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Original Article

High Fracture Rate of AVANTA Silicone Implant Following Arthroplasty of the Thumb MCP Joint of Rheumatoid Arthritis Patients with Boutonniere Deformities

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We retrospectively investigated the mid-term outcomes of arthroplasty using the AVANTA silicone implant for thumb metacarpophalangeal (MCP) joints with boutonniere deformity in patients with rheumatoid arthritis (RA). This study involved 36 thumbs of 33 RA patients with a mean follow-up period of 5.1 years (range, 2.0-13.3). Postoperatively, the mean extension was significantly increased and the mean flexion was significantly decreased ($p<0.001$, $p<0.001$, respectively), resulting in the mean arc of range of motion (ROM) shifting in the direction of extension after surgery. Implant fracture was observed in 10 thumbs (28%), and 4 of these (11%) underwent revision surgery. The survivorship with implant fracture and revision surgery as endpoints were 73.4% and 91.8% at 5 years, respectively. The preoperative arc of ROM and the postoperative flexion range of the implant-fracture group were significantly greater than those in the no-implant-fracture group ($p=0.039$, 0.034, respectively). These results suggest the importance of patient education and careful rehabilitation to prevent excessive flexion. Overall, the AVANTA silicone implant showed a relatively high rate of implant fracture at our institute.

Key words: AVANTA silicone implant, boutonniere deformity, implant fracture, thumb metacarpophalangeal joint arthroplasty, rheumatoid arthritis

Patients with rheumatoid arthritis (RA) commonly have deformities of the fingers, and approximately 60-80% of patients have pain or dysfunction in the thumb [1]. As the thumb assumes approximately 50% of the hand's workload [1] and is essential for pinching and gripping motions in opposition to the fingers, treatment of thumb deformity is extremely important to restore hand function. In spite of the marked improvement of disease control of RA over the past two decades with biologic and targeted synthetic disease-modifying anti-rheumatic drugs, a significant population of RA patients still requires surgical intervention for deformed and disabled fingers to enable better hand function and improve quality of life [2].

Although metacarpophalangeal (MCP) joint arthroplasty with a silicone implant has been universally performed in the second through fifth digits worldwide, MCP joint arthrodesis is more commonly performed in the thumb [3]. Few studies have reported the outcomes

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of thumb MCP joint arthroplasty [4-7]. Silicone implant arthroplasty is performed for severe deformity of the MCP joint of the thumb and other fingers in Japan. In this study, we retrospectively investigated the mid-term outcomes of silicone implant arthroplasty for thumb MCP joints with boutonniere deformities, the most common thumb deformity in RA [8].

Patients and Methods

We retrospectively reviewed the records of RA patients who underwent primary MCP joint arthroplasty of the thumb using the AVANTA silicone implant (San Diego, CA, USA) at Okayama University Hospital between January 2009 and December 2019. In all cases, the AVANTA implant was used, and the AVANTA Preflex implant was not used. The current study was approved by the ethics committee of Okayama University Hospital (Approval Number: 2210-042), and informed consent was obtained from all patients.

During the study period, MCP joint arthroplasty was performed in 58 thumbs of 49 RA patients. One patient (1 thumb) died, and 6 patients (11 thumbs) were lost to follow-up within 2 years after the surgery. Two thumbs of 2 patients who underwent implant removal for infection within 2 years were excluded. Preoperative thumb deformity was classified according to the system described by Nalebuff [8]. Eight thumbs of 7 patients with type II (n = 4), type III (n = 2), or type IV (n = 2) deformity were excluded from the analysis, and the outcomes of the remaining 36 thumbs of 33 patients with boutonniere deformity were investigated in this study.

