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Silastic replacement of the first metatarsophalangeal joint: historical evolution, modern concepts and a systematic review of the literature

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- Silastic implants for the first metatarsophalangeal joint (MTPJ) have been in use for over 50 years. Initial reports were associated with high failure rates leading to development of new designs that are currently in use.
- The aim of this article is to review the historical evolution and the outcomes of silastic implants for the treatment of end-stage OA of the first MTPJ. Databases were searched for studies reporting the outcomes of silastic implants for the first MTPJ. Various relevant search terminologies were used. Studies reporting the outcomes of metallic implants or arthrodesis were excluded.
- The literature search revealed 522 studies, of which 28 were included. Eight studies used single-stemmed implants and 20 used double-stemmed implants for their patients. Twenty-eight studies had a total of 2354 feet with silastic replacements in 1884 patients (1968 to 2003) with an average age of 53 years and the average follow-up was 85.3 months. There were a total of 5.3% (124 feet) failed prostheses. Improvement in pain was reported in 76.6% (1804 feet) with an average patient satisfaction rate of 84%. Radiological changes around the implants were found to be significantly higher with single-stemmed implants (30.3%) compared to the double-stemmed implants (14.7%) ($p < 0.05$).
- Significantly more single-stemmed implants failed (11%) than the double-stemmed implants (3.6%) ($p < 0.05$). Despite the initial reports of failed implants and complications, first- and second-generation silastic implants were associated with high patient satisfaction and pain improvement. Current literature lacks long-term outcomes of implants currently in use.

Keywords: first MTPJ replacement; silastic implants; silicone synovitis

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Introduction

Osteoarthritis (OA) of the first metatarsophalangeal joint (MTPJ) has been reported to affect between 35% and 65% of adults older than 65 years.[1] The pain and stiffness associated with osteoarthritis of the first MTPJ can lead to difficulties in activities of daily living and altered gait pattern.[2] End-stage arthritis or hallux rigidus has been well documented in the literature for more than a century, but a consensus on its management has not been established and, therefore, the surgical options remain controversial.[3] The traditional options for operative management of end-stage arthritis include excision arthroplasty, implant arthroplasty and arthrodesis. Excision arthroplasty has gradually become less popular with a limited value in current practice.[3–5] Arthrodesis, popularized by McKeever in 1952,[6] remains the gold standard and is the preferred choice due to its generally more predictable results, patient-reported outcomes and surgeons' familiarity with the procedure.[7] The options for replacement include a silastic (silicone) or a metallic implant. It follows the basic principles of any joint-replacement surgery aiming to reduce pain, restore joint kinematics, be long lasting and not be difficult to revise if it fails.[7] Initially, silicone implants were popular among surgeons and were utilized in patients who were too young and too active for joint replacement surgery.[8]

The initial reports on silastic implants showed higher rates of complication and early failure requiring revision,[9–12] leading to hesitancy among orthopaedic surgeons to continue using these implants. The current third-generation silastic implants were designed based on dynamic and static joint-specific anatomy. These have been in use since 1997 and are considered to be more durable than first- and second-generation implants.[13] The aim of this article is to review the historical evolution and the outcomes of silastic implants for the treatment of end-stage OA of the first MTPJ.

