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ORIGINAL ARTICLE

Long-Term Followup for Rheumatoid Arthritis Patients in a Multicenter Outcomes Study of Silicone Metacarpophalangeal Joint Arthroplasty

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Objective. **Rheumatoid arthritis (RA) often results in deformities at the metacarpophalangeal (MCP) joints. Patients with severe deformities can be treated by silicone metacarpophalangeal joint arthroplasty (SMPA). The objective of the study is to prospectively compare long-term outcomes for an SMPA surgical and a nonsurgical cohort of RA patients.**

Methods. **A total of 67 surgical and 95 nonsurgical patients with severe subluxation and/or ulnar drift of the fingers at the MCP joints were recruited from 2004–2008 in this multicenter prospective cohort study. Patients could elect to undergo SMPA or not. Outcomes included the Michigan Hand Outcomes Questionnaire (MHQ), Arthritis Impact Measurement Scales 2 (AIMS2), grip/pinch strength, Jebsen-Taylor Test, ulnar deviation, extensor lag, and arc of motion measurements at the MCP joints.**

Results. **There was no significant difference in the mean age, race, education, and income at baseline between the 2 groups. Surgical subjects had worse MHQ function and functional measurements at baseline. At 3 years, the mean overall MHQ score and the MHQ function, activities of daily living, aesthetics, and satisfaction scores showed significant improvement in the surgical group compared to the nonsurgical group. Ulnar deviation, extensor lag, and arc of motion in the MCP and proximal interphalangeal joints also improved significantly in the surgical group. No improvement was seen in the mean AIMS2 scores and grip/pinch strength. Complications were minimal with a fracture rate of 9.5%.**

Conclusion. **RA patients with poor baseline functioning showed long-term improvement in hand function and appearance following treatment with SMPA compared to nonsurgical controls.**

INTRODUCTION

Inflammation that leads to progressive damage to joints is a hallmark of rheumatoid arthritis (RA). The joints most often affected are the metacarpophalangeal (MCP) joints, with RA causing dislocation of the MCP joints and ulnar deviation of the fingers. This deformity often results in disability because of the inability to extend the fingers to grasp objects. Treatment for RA almost always requires medications to halt or slow the progression of joint damage. Surgical management for RA, which includes joint arthroplasty and arthrodesis, is recommended as a last resort.

Silicone implants have been used for many years to replace destroyed MCP joints in the rheumatoid hand. Historically, much of the evidence regarding the effectiveness of silicone metacarpophalangeal arthroplasty (SMPA) has relied on low (level 3–4) evidence from retrospective cohorts or case series (1–13). Prospective studies offered higher evidence (level 2), but these studies were hampered by small study sample sizes (N ranged from 12–21 patients) (14–17). More recently, a high level of evidence (level 1) has come from 2 randomized controlled trials (RCTs) that compared SMPA to other implants (18,19). The sample sizes for these RCTs were small, ranging from 33–52 patients, whereas the retrospective studies ranged from 28–264 patients. Followup time varied by study type with retrospective studies having longer followup (average range 2–14 years), whereas prospective studies (average range 1–3 years) and RCTs (range 1–2 years) had shorter followup. None of the studies used a control group consisting of patients who were managed medically without SMPA. The majority of studies focused on physical

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Significance & Innovations

- The study provides high-level long-term evidence on silicone metacarpophalangeal arthroplasty results.
- This is a large collaborative study between rheumatologists and hand surgeons.
- The study uses a hand-specific outcomes questionnaire to measure results.
- Surgical subjects are compared to a nonsurgical cohort with similar levels of deformities.

measurements, such as finger arc of motion and degree of ulnar drift, to assess outcomes. Overall, the results from these studies report that SMPA improves function of the rheumatoid hand (12). The degree of ulnar drift, extensor lag, and the arc of motion in finger joints show improvement after SMPA, but grip and pinch strength do not (1,2,8,10,16). Many studies evaluated health-related quality of life (HRQOL) using subjective assessments by surgeons or unvalidated questionnaires. Based on these measures, favorable outcomes were reported in hand function, activities of daily living (ADL), pain, aesthetics, and patient satisfaction (1,2,4–10,13,16).

The disparity between the results from functional measurements such as grip and pinch strength and patient-reported function fuels the ongoing debate regarding the true effectiveness of SMPA. For example, previous studies have found that rheumatologists and hand surgeons disagree on the effectiveness of hand surgery for RA patients (20,21). In a national survey of these 2 specialties, 34% of rheumatologists compared to 83% of hand surgeons believe SMPA improves hand function for RA patients. This disagreement in treatment options may partially explain the large variations in the surgical management of the rheumatoid hand in the US (22,23). It has been suggested that patients choose surgery to improve the appearance of the hands rather than improve function or lessen pain. Moreover, satisfaction with surgery has been found to be closely correlated with hand appearance (24,25). Finally, although these implants have been used for more than 4 decades, the true complication rate of these implants is still unknown.

