Published in final edited form as:

J Hand Surg Am. 2009 ; 34(5): 815–823. doi:10.1016/j.jhsa.2009.01.018.

A Multi-Center Clinical Trial in Rheumatoid Arthritis Comparing Silicone Metacarpophalangeal Joint Arthroplasty with Medical Treatment

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Abstract

Purpose—Metacarpophalangeal (MCP) joint deformities caused by rheumatoid arthritis can be treated using silicone metacarpophalangeal joint arthroplasty (SMPA). There is no consensus whether this surgical procedure is beneficial. The purpose of the study was to prospectively compare outcomes for a surgical and a non-surgical cohort of rheumatoid arthritis patients.

Methods—The prospective cohort trial was conducted from January 2004 to May 2008 at 3 referral centers in the US and England. Over a 3 year period, 70 surgical and 93 nonsurgical patients were recruited. One year data are available for 45 cases and 72 controls. All patients had severe ulnar drift and/or extensor lag of the fingers at the MCP joints. The patients all had one year follow-up evaluations. Patients could elect to undergo SMPA and medical therapy or medical therapy alone. Outcomes included the Michigan Hand Outcomes Questionnaire (MHQ), Arthritis Impact Measurement Scales (AIMS2), grip/pinch strength, Jebson-Taylor test and ulnar deviation and extensor lag measurements at the MCP joints.

Results—There was no difference in the mean age for the surgical group (60) when compared to the non-surgical group (62). There was also no significant difference in race, education, and

income between the two groups. At one year follow-up time, the mean overall MHQ score showed significant improvement in the surgical group, but no change in the non-surgical group, despite worse MHQ function at baseline in the surgical group. Ulnar deviation and extensor lag improved significantly in the surgical group, but the mean AIMS2 scores and grip/pinch strength showed no significant improvement.

Conclusion—This clinical trial demonstrated significant improvement for RA patients with poor baseline functioning treated with SMPA. The non-surgical group had better MHQ scores at baseline and their function did not deteriorate during the one year follow-up interval.

Keywords

Rheumatoid arthritis; Silicone Metacarpophalangeal Joint Arthroplasty; Clinical trial; The Michigan Hand Outcomes Questionnaire; Hand Surgery

Rheumatoid arthritis (RA) is the second most common type of arthritis after osteoarthritis.¹ A recent report from the National Arthritis Data Workshop estimates that 1.3 million adults in the United States have been diagnosed with RA. This disease is more common in women by affecting 1.06% of women in comparison to 0.61% of men in the United States.²

RA is a progressive and often crippling disease, which is responsible for lost work and wages as well as a decline in the quality of life for many patients. It has been estimated that 70% of RA patients have some type of hand impairment.³ These hand impairments hamper the ability of RA patients to perform activities of daily living (ADL) and in severe cases, live independently. Hand deterioration can occur quite rapidly. Dellhag and Bjelle monitored RA patients over a 5 year period and found that hand function worsened significantly during this time.⁴ Sherrer et al. found that by 10 years after diagnosis, 90% of RA patients had some measurable disability in ADL and 13% were nearly completely disabled.⁵ In the US, the costs associated with RA, including medical costs and lost wages, were estimated at \$8.7 billion annually in 1996.⁶

A common deformity in RA patients is the appearance of ulnar drift of the fingers and an inability of the fingers to extend (Figure 1). RA patients experience functional limitations due to difficulty with grasping, fine pinch and holding large objects. Since the introduction of the silicone metacarpophalangeal (MCP) joint arthroplasty (SMPA) to realign fingers over 40 years ago, a number of retrospective uncontrolled studies have been published that demonstrate the effectiveness of this operation in improving the appearance and posture of the hand.⁷⁻¹⁵ Recently, more prospective outcome studies (sample sizes ranging from 12 to 21) with 1 year follow-up have shown that the SMPA procedure is highly effective in correcting ulnar drift and improving health-related quality-of-life (HRQL), but hand function, as measured by arc of motion and grip strength, does not improve after surgery.¹⁶⁻¹⁹

