

Patient Perceived Recovery and Outcomes After Silastic Implant Arthroplasty Calvin J. Rushing DPM, Viraj R. Rathnayake DPM, Adam J. Oxios DPM, Gabriel P. Galan DPM, Steven M. Spinner, DPM Westside Regional Medical Center PMSR-RRA

Statement of Purpose

In some chronic musculoskeletal conditions, patients with persistent pain, and disability have still achieved recovery through behavioral adaptations (Readjustment), or cognitive coping (Redefinition). Although the pendulum shift from physician reported clinical indicators to patient reported outcomes measures has recently focused on quantifying residual pain, and disability to determine recovery (Resolution); whether patients are capable of coping with any ongoing deficit(s), and achieving other forms of recovery (Readjustment, Redefinition) has not been considered. The purpose of this retrospective case series was to identify alternate forms of recovery following silastic implant arthroplasty for hallux rigidus. Patient reported outcome measures were compared between patients who perceived themselves as recovered without/with residual deficits (Recovered-Resolved, Recovered-Not Resolved), vs. those not recovered. Holistic/procedure specific satisfaction, complications, and the re-operation/failure rate were recorded.

Introduction

Hallux Rigidus (HR) is the most common arthritic condition of the foot, and is characterized by progressive osteophyte formation, and cartilage destruction resulting in: joint pain, stiffness, and dorsiflexion restriction of the first metatarsophalangeal joint (FMPJ) complex (1-3). Currently, cheilectomy is favored for early stages of HR, while arthrodesis remains reserved for more advanced stages (4). Interim procedures to preserve/restore motion to the FMPJ have been described; although currently no consensus exists. Historically, physician recorded clinical indicators (PRCI's) were utilized to evaluate operative outcomes in hallux rigidus, however; frequently those finding did not parallel the patient reported outcomes measures, or satisfaction. As a result, a pendulum shift from PRCI's (subjective examination, radiographs) to patient reported outcomes measures (PROM's) has occurred, placing increased emphasis on quantifying patients residual pain, and disability to determine recovery (Resolution)(5). Due to the reliance of PROM's on measuring residual pain, and disability; whether patients are capable of coping with any ongoing deficit(s) is not considered, preventing them from capturing other forms of recovery.

In some chronic musculoskeletal conditions, patients with persistent pain, and disability have still achieved recovery through behavioral adaptations (Readjustment), or cognitive coping (Redefinition). As demonstrated by these investigations (6-8), recovery from some chronic foot and ankle aliments may not be predicated on the resolution of all symptomatology. Pinsker et al. (6) first introduced Beaton's alternate recovery model (8) which consists of: Resolution, Readjustment, and Redefinition to the lower extremity. Resolution is a recovery state characterized by resolution of all symptomatology, and is commonly accessed using traditional PROMS. Readjustment is a recovery state characterized by behavioral adjustments, and adaptations to living with the disorder. Lastly, Redefinition is a recovery state characterized by cognitive processes where symptoms and limitations are redefined, through a re-emphasis on remaining abilities, or reprioritizing what is important in life. Although other forms of recovery have been identified for patients following tibiotalar joint reconstruction (total ankle replacement, total ankle arthrodesis), and bipolar radiofrequency ablation with platelet rich plasma injection for refractory plantar fasciosis (6-7); no prior investigation has attempted to broaden our traditional definition of "recovery" in hallux rigidus by identifying these alternate forms of recovery.

The swanson silastic double-stemmed hinge prosthesis was first introduced in 1977 to act as a dynamic spacer, preserving motion and alleviating pain (11-12). While initially met with great enthusiasm; earlier implant materials/designs, improper patient selection/operative technique, and overutilization from 1967-1985 ultimately resulted in trepidation amongst FAS's regarding FMPJ implant arthroplasty (13-14). Titanium grommets, and shorter stems were later incorporated; reducing shear stress concentrated at the prosthetic hinge, and improving implant longevity (15). A recent metaanalysis concluded that patient satisfaction was highest for: double stemmed silicone implants and metallic hemi implants (14). Despite successful outcomes, concerns persist over: implant longevity, foreign body reactions/synovitis, mal-alignment, subsidence, and erosive osteolysis (16-22). Although some FAS currently eschew from the procedure, recent investigations have spurred renewed interest in FMPJ implant arthroplasty (23-26), and prior investigations may have belied its true value.