To better understand outcomes following SMPA, we conducted a multicenter prospective cohort study comparing RA patients with severe MCP joint deformities who elect to undergo SMPA to those who do not undergo SMPA. The inclusion of the nonsurgical control group was one of several unique aspects of this study. Outcome measures included both validated HRQOL questionnaires and standardized hand function tests. Lastly, this study achieved the unusual collaboration of rheumatologists and hand surgeons. The specific aim of the study is to assess the effectiveness of SMPA in RA patients with MCP joint deformity in order to provide high-level evidence for or against the procedure and to determine the long-term benefit of SMPA. This study presents the results from the 3-year followup after surgery or enrollment.

PATIENTS AND METHODS

The institutional review boards of all 3 study sites approved the protocol for this study. All subjects enrolled in the study were informed about the study requirements and signed consent forms. A detailed description of the study methods has been previously published (26).

Study sample. RA patients were referred by their rheumatologists to hand surgeons to 1 of the following 3 study sites: University of Michigan (Ann Arbor), Curtis National Hand Center (Baltimore, Maryland), and Pulvertaft Hand Centre (Derby, UK). All of the study sites are comprehensive centers dedicated to the treatment of upper extremity disorders and have a large rheumatology program, which enhanced patient accrual for this study. In addition, the heterogeneous racial composition from the 3 study sites ensures that minority groups are represented in this study. Inclusion criteria were 1) diagnosis with RA by a rheumatologist, 2) age $\geq$18 years, 3) ability to complete questionnaires in English, and 4) severe deformity at the MCP joints as determined by the sum of the average ulnar deviation and average extensor lag of the 4 fingers. The sum of these 2 measurements had to be $\geq$50°. This cutoff was determined by an expert panel to be the minimum level of deformity that would be needed before surgery would be considered. Exclusion criteria were 1) severe medical conditions precluding surgery (e.g., severe coronary artery disease, uncontrolled diabetes mellitus, chronic renal failure), 2) concomitant extensor tendon ruptures and MCP joint disease, 3) swan-neck or boutonniere deformities that require surgical correction, 4) patients who have undergone previous MCP joint replacement on the study hand, and 5) patients who have begun taking disease-modifying antirheumatic drugs (DMARDs) in the past 3 months.

Study design. This study applied a prospective cohort design. Patients were not randomized due to strong patient preferences regarding their choice for having surgery. A pilot study at 2 of the 3 sites was completed before the start of the study to determine if patients would agree to be randomized. Most patients would not consent to randomization because they have an inherent preference whether to have or not to have surgery. Therefore, patients chose whether or not to have surgery. If both hands were affected, patients chose the hand on which to have surgery. Surgical subjects had SMPA performed on all 4 fingers. The nonsurgical group chose which hand was the study hand. Subjects in the nonsurgical group could cross over to the surgical group after 1 year of enrollment in the study. Additionally, surgical subjects could elect to have surgery on their other affected hand 1 year after having surgery on the first hand. In addition to the time of enrollment, patients were assessed at 6 months, 1 year, 2 years, and 3 years postsurgery or enrollment. All outcomes were assessed at each followup visit. Patients were contacted by phone and/or mail for followup visits and were considered lost to followup if there was no response after numerous attempts.

Outcome measures. Outcomes were assessed at enrollment, 6 months, 1 year, 2 years, and 3 years after the surgery date for the surgical cohort or the enrollment date for the nonsurgical cohort. All functional measurements were performed on both hands, but the results presented are for the surgical or study hand. A certified hand therapist conducted the functional assessments that included grip strength, lateral pinch, 2-point pinch and 3-point pinch, and range of motion measurements for all the joints in each finger and for the wrist. The motion measurements included the degree of ulnar drift (angle of the fingers at the MCP joint), extensor lag (degree to which fingers lag when fully extended), and arc of motion (difference in degrees at joints when fingers are extended and flexed). The research coordinator administered the Jebsen-Taylor Test, which simulates ADL (27). Subjects performed various everyday type activities, including the following: 1) turning over 3- by 5-inch cards, 2) picking up small objects and placing them in a container, 3) stacking checkers, 4) simulated eating, 5) moving large empty cans, and 6) moving large weighted cans. The writing portion of the test was excluded, and the time to complete the tasks is measured in seconds. Two questionnaires were used: the Michigan Hand Outcomes Questionnaire (MHQ) (28,29) and the Arthritis Impact Measurement Scales 2 (AIMS2) (30). The MHQ is a hand-specific questionnaire, whereas the AIMS2 measures overall health status in RA patients. The MHQ contains 6 domains (function, ADL, work, pain, aesthetics, and satisfaction) and scores range from 0–100, with higher scores indicating better performance with the exception of the pain scale. For the pain scale, a higher score indicates more pain. The satisfaction domain asks about satisfaction with the overall performance of the hand and wrist. The MHQ queries subjects about both hands, but only the results for the surgical or study hand are analyzed. The AIMS2 contains 4 domains (physical, affect, symptom, and social interaction) and domain scores range from 1–10, with lower scores indicating better health status. Both questionnaires are validated for RA.