One problem in determining appropriate care for RA patients is the considerable disagreement between rheumatologists and hand surgeons regarding timing, indications, and outcomes of RA hand surgery.²⁰⁻²³ The care of RA patients is marked by large area variations between regions of the United States.²⁰ These large variations are reflected in a

national survey of rheumatologists and hand surgeons that showed that a minority of rheumatologists (34%) and a majority of hand surgeons (83%) had a positive view regarding outcomes of SMPA procedures.²³ In addition, rheumatologists indicated that this procedure should be reserved for patients with more severe deformity, whereas hand surgeons prefer to operate on patients earlier when they have less deformity. One of the main reasons for this disagreement is that outcomes data on RA hand surgery is often viewed by rheumatologists as unscientific and less than robust. These interdisciplinary controversies may be hampering care of RA patients and highlight the viewpoint of hand surgeons that RA patients with hand deformities are not referred sufficiently often for surgical consideration or are referred at a late stage.^{3, 23}

To address the ongoing debate regarding the SMPA procedure, we have initiated a three center international prospective cohort study as a collaborative effort between rheumatologists and hand surgeons to evaluate outcomes of SMPA procedures comparing patients treated with or without surgical intervention. Rheumatologists and hand surgeons worked jointly to recruit patients into the study and to assess the outcomes and complications associated with this commonly performed procedure. The specific aim of this study is to measure patient outcomes using functional and validated patient-rated outcomes questionnaires in an effort to assess the effects of SMPA on hand function and overall health-related quality-of-life. We hypothesize that RA patients who undergo SMPA will have clinically and statistically significant improvements as measured by the Michigan Hand Outcomes Questionnaire compared to non-SMPA patients.

Materials and Methods

Objectives

The objective of the study was to evaluate a prospective cohort of RA patients with MCP joint subluxation who elect to undergo SMPA or not undergo SMPA. Outcome measurements included a hand-specific instrument, the Michigan Hand Outcomes Questionnaire (MHQ) and three quantitative hand function tests (grip strength, pinch strength, and Jebsen-Taylor test). We also compared the global functioning of the surgical and non-surgical groups by using an arthritis specific instrument, the Arthritis Impact Measurement Scales (AIMS2).

Eligibility criteria

Study subjects were recruited from three sites: The University of Michigan (Ann Arbor, MI), Curtis National Hand Center (Baltimore, MD) and Pulvertaft Hand Centre (Derby, England). All aspects of the study were approved by the Institutional Review Boards at the University of Michigan, Curtis National Hand Center and the Pulvertaft Hand Centre. Patients diagnosed with RA were referred by their rheumatologists to one of the three centers. Patients were eligible to participate in the study if they had a diagnosis of RA, were 18 years of age or older and had the ability to complete questionnaires in English. Additionally, patients were eligible to participate in the study if the sum of the average MCP joint ulnar drift and average MCP joint extensor lag was equal to or greater than 50. For example, the ulnar deviation and extensor lag of the index, middle, ring and small fingers

were summed and then averaged. The sum of the two averages (ulnar deviation and extensor lag) must equal 50° or more. This threshold of MCP joint subluxation was determined by an expert panel of rheumatologists and hand surgeons to be the minimal deformity that would warrant surgical consideration for reconstruction. Exclusion criteria included: health problems that would prohibit surgery, extensor tendon ruptures in the study hand (which require a different therapy protocol), swan-neck or boutonniere deformities that would require surgery (which confounds the outcomes because of additional surgical procedures on the hand), previous MCP joint replacement and the initiation of disease-modifying antirheumatic drugs (DMARDs) within 3 months of enrollment (which may increase surgical infection risk).

Treatment allocation

The study design was a prospective cohort clinical trial with two treatment groups: SMPA surgery or no surgery. Because of strong patient preference, we could not randomize patients into the treatment groups. We found in the planning phase of this study that most patients would not consent to randomization because they had an inherent preference whether to have or not have surgery. In addition, most RA hand deformities are not perfectly symmetrical and patients frequently have a preference regarding the hand on which they want to have surgery first. For this reason, in this study, the surgical subjects could choose which hand would have surgery. Similarly, non-surgical subjects could choose which (hypothetical) hand would be the study hand, if they would have elected to have an operation. During the study, changes in the medical management of each patient were at the discretion of the patients' rheumatologists.

