Journal on Surgery
www.journalonsurgery.org

Research Article

ISSN: 2691-7785

Open Access, Volume 4

Intermediate-Term Follow-Up of Biopro® Modular Thumb Implant for Carpometacarpal Arthritis

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Abstract

Purpose: Basilar thumb arthritis is a common condition that can be associated with significant disability. While surgical management has historically consisted of trapeziectomy-type procedures, hemiarthroplasty has become an increasingly common alternative. While outcomes have been promising, they vary according to the implant used. We sought to evaluate the performance of the BioPro® Modular Thumb implant.

Methods: This was a retrospective review of 110 thumbs with carpometacarpal arthritis that underwent hemiarthroplasty between the years 2008 and 2016 with the BioPro® device. All thumbs had Eaton-Little Stage II or III arthritis. Patients were asked to complete preoperative and postoperative assessments using QuickDASH, as well as complete strength measurements using a dynamometer.

Results: Mean age was 61 years, with average final follow-up at 3.8 years. Forty thumbs completed QuickDASH and showed a 34.78-point improvement at average 2-year follow-up. Implant survivorship was 88.18% at average 3.8-year follow-up. The most common cause of revision was titanium metal allergy. No implants dislocated.

Conclusion: Outcomes of hemiarthroplasty using the BioPro® device were comparable or superior to alternatives and support its continued use.

Level of evidence: Level IV, Prognostic.

Keywords: Arthritis; Carpometacarpal joints; Hemiarthroplasty; Prosthetic implants; Thumb.

Manuscript Information: *Received: Dec 20, 2023; Accepted: Feb 09, 2024; Published: Feb 16, 2024*

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Citation: *Goodsett AT, Jupiter DC, Venugopal NK, Faillace JJ. Intermediate-Term Follow-Up of Biopro® Modular Thumb Implant for Carpometacarpal Arthritis. J Surgery. 2024; 4(1): 1047.*

Introduction

Basilar thumb arthritis is a common and debilitating condition affecting over 30% of postmenopausal women [1]. Patients experience significant pain and reduction in thumb strength, particularly thumb abduction and key-pinch [2,3]. Nonoperative management consisting of splinting, physical therapy, pain medication, and joint injection do not correct underlying pathology and generally do not provide satisfactory long-term outcomes [4]. Operative management includes joint arthrodesis, arthroplasty, and trapeziectomy with or without suspension of the first metacarpal via ligament reconstruction and tendon interposition (LRTI). While trapeziectomy with LRTI is the most prevalent [5,6], high-quality evidence has not demonstrated any technique to be definitively superior [7].

Carpometacarpal (CMC) joint fusion can provide symptomatic relief but may accelerate arthritis in the adjacent scaphotrapeziotrapezoidal and metacarpophalangeal (MCP) joints and is associated with a 13% risk of nonunion [8]. Trapeziectomy with LRTI for treatment of CMC arthritis was first described over 70 years ago and provides a good balance of symptomatic pain relief and maintenance of functional status [9]. However, patients generally report decreases in strength, including thumb abduction and key-pinch motions postoperatively [7]. Additionally, the removal of the trapezium results in a loss of height that invariably progresses in the following decade [10]. Short-term follow-up studies have not indicated clinical sequlae [11,12]; however, longer- term studies (greater than 7 years) have shown a negative correlation between degree of subsidence and functional outcomes [13]. Basilar thumb implants were first described in the early 1970s and included silicone implants, such as those utilized by Swanson [14,15], as well as metal-on-polyethylene designs described by de la Caffiniere and Aucouturier in 1973 [16]. While initially promising, various barriers limited widespread adoption. Appropriate sizing of the implant could be technically challenging, particularly in the case of monoblock systems, and complications such as CMC subluxation, silicone synovitis, or aseptic loosening frequently necessitated revision surgery [17-20]. Although there have been numerous advances in material science, implant design, and technique since then, various challenges persist, with patients reporting varying degrees of functional improvement postoperatively.

The BioPro® Modular Thumb Implant (BioPro, Port Huron, MI) is a more recent basilar thumb hemiarthroplasty system that has seen growing use. Advantages over previous systems include its material composition, modularity, and geometry that better approximates native thumb anatomy. The implant is composed of cobalt-chrome, although an all-titanium version is also available. It has modularity of both the metacarpal stem and head components. Modular heads permit better fit to the patient's trapezium to facilitate force distribution and socket congruency, while the ability to adjust stem length enables more precise soft-tissue tensioning. The stem component has two additional features: varus angulation and titanium spray coating. Increased varus angulation better approximates native thumb anatomy and biomechanics. This, in turn, theoretically reduces subluxation risk. The titanium plasma spray coating allows for cementless fixation of the component with associated bony ingrowth. This may have the benefit of mitigating implant subsidence and loosening. The goal of this study is to evaluate the efficacy of the BioPro® implant in the treatment of CMC arthritis. Outcomes of particular interest include pain reduction, postoperative gains or losses in functional status, and device survivorship.

