

HÁLLUX RÍGIDUS: PROSPECTIVE STUDY OF JOINT REPLACEMENT WITH HEMIARTHROPLASTY

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ABSTRACT

Objective: To report the results of medium-term follow-up after deploying ArthroSurface-HemiCap® in patients with diagnosis of Hállux Rigidus (HR). **Method:** Eleven patients underwent partial Arthroplasty of the first metatarsal-phalangeal joint. Six women and five men with an average age 51.9 years (46 to 58 years) and average postoperative follow-up of 3.73 years (3-4 years); were classified through the Kravitz system and evaluated by the American Orthopaedic Foot and Ankle Society (AOFAS) scales for hállux, Visual Analogical Scale (VAS) – analog functional pain - and range of motion in the first metatarsal joint in preoperative, postoperative after six months and present post-operative. **Results:** The results

show significant improvement of the three analyzed parameters, both for overall analysis and for pre and post-operative comparisons individually. The comparative analysis of each variable in the six months and the current postoperative periods do not show statistically significant differences, indicating maintenance of parameters during this interval. **Conclusion:** hemiarthroplasty of first metatarsophalangeal joint is a reproducible and safe option for the surgical treatment of hállux rigidus II and III, with significant improvement of the evaluated parameters for the studied population. **Level of Evidence IV, Case Series.**

Keywords: Hállux rigidus. Osteoarthritis. Hemiarthroplasty.

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INTRODUCTION

The osteoarthritis of the first, called Hállux Rigidus (HR), is a progressive degenerative disease of the articular cartilage, characterized by limitation of the arch of articular movement, mainly the extension (dorsiflexion), associated to pain, formation of osteophytes and functional limitation.

It represents the most common form of osteoarthritis of the foot and ankle, with annual prevalence of 2-10%,^{1,2} predominance in females in the ratio, 1:1.6³⁻¹⁰ and peak of incidence in the population after 50 years old.¹¹

In addition to the local trauma, inflammatory and metabolic diseases; biomechanical and anatomical factors that rise the mechanical overload in the first metatarsal-phalangeal articulation play a role in the physiopathogeny of HR.

The most adequate scientific correlations etiological with evidence are:^{12,13}

- Presence of the first long metatarsus
- Presence of the first elevated metatarsus
- Presence of hypermobility of the first ray
- Presence of interphalangeal hállux valgus

The painful symptoms and alteration of articular mechanics cause the transfer of the load to the lateral edge of the foot,^{14,15} and to external rotation of the hip of the affected member during the balance phase of the walk. These alteration in the march pattern modify the forces that normally act in the foot and result in metatarsalgia of the lateral rays.^{14,15}

The Kravitz¹⁶ Classification System used:

- Stage I - Functional limitation, without radiographic alterations;
- Stage II - Initial articular adaptation, with dorsal osteophytes;
- Stage III - Established osteoarthritis;
- Stage VI - Ankylosis, articular fusion.

The non-surgical treatment includes local cryotherapy, use of oral non hormonal anti-inflammatory drugs, intra-articular infiltration with corticosteroids and chondroprotectives, modification of the characteristics of footwear and physiotherapy. Upon failure of conservative treatment, surgical options are discussed in the literature.^{3-10,17-19} (Table 1)

Kravitz's stages II and III generate greater controversy in the literature regarding the type of the indicated surgical treatment.^{3,6-10,18,19}

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Table 1. Surgical procedures for Hallux Rigidus treatment.

Articular recovery	Cheilectomy (Level of evidence I)
	Osteotomy Proximal s (Level of evidence I)
	Osteotomy of the first metatarsus (Level of evidence III)
Articular Substitution	Arthroplasty proximal Phalange Resection (Level of evidence II)
	Arthroplasty first Metatarsus Resection (Level of evidence II)
	Interposition Arthroplasty (Level of evidence VI)
	Arthrodesis 1° MTTF (Level of evidence I)
	Partial Arthroplasty 1° MTTF (Level of evidence III)
Total Arthroplasty 1° MTTF (Level of evidence III)	

Currently, the standard surgical treatment in advanced cases is still metatarsal-phalangeal arthrodesis. Comparative studies show that the articular fusion present a higher patient satisfaction rate when compared to arthroplasty.^{9, 20} However, the loss of mobility is not well tolerated by young adult active patients and complications of this procedure include: non-consolidation - 10% of cases, malposition of the proximal phalange, limitation of sports activities and increased stress in the lateral rays.^{21, 22} Therefore, it becomes necessary to investigate procedures for maintaining joint mobility; restitution of the normal walking pattern keeping the "reel" mechanism of the plantar fascia, assisting impulse and reducing the impact during deambulation.²³ Arthroplasty of the first metatarsophalangeal allows improvement of painful symptoms and restitution of joint mobility.²⁴⁻²⁷

This surgical procedure can be classified into partial arthroplasty (replacement of the articular surfaces, base of the proximal phalange and the first metatarsal head) and total arthroplasty (replacement of both articular surfaces).²⁸ A systematic review of the literature shows the implants available for arthroplasty of the first metatarsophalangeal divided into four generations:¹⁹

- 1st generation - silicone implants, models for partial and total arthroplasty;
- 2nd generation - better quality silicone implants, for partial and total arthroplasty;
- 3rd generation - metallic prosthesis designed for partial and total arthroplasty, with "press-fit" type clamping system;
- 4th generation - metallic prosthetic designed for partial and total arthroplasty with medullar threaded rod fixing system.

