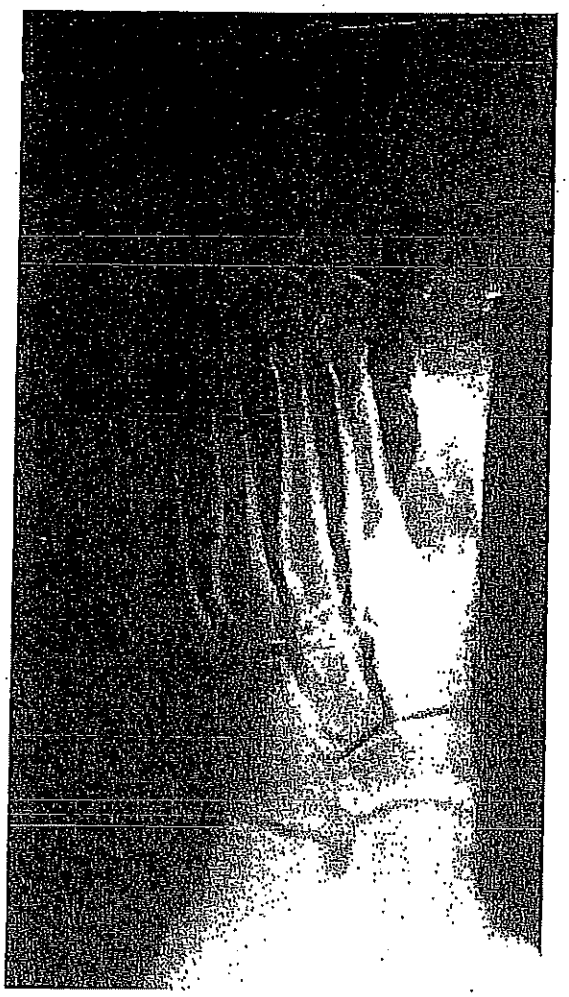

FIGURE 5 Severe cystic changes evident in both the first metatarsal and proximal phalanx 7 years postoperative.

17° (range, 1°–50°). The average total range of motion at the first metatarsophalangeal joint postoperatively was 32° (14° plantarflexion and 18° dorsiflexion). Preoperative data were not available for intermetatarsal angles, hallux valgus angles, or first metatarsophlangeal ranges of motion. Second metatarsalgia was reported in 9 of 40 feet (22.5%). An abnormal gait pattern was found in 7 of 40 feet (17.5%) including 10% with an antalgic gait, 5% with an apropulsive gait, and 2.5% with an assisted gait. Hallux purchase was also assessed by evaluating the ability to plantarflex the hallux onto the weightbearing surface. Nineteen of 40 feet (47.5%) were not purchasing the weightbearing surface (Table 2).

Discussion

The major objectives of the Silastic single- and double-stem flexible hinged implant arthroplasty are to relieve pain, allow shorter periods of recovery, preserve the length and proper alignment of the great toe, and provide stable function to the arthropathic first metatarsophalangeal joint. The 27 patients evaluated in this study were selected on the basis of age, activity level, and diagnosis. Several studies report good subjective findings after implant arthroplasty (1–8). Vanore et al. suggest that patient selection is paramount to a successful outcome for implant procedures and report a revision rate of 2% (9). However, a study by Granberry et al. that describes the inconsistencies between the subjective and objective findings regarding implant arthroplasty makes no mention of patient selection beyond the diagnosis (6). In fact, the authors report that they have abandoned the use of the Sutter[2] implant due to the high and increasing rate of failure, as demonstrated in their study radiographically (6).

Previous studies on arthroplasty of the first metatarsophalangeal joint with the use of Silastic implants have been reviewed (1–8). Implants have been reported to offer the potential advantage of a short period of recovery and restoration of the normal biomechanics of the joint (2). Gerbert has demonstrated that the Silastic implant was effective in eliminating first metatarsophalangeal joint pain, serving as a dynamic spacer in the preservation of proper joint space, and alignment for early range of motion (10). Previous in vitro and animal studies have shown that Silastic implants exhibited durable, biocompatible, and favorable clinical trials (2). Cracchiolo et al. reported that most of their patients demonstrated relief of pain and 82% were completely satisfied with the subjective and cosmetic result (4). In addition, there were no mechanical failures reported in their series of implant arthroplasties. Kampner described an excellent result in 69% of his patients and noted normal strength of plantarflexion of the great toe upon physical examination using the Sutter implant (7).

Consistent with previous studies, our review found that 63% of the patients rated thier results with the double-stem implant arthroplasty as "completely satisfied" at an average of 8.25 years following surgery. Twenty-six of 27 patients (96%) subjectively stated that they would undergo the procedure a second time. However, three implants (7.5%) had to be removed due to complications of infection, recurrent gout, and chronic ulceration beneath the first metatarsal head with intractable pain. Gout has not been reported as a contraindication for implant arthroplasty. Two of the three patients (66.6%) who had their implants removed stated they would repeat the procedure as they are asymptomatic to date (Table 1, Figs. 6 and 7). Our study found that 78% of the patients exhibited relief from bunion pain postoperatively which is significant from the 89% of patients that reported bunion pain initially.