Complications. Subjects were assessed for complications such as infections and deformities/fractures of the implants at followup visits. The integrity of the MCP joint implants in surgery subjects was assessed using radiographs at 6 months and 3 years after surgery. Each implant was categorized using the protocol by Bass et al (31) as intact, definitely fractured, or severely deformed. Radiographs were reviewed by 2 of the hand surgeons who were blinded to the study subjects and the subjects' study site. When the surgeons disagreed on their assessments, they worked together to achieve consensus. When consensus could not be reached, a third hand surgeon made the decision regarding fractures and/or deformities. Deaths were reported to the institutional review boards for each site.

Statistical analysis. The distribution of demographic variables and other baseline variables was compared between the surgical and nonsurgical groups using the 2-sample *t*-tests for continuous variables and chi-square tests for categorical variables. Because nonsurgical group subjects were allowed to cross over their treatment groups, all outcome data were censored beyond the time the study hand of the nonsurgical group patient was treated by SMPA. Baseline data including demographic and baseline values of the outcome variables were assessed for missing data. Baseline characteristics were also compared between those who were lost to followup and those who were not.

For all outcome measures of interest, means and 95% confidence intervals at each followup time were calculated by the study group. Unadjusted mean changes from baseline in various outcome measures between the surgical versus nonsurgical group at the 3-year followup time were calculated. Random-effects regression models were used to estimate and compare the 3-year outcomes between the 2 groups. For each outcome variable, the model used the baseline and 3-year outcome values as the dependent variable and an indicator for the surgical group, an indicator for 3-year time, and an interaction term of indicators of 3-year time by surgical group. Because of the baseline differences between the 2 groups, the models were also adjusted for the baseline values of the outcome variable, age, baseline severity (dichotomized as severe or not based on degree of deformity), education (high school and lower versus higher), income (>$50,000 versus lower), sex, and study site. All unadjusted and adjusted mean differences were calculated so the positive values corresponded to greater improvement in the surgical group relative to the nonsurgical group. We also obtained the propensity-stratified estimates of the between-group differences in 3-year outcomes (32). Propensities were estimated using a logistic regression model with receipt of SMPA as the dependent variable, and with all baseline covariates and baseline values of the outcome variables as predictors. For baseline variables with missing values, such as education and income, the variable was encoded for an extra level corresponding to those patients who are missing the covariates, and squared terms for continuous variables and appropriate interactions terms were also included.

We used multiple imputation method to account for missing covariates as well as missing outcomes (33). Five imputed data sets were created using all available baseline covariates we suspected or found to be relevant to missing data mechanism, including rheumatoid medication types used (DMARDs, biologic agents, or antiinflammatories), whether the study hand was a dominant hand or not, number of comorbid medical conditions, as well as demographic variables. The imputations also used all longitudinally measured outcome data and accounted for the correlation between a patient's longitudinally measured outcome data. Any imputed values outside of plausible range were truncated with the proper values. For the nonsurgical group patients who later received SMPA on their study hand, their outcome data after their receipt of SMPA were imputed based on all data prior to the time of receipt of their SMPA. Across the imputed data sets, covariate-adjusted between-group mean differences were estimated using the random-effects model, and the estimates were combined using Rubin's combining rules (34). All analyses including multiple imputations were performed using Stata 11.2 software (StataCorp).