Patients met with the occupational therapist prior to surgery to discuss the procedure and what to expect regarding therapy and rehabilitation time post-operatively. The occupational therapist explained that they would begin wearing a dynamic MCP joint extension splint five days after surgery. The tension of the dynamic splint is set to maintain full MCP joint extension at rest and allow maximal active MCP joint flexion. The extension dynamic splint is worn at all times for six weeks. After six weeks, dynamic extension splint is worn in the evenings only. The patients can start engaging in "light duty" hand activities during the day. At 12 weeks, splinting is discontinued, and patients resume unrestricted activity.

Outcome Measures

All outcome measures were completed at each of the study intervals: enrollment, 6 months, 1 year, 2 years, and 3 years. This paper will present the one year follow-up data. The patients are still being followed and the sample sizes for the 2 and 3 year cohort are as yet too small for analysis.

Study Questionnaires

The primary outcome instrument for measuring hand performance in this study is the MHQ.^{24, 25} The MHQ is a validated hand-specific outcome questionnaire and has been utilized in researching outcomes for RA,^{19, 26, 27} carpal tunnel syndrome,^{28, 29} distal radius fractures,³⁰⁻³² Dupuytren's disease,³³ and microvascular toe transfer.^{34, 35} The MHQ contains six domains: (1) overall hand function, (2) ADL, (3) pain, (4) work performance,

(5) aesthetics, and (6) patient satisfaction. Scores range from 0 to 100 with higher scores indicating better performance, except for the pain scale. For the pain scale, a higher score indicated more pain.

Study subjects also completed the Arthritis Impact Measurement Scales 2 (AIMS2).³⁶ The AIMS2 is a health status questionnaire specifically designed to measure health status in RA patients. The AIMS2 contains 12 scales, which can be combined into four domains: 1) physical, 2) affect, 3) symptom, and 4) social interaction. AIMS2 scores range from 1 to 10 with lower scores indicating better health status.

Functional Assessment

Functional assessments included: grip strength, lateral pinch, two-point pinch and three-point pinch. The Jebson-Taylor test was also administered at each study visit.³⁷ It is a test that simulates ADL and consists of seven components: (1) writing a short sentence, (2) turning over 3 by 5 inch cards, (3) picking up small objects and placing them in a container, (4) stacking checkers, (5) simulated eating, (6) moving large, empty cans, and (7) moving large, weighted cans. Because of the difficulty in interpreting the writing portion, this section of the test was omitted. The time required in seconds to complete each task is recorded for the subjects' dominant and non-dominant hands.

Data Analysis

Because study subjects agreed not to cross over to the other treatment group before the one year follow-up period, the effect of cross-over is not an issue in this current analysis. We first compared the distribution of demographic variables and baseline factors between the surgical group and the non-surgical group. Baseline analysis included descriptive statistics to describe the distribution of baseline variables in the two study groups. To compare the distribution of baseline variables between the two study groups, we apply the two-sample t-test for continuous variables, and chi-square tests for categorical variables.

For all outcome measures of interest, means and 95% confidence intervals at each follow-up time were calculated for the two groups. Differences in the average mean change-scores at one year from baseline were calculated as effect sizes for the surgical group compared with non-surgical group. Multiple regression models were used to obtain the covariate adjusted effect sizes and to test for the statistical difference in the one year change-scores between the two groups. The model used the change-scores as the dependent variable and an indicator for the surgical group as the primary independent variable. To adjust the effect sizes for baseline differences, the models were also adjusted for two different sets of covariates. In the first case, the mean difference in the change-scores was adjusted for the baseline values of the response variable. In the second case, the mean difference in the change-scores was adjusted for the baseline value of the response variable, age, severity (as degree of deformity), education (high school and lower versus higher), and gender. All effect sizes were calculated so the positive values corresponded to greater improvement in the surgical group relative to non-surgical group. Assessments of longitudinal trends were done graphically with the means and the 95% confidence intervals at each follow-up plotted over time for the two groups.

