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Seven Year Outcomes of the Silicone Arthroplasty in Rheumatoid Arthritis (SARA) Prospective Cohort Study

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Abstract

Objective—Rheumatoid arthritis (RA) causes destruction of the metacarpophalangeal (MCP) joints leading to hand deformities, pain, and loss of function. This study prospectively assessed long-term functional and health-related quality of life outcomes in RA patients with severe deformity at the MCP joints.

Methods—RA patients between the ages of 18–80 with severe deformity at the MCP joints were referred to one of the three study sites. Subjects who elected to undergo silicone metacarpophalangeal joint arthroplasty (SMPA) while continuing with medical management were followed in the SMPA cohort. Subjects who elected to continue with medical management alone without surgery were followed in the non-SMPA cohort. Objective measurements included grip and pinch strength as well as arc of motion, ulnar drift, and extensor lag of the MCP joints. Patient reported outcomes included the Michigan Hand Questionnaire (MHQ) and the Arthritis Impact Measurement Scales questionnaire. Radiographs of SMPA implants were assessed and graded as intact, deformed, or fractured.

Results—MHQ scores showed large improvements post-SMPA, and baseline-adjusted expected outcomes in the SMPA group were significantly better at year seven in function, aesthetics, satisfaction, and overall score compared to non-SMPA. SMPA subjects did not improve in grip or pinch strength, but achieved significant improvement and maintained the improvement long-term in ulnar drift and extensor lag.

Conclusion—Benefits of the SMPA procedure are maintained over seven years with low rates of implant fracture or deformity. Non-SMPA patients remained stable in their hand function over the seven year study duration.

Rheumatoid arthritis (RA) is a debilitating disease affecting 1% of the United States population over the age of 18¹ and causing 94% of people with RA to suffer from at least one hand or wrist symptom after two to four years of disease duration. The most frequently described symptoms are pain, hand stiffness, muscle weakness, paresthesia, and limited ability to form a fist.² Joint destruction of the hands adversely affects quality of life.^{3–5} The need for joint surgery is a marker of disease severity⁶ and surgery has been shown to predictably correct deformity, prevent flexion contraction, alleviate pain, improve function, and enhance quality of life.^{7,8} However, surgery is often regarded as a failure of medical treatment⁹ and is usually only considered in the late stages of RA.^{5,7,10} Although RA treatment strategies aim to prevent joint destruction before the need for surgery, this is not always possible and the finger joints may not respond to conventional RA medications.¹¹

Silicone metacarpophalangeal (MCP) joint implants were introduced almost 50 years ago to correct rheumatoid hand deformity.¹² Silicone metacarpophalangeal joint arthroplasty (SMPA) replaces the destroyed MCP joints, thereby placing the ulnarly subluxed fingers back onto the hand. The one-piece hinged design of the Swanson implant is preferred for, and most widely used in, RA patients. Despite widespread use, a systematic review of silicone MCP joint arthroplasty showed that outcomes data were lacking for this procedure.¹³ Studies were primarily retrospective, had small samples, did not use standardized subjective outcomes measures, and did not compare results to a control group. The lack of high-quality surgical outcomes data for rheumatoid hand procedures serves as a barrier for surgical referrals from rheumatologists.¹⁰

We have conducted a long-term, prospective, multi-center outcomes study of silicone MCP joint arthroplasty. This study has recruited the largest cohort to date of RA patients with severe deformity at the MCP joints. Subjects have been followed prospectively to assess long-term functional and health-related quality of life outcomes. The purpose of this study is to describe the final outcomes assessment (7 years) of RA patients who underwent SMPA compared to a group of control patients who had equal hand deformity, but were treated only medically. We will assess whether the outcomes of this procedure are maintained in the long-term and describe any adverse events.

Patients and Methods

Patients were recruited to a prospective, multicenter, international National Institutes of Health (NIH)-funded study, the Silicone Arthroplasty in Rheumatoid Arthritis (SARA) study. The objective of this study was to evaluate a cohort of RA patients with severe MCP

joint deformity who elect to have SMPA as well as medical management (SMPA group) compared to patients who elect to be medically-managed alone without SMPA (non-SMPA group). There were three study sites: University of Michigan (UM) (Ann Arbor, MI), Curtis National Hand Center (CH) (Baltimore, MD), and Pulvertaft Hand Centre (PH) (Derby, England), three sites that are internationally recognized for their expertise in treating the rheumatoid hand. All aspects of the study were approved by the institutional review board at each respective study site. All study sites followed a standardized protocol for surgery, post-operative hand therapy, and study assessments, as outlined in a Manual of Operating Procedures. Study participation did not influence medical management and was the sole responsibility of each patient's treating rheumatologist. The University of Michigan was the data coordinating center and this study underwent review via a NIH-appointed Observational Safety and Monitoring Board every 6 months. The study had a target enrollment of 190 (85 in each group) to detect with 90% power a 0.6 standard deviation between-group difference in the function scale of the Michigan Hand Outcomes Questionnaire at one year (primary endpoint) with 0.01 significance level, assuming 10% dropout in the first year.