[2]Sutter Biomedical, San Diego, CA.

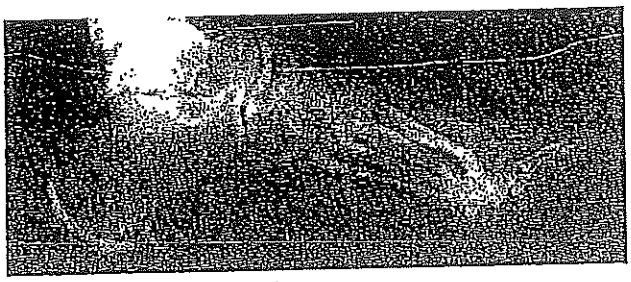

FIGURE 6 Nine years after implant removal for gout, bony regrowth and remodeling are noted although the patient remained asymptomatic.

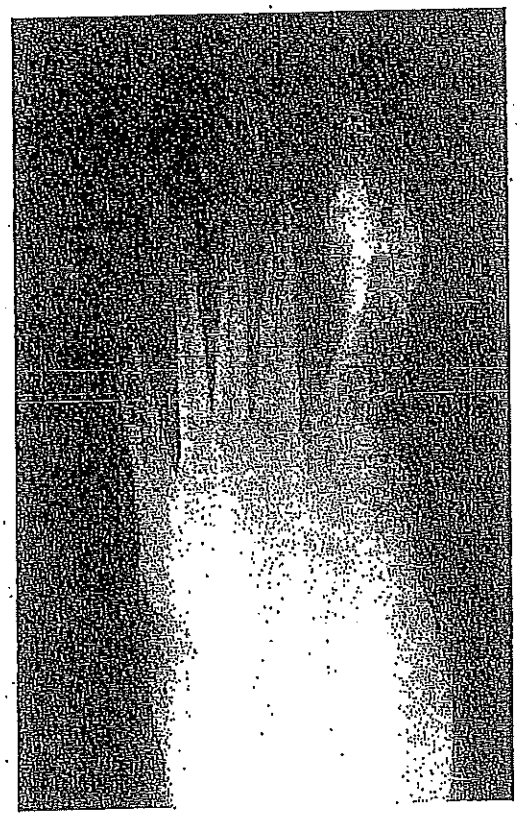

FIGURE 7 Nine years after implant removal for gout, bony regrowth and remodeling are noted although the patient remained asymptomatic.

The postoperative range of motion and the correction of deformities has been encouraging. The function of the great toe was represented by the 32° average range of motion after surgery which is consistent with the findings of Cracchiolo et al. (35°) (4), Pontell and Gudas (49°) (8), and Swanson et al. (52°) (2). Gerbert emphasized that approximately 50° of postoperative range of motion is to be expected regardless of the preoperative range of motion (10). The postoperative intermetatarsal angle was measured to be an average of 10°. The postoperative hallux valgus angle was less than 20° in the majority of the cases. Although preoperative intermetatarsal and hallux valgus angles were not available, the data reveal that the majority of the patients were within normal measurements after the implant procedure.

The radiographic results demonstrated that the implants were generally well tolerated and maintained by soft tissue and bone. A single fractured implant was noted radiographically among the 40 double-stem implants (2.5%), but the patient remained asymptomatic. Kampner found a 9% incidence of fracture in his series of Sutter implant arthroplasty at an average follow-up of 7.4 years (7). There were no radiographic data to suggest bone degradation or alignment displacement of the implants. The three removed double-stem flexible hinged implants did not show an inflammatory reaction consistent with detritic synovitis.

The amount of radiographic implant destruction in this study was found to be in agreement with previous literature (4). However, Granberry et al., in their series of hinged Sutter implant arthroplasies, state that the subjective results were not significantly associated with radiographic evidence of failure of the implant (6). Granberry et al. noted that mechanical failure was revealed radiographically in 57% of the implants at a mean follow-up of 3 years (range, 24–64 months) (6). Furthermore, the authors reported that 29% (21 of 73) of implants fractured with only 43% (9 of 21) describing pain related to the implant fracture. Ninety-one percent (19 of 21) of the patients with fractured implants in the Granberry study were satisfied with the result of their surgery (6).

The authors' results were not consistent with Granberry et al. who found that the frequency of mechanical failure of the implant increased with the duration of implantation. Furthermore, this study had an average follow-up duration of 5.25 years longer than Granberry et al. The authors' objective findings were more indicative of the questionnaire findings due to the judicious patient selection leading to the limited activity levels of the patients. This study had an average patient age of 63 (range, 49–79) while Granberry et al. had an average patient age of 55 years (range, 23–78), thus illustrating the importance of age selection in the longevity of silicone implants.

The subjective results reported by the patients in this study were found to be consistent with previous studies in that the implant provided relatively fast relief of pain and acceptable cosmetic results (1–8). Only 18.5% (5 of 27) of patients said they were experiencing postoperative pain and 96% (26 of 27) said they would undergo the procedure a second time. However, there was some recurrence of asymptomatic bunion deformity in some of the patients diagnosed with rheumatoid arthritis. Nevertheless, patients were able to wear sensible shoegear without difficulty. The subjective results of this study were found to be successful and consistent with other current literature (4).