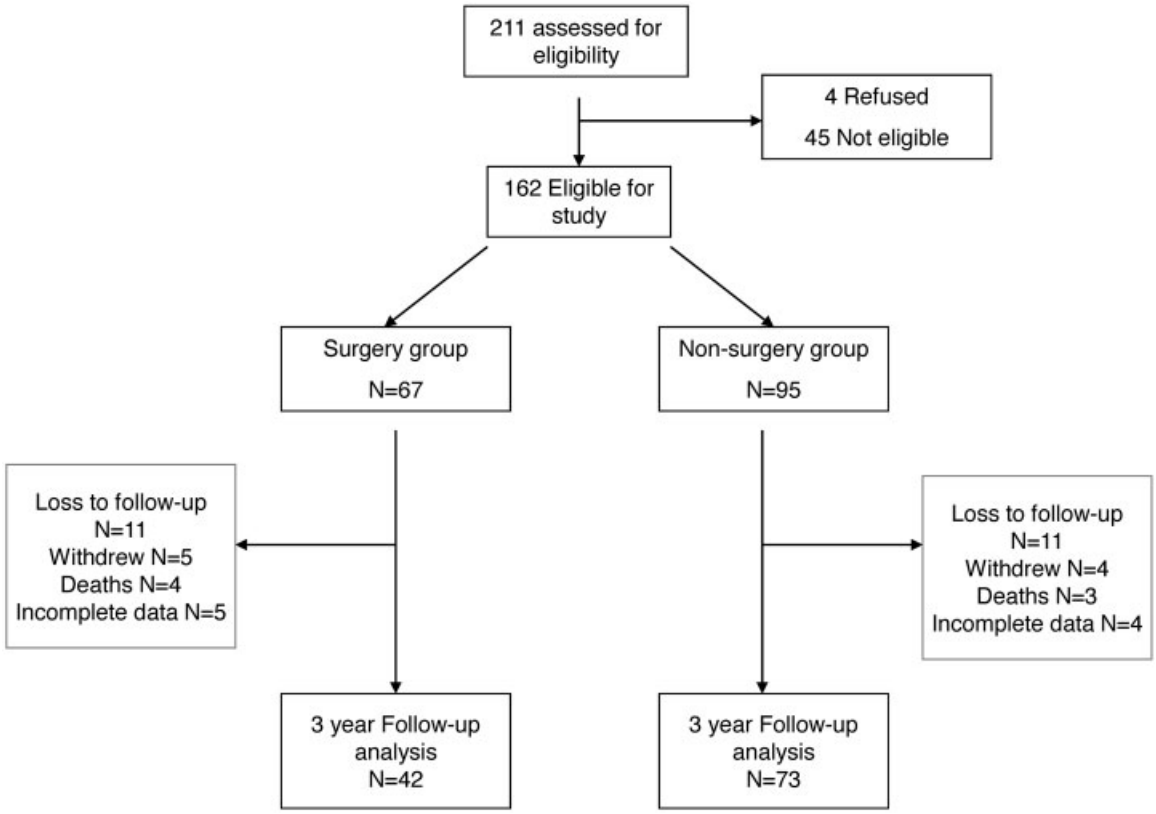

Figure 1. Study flow chart.

RESULTS

A total of 162 subjects (67 surgical and 95 nonsurgical) were enrolled in the study. Two control subjects chose to have surgery on the study hand after 1 year, and 10 surgical subjects elected to have surgery on their other affected hand 1 year after having the initial SMPA on the study hand. The 1-year results have been presented previously (26). Due to withdrawals (n = 9), deaths (n = 7), losses to followup (n = 22), and missing data (n = 9), 3-year data were available in 42 surgical (63%) and 73 (77%) nonsurgical subjects (including 2 subjects who had surgery on their study hand prior to their 3-year followup time) (Figure 1).

Baseline demographic information by surgical status is shown in Table 1. Baseline data were missing for ≤5% patients except for income (8% had missing income). The 2 study groups were not significantly different at baseline in terms of age, race, education, and income. The surgical group had a lower percentage of men compared to the nonsurgical group. Those who were missing versus not missing 3-year outcome data were not different with respect to various demographic variables, but having missing data depended on the baseline values of the outcomes and the magnitude of the change in the outcome values. Specifically, in both the nonsurgical and surgical groups, those who were missing the 3-year MHQ data tended to have more severe baseline symptoms than those not missing the 3-year followup data ($P = 0.02$ based on baseline MHQ). In addition, in the surgical group, greater improvement in MHQ values from baseline to 2 years was associated with a greater likelihood of missing the 3-year MHQ outcome data ($P = 0.03$), and therefore the completers-only analysis (e.g., analysis of crude change) was expected to give a smaller effect associated with surgical group.

Table 1. Comparison of demographic values for surgical versus nonsurgical subjects*

Demographic variables	SMPA (n = 67)	Non-SMPA (n = 95)	*P*
Age, mean ± SD years	60 ± 8	62 ± 11	0.24
Male, no. (%)	12 (18)	32 (35)	0.03
White race, no. (%)†	58 (94)	79 (86)	0.14
High school degree or less, no. (%)†	35 (56)	38 (41)	0.07
Income ≤$50,000, no. (%)†	47 (77)	60 (68)	0.24

* SMPA = silicone metacarpophalangeal joint arthroplasty.
† Eight (5%) participants are missing race and education data, and 13 (8%) are missing income data.