Eligibility Criteria

A detailed protocol has been previously described.⁵ Inclusion criteria were: 1) diagnosis of RA by a rheumatologist, 2) age 18–80 years, and 3) severe deformity at the MCP joints determined by combined ulnar deviation and extensor lag 50 degrees on average for each finger. Exclusion criteria were: 1) severe medical conditions preventing safe elective surgery, 2) existing tendon rupture or swan-neck boutonniere deformities requiring surgical correction, 3) prior MCP joint arthroplasty on the study hand, and 4) initiation of disease-modifying anti-rheumatic drugs within 3 months of enrollment. Consecutive patients identified by their treating rheumatologist as having RA and having severe deformity at their MCP joints were referred to one of the study sites for consultation by a hand surgeon (KCC, FDB, or EFSW) who performed all SMPA procedures at his study site. A study coordinator at each site described the study to eligible patients and obtained consent. Patients elected to be in the SMPA or in the non-SMPA group as well as on which hand they wanted to have surgery (SMPA group) or on which hand they would hypothetically have surgery (non-SMPA group). Patients in the SMPA group were eligible to have their other hand operated on one year after surgery of their first hand, if they so elected. Patients in the non-SMPA group were eligible to “crossover” into the SMPA group one year after study enrollment, if they so elected.

Clinical Measures

Patients were evaluated at enrollment, 6 months, 1 year, and yearly thereafter up to 7 years. Follow-up for SMPA patients occurred on the anniversary of the surgery date. Patients unwilling or unable to return to the study site for complete functional assessments were asked to complete study questionnaires from home. Functional assessments included grip strength, lateral pinch, 2-point pinch, 3-point pinch, and Jebsen-Taylor Test (JTT). The JTT is a timed test simulating ability to complete 7 activities of daily living.¹⁴ A designated hand therapist at each study site used a standardized protocol to complete range of motion measurements including ulnar drift and extensor lag at the MCP joints. Arc of motion at the MCP joints was calculated as absolute flexion angle minus extension lag angle. For

example, if a patient had an absolute flexion angle of 80 degrees, but an extension lag of 16 degrees, his/her arc of motion would be 64 degrees. Hyperextension of the MCP joint was treated as zero extension in the calculation. Ulnar drift, extensor lag and arc of motion are each reported as the average respective measurement of all four fingers of the study hand at the MCP joint.

Patient Reported Outcomes

The Michigan Hand Questionnaire (MHQ) is a validated, hand-specific legacy questionnaire in hand surgery that has previously been used in evaluating RA.^{5,15–21} We used the function score of the MHQ as the primary outcome measure, for which a standardized effect size of 0.6 was considered a clinically meaningful between-group effect size in RA patients based on pilot data and expert consensus. Based on the current study data, the intra-person correlation of the function score was high ($\rho = 0.73$) across the repeated assessments from year 1 to 7. The Arthritis Impact Measurement Scales (AIMS2) questionnaire is a health status questionnaire specifically designed to measure the global health of RA patients.²²

Radiograph Assessment

Radiographs from SMPA subjects were independently assessed for implant fracture by two of the study hand surgeons (FDB, EFSW). Results were compared, and consensus was reached on any differing values. The implant from each finger was graded as intact, severely deformed, or definite fracture, based on established criteria.²³ A definite fracture had to meet all three of the following criteria: 1) lucent lines or fragmentation of the midportion of the implant, 2) 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) 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. Severely deformed implants were those that did not fulfill all 3 criteria for a definite fracture, and intact implants were those that did not fulfill any criteria for a definite fracture.