The purpose of this retrospective case series was to compare the PROMS of patients who perceived themselves as recovered without/with residual deficits (without deficits, Recovered-Resolved)(with deficits, Recovered-Not Resolved) vs. those not recovered following silastic implant arthroplasty. Secondary objectives included an assessment of outcome based on holistic/procedure specific satisfaction, complications, and re-operation/failure rate. A priori hypotheses was that Recovered-Resolved (RR) and Recovered-Not Resolved (RNR) patients would report better PROM scores compared to Not Recovered patients (NR); with >75% being very satisfied/satisfied (scoring 1-2), and willing to recommend/re-undergo the procedure again. Conversely, Not-Recovered (NR) patients would report lower PROM scores; with >75% not satisfied (scoring 0), and unwilling to recommend/re-undergo the procedure again

Patients/Materials & Methods

Under Institutional Review Board (IRB) approval, a retrospective case series was conducted on all patients who underwent implant arthroplasty with the swanson silastic double-stemmed hinge prosthesis by a single senior FAS (S.M.S.) at our institution from July 2006 to July 2016. Patients were identified initially by the Current Procedural Terminology Code (28293), which was then cross-referenced with the International Classification Of Diseases, Ninth Revision, Diagnosis Code (735.2), and record to ensure accuracy. Patients with incomplete medical records, concomitant interventions, or less than one year follow up were excluded from the final analysis. The retrospective review, prospective data collection, and analysis was performed by resident FAS of varying post-graduate years not directly involved in the operative intervention.

From July 1, 2006 to July 1, 2016, 60 silastic implant arthroplastys were performed. Of the 60 patients identified, 3 were excluded for incomplete records, concomitant/revisional interventions, or follow up less than 1 year. Of the remaining 57 patients meeting the inclusion criteria, 29 (29/57, 50.9%) were lost to follow up (16/57, 29.8%) or refused to participate (12/57, 21.1%) leaving 28 of 57 eligible patients (28 index procedures); representing a 49.1% response rate. Twenty four patients were female (24/28, 85.7%), and 4 were male (4/28, 14.3%), with a mean age of 65.6 years (range 45 to 86 years), and mean follow up duration of 66.6 months (range, 12.6 months to 132.5 months).

Following the retrospective review, prospective follow up was conducted via a telephone survey to obtain: patient perceived recovery (PPR), PROM's, "holistic"/"procedure specific" satisfaction, complications, and the reoperation/failure rate. PPR was first assessed by asking the patient to choose the statement that best described their current state of recovery, as described prior (6-7). Patients who selected the statement "I am better with no residual symptoms" were classified as Recovered-Resolved (RR). Patients who selected the statement "I am better with some residual symptoms or limitations that I can cope with" were classified as Recovered-Not Resolved (RNR). Patients who choose the statement "I am not better" were classified as Not Recovered (NR). PROM's were then assessed utilizing a modified foot function index (FFI), and a verbal analog scale (VAS) for pain (0-10). "Holistic" satisfaction was accessed utilizing a semi-quantitative scale of 3 grades (2-very satisfied, 1-satisified, 0 not satisfied), followed by "procedure specific" satisfaction based on the patient's willingness to recommend the procedure to family/friends, and re-undergo the procedure knowing what they know now. A priori hypotheses was that Recovered-Resolved (RR) and Recovered-Not Resolved (RNR) patients would report better PROM scores compared to Not Recovered patients (NR); with >75% being very satisfied/satisfied (scoring 1-2), and willing to recommend/re-undergo the procedure again. Conversely, Not-Recovered (NR) patients would report lower PROM scores; with >75% not satisfied (scoring 0), and unwilling to recommend/re-undergo the procedure again. Lastly, complications, and re-operations were recorded, and the failure rate determined.

Statistical Analysis

Univariate descriptive statistics for demographic variables were generated for the entire sample, and then stratified by recovery group. Values are expressed as counts (percentage), and means (standard deviation) as appropriate. Fisher exact tests and Kruskal Wallis tests were used to compare categorical, and continuous variables respectively. Spearman correlation was used to assess relationships between holistic/procedure specific satisfaction, and the PROMS (FFI, VAS). Two sided p-values of <0.05 were considered statistically significant. All data was analyzed in Statistics and Data (STATA) Version 12.