Results

A total of 163 patients were enrolled in the study from January 2004 to May 2008. Four patients assessed for eligibility declined to participate in the study. This is the largest cohort thus far assembled to evaluate the effects of the SMPA procedure. Of these patients, 70 were surgical cases and 93 were non-surgical cases. The study was designed as a long-term comparative hand outcomes study to have 90% power to detect a 0.6 standardized effect size (as changes from baseline in hand-specific outcomes at one year) between the surgical and non-surgical groups using a two-sided 0.01 level two-sample t-test. We report here preliminary results from one year outcome data available for 45 cases and 72 controls. Table 1 compares the demographic data for the surgical and non-surgical groups. The two groups were found to be statistically comparable in age, race, income and education though more women elected to have surgery.

Tables 2-5 show outcomes at baseline, 6 months and 1 year for surgical and non-surgical cases. Mean MHQ scores (Table 2 and Figure 2) for the surgical group are lower at baseline than in the non-surgical group for all domains ($p < 0.01$ for all domains) indicating more patients in the surgical cohort have more self-perceived functional impairment in their hands and worse hand outcomes in general. The MHQ scores for the surgical cohort increased substantially at 6 months and approached or surpassed the scores for the non-surgical group at 1 year. The adjusted effect sizes at 1 year were significantly greater than zero for all MHQ subscales and the overall scale, indicating significant improvement in the surgical group. The exception to this trend is the MHQ work subscale. MHQ scores in the non-surgical group did not change significantly for any of the scales from baseline to 1 year.

Physical measurements (Table 3) did not show the same level of improvement as seen with the MHQ data. All physical measurements reflected statistically significant worse function ($p < 0.05$) at baseline in the surgical group compared to the non-surgical group, except key lateral pinch ($p = 0.10$). For most functional outcomes, the outcomes in the surgical group worsened at 6 months and improved to baseline values at 1 year. None of the adjusted effect sizes was significant. Although the Jebson-Taylor test did show improvement at 1 year from baseline in the surgical subjects by decreasing the time to complete tasks from 55.8 seconds at baseline to 44.4 seconds at 1 year, the baseline-adjusted effect size was not significant at one year.

AIMS2 outcome data (Table 4) showed the greatest improvement in the physical domain for surgical patients and minimal improvement for the affect, symptom and social interaction domains. Surgical scores for all AIMS domain were significantly higher (worse outcome) at baseline as compared to controls ($p < 0.01$ for all domains, except $p = 0.04$ for social interaction) and remained higher at 6 months and 1 year. AIMS2 scores for non-surgical patients did not show any improvement and remained essentially the same from baseline to 1 year. None of the adjusted effect sizes was significant.

In contrast to other measurements, the mean degree of ulnar drift for the two treatment groups was similar ($p = 0.23$) at baseline (Table 5). However, the surgical cases showed remarkable improvement in ulnar drift at 6 months and 1 year. Extensor lag was greater ($p <$

0.001) at baseline for surgical cases as compared to non-surgical cases, but was substantially lower than non-surgical cases at 6 months and 1 year. The arc of motion is defined as the flexion – extension lag at a particular joint. The arc of motion for the MCP joint was lower ($p < 0.001$) for surgical cases at baseline as compared to non-surgical cases, with the greatest increase for the surgical group at 6 months and a smaller increase at 1 year. Mean scores for non-surgical group for all three measurements did not change from baseline to 1 year. The changes from baseline in ulnar drift and extensor lag were significantly greater in the surgical group than in the non-surgical group both at 6 months and at 1 year.

Adverse Effects

One patient had a K-wire infection from a PIP joint fusion. Two patients required revision SMPA. One patient because of substantial ulnar drift post-operatively and another patient because of a dislocated right little finger implant.