Statistical Analysis

Descriptive summary statistics of baseline variables were calculated and compared between the SMPA group and the non-SMPA group. At each follow-up visit, baseline characteristics were compared between those subjects who were losses to follow-up at and beyond that time versus those subjects who were not. For two non-SMPA subjects who crossed over to the SMPA group after one year, outcome data were censored after their study hand was treated with SMPA. Crude means and standard deviation of all outcome measures were calculated at baseline and at 3, 5 and 7 years after enrollment. For each outcome measure, a random-effects regression model with subjects as random intercepts was used to compare baseline-adjusted outcomes between the study groups over the 7 year follow-up period. Specifically, each outcome measure models used all follow-up values of the outcome measure as the dependent variable, and an indicator for the SMPA group, follow-up years, and an interaction term of follow-up year by SMPA group indicator as independent variables. Each model included all study participants with at least one follow-up value for the outcome measure. Because of the observed baseline differences between the two groups, each model was adjusted for baseline values of the outcome measure, baseline age, sex, baseline severity

(dichotomized as severe versus not based on degree of deformity), race (white versus not), education (high school and lower versus higher), use of biologic medication at each follow-up time, and study site as fixed effects. Predicted marginal means between study groups at 3, 5 and 7 years after enrollment, adjusting for baseline difference, were compared based on this model. Owing to large selection bias, baseline-adjusted estimates can give potentially misleading estimates. For our MHQ measures showing positive outcomes, we therefore also obtained average treatment effect on the treated (ATT) using both propensity matching and inverse-probability-of-treatment-weights where propensities are estimated using a separate logistic regression model for selecting SMPA using baseline predictors.²⁴ The ATT estimates the average benefit from SMPA in those who were treated as a result of SMPA. To further account for missing data, including missing outcomes due to losses to follow-up and deaths, we also attempted multiple imputation methods, but imputation that adequately address the complicated nature of our data did not reach convergence. All analyses were performed using Stata 14.0 (StataCorp LP, College Station, TX).

Results

Subject enrollment began in 2003 and ended in 2008. At baseline, 73 SMPA and 97 non-SMPA subjects were enrolled from the three study sites (Figure 1). Prior to the seven year follow-up, 17 (10%) subjects died and 15 (9%) subjects withdrew. Patients who withdrew from the study stated that they no longer wanted to participate/return for measurements/complete questionnaires. Follow-up data were collected at 3, 5 and 7 years after enrollment, respectively, from 75% (46/61), 50% (28/56) and 43% (23/53) of the active SMPA subjects and 81% (72/89), 65% (56/86) and 61% (52/85) of the active non-SMPA subjects. Not all participants provided complete outcome data at each assessment time. Two non-SMPA subjects crossed over to SMPA by year 2 and received surgery on their study hand, and 11 patients in the SMPA group chose to have surgery on their opposite hand at least one year after having surgery on their first hand. Generally, at each follow-up time, patients with higher MHQ summary scores at baseline and White race were less likely to miss follow-up assessments, and SMPA group subjects and males were more likely to miss follow-up assessments.

Table 1 provides the demographic data of the enrolled study sample. There were no significant differences at baseline in age, race, or income between the SMPA group and the non-SMPA group. Men and those with more than high school education were significantly more likely to opt for the non-SMPA group than the SMPA group. When compared by site and country, subjects did not differ by age ($p=0.63$), gender ($p=0.21$) or baseline severity ($p=0.98$), but they differed in race ($p<0.01$), education ($p<0.001$) and income ($p=0.002$). The directions of the differences were expected. Specifically, race was more similar between UM and PH with Whites being more than 90%, but only 61.5% were Whites in CH. Income and education were similar between the two US sites but both were significantly lower at the UK site.

Table 2a shows the results from the MHQ as well as the AIMS2. At baseline, the non-SMPA group had better scores in all domains of the MHQ compared to the SMPA group. Over the seven years of follow-up, although the SMPA group generally did not have better MHQ

scores than the non-SMPA group, the SMPA group showed large improvement that was maintained; for example, the crude change at year seven in function score was 0.61 SD (=14/23). At year seven, the baseline-adjusted comparisons showed significantly better predicted outcomes for SMPA patients in function, aesthetics, satisfaction, and overall summary score (Table 2b). The ATT estimates of MHQ function showed significant beneficial effect until year five, with an estimate of 9.3 (95% CI=1.2, 17.5; $p=0.03$), but the ATT estimates showed a reduction in benefit at years six and seven, with a smaller ATT estimate for function at year six (8.1, 95% CI= -0.4, 16.6; $p=0.06$) and little average benefit from SMPA at year seven in those who were treated (4.2, 95% CI = -3.9, 12.2; $p=0.31$). ATT estimates of other MHQ domains showed similar results with generally diminishing benefit after year 5. In the AIMS2, at baseline, all domains except Social Interaction were significantly worse in the SMPA group. At the three year follow-up, the scores for all of the domains improved for the SMPA group, but the scores for the non-SMPA group tended to remain similar to the baseline scores. Over time, the non-SMPA group continued to score better (lower) than the SMPA group in all domains, but the adjusted between-group differences were not significant at any follow-up.