	Recovered-Resolved	Recovered-Not Resolved (RNR) (n = 12)	Not Recovered (NR) (n = 2)	Total Sample (n = 28)	P-value
	(RR) (n = 14)				
Patient Demographics					
Male, n(%)	1 (7.0)	3 (25)	0 (0)	5 (23)	
Female, n(%)	13 (93.0)	9 (75)	2 (100)	23 (77)	0.36
Age (y), mean(range)	66.85 (57 - 86)	64.08 (45 - 74)	65.5 (58 - 73)	65.57 (45-86)	0.916
Follow-up (m), mean(range)	70.79 (18.2 - 114)	61.03 (12.6 - 132.5)	70 (63 - 77)	66.6 (12.6 - 132.5)	0.172
Patient Reported Outcome Measures					
Modified FFI score, mean(SD)	7.64 ± 4.56	24.60 ± 14.89	40.58 ± 15.8	17.26 ± 16.74	<0.001*
VAS score, mean(SD)	0.5 ± 0.85	3.1 ± 1.72	6.5 ± 4.94	2.03 ± 2.38	<0.001*
Holistic Satisfaction					
Very Satisfied, n (%)	9 (64)	8 (67)	0 (0)	17 (61)	
Satisfied, n (%)	5 (36)	4 (33)	0 (0)	9 (32)	
Not Satisfied, n (%)	0 (0)	0 (0)	2 (100)	2 (7)	<0.026*
Procedure Specific Satisfaction					
Recommend/Re-undergo, n (%)	14 (100)	9 (90)	1 (50)	27 (96.4)	0.072
Complications					
No complication, n (%)	13 (93)	4 (33.3)	0 (0)	5 (18)	
Metatarsalgia, n (%)	0 (0)	4 (33.3)	1 (50)	1 (3.5)	
Short toe, n (%)	0 (0)	1 (8.3)	0 (0)	2 (7)	
Arthrofibrosis, n (%)	1 (7)	2 (16.8)	0 (0)	2 (7)	
MDCN palsy, n (%)	0 (0)	0 (0)	1 (50)	1 (3.5)	
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Recovery Group Identification and Trends: Overall, 50.0% (14/28) of patients perceived themselves as Recovered-Resolved (RR), and 7% (2/28) as Not Recovered (NR). The remaining 43% (12/28) perceived themselves as Recovered- Not Resolved (RNR) despite residual pain, and disability they were coping with. Between groups, no significant differences were identified with respect to: gender, age, or follow up duration (Table).

A logical gradient was identified between recovery groups; with RR patients reporting the lowest residual pain scores (VAS 0.5, SD 0.85), and less functional limitation (FFI 7.64, SD 11.92) compared to RNR, and NR patients. RNR patients reported significantly higher residual pain (VAS 3.1, SD 1.72), and functional limitation (FFI 24.60, SD 14.89) compared to RR patients. Despite this, RNR patients still identified themselves as "recovered"; suggesting there is a residual deficit level with which patients can cope. The NR group reported the highest residual pain scores (VAS 6.5, SD 4.94), with the most functional limitation (FFI 40.58, SD 15.80); suggesting there is a residual deficit level with which some patients may be unable to cope. Between recovery groups, the PROM's were statistically significant; providing credibility to the proposed recovery theory for refractory PF (Table, Figure 1). No correlation was identified between the the PROMS (FFI, VAS) and "holistic" (p=0.330/ p=0.830); or "procedure specific" satisfaction (p=0.092/p=0.082)

Holistic And Procedure Specific Satisfaction: In the RR group, all were very satisfied (9/14, 64%) or satisfied (5/14, 36%) and all (29/29, 100%) would recommend/reundergo the procedure again. Similarly in RNR group, patients were either very satisfied (8/12, 67%) or satisfied (4/12, 33%), and all (10/10, 100%) would recommend/re-undergo the procedure again. Therefore, the priori hypothesis regarding RR and RNR patients was met. Conversely, all patients in the NR group (2/2, 100%) reported both holistic, and procedure specific dissatisfaction. This group expressed persistent deficit(s), which affect them on a daily basis, and prevented their recovery (Table, Figure 2). The priori hypothesis regarding NR patients was met.