The characteristics of the patients included in this study are shown in Table 1. The mean age at the time of surgery was 62.7 ± 12.8 years, and the mean disease duration was 26.1 ± 11.2 years. The mean preoperative 28-Joint Disease Activity Score (DAS28) using C-reactive protein (CRP) was 2.62 ± 0. 90. The mean follow-up period was 5.1 (range, 2.0-13.3) years. In cases with instability in the interphalangeal (IP) joint of the thumb, IP joint arthrodesis was performed in addition to MCP arthroplasty (n = 14). Twelve thumbs underwent IP joint arthrodesis at the same time as MCP joint arthroplasty and 2 thumbs underwent it before the thumb surgery. Twenty-eight surgeries were performed at the same time as MCP joint arthroplasties of other fingers.

Clinical evaluation was based on the pre- and postoperative range of motion (ROM) of the MCP joint of the thumb, the grip and pinch strengths, the Disabilities of Arm, Shoulder and Hand (DASH) score [9], the Hand 20 score [10], and the Health Assessment Questionnaire-Disability Index (HAQ-DI) [11]. For radiographic evaluation, standard anteroposterior and oblique radiographs of the hand were taken at 3, 6, and 12 months in the first year after surgery and approximately every 12 months thereafter. The implants were categorized as intact, fracture, or severe deformity. Implant fracture was defined if at least one of the following three findings was present, as described by Bass *et al.* [12]: (1) when there were lucent lines or fragmentation of the midportion of the implant, (2) when there was translation in the coronal or sagittal plane of the base of the proximal phalanx relative to the neck of the metacarpal of more than one-half the diameter of either bone, and (3) when there was proximodistal overlap of the base of the proximal phalanx and the neck of the metacarpal of more than one-half the width of the midportion of the implant (Fig. 1). Severe deformity was defined as deformity in the implant not fulfilling the above three criteria.

Table 1 Baseline patient characteristics

Variable	Total 36 thumbs (33 patients)
Age (years)	62.7 ± 12.8
Female/male (n)	33/3
Disease duration (years)	26.1 ± 11.2
DAS28-CRP	2.62 ± 0.90
Follow-up period (years, range)	5.1 (2.0–13.3)
Dominant hand (n)	23
IP joint arthrodesis (n)	14
Larsen grade (n)	III: 15, IV: 17, V: 4
Implant size (n)	#20: 2, #30: 20, #40: 14

Values for age, disease duration and DAS28-CRP are expressed as mean ± SD.

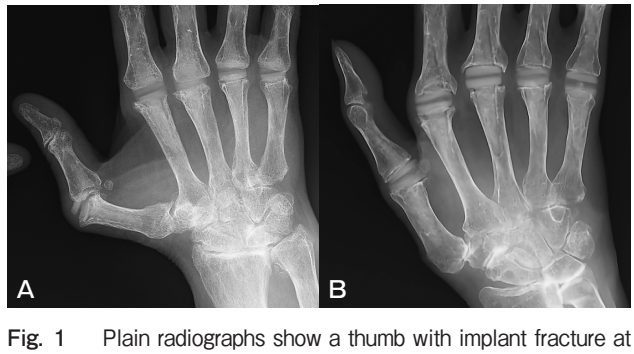

Fig. 1 Plain radiographs show a thumb with implant fracture at 4.1 years (**A**) and a thumb with no implant fracture at 7.2 years after surgery (**B**).

Subsidence of the implant was evaluated by the change or loss of metacarpophalangeal joint distance (MCJD) [12]. This value was obtained by measuring the distance in millimeters from the base of the proximal phalanx to the lines transacting the metacarpal neck both radially and ulnarly, and these two values were averaged. Finally, the difference of MCJD (ΔMCJD) was calculated from the two sets of radiographs taken immediately after surgery and at the time the postoperative outcome was evaluated. Postoperative outcomes were evaluated at the final follow-up examination or when an implant fracture was noted. Revision surgery was indicated for pain, decrease in function, or instability that posed problems for patients.