For the objective measurements (Table 3a), non-SMPA patients had significantly stronger grip, 2-point, and 3-jaw pinch strength at baseline compared to SMPA patients (all $p<0.05$). During the follow-up periods, the SMPA group maintained their baseline level of strength in all measures, but the pinch strengths somewhat diminished in the non-SMPA group, resulting in no significant baseline-adjusted between-group differences during follow-up times, except the between-group difference in grip strength at three years.

Of the objective measures, at baseline, ulnar drift, extensor lag, and arc of motion all showed worse or significantly worse outcomes in the SMPA group than the non-SMPA group (Table 3a). Over the seven years of follow-up, however, the SMPA group consistently showed better outcomes than the non-SMPA group for each of these measures. Even at year seven, ulnar drift, extensor lag, and arc of motion all showed better outcomes in crude means for the SMPA group than the non-SMPA group, and the significantly better outcomes associated with the SMPA group remained for each measure even after adjustments (Table 3b).

In SMPA patients, one mild and three moderate implant-specific adverse events (AEs) occurred during the study. The mild AE was a k-wire infection from PIP joint fusion. The k-wire was removed and the infection resolved with antibiotics. Moderate AEs included one subject who required new joint replacement after ulnar deviation of the fingers 2 years after the original SMPA, one subject who had a dislocated implant of the little finger a few weeks after the original SMPA that required replacement, and one subject who had sepsis of the MCP joints 6 years after the original SMPA and required replacement of 2 of the implants. The majority of implants remained intact at each assessment period (Table 4).

Discussion

In this long-term assessment of the SMPA procedure, we found that benefits of the procedure, including improvement in function, aesthetics, ulnar drift, and extensor lag, were maintained at the seven year postoperative follow-up. Non-SMPA subjects generally

remained stable in their hand function over the seven year study duration. When the SMPA cohort was compared with the non-SMPA cohort, the covariate-adjusted difference showed significant benefits associated with SMPA hand outcome as measured by the MHQ function, aesthetics, and satisfaction scores, with no measures showing significantly better outcomes for the non-SMPA group. Although the average treatment effect estimate (ATT estimate) showed a decline over time for the average benefit from SMPA in those treated, the function score benefit as shown by the ATT estimate remained significant at year five. One of the great benefits of this study is the ability to educate patients and providers in the long-term outcomes of SMPA as well as the prognosis of hand function whether patients choose to or choose not to undergo this procedure.

We found that objective measurements, such as grip and pinch strength, did not significantly improve after SMPA. These results are consistent with what we have found in our previous studies^{4,5,17,25} and with what others have found.^{26–29} The MCP joint arc of motion at 7 years for SMPA subjects observed in this study is similar to that observed in some studies^{30–34} but less than others.^{26,27,35,36} The adjusted mean arc of motion was significantly greater in the SMPA subjects compared with the non-SMPA subjects at 7 years, and the improvement of extensor lag puts the fingers in an extended posture, which is considered to be more functional for completing activities of daily living.^{13,27,34,37} In our study, the radiographic assessment of implants showed the percentage of fractures to be no more than 10%. Other studies of the Swanson implant have reported fracture rates ranging from as low as 0–3%^{26,27,32,33,38} to a mid-range of 11–17%^{28,31,39} to upper ranges of 21–34%.^{29,36,37} Average follow-up in these studies ranged from 2 to 10 years. Although these studies all used radiographs to assess fracture, they did not necessarily use the Bass criteria, a standardized measurement specifically developed to assess implant fracture, that were utilized in this study.

This study began in 2000 with a systematic review of the SMPA procedure¹³ that suggested benefits of the procedure but a lack of prospective studies with standardized outcomes data. Our national survey of rheumatologists and hand surgeons^{8,10} revealed that the lack of reliable outcomes data led rheumatologists to doubt the effectiveness of rheumatoid hand procedures, giving them pause when considering a referral for hand surgery consultation. Medicare data have shown that RA patients who live in areas where there is a higher density of rheumatologists are less likely to receive arthroplasty than those living in lower density areas.⁴⁰ Thus began the SARA Study, a collaboration between hand surgeons and rheumatologists for the long-term assessment of the SMPA procedure for rheumatoid hand deformity. We began by collecting pilot data of 16 SMPA patients from one site before applying for NIH funding. These data showed significant improvements in patient-reported outcomes at one year post-operative.²⁵ We also found that improved function is the most important reason patients choose to undergo the SMPA procedure, followed by decreased pain.⁴¹ Studies exposing the variation in rheumatoid hand surgical practice patterns across the US⁷ and the world⁴² prompted us to involve three study sites, one being international, thus improving the study sample size and subject variability. Outcomes data from the SARA Study were published at the 1 year,⁵ 3 year⁴ and 5 year¹⁷ follow-up intervals. All studies have been consistent in showing that SMPA subjects improved postoperatively and

maintained their enhanced outcomes. Non-SMPA subjects maintained their baseline function over time.