Table 2. Mean scores for surgical (SMPA) vs. nonsurgical subjects*

	Preoperative		2-year		3-year	
	SMPA	**Non-SMPA**	**SMPA**	**Non-SMPA**	**SMPA**	**Non-SMPA**
MHQ†	n = 63	n = 93	n = 48	n = 79	n = 40	n = 71
Function	37 ± 22	58 ± 19‡	62 ± 19	58 ± 22	59 ± 19	58 ± 21
ADL	34 ± 26	59 ± 24‡	58 ± 29	61 ± 25	55 ± 27	61 ± 27
Work	41 ± 22	59 ± 23‡	54 ± 27	61 ± 26	51 ± 28	61 ± 27
Pain	49 ± 26	36 ± 25§	36 ± 25	32 ± 25	38 ± 26	31 ± 24
Aesthetics	33 ± 22	47 ± 24‡	66 ± 23	53 ± 21	60 ± 21	54 ± 20
Satisfaction	27 ± 20	47 ± 25‡	61 ± 27	51 ± 25	55 ± 25	53 ± 25
Overall	37 ± 17	56 ± 19‡	61 ± 21	59 ± 20	57 ± 20	59 ± 21
AIMS2¶	n = 63	n = 93	n = 48	n = 79	n = 40	n = 71
Physical	4.0 ± 2.4	2.5 ± 1.9‡	3.3 ± 2.2	2.5 ± 2.0	3.4 ± 2.3	2.6 ± 2.2
Affect	4.2 ± 1.9	3.1 ± 1.8‡	3.7 ± 1.8	2.9 ± 1.7	3.7 ± 2.3	2.7 ± 1.6
Symptom	5.7 ± 2.8	4.3 ± 2.4§	4.6 ± 2.4	3.9 ± 2.3	5.0 ± 2.3	4.0 ± 2.5
Social interaction	4.1 ± 2.0	3.6 ± 1.4§	4.1 ± 2.1	3.7 ± 1.3	4.1 ± 2.1	3.5 ± 1.6
Objective measurements	n = 67	n = 95	n = 45	n = 74	n = 39	n = 66
Grip strength, kg	5.4 ± 5.2	8.6 ± 7.4§	6.1 ± 4.4	10.6 ± 7.5	6.0 ± 4.2	9.7 ± 5.9
Key (lateral) pinch, kg	3.5 ± 2.2	4.0 ± 1.8	3.2 ± 1.9	3.7 ± 1.9	3.0 ± 2.0	3.4 ± 1.8
2-point (tip) pinch, kg	2.5 ± 1.6	3.1 ± 1.5§	2.4 ± 1.5	2.9 ± 1.5	2.2 ± 1.4	2.7 ± 1.3
3-jaw (palmar) pinch, kg	2.5 ± 1.5	3.2 ± 1.4§	2.5 ± 1.4	3.2 ± 1.5	2.4 ± 1.5	2.7 ± 1.2
Jebsen-Taylor (seconds)#	55 ± 27	43 ± 12‡	43 ± 11	39 ± 10	44 ± 13	40 ± 12
Ulnar drift#	37 ± 15	35 ± 15	14 ± 9	33 ± 16	14 ± 11	34 ± 17
Extensor lag#	65 ± 23	47 ± 18‡	25 ± 14	48 ± 23	29 ± 15	53 ± 21
MCP arc of motion	20 ± 15	37 ± 18‡	33 ± 17	33 ± 20	30 ± 14	29 ± 16
PIP arc of motion	56 ± 27	70 ± 22‡	66 ± 25	67 ± 22	64 ± 26	67 ± 21

* Values are the mean ± SD unless indicated otherwise. SMPA = silicone metacarpophalangeal joint arthroplasty; MHQ = Michigan Hand Outcomes Questionnaire; ADL = activities of daily living; AIMS2 = Arthritis Impact Measurement Scales 2; MCP = metacarpophalangeal joint; PIP = proximal interphalangeal joint.
† All MHQ domain scores and overall score can range from 0–100, and higher scores correspond to better outcomes, except for pain, where higher scores correspond to greater pain.
‡ $P < 0.001$ for between-group differences at baseline.
§ $P < 0.05$ for between-group differences at baseline.
¶ All AIMS2 subscales can range from 0–10, and higher scores correspond to worse outcomes.
# Higher values correspond to worse outcomes.

Surgical subjects were significantly different from nonsurgical subjects for the majority of baseline measurements (Table 2). In particular, surgical subjects had worse hand functioning as measured with the MHQ; mean overall MHQ score was 37 in the surgical group and 56 in the nonsurgery group. Figure 2 plots the mean overall MHQ scores, aesthetics, satisfaction, and pain domain scores over time by the study groups. In general, hand outcomes of the surgical patients improved from their initial state to a level similar to the control group by 6 months, and this improvement was maintained to 3 years. In the aesthetics and satisfaction domains, the surgical patients improved to substantially higher levels than those of the nonsurgical patients at 6 months, but the domain scores slowly decreased after 1 year. AIMS2 subscales all showed significantly worse health in surgical than in nonsurgical patients at baseline, and over the 3 years of followup the surgical group did not show better outcomes than the nonsurgical group.

The degrees of ulnar drift and lateral pinch strength were similar at baseline between the 2 study groups, but grip and tip and palmar pinch strength were worse in surgical patients compared to nonsurgical patients. Standard functional measurements of grip strength, pinch strength, and ulnar drift and extensor lag showed different responses to treatment. For example, grip strength showed some improvement over time in both groups, but the surgical group still showed less strength compared to nonsurgical subjects over time. No improvement was seen for all 3 types of pinch strength (key, 2-, and 3-point) over the entire time period. The most dramatic results were seen for degree of ulnar drift, extensor lag, and arc of motion, where the surgical group showed significant improvement after SMPA, which remained through the 3 years of followup time, and the nonsurgical group showed little change.