Kaplan-Meier analysis was used for survival analysis of implant fracture and revision surgery. To compare pre- and postoperative clinical outcomes, statistical analysis was performed by the Wilcoxon signed-rank test. The thumbs were classified into two groups according to the presence of implant fracture for comparison of characteristics and clinical outcomes by Mann-Whitney *U*-test and chi-squared test, as appropriate. All statistical analyses were performed using statistical software easy R [13] with values of $p < 0.05$ regarded as significant.

Results

The pre- and postoperative clinical outcomes are shown in Table 2. The mean extension was significantly increased from -58.6 ± 15.8 degrees preoperatively to -16.4 ± 12.9 degrees postoperatively, while the mean flexion was significantly decreased from 75.7 ± 12.8 degrees preoperatively to 52.0 ± 25.4 degrees postoperatively. As a result, the mean arc of ROM improved significantly in the direction of extension. The mean grip strength improved from 81.4 ± 47.2 mmHg preoperatively to 84.5 ± 45.1 mmHg postoperatively, and the mean pinch strength increased slightly from 1.54 ± 1.34 kg preoperatively to 1.73 ± 1.08 kg postoperatively, showing no significant difference between before and after surgery. The DASH score was changed from 44.8 ± 17.4 preoperatively to 42.6 ± 19.6 postoperatively, without a significant difference. The Hand20 score was significantly improved from 58.9 ± 21.1 preoperatively to 50.8 ± 22.3 postoperatively, but the HAQ-DI score significantly worsened from 1.17 ± 0.65 preoperatively to 1.47 ± 0.71 postoperatively.

Radiographic implant fracture was observed in 10 thumbs of 10 patients, and the mean period from surgery to implant fracture was 4.6 (range, 2.3-9.3) years. Most cases with an implant fracture showed recurrent boutonniere deformity. Severe deformity of the implant was observed in 7 thumbs of 7 patients. The mean ΔMCJD, an evaluation of subsidence, was 1.8 ± 1.3 mm. Revision surgery was performed in 4 of the 10 thumbs with implant fracture; revision arthroplasty with a new silicone implant was performed in 3 thumbs, and arthrodesis was performed in 1 thumb. Kaplan-Meier analysis showed survival rates of 73.4% (95% confidence intervals (CI), 51.6% to 86.5%) with implant fracture as the endpoint, and 91.8% (95% CI, 71.1% to 97.9%) with revision surgery as the endpoint at 5 years (Fig. 2 and 3).

Next, the thumbs were classified into two groups according to the presence of implant fracture. The major characteristics and clinical outcomes of both groups are shown in Table 3. The implant-fracture and no-implant-fracture groups had mean preoperative arcs of ROM of 24.8 ± 14.2 degrees and 13.8 ± 12.1 degrees, respectively, and mean postoperative flexion values of

Table 2 Pre- and postoperative clinical outcomes

	preoperative	postoperative	*P*-value
ROM extension (°)	−58.6 ± 15.8	−16.4 ± 12.9	< 0.001
ROM flexion (°)	75.7 ± 12.8	52.0 ± 25.4	< 0.001
ROM arc (°)	16.9 ± 13.5	35.6 ± 22.5	< 0.001
Grip strength (mmHg)	81.4 ± 47.2	84.5 ± 45.1	0.83
Pinch strength (kg)	1.54 ± 1.34	1.73 ± 1.08	0.43
DASH score	44.8 ± 17.4	42.6 ± 19.6	0.16
Hand 20 score	58.9 ± 21.1	50.8 ± 22.3	< 0.01
HAQ-DI score	1.17 ± 0.65	1.47 ± 0.71	< 0.01

Values are expressed as mean ± SD.
P values < 0.05 are significant by the Wilcoxon signed-rank test.