A limitation of this study is the losses to follow-up. The SMPA subjects were more likely to miss follow-up outcomes than the non-SMPA subjects, presumably because the surgical patients achieved the goals of the surgical treatment and did not feel the need for follow up visits. Also, subjects with higher baseline MHQ scores were less likely to miss follow-up appointments. Thus, patients who were higher functioning may have been more motivated to continue study participation. All between-group comparisons during follow-up years were made using longitudinal data models adjusting for baseline values of outcomes as well as other variables associated with missing outcomes. Hence, to the extent that “missingness” is at random, the comparisons of outcomes based on these models are expected to be unbiased.⁴³ However, it remains possible that the “missingness” could bias the results towards better outcomes in the SMPA group if, for example, participants with poor surgical outcomes tended to dropout. We attempted to minimize losses by sending letters and calling patients for follow-up appointments, but many patients did not live in the immediate study area and were not able or willing to return for follow-up. There is also the possibility of assessor bias because we were unable to blind the hand therapists from the subject’s cohort status when taking range of motion measurements. Another limitation is selection bias. There might be fundamental differences in the two groups which affected their choice of treatment as well as outcomes. Although we controlled for measured confounding variables such as age, education and baseline severity, we cannot adjust for unmeasured confounding, and given that this is an observational study of long-term outcomes, our results should be interpreted cautiously.

Despite the substantial losses to follow-up, the strengths of this study include the prospective, long-term assessment of subjects with similar measures of severe hand deformity, the use of standardized outcomes measures, and the inclusion of a control group. All of these factors result in a study that is unique compared to others that have studied SMPA, and it is the only prospective long term outcomes study of its kind in hand surgery.

Previous studies have shown that there is a declining rate of surgical intervention for RA joint deformities.^{44–50} However, data from Medicare patients show MCP joint arthroplasty to be the most commonly performed surgical procedure on the hand for RA patients.^{40,44} Although optimal treatment strategies for RA demonstrate radiographic protection as measured by cartilage loss and bone erosions, the extent to which current aggressive medical management of RA prevents MCP joint deformities is poorly understood. Our finding that the benefits of SMPA are maintained in the long term provides an evidence-based foundation for continuing to offer this procedure to selected RA patients.

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Significance & Innovations

- This is the largest prospective cohort study of rheumatoid arthritis joint replacement surgery to date with the longest follow-up and is the culmination of over 10 years of work.
- This study involved a unique collaboration between rheumatologists and hand surgeons, with surgical and non-surgical patient cohorts.
- This study found that benefits of silicone metacarpophalangeal joint arthroplasty, such as improved function and decreased ulnar drift, were maintained over seven years of follow-up.
- Previous studies of silicone metacarpophalangeal joint arthroplasty did not compare surgical patients to non-surgical patients. We found that patients who did not choose to undergo this procedure (non-surgical patients) maintained their baseline hand function over the seven year study duration.

Figure 1. Study Enrollment and 7 Year Follow-up Flowchart

Year 7 study status indicates cumulative numbers of withdrawals, deaths, and losses to follow-up prior to the 7 year assessment. Dashed arrow is used to indicate the slow change in time from baseline to 7 year follow-up.

Table 1

Demographic Characteristics of Study Enrollees

Demographic Variables		SMPA (N=73)	Non-SMPA (N=97)	P-value
Age, mean (SD)		59.8 (8.2)	61.8 (10.5)	0.18
Male, No. (%)		13 (17.8)	33 (34.0)	0.02
Race, White, No. (%) ^a		62 (91.2)	81 (86.2)	0.33
Education	High School Degree, No. (%) ^a	39 (57.4)	39 (41.5)	0.05
Income	\$50,000, No. (%) ^a	51 (77.3)	62 (68.9)	0.25

^aEight (5%) participants are missing race and education data and 14 (8%) are missing income data; percentages are calculated out of those with non-missing data for each characteristic.