Methods

This is a retrospective single-cohort study of 95 patients (110 thumbs, 15 bilateral implants) with Eaton-Littler Stage II or III osteoarthritis of the trapeziometacarpal joint who were treated with a basilar thumb hemiarthroplasty using the BioPro® Modular Thumb Implant between the years 2008 and 2016. The study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. Exclusion criteria included prior infection of the operative hand, presence of Eaton-Littler Stage IV osteoarthritis (for which other treatments are indicated), or prior diagnosis of inflammatory-type arthritis. Prior to surgery, patients were requested to voluntarily complete a preoperative qualitative assessment of their functional status utilizing the QuickDASH (Disabilities of the Arm, Shoulder and Hand) survey, as well undergo bilateral strength measurements of the hands. These measurements included grip strength, tip pinch, three-jaw-chuck, and key pinch. Strength measurements were obtained utilizing a calibrated dynamometer set consisting of 2 separate devices for hand and pinch strength, respectively. At the first follow-up visit more than 6 weeks postoperatively, patients were again requested to complete a QuickDASH form and repeat strength measurements using the same dynamometer set. For patients that recorded multiple sets of data over serial follow-up appointments, the most recent data set was used in the final analysis. Pre- and postoperative QuickDASH scores were compared using a 2-tailed paired t test with statistical significance considered at $P<0.05$.

Results

Of the 95 total patients (110 thumbs) who elected to undergo thumb arthroplasty, 31 patients were male (37 thumbs, 33.6%) and 64 female (73 thumbs). Average patient age at date of service was 61 years (standard deviation [SD]=9.1). Average duration between surgery and final recorded follow-up was 3.8 years (SD=2.5). Relevant data are summarized in Table of the original 110 thumbs, 40 thumbs (17 male, 42.5%; 23 female) recorded both a pre- and postoperative QuickDASH. This subpopulation was comparable to the general study population in terms of age (59 years, SD=9.0) and average final follow-up (4.0 years, SD=1.9). The average QuickDASH scores were 49.55 (SD=14.6) preoperatively and 20.8 (SD=22.7) postoperatively. This decrease was statistically significant ($P<0.00001$). Higher preoperative QuickDASH score was correlated with increased improvement ($R2=-0.212$) across the entire study population (Figure 1). Women on average reported slightly higher preoperative QuickDASH scores (49.84) and slightly greater postoperative improvement (-29.2) compared to men (52.17 and -25.53). A further subpopulation of 9 thumbs had at least 2 postoperative QuickDASH scores that could be trended. In this subpopulation, average preoperative QuickDASH was 54.11 (SD=9.4). Average initial QuickDASH measurement occurred 2.0 years postoperatively, with an average score of 19.33 (SD=17.9). Average final QuickDASH was measured 6.2 years postoperatively (SD=1.3), with average QuickDASH score of 14.44 (SD=14.2), representing an additional decrease of 4.89 points.

While 43 thumbs had postoperative assessment, only 10 (5

male, 5 female) of these had corresponding preoperative data and were thus considered in the analysis. None of these thumbs represented bilateral implants. Additionally, 7 thumbs were left thumbs and 3 thumbs were right thumbs; hand dominance was not available. Average age at surgery was 57 years (SD=10). Average final follow-up was 5.0 years (SD=1.5). The relevant data are summarized in Table 2. Of the original 110 thumbs, there were 13 postoperative complications requiring revision. The most common cause was titanium metal allergy (5 thumbs), followed by postoperative trapezium fracture (2 thumbs), persistent pain with revision to LRTI (2 thumbs), infection (1 thumb), and instability resolved with head upsizing (1 thumb). Two thumbs were revised without a documented reason. Four thumbs with titanium allergy were revised to a NuGrip (LMT Surgical, Milton QLD, Australia) pyrocarbon implant and the fifth thumb was revised to LRTI. None of the 110 thumbs dislocated at any point postoperatively. These results are summarized in Table 3.

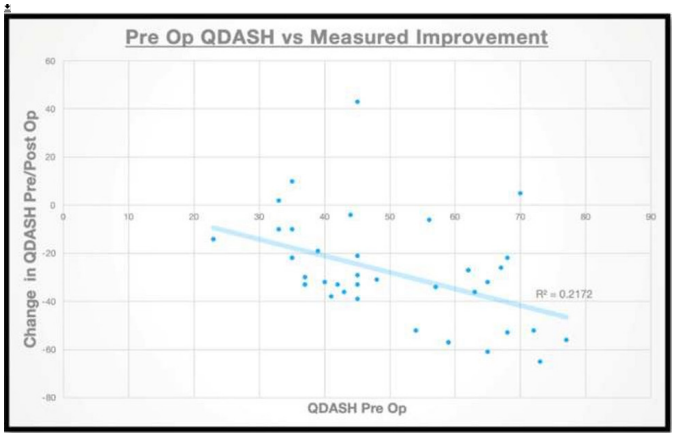

Figure 1: Scatterplot of preoperative QuickDASH scores compared to postoperative improvement.