Historical evolution of silastic implants

For surgical management of hallux rigidus, following the unsuccessful results of acrylic methacrylate implants by Endler in 1951,[14] and the duralumin double-flanged design by Seeburger in 1964,[15] Swanson introduced his first-generation single-stemmed silicone implants in 1967 (Dow Corning Corporation, Midland, Michigan, United States).[16] He replaced the base of the proximal phalanx and used these implants as spacers in conjunction with Keller excision arthroplasty to maintain the normal weight-bearing property of the first MTPJ.[16] This implant relied on the viscoelastic properties of silicone to achieve dorsiflexion. Due to the early (within four years) and high failure rates (57%) of these implants,[17] Swanson designed, in 1974, a double-stemmed hinge made of silicone elastomer (second-generation) to offer a constrained design.[18] Sutter also created two different designs for double-stemmed implants with 15 degrees of built-in angulation in the sagittal plane that relied on the hinge to allow dorsiflexion.[19,20] Although early results (within three years) were promising in terms of pain improvement (69%),[21,22] there were three main concerns identified with these implants: limited plantarflexion compromising normal propulsion during gait cycle (30%), painful plantar keratosis under the metatarsal heads (69%) and periarticular osteophytes formation (53%).[21] Despite reports of patient satisfaction rates greater than 80% in the short term, these implants gradually started to fail because of excessive wear and the semi-constrained design.[23] Many complications with silastic prostheses emerged in the 1980s. Specifically noted complications included soft tissue inflammatory reaction simulating infection, silicone particulate synovitis, osteolysis, prosthetic wear and fragmentation with proximal migration of silicone particles causing inguinal lymphadenopathy.[12,21,24–30] Swanson believed that sharp bony edges and excessive shearing forces caused implant wear particles, which subsequently resulted in reactive synovitis and lytic bone changes.[18] This belief led to the development of bone liners, or grommets, to protect the implant from the sharp edges.[31] Many materials, including stainless steel and cobalt chrome, were researched for this purpose; however, titanium had the most favourable interaction at the grommet–bone interface. For this reason, titanium grommets have been available for use with silastic implants since 1985 to help provide more durability to silicone implants.[23,31–33] Despite the development of titanium grommets, reports of complications continue to surface, therefore few orthopaedic foot and ankle surgeons currently use these implants.[34]

The concept of the design of second-generation implants was to have the metatarsal head and the base of the phalanx purchase the ground during weight bearing. However, the fact that the metatarsal head rests on the sesamoid complex and stays in an elevated position with reference to the proximal phalanx base, was not taken into account.[35] The advancement of computerized technology led to the development of silicone elastomers of varying densities demonstrating better physical properties in critical areas of tensile strength and tear resistance.[13] This became the basis of third-generation silastic implants for the first MTPJ.[13]

Currently there are three silastic double-stemmed hinge implants available: the Swanson (Wright Medical® Technology Inc., Memphis, Tennessee, United States), Primus (Futura®, Tornier Inc., Bloomington, Minnesota, United States) and Sgarlato Gait (Sgarlato® Labs Inc., San Jose, California, United States).[23] The hinge portion becomes encapsulated with collagenous tissue which helps to provide stability after the collateral ligaments are sacrificed.[31,32] The Swanson hinge is available in sizes 0 through 7, the Primus hinge has four sizes and the Sgarlato hinge has three sizes [23].

Methodology

Search strategy

Literature search was conducted through the databases PubMed (MEDLINE), Ovid, Cochrane Library (Cochrane Systematic Reviews and Cochrane Bone, Joint and Muscle Trauma Group), Embase, ScienceDirect, Google Scholar and ISI Web of Knowledge. Articles published up to 2018 were searched but no historical time frame was applied for the start date of the search. The search was limited to articles available in the English language only.

Search terminologies

The National Library of Medicine's (NLM) Medical Subject Headings (MeSH) terms were selected and used along with text words. MeSH terms provided a consistent way to retrieve information where different terms had been used by authors for the same concept. The terminologies used included "Silastic replacement" OR "arthroplasty" OR "Swanson implant" for "first metatarsophalangeal joint" OR "big toe joint" OR "hallux rigidus".

Inclusion criteria

All types of the articles reporting the outcomes of single- or double-stemmed silastic implants were included. In the first phase the abstracts of the relevant articles were reviewed. In the second phase full texts of selected articles were obtained from electronic databases and in hard copy format. These included the articles on single-stemmed and double-stemmed silastic replacement implants used for the first MTPJ.