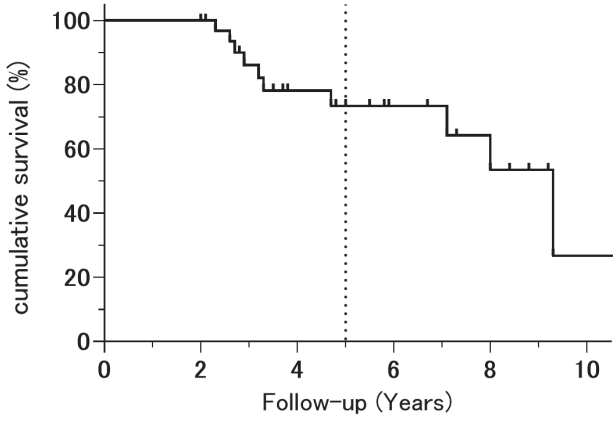

Fig. 2 The 5-year Kaplan-Meier survival rate with implant fracture as the endpoint was 73.4%.

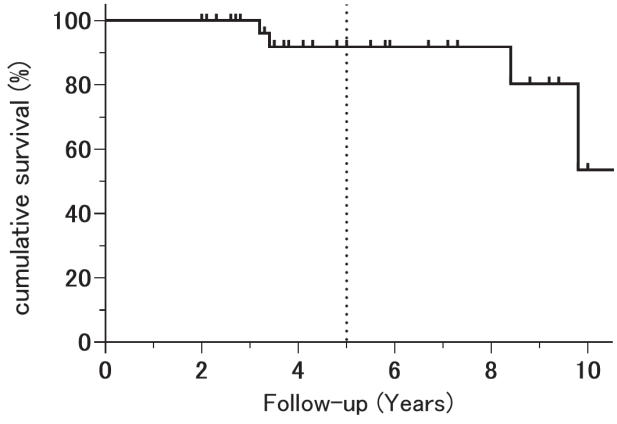

Fig. 3 The 5-year Kaplan-Meier survival rate with revision surgery as the endpoint was 91.8%.

Table 3 Baseline characteristics and clinical outcomes of the thumbs classified into two groups according to the presence of implant fracture

	Implant fracture (+) (n=10)	Implant fracture (−) (n=26)	*P*-value
Age (years)	62.9 ± 8.3	62.6 ± 14.2	0.85
Female/male (n)	9/1	24/2	1
Disease duration (years)	23.3 ± 9.0	27.2 ± 12.0	0.33
DAS28-CRP	2.48 ± 1.09	2.68 ± 0.83	0.72
Dominant hand (n)	7	16	0.72
IP joint arthrodesis (n)	2	12	0.26
Follow-up period (years)	4.6 ± 2.6	4.7 ± 2.8	0.97
Larsen grade (n)	III: 5, IV: 4, V: 1	III: 10, IV: 13, V: 3	0.87
Implant size (n)	#20: 0, #30: 7, #40: 3	#20: 2, #30: 13, #40: 11	0.60
ΔMCJD (mm)	1.6 ± 1.1	1.9 ± 1.3	0.66
Preoperative			
ROM extension (°)	−53.0 ± 13.6	−60.8 ± 16.3	0.14
ROM flexion (°)	77.8 ± 13.8	74.6 ± 12.5	0.38
ROM arc (°)	24.8 ± 14.2	13.8 ± 12.1	0.039
Grip strength (mmHg)	72.6 ± 46.6	85.0 ± 47.9	0.53
Pinch strength (kg)	1.54 ± 1.02	1.54 ± 1.49	0.60
DASH score	46.9 ± 20.9	44.0 ± 16.2	0.50
Hand 20 score	60.5 ± 25.0	58.3 ± 19.9	0.64
HAQ-DI	1.29 ± 0.63	1.12 ± 0.66	0.37
Postoperative			
ROM extension (°)	−20.6 ± 15.7	−14.8 ± 11.6	0.22
ROM flexion (°)	65.5 ± 22.2	46.8 ± 25.0	0.034
ROM arc (°)	44.9 ± 22.9	32.1 ± 21.8	0.15
Grip strength (mmHg)	75.7 ± 43.9	88.0 ± 46.0	0.78
Pinch strength (kg)	1.76 ± 0.96	1.72 ± 1.15	0.81
DASH score	49.7 ± 22.4	39.9 ± 18.1	0.17
Hand 20 score	59.3 ± 25.9	47.5 ± 20.3	0.09
HAQ-DI	1.74 ± 0.85	1.37 ± 0.63	0.16

Values are expressed as mean ± SD.
The follow-up period was from surgery to implant fracture in the implant-fracture group.
P values <0.05 are significant by the Mann–Whitney *U*-test and the chi-squared test.