Table 1: Participants' demographics, clinical characteristics and statistics of differences between groups.

	DCD	TD	p
N	21	20	
Gender (Male:Female)	16:5	11:9	.15
Age (mean years ± SD)	7y9m ± 1.5	7y8m ± 1	.75
IQ (mean standard score ± SD)	99.9 ± 14	-	
mABC2 Me percentile (IQR)	5 (2.7-5)	63 (50-77.2)	<.001
mABC2 manual dexterity Me percentile (IQR)	5 (2-9)	50 (25-75)	<.001
DCDQ'07 Me total score (IQR)	39 (35-42)	66 (60-69)	<.001
Co-occuring diagnosis (N(%))			
Pure DCD	3 (14%)	-	
Language Disorders	6 (29%)	-	
Learning Disorders	2 (10%)	-	
ADHD, language disorders, behavioural problems, learning disorders or ASD	19 (90%)	-	

DCD: children with Developmental Coordination Disorder; TD: typically developing children; M, male; F: female; Me: median; IQR: interval quartile range; IQ: intelligence quotient; mABC-2: Movement ABC-2 test; ADHD: attention deficit hyperactivity disorder; ASD: autism spectrum disorder.

Table 2: Prevalence of intestinal parasitic infections and infection rate among immunocompromised and control groups.

Parasite	Hemodialysis N (%)	Chemotherapy N (%)	Total of immunocompromised N (%)	Control N (%)	*P* value
Blastocystis hominis	28 (10.1%)	29 (8%)	57 (8.9%)	16 (4%)	
Entamoeba coli	7 (2.5%)	3 (0.8%)	10 (1.6%)	1 (0.25%)	
Endolimax nana	2 (0.7%)	2 (0.6%)	4 (0.6%)	1 (0.25%)	
Iodamoeba butschlii	2 (0.7%)	3 (0.8%)	5 (0.8%)	2 (0.5%)	
Chilomastix mesnili	2 (0.7%)	1 (0.3%)	3 (0.5%)	1 (0.25%)	
Giardia lamblia	0 (0%)	0 (0%)	0 (0%)	8 (2%)	
Cryptosporidium spp.	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Strongyloides stercoralis	1 (0.36%)	2 (0.55%)	3 (0.5%)	0 (0%)	
Taenia spp.	0 (0%)	1 (0.28%)	1 (0.15)	0 (0%)	
Infected	42 (15%)	41 (11.3%)	83 (13%)	29 (7.3%)	0.008
Non-infected	237 (85%)	321 (88.7%)	558 (87%)	370 (92.7%)	

Table 3: Multivariate analysis.

Variables	PFS		OS		STFS*	
	HR	p-value	HR	p-value	HR	p-value
Age (per year)	-	-	1.01 (0.99-1.02)	0.23	-	-
Karnofsky index (per 10%)	0.93 (0.81-1.07)	0.3	0.96 (0.82-1.12)	0.75	0.88 (0.69-1.12)	0.3
FNCLCC grade (3 vs 1-2)	2.64 (1.87-3.73)	**<0.001**	2.47 (1.72-3.55)	**<0.001**	2.88 (1.54-5.4)	**0.001**
AJCC T stage (T3-4 vs T1-2)	2.47 (1.48-4.12)	**<0.001**	3.63 (2.05-6.43)	**<0.001**	5.11 (1.86-13.99)	**0.002**
EQD2 (≥64 vs <64 Gy)	-	-	0.47 (0.28-0.81)	**0.007**	0.53 (0.20-1.41)	0.2
Presentation						
Unresected 1° tumor	-	Ref	-	Ref	-	Ref
R2 resected 1° tumor	0.61 (0.29-1.25)	0.18	0.35 (0.15-0.82)	**0.016**	0.47 (0.08-2.75)	0.4
Unresected recurrence	1.42 (0.82-2.44)	0.21	1.24 (0.71-2.17)	0.44	3.85 (1.41-10.48)	**0.008**

*In patients who had not received prior systemic treatment.
AJCC: American Joint Committee On Cancer; EQD2: Equivalent Dose In 2 Gy Fractions; LF: Local Failure; OS: Overall Survival; PFS: Progression-Free Survival; STFS: Systemic Treatment-Free Survival.