Exclusion criteria

Articles reporting the outcomes of metallic implants, ceramic implants, excision arthroplasty or arthrodesis of

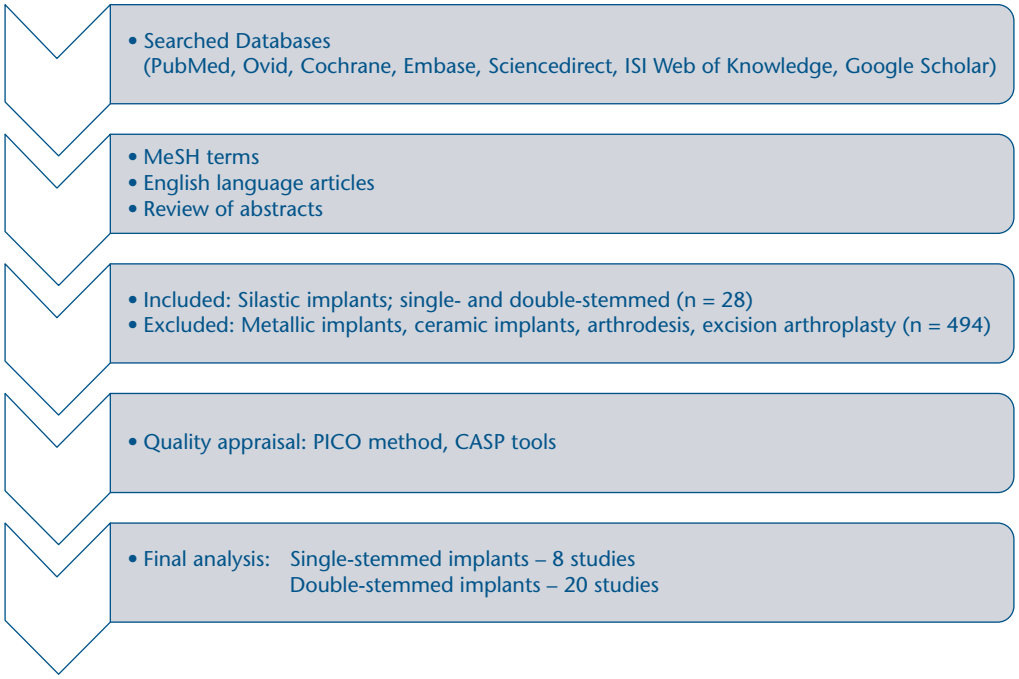

Fig. 1 Flow diagram of search methodology.

the first MTPJ were excluded. Any articles not available in the English language were excluded.

Quality appraisal

The PICO method (Population, Intervention, Comparison and Outcome) and CASP tools (Critical Appraisal Skills Programme) were used to appraise the quality of selected studies and analyse their results.[36,37] Chi-square tests were utilized to calculate p-values. A p-value of less than 0.05 was considered significant. Figure 1 presents the summary of search methodology.

Results

The initial search revealed 522 articles from the searched databases. Twenty-eight articles were selected for final inclusion, which were most relevant to the use of silastic implants. There was only one prospective study,[9] whilst all the others were retrospective studies. Twenty-eight studies had a total of 2354 feet with silastic replacements in 1884 patients. The studies took place and their outcome results were collected between 1968 and 2003. The average age of patients was 53 years among all the studies, the youngest patient being 15 years old and the oldest 82 years old in different studies. The average follow-up was 85.3 months. Among all the studies there were a total of 5.3% (124 feet) failed prostheses. Improvement in pain was reported in 76.6% (1804 feet). The average rate of patient satisfaction was 84%. There was a reported incidence of 3.6% (85 feet) of superficial infection, early inflammation of the wound and synovitis. Incidence of deep infection was 1.7% (40 feet). Radiological lucencies, cyst formation, bone resorption and osteophytes formation, of varying degree, were reported in 18.2% cases (429 feet). Implant fracture and fragmentation occurred in 4.3% cases (101 feet). Eighty-four implants (3.6%) required removal due to infection, fracture or persistent pain after surgery. The length of time from surgery to implant failure or removal was found to be highly variable among different studies.

The demographic data of the studies is listed in Table 1 and the outcomes are presented in Table 2. The comparative analysis of single- and double-stemmed implants is presented in Table 3.