At 3 years, the surgical group showed significant improvement from baseline in MHQ scores, whereas the nonsurgical group showed minimal to no improvement (Table 3). The between-group difference at 3 years from baseline was highly significant for the overall MHQ score as well as the function, ADL, aesthetics, and satisfaction domains, all showing greater improvement in hand outcomes in the SMPA group than in the nonsurgical group. The between-group difference estimated using the imputed data gave similar findings, although only ADL was highly significant. For the propensity-stratified estimates, the propensity model had an area under the receiver operating curve of 0.91. The propensities were trimmed for nonoverlapping ranges, which led to a much reduced sample size of 88 patients, and of those, only 59 patients provided 3-year MHQ data. Despite the much smaller sample size, the propensity-stratified estimate of the between-group difference of the 3-year MHQ overall summary score was 14.8

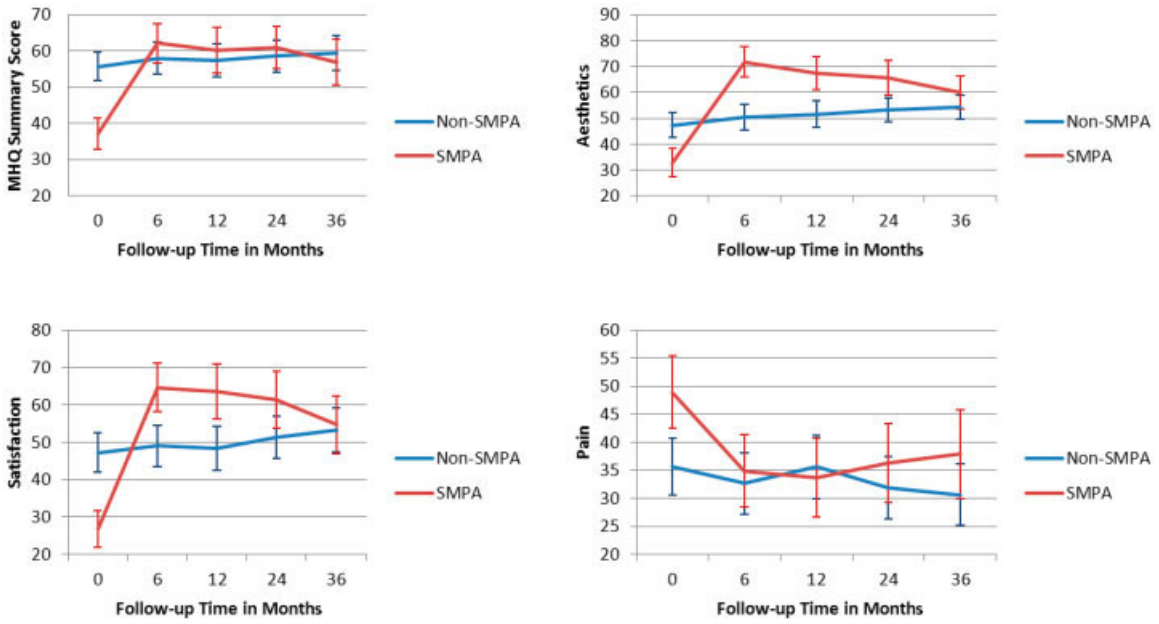

Figure 2. Means and 95% confidence intervals from baseline to 3 years for select Michigan Hand Outcomes Questionnaire (MHQ) scores, surgical versus nonsurgical subjects. SMPA = silicone metacarpophalangeal arthroplasty.

($P = 0.002$). Similarly, the propensity-stratified estimates of the MHQ domains were 17.6 ($P = 0.002$) for function, 15.7 ($P = 0.001$) for ADL, 7.1 ($P = 0.27$) for work, 6.2 ($P = 0.37$) for pain, 21.1 ($P = 0.001$) for aesthetics, and 21.2 ($P = 0.003$) for satisfaction.

The AIMS2 score changes were minimal, with no significant between-group differences (Table 3). Objective measures such as grip and pinch strength did not show greater improvement for the surgical group compared to the nonsurgical group, except for the Jebsen-Taylor Test (Table 4). For each of ulnar drift, extensor lag, MCP arc of motion, and proximal interphalangeal arc of motion, significant improvements were seen in the SMPA group, whereas worsening was seen in nonsurgical groups in general, and the adjusted between-group differences were significant at 3 years, using both all available data and multiple-imputed data.

We analyzed the outcomes of the study (surgical) hand and the control (nonsurgical) hand in the SMPA group to determine if we would find comparable results to those

Table 3. Crude and adjusted changes from baseline to 3 years for MHQ and AIMS2 scales*