Table 2

a. Unadjusted Means (SD) of Subjective Measurements

MHQ ^a	Baseline		3 Year ^c		5 Year ^c		7 Year ^c	
	SMPA (N=69)	Non-SMPA (N=95)	SMPA (N=44)	Non-SMPA (N=72)	SMPA (N=27)	Non-SMPA (N=55)	SMPA (N=23)	Non-SMPA (N=52)
Function	38 (23)	57 (19) ^{††}	60 (20)	57 (21) ^{††}	54 (24)	61 (19) ^{††}	56 (18)	59 (18) [†]
ADL	36 (27)	59 (24) ^{††}	55 (28)	61 (27) ^{††}	56 (30)	64 (26) [†]	56 (26)	63 (24)
Work	42 (23)	58 (23) ^{††}	52 (29)	61 (28)	51 (30)	63 (27)	47 (25)	64 (26)
Pain	48 (27)	36 (25) [†]	37 (26)	31 (24) [†]	37 (30)	27 (21)	34 (18)	26 (20)
Aesthetics	32 (22)	47 (24) ^{††}	61 (22)	54 (20) ^{††}	61 (26)	56 (20) ^{††}	60 (23)	61 (23) [†]
Satisfaction	28 (21)	47 (25) ^{††}	56 (27)	53 (25) ^{††}	53 (27)	53 (25) ^{††}	54 (19)	55 (24) [†]
Overall	38 (18)	55 (19) ^{††}	58 (22)	59 (21) ^{††}	57 (24)	62 (19) ^{††}	57 (17)	63 (19) [†]
AIMS2 ^b	Baseline		3 Year		5 Year		7 Year	
	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA
Physical	3.8 (2.4)	2.5 (1.9) ^{††}	3.3 (2.3)	2.6 (2.2)	3.4 (2.4)	2.3 (2.0)	3.2 (2.2)	2.3 (1.9)
Affect	4.1 (1.9)	3.1 (1.8) ^{††}	3.7 (2.2)	2.7 (1.6)	3.1 (1.6)	2.4 (1.3)	3.4 (1.6)	2.4 (1.4)
Symptom	5.5 (2.9)	4.3 (2.4) [†]	5.0 (2.2)	4.0 (2.5)	4.4 (2.7)	3.5 (2.5)	4.7 (2.5)	3.4 (2.2)
Social Interaction	4.1 (2.0)	3.6 (1.4)	4.1 (2.1)	3.6 (1.6)	3.5 (1.4)	3.5 (1.4)	4.2 (1.8)	3.4 (1.3)

b. MHQ and AIMS2 subscales – Crude and adjusted changes from baseline to 7 years, and covariate adjusted difference between SMPA versus non-SMPA group based on (1) complete data and (2) all available data

MHQ	Crude Change ^a		Adjusted ^b Change ^a		Adjusted ^{c,d}	
	SMPA N = 23	Non-SMPA N = 52	SMPA N = 23	Non-SMPA N = 49	Difference (1) N = 72	Difference (2) N = 144
Function	15 (6, 24)	-3 (-8, 2)	9 (2, 17)	-1 (-5, 4)	10 [*] (1, 20)	12 [*] (5, 19)
Activities of Daily Living	14 (4, 24)	-1 (-5, 4)	9 (1, 17)	1 (-4, 6)	8 (-3, 18)	8 (-1, 16)
Work	1 (-4, 7)	2 (-11, 15)	-2 (-12, 7)	3 (-3, 9)	-6 (-18, 6)	6 (-3, 15)
Pain	6 (-7, 18)	1 (-5, 6)	1 (-7, 9)	3 (-2, 8)	-2 (-12, 8)	3 (-6, 12)

b. MHQ and AIMS2 subscales – Crude and adjusted changes from baseline to 7 years, and covariate adjusted difference between SMPA versus non-SMPA group based on (1) complete data and (2) all available data

	25 (11, 39)	9 (4, 14)	23 (14, 32)	10 (4, 16)	13* (2, 25)	12* (2, 21)
Aesthetics						
Satisfaction	22 (9, 34)	2 (-4, 9)	16 (6, 25)	5 (-1, 11)	10 (-2, 23)	10* (0, 19)
Overall	14 (5, 23)	2 (-2, 5)	11 (4, 17)	3 (-1, 7)	8 (-1, 16)	10* (3, 17)
AIMS2	N = 23	N = 52	N = 23	N = 49	N = 72	N = 144
Physical	-4 (-1.0, .3)	-2 (-5, .2)	-5 (-1.0, .1)	-2 (-6, .2)	-3 (-1.0, .5)	.1 (-.5, .7)
Affect	.4 (-1, .9)	.2 (-.2, .5)	-0 (-.5, .5)	.3 (-.0, .7)	-4 (-1.0, .3)	.4 (-.2, .9)
Symptom	.3 (-.9, 1.5)	.3 (-.2, .7)	-0 (-.9, .9)	.4 (-.2, 1.0)	-4 (-1.5, .7)	.1 (-.8, .9)
Social Interaction	-.1 (-.9, .7)	-.1 (-.3, .2)	-.4 (-.9, .1)	.1 (-.3, .4)	-.5 (-1.2, .2)	.1 (-.5, .7)