65.5 ± 22.2 degrees and 46.8 ± 25.0 degrees, respectively. The mean preoperative arc of ROM and the mean postoperative flexion range of the implant-fracture group were significantly greater than those of the no-implant-fracture group ($p = 0.039$, 0.034, respectively). There were no significant differences in the other items.

A receiver operating characteristic (ROC) curve, constructed to assess the postoperative extension angle to predict implant fracture, yielded an area under the curve (AUC) of 0.73 (95% CI, 0.53-0.92). The cut-off value of 74 degrees established from the ROC curve had a sensitivity of 60% and a specificity of 88%. In this study, among 9 thumbs with 74 degrees or greater of postoperative flexion, implant fracture occurred in 6 thumbs (67%).

Discussion

For a destroyed thumb MCP joint, arthrodesis is recommended as the gold standard for patients with monoarticular involvement whereas arthroplasty is recommended for patients with extensive involvement of the CMC or IP joint as well as the MCP joint [14]. Arthrodesis for two or more of the IP, MCP, and CMC joints of the thumb makes it difficult to oppose the thumb to the other fingers, resulting in a decline in activities of daily living. Arthroplasty allows extra motion of the MCP joint, which reduces the loads on the IP and CMC joints.

Implants made of silicone have been widely used in finger arthroplasty. Silicone implants have been developed since the 1960s and were first reported by Swanson in 1972 [15]. However, while arthroplasty is commonly performed in the second through fifth digits, few studies have reported the long-term outcomes of thumb MCP joint arthroplasty with a silicone implant. In our review of the literature, there have been only four studies reporting mid- or long-term outcomes of thumb MCP joint silicone implant arthroplasty (Table 4).

Swanson and Herndon [4] reported the first case series of thumb MCP joint arthroplasty in 44 thumbs of 34 patients. Implant fracture occurred in 5 thumbs, and the mean period to implant fracture was 2.8 years. Four thumbs required revision surgery. Arthrodesis was performed in 2 thumbs because of implant fractures, and 2 thumbs received repeated arthroplasty, 1 because of an implant fracture and the other because of flexion deformity recurrence. Figgie *et al*. [5] reported postoperative results for 43 thumbs of 38 patients with RA. Eleven patients underwent IP joint arthrodesis at

Table 4 Previous publications concerning thumb MCP joint arthroplasty with silicone implants

Author (s)	Follow-up period (years) (range)	Implant	Thumbs (n)	Thumbs with RA (n) (%)	Implant fracture (n) (%)	Period to implant fracture (years)	Revision surgery (n) (%)
Swanson *et al*. (1977) [4]	2.5 (2.0–6.5)	Swanson	44	42 (95%)	5 (11%)	2.8	4 (9%) Arthrodesis: 2 Removal implant: 2
Figgie *et al*. (1990) [5]	6.5 (3.0–13)	Swanson	43	43 (100%)	0 (0%)		1 (2%) Arthrodesis: 1
Nemoto *et al*. (2018) [6]	3.7	Swanson flexible hinge toe implant	56	56 (100%)	0 (0%)		1 (2%) Removal implant: 1
Cefalu *et al*. (2019) [7]	5.8 (4.4–7.1)		20	12 (60%)			2 (10%) Arthroplasty with implant: 1 Arthrodesis: 1
Our study	5.1 (2.0–13.3)	AVANTA	36	36 (100%)	10 (28%)	4.6	4 (11%) Arthroplasty with implant: 3 Arthrodesis: 1