Discussion

The outcomes movement began in the late 1980's as a response to the rising cost of health care.³⁸ The medical community, if it was going to succeed in containing costs, needed to determine whether medical services given resulted in improved patient outcomes. The Agency for Healthcare Research and Quality (AHRQ) was created by Congress to identify research that would directly improve patient outcomes, result in changes in clinical practice and lead to the development of guidelines for the appropriate use of medical services.^{39, 40} As a means of evaluating outcomes research, AHRQ developed a model to determine the level of impact.⁴¹ A level 1 study has the lowest level of impact and does not provide enough evidence to change policy or clinical practice. Level 4 studies have the highest level of impact and show an improvement in health outcomes as a direct result of a medical intervention. Level 4 studies must have a control group and are usually clinical trials. Although the outcomes movement is several decades old, the number of level 4 studies published is inadequate in many medical fields, particularly in hand surgery.^{42, 43}

Clinical trials are used routinely to test the effectiveness of medical treatments for RA. A large body of evidence has been accumulated about a variety of drugs that can be used in the management of this disease.⁴⁴⁻⁴⁶ Nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, disease-modifying antirheumatic drugs (DMARDs) and analgesics have been used for many years. Although they often do not stop the progression of the disease, these drugs are very helpful in reducing the symptoms of RA, including inflammation and pain. New biologic agents have emerged that may actually prevent joint destruction altogether and have substantially changed the management of RA.

In contrast to rigorous research programs to test new drug in the treatment of RA, high level evidence studies to evaluate surgical innovations for this disease are lacking. Previous studies have been mostly retrospective chart reviews with no control group, and none included validated outcomes questionnaires.¹⁴ Given the current state of surgical research in RA, it is not surprising that rheumatologists view surgical outcomes studies with skepticism, and thus the controversy regarding SMPA persists. The aim of this study is to provide outcomes data regarding the benefits of SMPA by evaluating a prospective cohort of RA

patients. Recruitment of patients from three different practice settings enhances generalizability. The University of Michigan is a tertiary referral academic center with a large collaborative program in the care of the RA patients, the Curtis National Hand Center draws patients from around the United States for hand surgery expertise, and the Pulvertaft Hand Center in Derbyshire, England is a renowned center in the United Kingdom for RA treatment.

This clinical trial involved recruitment of a cohort of RA patients with defined MCP joint deformities who entered a surgery plus medical therapy group or a medical therapy alone group. Although the surgical group had worse self-reported MHQ scores at baseline when compared to the non-surgical group, the outcomes at 1 year follow-up period showed significant improvement in hand function after SMPA. Surgical patients reported significant improvement in function, aesthetics, ADL and satisfaction with their hand 1 year after surgery. Surgical cases also had significant decreases in ulnar drift and extensor lag after reconstruction. Overall health as measured by the AIMS2 questionnaire did not show any improvement at 1 year. AIMS2 has construct validity in measuring the general health impairment in RA, and our study showed that general RA health cannot be improved simply with hand reconstruction alone. The change in values for grip strength and pinch strength were not significant. These results are consistent with previous studies that show improvement in ulnar drift, extensor lag and HRQL after surgery but no improvement in the other standard functional measures.^{14, 19, 47}

In contrast, the non-surgical group showed no improvement or deterioration in hand function during 1 year follow-up. Overall, the non-surgical group began the study with better function as measured using outcomes questionnaires and functional tests. This result is not surprising because one would expect that patients who report better hand function would not elect to have surgery. This group is continuing with medical therapy and the lack of deterioration in hand function provides evidence of the effectiveness of RA medications in curbing the destructive effect of RA.

This study did not randomize subjects into treatments groups due to strong patient preference and issues with equipoise by participating surgeons and rheumatologists. But despite a non-randomized design, both groups had similar baseline data in age, race, education, and income. Our surgical group had more women and we adjusted for gender as well as age and education in the analysis. Baseline values for most of the outcomes were different for the two treatment groups. Patients with poorer self-reported hand function at baseline elected to have surgery. Although the mean values of the outcome variable for the two treatment groups differed at baseline, the distributions of the two groups had a good overlap. We computed the effect sizes, adjusting for baseline values of the outcome variable.

The results presented in this paper only include up to 1 year of follow-up. Long term retrospective studies of SMPA have demonstrated high rates of implant fractures but patient satisfaction with the procedure remains good.^{8, 9, 15} We are continuing to follow this important cohort of patients and will be able to determine if improvements in hand outcomes for SMPA patients are maintained or if either group shows worsening over time. The results demonstrate that SMPA is a good treatment option, especially for patients with poor hand

function and in whom medical therapy alone has not alleviated symptoms and slowed the progression of the disease. The information obtained in this study will help to bridge the gap between rheumatologists and hand surgeons in the common goal of improving the quality of life for patients with RA.