Discussion

Joint replacement surgery can be described as very satisfying when it goes well, and a challenging nightmare when it goes wrong. The results of silastic replacement have been quite variable because of many factors involved, including the type of implant, the patient population, the age and functional abilities of the patient, the duration of follow-up and the presence of associated deformities of the foot.[38] Hallux rigidus is also associated with soft tissue contracture, which limits motion. As with any joint replacement, the postoperative range of motion is correlated with the preoperative range of motion. Motion

Table 1. Characteristics of individual studies

Author(s)	Year published	Single-stem (SS) or double-stem (DS)	Study period	No. of feet	No. of patients	Average age (years)	Age range (years)	Average follow-up (months)
Swanson[16]	1972	SS	1968–1971	73	55	54		
Wenger and Whalley[63]	1978	DS		86	69	51	20–76	24
Swanson et al[18]	1979	SS	1968–1978	165	165	53	15–79	48
Swanson et al[18]	1979	DS	1968–1978	105	105			30
Mölster et al[59]	1980	SS	1972–1978	26	25	56	22–71	47
Gudmundsson and Robertsson[60]	1980	SS	1974–1976	37	29	54	22–81	64
Cracchiolo et al[61]	1981	DS		159	159			45
Sethu et al[51]	1980	SS		77	62	50	20–80	60
Kampner[29]	1984	DS	1971–1982	103	71	56	N	89
Verhaar et al[27]	1989	SS	1980–1985	58	43	39	17–60	59
Laird[62]	1990	DS	1979–1987	228	158	38	16–72	48
Shankar et al[57]	1991	DS	1982–1986	106	89			28
Granberry et al[21]	1991	DS	1982–1986	73	52	55	23–78	
Cracchiolo et al[9]	1992	DS	1974–1987	86	66	53	27–72	70
Moeckle et al[50]	1992	DS	1980–1985	67	45	56	36–79	72
Rahman and Fagg[30]	1993	SS	1980–1990	78	55			
Helal[44]	1997	DS		203	156	50	27–73	132
Lemon and Pupp[45]	1997	DS	Up to 1986	66	50	55	24–78	161
Bonet et al[48]	1997	DS	1981–1989	40	27	63	49–79	99
Ashford et al[64]	2000	DS	1994–1998	22	20	61	48–80	33
Hanyu et al[43]	2001	DS	1983–1990	60	39			144
Bommireddy et al[47]	2003	DS	1981–1996	42	32	64	N	96
Harrison and Loughead[65]	2003	SS	1972–1983	13	11	52	N	212
Smetana and Vencálková[41]	2003	DS	1987–2001	108	97	50	17–82	57
Ter Keurs et al[42]	2011	DS	1984–2000	59	48	58	N	108
Morgan et al[40]	2012	DS	1988–2003	108	83	55	N	102
van Duijvenbode et al[46]	2013	DS	1981–1999	43	36	53	43–63	228
Kanzaki et al[49]	2014	DS	1982–1992	63	37			76

limitations can put stress on the prosthesis–bone interface and can potentially lead to failure.[39]

The available studies primarily relate to first- and second-generation silastic implants. There were very few studies which might have included some more-recent-generation implants (launched in 1997) for their patients,[40–42] as estimated from the study period. However, these studies did not clearly describe any change of implants after 1997. There was only one prospective study,[9] while all the others were retrospective. This meant these studies were subject to the risk of bias in multiple domains due to missing data, lack of control over the available data, lack of control group, lost follow-up and potential difficulties for patients in recalling their pre- and postoperative symptoms due to the years since surgery. There were only four studies which presented their results with more than 10 years of average follow-up,[43–46] seven studies had an average follow-up of more than five years,[9,29,47–51] while the remaining 17 studies had an average follow-up of less than five years. The study with longest follow-up duration had a mean follow up of 19 years (14 to 24 years).[46] Two studies used a questionnaire-based postal follow-up,[45,46] while all the others included a physical review of the patients using subjective and objective measures. Comparing the single- and double-stemmed implants, there were no significant differences between the average age, the average length of follow-up, the average patient satisfaction rates and the average improvement in pain level after surgery.