^a All MHQ domain scores and overall score can range from 0 to 100, and higher scores correspond to better outcomes, except for pain where higher scores correspond to greater pain

^b All AIMS2 subscales can range from 0 to 10, and higher scores correspond to worse outcome

^c Excludes assessments from non-SMPA subjects who crossed over to SMPA group

[†] $P < 0.05$ and

^{††} $P < 0.001$;

p-values for between-group comparisons at baseline are unadjusted comparisons based on t-tests, and p-values for between-group comparisons at follow-up times are from the random-effect regression models comparing baseline adjusted between-group marginal means

Cell values are means (95% confidence interval).

^a Changes are calculated so that positive values reflect improvement: 7 year minus baseline values for all MHQ subscales, except pain, and baseline minus 7 year values for all AIMS2 subscales and Pain subscale of MHQ

^b Based on a regression model with change from baseline to year 7 as the dependent variable and adjusting for baseline values of the outcome variable, age, gender, baseline severity stage, education level, income level, study site, use of biologic at baseline and SMPA group indicator

^c Difference between SMPA vs. non-SMPA group at seven years, based on a regression model described under footnote “b”; positive scores reflect better outcomes in SMPA group relative to non-surgical group

^d Based on a linear mixed model using all available follow-up scores calculated at 6 months, 1, 2, 3, 4, 5, 6, and 7 years as the dependent variable, adjusting for baseline values of the outcome variable, age, gender, baseline severity stage, study site, SMPA group indicator, biologic use at each year, time in months since enrollment, time by group interaction and age by group interaction

* $p < 0.05$ and

** $p < 0.001$.

Table 3

a. Unadjusted Means (SD) of Objective Measurements

Measurement	Baseline		3 Year ^b		5 Year ^b		7 Year ^b	
	SMPA (N=73)	Non-SMPA (N=97)	SMPA (N=41)	Non-SMPA (N=65)	SMPA (N=25)	Non-SMPA (N=45)	SMPA (N=21)	Non-SMPA (N=41)
Grip Strength (kg)	5.6 (5.3)	8.8 (7.7) [†]	6.4 (4.4)	9.9 (6.1) [†]	6.4 (5.7)	9.0 (5.5)	6.0 (5.7)	8.5 (5.3)
Lateral Pinch (kg)	3.5 (2.3)	4.1 (1.8)	3.1 (2.1)	3.5 (1.9)	3.2 (2.3)	3.3 (1.6)	2.6 (2.5)	2.9 (1.6)
2-point Pinch (kg)	2.5 (1.6)	3.1 (1.6) [†]	2.3 (1.4)	2.7 (1.3)	2.1 (1.8)	2.4 (1.4)	1.7 (1.9)	2.1 (1.4)
3-jaw Pinch (kg)	2.5 (1.5)	3.2 (1.4) [†]	2.5 (1.6)	2.8 (1.3)	2.3 (1.9)	2.5 (1.1)	2.0 (2.0)	2.5 (1.3)
Jebsen-Taylor Test (s)^{dc}	54 (26)	43 (11) ^{††}	44 (13)	40 (12)	46 (18)	40 (15)	51 (41)	39 (11)
Ulnar Drift (°)^a	37 (15)	35 (15)	14 (11)	35 (17) ^{††}	18 (15)	32 (14) ^{††}	18 (12)	32 (14) ^{††}
Extensor Lag (°)^a	64 (23)	49 (19) ^{††}	29 (15)	54 (21) ^{††}	30 (12)	49 (20) ^{††}	27 (14)	51 (20) ^{††}
MCP AOM (°)	20 (16)	36 (19) ^{††}	31 (14)	28 (16) ^{††}	32 (12)	30 (18) ^{††}	30 (13)	28 (16) ^{††}

b. Objective Measures – Crude and adjusted changes from baseline to 7 years, and covariate adjusted difference between SMPA versus non-SMPA group based on (1) complete data and (2) all available data