	Crude change		Adjusted change		Adjusted difference†	Adjusted difference with imputation‡
	SMPA	Non-SMPA	SMPA	Non-SMPA		
MHQ§	n = 40	n = 71	n = 40	n = 71	n = 111	n = 162
Overall	18 (12, 24)	2 (−0.4, 5)	19 (15, 22)	3 (−0.1, 5)	16 (12, 21)¶	14 (−1, 30)
Function	21 (13, 28)	−2 (−5, 1)	21 (17, 26)	−1 (−5, 2)	22 (17, 28)¶	18 (0, 36)#
ADL	17 (12, 23)	2 (−2, 5)	18 (14, 22)	2 (−1, 5)	16 (11, 21)¶	21 (11, 32)¶
Work	8 (1, 14)	2 (−2, 7)	8 (3, 13)	3 (−1, 7)	6 (−1, 12)	10 (−12, 33)
Pain	9 (−0.8, 18)	3 (−2, 7)	10 (4, 15)	3 (−1, 8)	6 (−1, 13)	8 (−14, 30)
Aesthetics	28 (19, 37)	5 (0.6, 9)	28 (23, 33)	5 (1, 9)	23 (16, 29)¶	20 (4, 37)#
Satisfaction	28 (19, 36)	4 (−0.5, 9)	28 (22, 33)	4 (−0.0, 9)	24 (17, 31)¶	19 (4, 33)#
AIMS2**	n = 40	n = 71	n = 40	n = 71	n = 111	n = 162
Physical	0.1 (−0.2, 0.5)	−0.0 (−0.3, 0.2)	0.2 (−0.1, 0.5)	−0.0 (−0.3, 0.2)	0.2 (−0.1, 0.6)	0.7 (−1.1, 2.5)
Affect	0.3 (−0.3, 0.8)	0.2 (−0.1, 0.5)	0.3 (−0.1, 0.6)	0.2 (−0.1, 0.5)	0.1 (−0.4, 0.5)	0.3 (−1.1, 1.8)
Symptom	0.7 (0.1, 1.3)	0.1 (−0.4, 0.5)	0.7 (0.2, 1.2)	0.1 (−0.3, 0.5)	0.6 (−0.0, 1.2)	0.2 (−1.3, 1.8)
Social interaction	0.1 (−0.4, 0.6)	−0.0 (−0.3, 0.3)	0.1 (−0.3, 0.4)	−0.0 (−0.3, 0.3)	0.1 (−0.3, 0.6)	0.2 (−1.0, 1.5)

* Values are the mean (95% confidence interval) unless indicated otherwise. Using random-effects model with baseline and year 3 outcome values as the dependent variable and adjusted for baseline values of the outcome variable, age, sex, baseline severity stage, education level, income level, study site, 3-year indicator, silicone metacarpophalangeal joint arthroplasty (SMPA) group indicator, and SMPA group by 3-year time interaction. MHQ = Michigan Hand Outcomes Questionnaire; AIMS2 = Arthritis Impact Measurement Scales 2; ADL = activities of daily living.
† Between-group differences at 3 years; positive scores reflect better outcomes in SMPA group relative to nonsurgical group.
‡ Based on 5 imputations.
§ Positive values reflect improvement; calculated as 3-year minus baseline values for all scales, except pain, where it is baseline minus 3-year values.
¶ $P < 0.001$.
# $P < 0.05$.
** Changes are calculated as baseline minus 3-year values so that positive values reflect improvement.

Table 4. Crude and adjusted changes from baseline to 3 years for objective measures*

	Crude change		Adjusted change		Adjusted difference†	Adjusted difference with imputation‡
	SMPA	Non-SMPA	SMPA	Non-SMPA		
Objective measures	n = 39	n = 66	n = 39	n = 66	n = 105	n = 162
Grip strength§	0.5 (−1.5, 2.5)	1.5 (0.3, 2.6)	0.9 (−0.4, 2.2)	1.5 (0.6, 2.5)	−0.6 (−2.2, 1.0)	0.3 (−2.0, 2.6)
Jebsen-Taylor¶	6.5 (2.0, 11.1)	2.6 (−0.0, 5.1)	6.7 (3.8, 9.6)	2.5 (0.2, 4.7)	4.2 (0.5, 7.9)#	9.7 (−32.7, 13.3)
2-point pinch§	−0.1 (−0.5, 0.2)	−0.2 (−0.5, 0.3)	−0.2 (−0.4, 0.1)	−0.2 (−0.5, −0.0)	0.1 (−0.2, 0.4)	0.1 (−0.4, 0.6)
3-point pinch§	−0.0 (−0.4, 0.4)	−0.3 (−0.6, −0.1)	−0.0 (−0.3, 0.3)	−0.3 (−0.5, −0.1)	0.3 (−0.0, 0.7)	0.3 (−0.2, 0.8)
Key pinch§	−0.2 (−0.7, 0.2)	−0.4 (−0.8, −0.1)	−0.2 (−0.6, 0.1)	−0.4 (−0.7, −0.2)	0.2 (−0.2, 0.7)	0.7 (−0.6, 2.0)
Average ulnar drift¶	20.6 (16.0, 25.3)	−0.9 (−4.5, 2.6)	21.2 (17.8, 24.6)	−1.1 (−3.8, 1.6)	22.3 (17.9, 26.6)**	19.8 (12.0, 27.6)**
Average extensor lag¶	30.4 (22.7, 38.1)	−7.9 (−11.5, −4.4)	31.7 (27.1, 36.2)	−7.7 (−11.2, −4.1)	39.3 (33.6, 45.1)**	38.9 (27.5, 50.4)**
MCP arc of motion§	9.2 (3.1, 15.3)	−9.5 (−13.2, −5.8)	10.1 (6.2, 14.0)	−9.2 (−12.3, −6.2)	19.3 (14.4, 24.3)**	19.0 (12.3, 25.7)**
PIP arc of motion§	6.9 (1.4, 12.4)	−2.6 (−5.2, 0.0)	7.5 (4.2, 10.9)	−2.6 (−5.2, 0.1)	10.1 (5.8, 14.3)**	10.4 (−4.3, 25.2)**