Discussion

Trapeziectomy with LRTI has a proven effective history in the surgical management of CMC arthritis. It provides good pain relief while maintaining acceptable thumb mobility and strength. Surveys of current practice show that it remains the dominant treatment modality [5,6]. CMC arthroplasty represents an alternative intervention with the ability to provide comparable, or even superior outcomes. While still performed by a minority of surgeons, it has grown in popularity, aided by advancements in surgical techniques, material science, and implant design [5]. However, there remains a paucity of data regarding outcomes, especially with newer implant designs.

In this study, qualitative data from pre- and postoperative QuickDASH scores demonstrated a dramatic reduction in our patients' pain and associated improvement in functional status. For patients with a completepre- and postoperative QuickDASH assessment, average improvement was 34.78 points at initial average 1.99 year follow-up, and this further improved an additional 4.89 points at secondary 6.16 year follow-up. These results are comparable to other QuickDASH outcomes in the literature regarding CMC arthroplasty. For example, [21] demonstrated a 21.2 QuickDASH point decrease at mean 4.1 year follow-up with a Stryker Ivory prosthesis. While no LRTI data has been currently collected by the authors for direct comparison, other meta-analyses have shown CMC arthroplasty to outperform LRTI with regard to short-term functional outcomes [22]. Found an average 4.8 point greater improvement in patients treated with joint replacement, found an average 4.3 point greater improvement; the follow-up intervals of the studies were highly varied [23]. Proposed minimum clinically important difference (MCID) values for QuickDASH range from 6.8 to 15,24,25. Depending on the methods and sample population used to anchor. This suggests that the aforementioned difference is not clinically realized. However, it is worth investigating this conclusion in more detail. As noted earlier, a greater degree of improvement in our patients was seen in those with greater preoperative impairment. While this is not surprising, it would be interesting to examine the strength of this trend in an LRTI population. Patients of varying preoperative disability may realize differing benefits of LRTI vs joint replacement-type procedures, and the relative differences seen in these subpopulations may exceed MCID. Quantitative strength data using a dynamometer was statistically underpowered. No statistically significant differences in pre- and postoperative strength were found. However, the available data suggests a trend of superior outcomes in the operative hand compared to the nonoperative hand. This aspect of the study represents a potential avenue for additional study, with additional effort taken to capture preoperative data for future comparisons. The currently available data can be used to augment further analysis.

Total survivorship of the original implants was 88.18% at the mean follow-up of 3.8 years. The most common reason for revision was titanium metal allergy. Four of these cases were successfully resolved with revision to a non-titanium joint replacement implant and a fifth underwent revision to LRTI without sequelae. A complication with similar presentation was observed in the experience of Thorkildsen and Røkkum [26] with the Electra implant, which features a titanium stem, and warrants future investigation. A total of 5 thumbs underwent revision to LRTI for trapezium fragmentation (n=2), persistent pain (n=2), and allergy (n=1).

Notably, none of the implants loosened nor dislocated, which represent the most common complications of CMC arthroplasty necessitating revision as documented in the literature [27]. A single thumb was revised to a larger head due to subjective instability without dislocation, with subsequent resolution of symptoms. Overall, these results represent a complication rate comparable to or lower than multiple other prostheses [27,28], though still higher than LRTI [27].

Pritchett and Habryl have previously published on their experiences with the BioPro® implant in a population of 159 thumbs [29]. In their study, the implant had a 6-year survivorship of 94% and no dislocations, again suggesting its inherent resilience against this particular complication. The authors posited this was due to the varus stem angulation and modular nature of the implant's head permitting more accurate filling of the trapezium. Their surgical technique is well-documented, and we concur that appropriate operative technique is vital to optimizing component positioning and achieving satisfactory outcome.

As the understanding of CMC arthritis and its treatment continues to advance, the viability of CMC arthroplasty continues to be validated. This paper represents another large-population cohort of thumbs that have obtained excellent short- to intermediate-term outcomes with the BioPro® implant. While complications with the implant are higher than LRTI, joint replacement surgery never precluded successful revision to satisfactory outcome. As the studied patient population matures, further functional outcome trends will be of particular interest. A long-term sequelae of the LRTI procedure is metacarpal subsidence with resulting biomechanical disadvantage [12]. It is possible that a relative advantage of arthroplasty to LRTI is only realized in the long term, after the impacts of metacarpal subsidence become apparent.

Declarations

Conflicts of interest: John J. Faillace has received payments in the form of royalty/license from Extremity Medical and BioPro, travel/lodging and honoraria from BioPro, current or prospective ownership interest from Tyber Medical LLC, and food and beverage from Stryker Corporation, BioPro, Sanara MedTech, Endo Pharmaceuticals, and AXOGEN in the last 5 years. The other authors have no conflicts of interest to declare.

Source of funding: None.

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