Acknowledgements

The authors acknowledge the assistance of the following participants of the SMPA Study Group: Sandra V. Kotsis, MPH, Heidi Reichert, MA (University of Michigan), Lorraine A. Zellers, CRC (Curtis National Hand Center), Mary J. Bradley, MSc (Pulvertaft Hand Centre) and the referring rheumatologists in Michigan, Derby and Baltimore. The authors also greatly appreciate the assistance of Jeanne M. Riggs, OTR, CHT, Kurt Hiser, OTR, Carole Dodge, OTR, CHT, Jennifer Stowers, OTR, CHT, Cheryl Showerman, OTR, Jo Holmes, OTR, Victoria Jansen, PT and Helen Dear, OTR in taking measurements for the study patients.

Supported in part by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (R01 AR047328) and a Midcareer Investigator Award in Patient-Oriented Research (K24 AR053120) (to Dr. Kevin C. Chung).

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Figure 1.
Example of deformities in rheumatoid hand and results following SMMPA. The right unoperated hand shows the ulnar drift and extension lag of the fingers due to disease at the MCP joints. The left hand was corrected by SMMPA.

Figure 2.
Mean MHQ Overall Score for Surgical and Non-surgical Subjects Over Time (months)

Table 1
Comparison of Demographic Values for Surgical vs. Non-Surgical Subjects

Demographic variables	Surgery (N=70)	Non-surgical (N=93)	P- value
Age, mean (SD)	60 (8)	62 (11)	0.33
Women, No. (%)	57 (81)	62 (67)	0.04
Race, White, No. (%)	59 (84)	76 (82)	0.10
Education, High School Degree, No. (%)	36 (51)	37 (40)	0.11
Income, \$50,000, No. (%)	49 (70)	58 (62)	0.42

Table 2
Comparison of Michigan Hand Outcomes Questionnaire (MHQ) Scores for Surgical (SMPA) vs. Non-Surgical Subjects

MHQ Scale	Preoperative		6-Month Postoperative		1-Year Postoperative		Adjusted Effect Size* (Baseline)		Adjusted Effect Size** (Baseline & Covariates)	
	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA	Effect Size	p-value	Effect Size	p-value
Function	36 (22)	58 (18)	64 (19)	59 (21)	60 (24)	59 (22)	15.4	<.001	14.4	0.001
ADL	34 (26)	60 (24)	55 (29)	60 (26)	55 (31)	60 (25)	13.3	<.001	13.2	0.001
Work	41 (22)	59 (23)	50 (28)	63 (28)	47 (28)	61 (26)	0.1	0.981	1.3	0.774
Pain	49 (26)	35 (25)	35 (25)	33 (26)	34 (24)	35 (26)	8.3	0.033	8.2	0.063
Aesthetics	32 (22)	48 (24)	71 (22)	50 (23)	66 (23)	52 (23)	20.5	<.001	21.4	<.001
Satisfaction	26 (20)	48 (25)	64 (24)	49 (26)	61 (27)	49 (26)	26.1	<.001	24.1	<.001
Overall Score	37 (18)	56 (18)	61 (20)	58 (21)	59 (22)	58 (20)	16.3	<.001	15.6	<.001

Abbreviations: ADL, activities of daily living; SMPA, Silicone Metacarpophalangeal Joint Arthroplasty.

Cell values are means (SD).

* Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline values of the response variable.

** Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline value of the response variable, centered age, centered severity, education (high school and lower versus higher), and gender.

Higher pain scores correspond to greater pain.