* Values are the mean (95% confidence interval) unless indicated otherwise. Using random-effects model with baseline and year 3 outcome values as dependent variable and adjusted for baseline values of the outcome variable, age, sex, baseline severity stage, education level, income level, study site, 3 year indicator, silicone metacarpophalangeal joint arthroplasty (SMPA) group indicator, and SMPA group by 3-year time interaction. MCP = metacarpophalangeal joint; PIP = proximal interphalangeal joint.
† Between-group differences at 3 years; positive scores reflect better outcomes in SMPA group relative to nonsurgical group.
‡ Based on 5 imputations.
§ Changes are calculated as 3-year minus baseline values, and positive values reflect improvement.
¶ Changes are calculated as baseline minus 3-year values, and positive values reflect improvement.
# $P < 0.05$.
** $P < 0.001$.

found in Tables 3 and 4. The analysis looked at the difference in mean scores from baseline to 3 years for the 2 hands (Supplementary Table 1, available in the online version of this article at http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658). The results were similar to the analyses comparing SMPA and nonsurgical subjects; significant differences were found between study and control hands in the change in mean values from baseline to 3 years for arc of motion, ulnar drift, extensor lag, and overall MHQ score.

We also compared results by study center. Patients in all centers showed significant improvement in MHQ, but even after adjusting for covariates, including the use of biologic agents, the 2 US sites showed significantly greater improvement than the UK site. A previous article noted the differences between the US and the UK sites, which were attributed to differences in the health care systems between countries (35).

Regarding adverse events, 1 patient had an infection from a proximal interphalangeal joint fusion. Two patients required revision SMPA due to ulnar drift and dislocation of the implant, respectively. Fractures and deformities of the silicone implant were assessed using radiographs. Of the 69 surgical cases, 42 had radiographs taken at 3 years after surgery. Four (9.5%) subjects had definite fractures in at least 1 finger, and 7 (16.7%) had at least 1 severely deformed joint. Seven subjects died prior to the 3-year assessment. None of the deaths were determined to be related to the study.

DISCUSSION

The evidence-based medicine movement stresses the importance of finding the highest available evidence and combining that information with physician experience and patient preferences when determining the course of treatment. There is a substantial amount of high-level evidence through RCTs that medications can slow or stop the progression of RA. Surgery, and in particular SMPA, cannot prevent the physical damage of RA, but there is some evidence that it can restore function to the hands of affected RA patients. The results presented in this article are from the largest collaborative study between hand surgeons and rheumatologists on SMPA.

The results from extended followup of this cohort of surgical and nonsurgical subjects showed that the benefits of SMPA continue through 3 years after surgery. The main outcome of the study is hand function as assessed using the MHQ. Surgical patients, when compared to nonsurgical patients, reported significant improvements from the MHQ in hand function, ADL, aesthetics, and satisfaction over time. For example, the average scores for these domains increased by 22, 16, 23, and 24 points, respectively, after adjusting for other variables. The minimum clinically important difference calculated for the MHQ function and ADL domains are 13 and 3, respectively (36). Our results for these domains are well over this threshold. Previous studies have reported improvements in pain, aesthetics, satisfaction, ADL, and function after SMPA. However, these results were not based on validated HRQOL questionnaires.

Surgical subjects as compared to nonsurgical subjects show a dramatic improvement in the degree of ulnar drift, extensor lag, and arc of motion at the MCP joint. We found an average 20° improvement in ulnar drift and 30° improvement in extensor lag over 3 years. Previous studies that did compare objective measures before and after surgery had similar results. These studies found ulnar drift to improve from 9–30° postoperatively and extensor lag improved from 34–47° (1,2,8,10,11,16). Arc of motion in our study increased 9° on average over 3 years, whereas other studies have reported from −11 to 34° postoperative improvement (1–5,7,8,10,11,16,17). The lack of improvement in grip strength in this study has been confirmed previously (8). SMPA allows the patient to open and close their hands more easily, but does not increase the strength of the hand or pinch of the fingers. There is no reference standard for determining hand function, but research has shown that patient-reported outcomes, such as those reported in the MHQ, are more sensitive patient-oriented measures of outcomes than traditional measures such as grip and pinch strength (37).

Complications from SMPA in our cohort were minimal at 3 years. One complication that can arise from SMPA is implant fracture. Previous studies of implant fracture specifically for the silicone implant have found rates ranging from 0–67% (5–8,10,11,14,28,29,31,38–42). Overall, the 3-year fracture rate of 9.5% for this cohort is low.

The most important outcome for rheumatoid patients and hand surgeons considering surgery is improved function. Our 3-year results have demonstrated that the SMPA procedure will improve function and ADL and restore the appearance of severely deformed rheumatoid hands. More importantly, the baseline adjusted difference between SMPA versus nonsurgically treated hands remained significant, indicating that at 3 years after surgery, SMPA-treated patients continued to have better hand outcomes than comparable nonsurgically treated patients.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Chung had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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