Values for follow-up period are expressed as mean (range).

the time of MCP joint arthroplasty for malalignment and instability. Further, in 24 cases, arthroplasty of the MCP joint was performed in the index fingers, which is important for pinching movements. There was no implant fracture, but there was bone resorption in 5 thumbs and bony sclerosis around the implant stems in 27 thumbs. One thumb required implant removal and MCP joint arthrodesis for instability. Nemoto *et al.* [6] reported a retrospective case series study of 56 thumbs with boutonniere deformities from RA. In addition to MCP joint arthroplasty, IP joint arthrodesis was performed for 20 thumbs. There were no implant fractures. One thumb required implant removal due to postoperative infection. More recently, Cefalu *et al.* [7] reported on a series of 20 thumbs of 18 patients. Eight thumbs underwent concomitant MCP joint arthroplasty of the non-thumb digits, and 6 thumbs underwent simultaneous IP joint arthrodesis. Implant fracture was not mentioned. Among 3 thumbs with planned revision surgery, 2 had preoperative risk factors, 1 with post-traumatic instability and failed fusion, and the other with significant preoperative instability and IP joint hyperextension deformity.

The current study investigated the clinical results of AVANTA silicone implant arthroplasty for thumbs of RA patients with boutonniere deformities. The rate of implant fractures was higher than those reported in the previous literature while the proportion requiring revision surgeries was comparable.

The AVANTA implant, also known as the Sutter implant, was introduced in 1987. Similar to the Swanson implant, the AVANTA implant relies on fixation by a biological "encapsulation process" [15]. The silicone implant is only a dynamic spacer to maintain alignment and prevent its excessive movement. If the implant does not move more than a 1-2 mm distance, a firm fibrous soft-tissue capsule forms surrounding the implant as the body's innate response to foreign substances. This fibrous capsule has the character of a ligamentous structure and has the benefit of improving joint stability. The implant also undergoes a slight gliding motion within the intramedullary canals during extension and flexion. This is called a piston effect and improves the life of the implant. The AVANTA implant has a rectangular-shaped hinge with a more palmar location than the Swanson implant. Therefore, the AVANTA implant has a more palmar center of rotation, which theoretically should reduce the extension deficit [16]. While the Swanson implant stem meets the hinge with a gentle curve, the AVANTA implant stem does so at a sharp angle and therefore may be more vulnerable to fractures in this area [17]. A study of the Swanson implants in the second through fifth digits showed that 28% of implants had broken in 102 arthroplasties at a mean follow-up of 10 years [18]. On the other hand, a study of the AVANTA implant reported an implant fracture rate of 45% when followed for more than 3 years [12]. Goldfarb *et al.* [19] reported that at a mean follow-up of 9 years, 31 (52%) out of 60 AVANTA implants and 99 (67%) out of 148 Swanson implants were broken. The implant fracture rate of the AVANTA implant was equal to or higher than that of the Swanson implant.

In this study, the preoperative arc of ROM and the postoperative flexion range of the implant-fracture group were significantly greater than those of the no-implant-fracture group. Cefalu *et al.* [7] reported that preoperative MCP joint instability is a risk factor for failure of surgery. In cases of severe boutonniere deformity, with palmar dislocation of the proximal phalanx and flexion contracture of the MCP joint, the increasing arc of ROM from the flexed position may increase instability.