Objective Measure	Crude Change			Adjusted ^c Change		Adjusted ^d Difference (1) N = 59	Adjusted ^{d,e} Difference (2) N = 144
	SMPA N = 23	Non-SMPA N = 49		SMPA N = 21	Non-SMPA N = 38		
Grip Strength^a	-1.2 (-3.9, 1.6)	1.7 (2, 3.2)		-5 (-2.5, 1.5)	1.4 (-0, 2.7)	-1.9 (-4.4, .7)	-1.6 (-4.2, .9)
Jebsen-Taylor Test^{bf}	-4.3 (-22.7, 14.1)	.5 (-2.3, 3.3)		-5.6 (-18.0, 6.9)	.9 (-7.9, 9.7)	-6.4 (-22.8, 9.9)	-2.1 (-9.3, 5.2)
Two Point Pinch^a	-1.2 (-1.7, -.7)	-.6 (-1.1, -.2)		-.5 (-9, -.1)	-.3 (-6, -.0)	-.2 (-7, .4)	-.4 (-9, .1)
Three Point Pinch^a	-.9 (-1.6, -.2)	-.6 (-1.0, -.2)		-.4 (-.8, .1)	-.5 (-9, -.2)	.2 (-5, .8)	-.7 (-1.7, .2)
Key Pinch^a	-1.5 (-2.0, -.9)	-.7 (-1.2, -.2)		-.7 (-1.3, -.2)	-.4 (-8, .0)	-.4 (-1.1, .4)	-.3 (-9, .4)
Average Ulnar Drift^b	22.5 (17.7, 27.3)	-.2 (-4.5, 4.2)		20.7 (14.9, 26.4)	-.5 (-4.6, 3.5)	21.2 (13.7, 28.7)^{**}	18.6 (12.3, 24.8)^{**}
Average Extensor Lag^b	35.7 (27.2, 44.1)	-8.5 (-13.1, -3.9)		30.7 (23.2, 38.3)	-6.5 (-11.8, -1.2)	37.2 (27.3, 47.2)^{**}	32.5 (24.2, 40.7)^{**}
Metacarpophalangeal Joint Arc of Motion^a	9.9 (1.3, 18.4)	-10.5 (-15.2, -5.8)		4.5 (-2.8, 11.8)	-7.2 (-12.2, -2.3)	11.8 (2.2, 21.3)[*]	13.6 (5.7, 21.4)^{**}

Cell values are means (SD); MCP AOM is metacarpophalangeal joint arc of motion

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^b Higher values correspond to worse outcomes

^c Excludes assessments from non-SMPA patients who received surgery after one year of enrollment

^d Writing portion of the Jebsen-Taylor Test was omitted due to confounding from hand dominance

^e $p < 0.05$ and

^f $p < 0.001$;

p-values for between-group comparisons at baseline are unadjusted comparisons based on t-tests, and p-values for between-group comparisons at follow-up times are from the random-effect regression models comparing baseline adjusted marginal means.

Cell values are means (95% confidence interval)

^a Changes are calculated as 7 year minus baseline values, and positive values reflect improvement

^b Changes are calculated as baseline minus 7 year values, and positive values reflect improvement

^c Based on a regression model with change from baseline to year 7 as dependent variable, adjusting for baseline values of the outcome variable, age, gender, baseline severity stage, education level, income level, study site, use of biologic at baseline and SMPA group

^d Difference between SMPA vs. non-SMPA group at seven years, based on a regression model described under footnote ^c; positive scores reflect better outcomes in SMPA group relative to non-surgical group

^e Based on a linear mixed model using all available follow-up scores at 6 months, 1, 2, 3, 4, 5, 6, and 7 years as the dependent variable, adjusting for baseline values of the outcome variable, age, gender, baseline severity stage, study site, SMPA group indicator, biologic use at each year, time in months since enrollment, time by group interaction and age by group interaction

^f Writing portion of the Jebsen-Taylor Test was omitted due to confounding from hand dominance

* $p < 0.05$;

** $p < 0.001$

Table 4

Radiographically Assessed Implant Status per Year in SMPA group (Number (%))

Post-operative Year	Radiographically Assessed Implant Status		
	Intact	Severely Deformed	Definite Fracture
Year 3 (N=166) *	150 (90)	10 (6)	6 (4)
Year 5 (N=72) *	56 (78)	9 (12)	7 (10)
Year 7 (N=60) *	41 (68)	16 (27)	3 (5)

*
N reflects number of joints with radiographs

Note: The prevalence of fracture in year 5 or 7 can be lower than the prevalence of the earlier year due to patients being losses to follow-up.