The incidence of superficial infection, wound-related inflammatory changes and synovitis was found to be slightly higher with single-stemmed implants (4.4%) compared to double-stemmed implants (3.4%), but this difference was not found to be significant. There are several reports in the literature demonstrating synovial reaction to particulate silicone rubber, most commonly describing these reactions in finger implants.[27,52–56] In addition to local inflammatory response, these studies also described a distant spread by vascular and lymphatic channels. Inflammatory response, particularly observed with single-stemmed implants, was believed to occur due to articulation of hemiarthroplasty implant with degenerated and incongruent joint surface of the metatarsal head.[56] Clinically, silicone synovitis presents as joint pain and inflammation with tender swelling of regional lymph nodes.[23] This usually requires removal of the implant, which resolves the symptoms.[28] The incidence of deep infection was found to be slightly higher in double-stemmed

Table 2. Outcomes of the included studies

Author(s)	Pain improved (feet) (*n*)	Patient satisfaction (%)	Superficial infection	Deep infection	Radiological lucencies/cysts/ resorption	Implant fracture/ fragmentation	Implants failed (*n*)	Implants revised (*n*)	Authors recommended
Swanson[16]	73		0	0	1		0	0	Yes
Wenger and Whalley[63]	84	86%	11	0	6	1	1	2	Yes
Swanson et al[18]	Majority		1	2	1		2	1	Yes
Swanson et al[18]	105			1	0	0	1	1	Yes
Mölster et al[59]	23	84%	2	1	24	0	2	2	Yes
Gudmundsson and Robertsson[60]	35	93%	14	0	34	5	2	2	Yes
Cracchiolo et al [61]	159		2	2	0	1	2	1	Yes
Sethu et al[51]	58	92%	5	1	2	1	1	1	Yes
Kampner[29]	81	79%		3		10	10	14	Yes
Verhaar et al[27]					34	1	49	4	No
Laird[62]	191	88%	6	0	2	0	3	3	Yes
Shankar et al[57]	93	88%	16	2	52	0	0	2	Yes
Granberry et al[21]	54	74%	1	1	39	21	4	4	Use with caution
Cracchiolo et al[9]	71	83%	5	2	32	8	4	4	Yes
Moeckle et al[50]	59	86%	3	2	6	7	3	3	Yes
Rahman and Fagg[30]		84%			56			3	No
Helal[44]	179	78%		14	2	6	20	20	Yes
Lemon and Pupp[45]	156	91%					0		Yes
Bonet et al[48]	34	85%	0	1	9	1	2	3	Yes
Ashford et al[64]	17	85%					1	1	Yes
Hanyu et al[43]		74%		2	9			4	Yes
Bommireddy et al[47]	38	75%	12	0	17	1	0	0	Yes
Harrison and Loughead[65]		85%	1	1	8	4	2	2	Yes
Smetana and Vencálková[41]	65	79%	6	2	17	6	6	1	Yes
Ter Keurs et al[42]	47	77%		3	30	0	3	3	Yes
Morgan et al[40]	82	85%	0	0	25	0	3	0	Yes
van Duijvenbode et al[46]	43	90%					3	3	Yes
Kanzaki et al[49]	57		0	0	23	28	0	0	Yes

implants (1.9%) compared to single-stemmed implants (0.95%) ($p > 0.05$). The reported incidence of silicone synovitis varies between 0% and 26% in different studies; however, it does not always necessitate removal of the implant.[9,47,57,58]

The incidence of radiological changes around the implants (lucent areas, cysts, resorption and osteophyte formation) was found to be significantly higher in patients with single-stemmed implants (30.3%) compared to the double-stemmed implants (14.7%) ($p < 0.05$). It is important to note that these changes do not necessarily correlate with patients' subjective satisfaction.[9,30,40,42,49,57,59,60] It is believed that satisfactory function continues even after radiographic deterioration because the implant acts as a spacer via encapsulation rather than a fixed hinge.[40] It is considered as the body's response to surgical intervention with the implant serving as a template for the proper deposition and alignment of encapsulating collagen tissues.[9,61]