The AVANTA implant is designed to provide a greater increase in the ROM, but in turn is more structurally vulnerable to implant fracture compared with the Swanson implant; indeed, the increasing flexion range may be a risk factor. Iwamoto *et al.* [20] reported that postoperative MCP flexion range was one of the risk factors for early implant fracture in silicone MCP joint arthroplasty although their study focused on the second through fifth digits. In the current study, the postoperative flexion range of the implant-fracture group was significantly greater than that of the no-implant-fracture group. Postoperative outcomes were evaluated when an implant fracture was noted in the implant fracture group. It is possible that the postoperative flexion range increased as a result of implant fracture. However, in 7 of the 10 thumbs we evaluated, the mean most recent flexion range before the notice of implant fracture showed a mean of 60.3 ± 11.8 degrees and the flexion range when we noted implant fracture showed a mean of 62.9 ± 22.9 degrees; the postoperative flexion range was not significantly greater than the most recent flexion range before the notice of implant fracture ($p = 0.53$ by Wilcoxon signed-rank test). Further, joint

instability was not noted in the clinical findings. The silicone implant is only a dynamic spacer; joint stability is achieved by the soft-tissue encapsulation process. It is possible that the implant fracture did not immediately affect joint instability and an increasing postoperative flexion range posed a risk for implant fracture in the thumbs as previously reported for MCP joints of the second through fifth digits. In the AUC analysis, the cut-off value for risk of implant fracture was the postoperative flexion range of 74 degrees.

In the current study, the mean postoperative thumb ROM was -16 degrees of extension and 52 degrees of flexion. According to the Japanese Orthopaedic Association and the Japanese Society of Rehabilitation Medicine, the mean ROM of the thumb MCP joint in healthy individuals is 10 degrees of extension and 60 degrees of flexion, although few situations in daily life require deep flexion of the thumb. Hume *et al*. [21] reported that the functional ROM of the thumb MCP joint is -10 degrees of extension and 32 degrees of flexion to perform activities of daily living, while for MCP joints of other fingers the functional ROM is -33 degrees of extension and 73 degrees of flexion. As excessive flexion of the MCP joint may be a risk factor for implant fracture, we have modified the postoperative schedule of rehabilitation as follows: Immediately after surgery, only MCP joint extension exercises are performed. The MCP joint flexion exercises are performed beginning two weeks after surgery. At this time, aggressive flexion exercises are not performed and the passive flexion angle is limited to 40 degrees. IP joint active flexion exercise is recommended with the MCP joint held in extension. Then, the opposition of the thumb and pinching are trained. The goal of rehabilitation is to obtain a slightly stiffer MCP joint with flexion of 30 to 40 degrees, which is sufficient for daily living. It is also important to educate patients to reduce opportunities for MCP joint flexion greater than 40 degrees.

It should be noted that not all cases of implant fracture require revision surgery. The AVANTA implant, similar to the Swanson implant, is only a dynamic spacer; joint stability is achieved by the encapsulation process, by which a fibrous capsule is formed around the joint. Even if implant fracture occurs, it will not always cause joint instability or functional disability. In this study, revision surgery was required in 4 thumbs, although implant fracture occurred in 10 thumbs. In these 4 thumbs, patients had trouble with pain and functional disability, and revision surgery was performed at the same time as surgery on other fingers.

This study had several limitations. First, the study was retrospective, and the sample size was small. The number of thumbs was underpowered to perform multiple logistic regression analysis, and the risk factors for implant fracture could not be analyzed statistically. Second, we only evaluated the thumbs and did not consider the index through little fingers. In 28 out of 36 thumbs, surgery was performed at the same time as surgery on other fingers. In these cases, the other fingers may have affected the score, although the Hand20 score was significantly improved after surgery. Third, in comparing this study with previous literature, the type of implant was different though all were made of silicone. Further, the clinical background of patients with RA was different, complicating any direct comparisons.

In conclusion, the mid-term clinical outcomes of MCP joint arthroplasty with the AVANTA silicone implant for boutonniere deformity of the RA thumb showed a relatively high rate of implant fracture. The increased preoperative arc of ROM might be a risk factor for implant fracture. Thumb MCP joints with preoperative instability should be followed carefully. Moreover, the postoperative flexion range was greater in the implant fracture group. With regard to the postoperative flexion range, patient education and careful rehabilitation are important to prevent excessive flexion in the acquisition of functional ROM.

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