The most common complication reported was pain under the lesser metatarsals (transfer metatarsalgia) of varying severity from lateralization of the load in 5 patients (5/28). Arthrofibrosis of the FMTPJ complex (2/28= 7%), medial dorsal cutaneous (MDC) nerve palsy (1/28=3.5%), a shortened big toe (1/28=3.5%), and a plantar plate rupture of the 2nd MPJ (1/28=3.5%) were also reported. Overall, 10 patients (10/28=36%) continue to experience some form of residual pain, and disability; with 8 of these patients identifying as RNR (8/10=80%). This finding further suggests there is a residual deficit level with which some patients can cope following SIA. The remaining 2 (2/10, 20%) patients with residual pain, and disability identified as NR. In The NR group, persistent arthrofibrosis of the FMTPJ complex (1/2= 50%), and MDC nerve palsy were reported (1/2=50%). Patients in the NR group (2/28=7%) were unable to cope with their residual pain, and disability; which significantly affects them on a daily basis. Interpreted collectively, Implant survivorship was 100% with no re-operation's or the FMPJ SIA failures at a mean follow up of 66.6 months (range, 12.6 months to 132.5 months)(Table).

Results

Functional Status And Pain:



Complications, Reoperations, and Failure Rate:

To the best of our knowledge, this study is first to attempt to broaden our traditional definition of "recovery" in patients with HR undergoing FMPJ SIA. PPR was grouped into: Recovered-Resolved (50%), Recovered-Not Resolved (43%), and Not-Recovered (7%). Between recovery groups, the PROM's demonstrated statistical significance, and followed a logical gradient; providing credibility to the proposed recovery theory. Despite only 50% of patients reporting complete symptom resolution (RR group); the majority of patients perceived themselves as recovered (92%, 26/28) and both holistic/and procedure specific satisfaction was high (93%; 26/28)(96%; 27/28). Within the RNR group, patients experiencing transfer metatarsalgia (n=5), arthrofibrosis (n=2), a shortened toe (n=1), and a plantar plate rupture (n=1) still perceived themselves as recovered despite their residual pain, and disability at a mean of 61 months (range, 12.6 to 132.5 months). This finding suggests there is a residual deficit level that may be reached post-operatively with which some patients will be able to cope. Had the outcomes of this cohort been accessed with traditional PRCI's and PROMs alone; alternate forms of recovery could not have been identified. Promising studies recently on FMPJ implant arthroplasty have sparked renewed interest in the

procedure (22-27), although currently no consensus exists amongst FAS's. Our anecdotal success with SIA may be attributed to our: patient selection, preoperative discussions, and operative technique. At our institution, SIA is reserved for older patients (> 50 years old) with moderate to severe HR (Coughlin Grade 3-4), a rectus alignment (hallux valgus angle <18), and the desire to restore/preserve motion to the FMPJ complex. Our findings suggest that recovery in HR is likely a complex, multifactorial process not always predicated on the resolution of all symptomatology. Other factors in chronic musculoskeletal conditions such as anxiety, and depression are known to affect patient's perception of pain, disability, satisfaction, and perhaps perceived recovery (28-29). Recent evidence suggests those with greater medical comorbidity (including anxiety, and depression), and worse preoperative pain/disability actually have higher expectations from foot and ankle surgery (30). Physician-patient communication preoperatively has been identified as a strong predictor of post-operative patient satisfaction, and likely influences PPR (7). Alternate forms of recovery have been well described, and recently applied to the lower extremity

for chronic conditions where complete symptom resolution is not always possible (6-7). In these conditions, most patients perceive a satisfactory outcome if able to reach an improved residual deficit level with which they can cope (6-7). These alternative recovery theory(s) have been slow to migrate to orthopedic subspecialties, in part due to the pendulum shift from physician recorded clinical indicators (PRCI's) to PROM's (7). Governments and payees alike continue to become increasingly interested in patient centric outcome measures; with FAS becoming increasingly responsible for both economic efficiency, and patient outcomes. This collaboration continues to become more physician directed overtime, relying on reported evidence to guide operative management. While PROM's provide direct, patient centric data regarding an intervention; too many measures evaluating similar conditions are currently in use, and compound the difficulty in comparing operative interventions (28). Additionally, due to the reliance of PROM's on measuring residual pain, and disability to determine recovery (Resolution); whether patients are capable of coping with any ongoing deficit(s) is not considered, preventing them from capturing other forms of recovery.

In conclusion, silastic implant arthroplasty affords high PPR, and satisfaction for HR. Despite only 50% of patients reporting complete symptom resolution, the majority reached a residual deficit level with which they could cope, and satisfaction was high. These findings suggest that recovery, and satisfaction in HR may not be predicated on the complete resolution of all symptomatology. FAS should be cognizant of the inherent limitations of PROM's in assessing other forms of recovery, and moving forward; our definition of "recovery" should be broadened when interpreting operative outcomes for patients with HR.





Discussion

References