The double-stemmed implants suffered from more fractures and fragmentations (4.9%) than the single-stemmed implants (2%) ($p < 0.05$). The incidence of implant fracture has been reported as between 1% and 11% in different studies,[16,21,22,49] however, implant fracture is not necessarily associated with a poor outcome. Significantly more single-stemmed implants failed (11%) than the double-stemmed implants (3.6%) ($p < 0.05$). However, the failed implants that required removal or revision were comparable in the two groups. This was due to the patients with low level of symptoms or not wishing to undergo any further surgery and can possibly be explained by the encapsulation mechanism described above. High frequency of implant failure was found to be related to the length of time the implant had been in place (four years or more).[21,51]

The authors of two studies recommended discontinuing the use of these silastic implants due to higher failure rates and significant complications.[27,30] Both studies used single-stemmed implants. Another study recommended the use of double-stemmed silastic implants 'with caution' in selected patients.[21] The authors of all the other studies recommended to continue using silastic implants as they provided higher satisfaction and improvement in pain levels related to hallux rigidus. However, a general consensus among most of the authors was to avoid using them in younger patients and those with higher physical demands to avoid early failure.[27,42,45,47,48,60]

Three studies assessed the use of titanium grommets with double-stemmed implants.[42,46,49] Two of these studies reported a higher incidence of radiological lucencies and implant failure without the use of grommets and

Table 3. Comparative analysis of single- and double-stemmed implants

Outcomes	Single-stemmed implants [*n* (%)]	Double-stemmed implants [*n* (%)]
No. of studies	8	20
Study period	1968–1983	1974–2003
No. of feet	527	1827
No. of patients	445	1439
Average age (years)	51 (15–80)	54.4 (16–82)
Average follow-up (months)	81.6	86.4
Improvement in pain	88.7%	88.4%
Average patient satisfaction	87.6%	82.5%
Superficial infection	23.0 (4.4%)	62.0 (3.4%)
Deep infection	5.0 (0.9%)	35.0 (1.9%)
Radiological lucencies/cysts/ resorption/osteophytes	160.0 (30.3%)	269.0 (14.7%) ($p < 0.05$)
Implant fracture/fragmentation	11.0 (2%)	90.0 (4.9%) ($p < 0.05$)
Prostheses failed	58.0 (11%)	66.0 (3.6%) ($p < 0.05$)
Prostheses removed	15.0 (2.9%)	69.0 (3.8%)

recommended that they be used routinely,[42,49] while the third study did not find any significant differences in the outcomes of implants with or without the use of grommets.[46]

During the early years, silastic implants were also used to treat degenerative first MTPJ problems associated with hallux valgus deformity. Studies that reviewed the results of these patients reported initial improvement in pain and deformity correction but a higher incidence of subsequent recurrence of hallux valgus deformity.[16,18,30,51,60,62,63] Therefore the use of silastic implants for treating hallux valgus deformity was not recommended.

This article is an effort to provide a systematic review of the available literature on the outcomes of silastic implants including very early reported studies. To the author's knowledge there is no such review available in the literature. The strengths include a detailed analysis of the currently reported and historical studies utilizing appropriate critical appraisal tools. The author believes that the results of this review will provide surgeons with a detailed account of the results and initial complications related to the design of the implants and a forward direction to conduct future studies. The weaknesses of this review include the fact that the available studies provided are only Level-IV evidence. Furthermore, these studies were analysed by only one author. However, with the use of relevant research tools, sufficient data were extracted and have been presented in a logical manner.

Conclusion

The available studies have shown that the silastic joint replacement can be a good alternative to arthrodesis in older and less active patients who wish to preserve the movements of their first metatarsophalangeal joint. Several historical studies have reported high satisfaction rates and subjective and objective improvements for treating hallux rigidus with the use of previous generations of silastic implants but were fraught with implant-related complications, in particular with the use of single-stemmed implants. Most of the available studies have smaller patient populations, shorter follow-up and flaws in study designs with a few reporting long-term results of the older implants for relatively larger numbers of patients. There is a lack of long-term follow-up of the current implants in the literature. Some of the implants in current use have no published results. More long-term prospective and randomized controlled studies with larger patient cohorts are needed to build a robust evidence base for the use of current generation of silastic implants as an alternative to the traditional arthrodesis procedure.

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