Table 3
Comparison of Physical Measurement Scores for Surgical vs. Non-Surgical Subjects

Physical Measures	Preoperative		6-Month Postoperative		1-Year Postoperative		Adjusted Effect Size* (Baseline)		Adjusted Effect Size** (Baseline & Covariates)	
	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA	Effect Size	p-value	Effect Size	p-value
Grip Strength (kg)	5.7 (6)	8.5 (7)	4.6 (4)	9.6 (8)	6.2 (5)	9.8 (8)	-1.28	0.140	-1.46	0.132
Key (lateral) pinch (kg)	3.5 (2)	4.0 (2)	3.1 (2)	4.2 (2)	3.1 (2)	4.0 (2)	-0.25	0.268	-0.25	0.327
2-point (tip) pinch (kg)	2.5(2)	3.1 (2)	2.3 (1)	3.1 (2)	2.7 (2)	3.1 (2)	0.08	0.683	0.12	0.603
Three-jaw (palmar) pinch (kg)	2.6 (2)	3.1 (1)	2.4 (1)	3.2 (2)	2.5 (1)	3.1 (1)	0.02	0.934	-0.02	0.914
Jebson-Taylor (s) ♣	56 (27)	43 (10)	48 (19)	40 (11)	44 (16)	40 (10)	1.75	0.359	1.69	0.440

Abbreviations: SMPA, Silicone Metacarpophalangeal Joint Arthroplasty.

Cell values are means (SD).

* Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline values of the response variable.

** Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline value of the response variable, centered age, centered severity, education (high school and lower versus higher), and gender.

♣ Higher Jebson-Taylor scores correspond to worse outcome.

Table 4
Comparison of Arthritis Impact Measurement Scales 2 (AIMS2) Scores for Surgical vs. Non-Surgical Subjects

AIMS2 Scale	Preoperative		6-Month Postoperative		1-Year Postoperative		Adjusted Effect Size* (Baseline)		Adjusted Effect Size** (Baseline & Covariates)	
	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA	Effect Size	p-value	Effect Size	p-value
Physical	4.0 (2)	2.4 (2)	3.4 (2)	2.5 (2)	3.3 (2)	2.4 (2)	0.24	0.261	0.28	0.241
Affect	4.1 (2)	3.0 (2)	3.7 (2)	2.7 (2)	3.7 (2)	2.7 (2)	0.03	0.895	0.23	0.343
Symptom	5.6 (3)	4.3 (2)	5.1 (3)	4.0 (3)	4.8 (3)	4.0 (3)	0.30	0.367	0.14	0.716
Social interaction	4.2 (2)	3.6 (1)	3.9 (2)	3.7 (1)	3.9 (2)	3.5 (1)	0.10	0.637	0.20	0.397

Abbreviations: SMPA, Silicone Metacarpophalangeal Joint Arthroplasty.

Cell values are means (SD).

* Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline values of the response variable.

** Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline value of the response variable, centered age, centered severity, education (high school and lower versus higher), and gender.

For all AIMS2 subscales, higher scores correspond to worse outcome.

Table 5

Angle of Motion Scores for Surgical vs. Non-Surgical Subjects

Angle of Motion scores [♣]	Preoperative		6-Month Postoperative		1-Year Postoperative		Adjusted Effect Size [*] (Baseline)		Adjusted Effect Size ^{**} (Baseline & Covariates)	
	SMPA	Non-SMPA	SMPA	Non-SMPA	SMPA	Non-SMPA	Effect Size	p-value	Effect Size	p-value
Ulnar Drift	37 (16)	34 (14)	13 (12)	30 (14)	13 (11)	34 (14)	21.27	<.001	23.70	<.001
Extensor Lag	65 (23)	47 (18)	26 (15)	46 (23)	29 (14)	49 (21)	28.10	<.001	30.07	<.001
MCP joint arc of motion	19 (15)	37 (18)	32 (17)	37 (21)	31 (15)	34 (17)	5.90	0.068	7.61	0.032

Abbreviations: MCP, Metacarpophalangeal; SMPA, Silicone Metacarpophalangeal Joint Arthroplasty.
Cell values are means (SD).

* Mean difference in the response variable (1 year change score) between the SMPA and control group, adjusting for the centered baseline values of the response variable.

** Mean difference in the response variable (1 year change score) between the SMPA and Non-SMPA group, adjusting for the centered baseline value of the response variable, centered age, centered severity, education (high school and lower versus higher), and gender.

♣ Higher values correspond to worse outcome.