An important advantage of partial arthroplasty is to preserve the bone, which allows, when necessary, carrying out rescue arthrodesis without subsequent bone graft. The prosthetic replacement of the first metatarsal head, were first used in 2005, with cobalt chrome implant in the articular surface, and titanium intramedullary rod (Arthrosurface HemiCAP). The system allows anatomic reconstruction of the articular surface of the metatarsal head, joint decompression, preservation of the extensor mechanism of the first ray and range of motion gain; it also allows the association with osteotomies of the proximal phalange, and thus, the correction of large hállux deformities. The published results of articular replacement of the first metatarsophalangeal joint with short-term follow-up are promising; however the procedure is under investigation and improvement of the employed materials and technique. The results in the literature motivate the prospective analysis of the experiments of the Foot and Ankle group with the surgical technique.

OBJECTIVE

Compare the pre-and postoperative findings visual of the Visual Analog Pain Scale (VAS), the Functional Scale of the American Orthopedics Foot and Ankle Society (AOFAS) for Hállux, and range of motion for patients with Hállux Rigidus grade II and III submitted to partial joint replacement with Arthrosurface-HemiCAP® implant.

MATERIALS AND METHODS

After approval from the Scientific Committee and the Ethics Committee of the University, we selected 11 patients for treatment of Hállux Rigidus through partial arthroplasty of the first metatarsophalangeal with the Arthrosurface-HemiCAP® technique from June 2008 to May 2009.

All selected patients were diagnosed with Hállux Rigidus stage II or III, with no history of rheumatic diseases, metabolic diseases, foot infection or sequelae from fracture of the first metatarsus or proximal phalange of the hállux.

Excluding Criteria:

- Rheumatic diseases;
- Autoimmune diseases;
- Diabetes *Mellitus*;
- Liver and kidney diseases;
- Loss of tracking.

All patients were initially treated with appropriate footwear orientation and stretching of the triceps surae muscles for six months without symptomatic improvement.

The surgical procedure was performed by two surgeons specialize in foot and ankle through the dorsal access way preserving the insertion of the extensor mechanism of the hállux.

The protocol of postoperative follow-up regarding the surgical dressing type, load and progression of motor rehabilitation is consistent with that standard by the Foot and Ankle Group of our institution. (Annex 1)

Selected patients underwent assessment following the steps listed below, in the preoperative, six months postoperative and current status:

1. Pain Scale VAS²⁹
 2. American Orthopedics Foot and Ankle Society (AOFAS) Functional scale for hállux³⁰
 3. Motion Range (MR) clinically measured with a goniometer.
- The data harvesting protocol is described in Annex 2.

Statistical analysis of the results.

The results analysis of the AOFAS hállux scale, VAS and range of motion for the first metatarsophalangeal joint during the measurements intervals, considered dependent variables and not-normally distributed, was performed using the Friedman test for nonparametric findings with significance values of $p < 0.05$.

RESULTS

Table 2 shows age, tracking time (in years), values of AOFAS Hállux scale VAS pain scale - and range of motion (in degrees) of the first metatarsophalangeal joint (in degrees) in the measurement intervals.

Table 3 shows the descriptive analysis of the collected data.

Table 4 presents the results of statistical analysis using Friedman test and Dunn's multiple comparisons, considering $p < 0.05$ as statistically significant.

Table 2. Distribution of patients by age, gender, time of follow up (in years), AOFAS scale, Visual Analog Scale for pain and Range of motion (in degrees) of the first metatarsophalangeal joint.

Patient number	Age (years old)	Time of follow up (unit?)	AOFAS# pre	AOFAS# 6m	AOFAS# current	VAS* pre	VAS* 6m	VAS* current	Mr** pre (degrees)	Mr** 6m (degrees)	Mr** current (degrees)	Gender
1	53	4	32	87	80	6	1	1	10	50	30	F
2	51	4	32	87	80	7	1	1	10	50	30	F
3	46	4	32	77	80	7	2	1	0	40	20	M
4	58	4	32	87	75	7	1	0	10	40	20	F
5	53	3	32	77	75	6	2	1	0	40	20	F
6	47	3	32	77	75	7	4	0	0	20	0	M
7	50	4	32	87	75	7	1	1	10	50	20	M
8	52	4	32	77	75	6	1	0	0	40	20	M
9	56	3	32	77	75	7	2	2	0	50	20	F
10	51	4	32	87	80	7	1	0	0	50	30	M
11	54	4	32	87	80	6	1	1	10	50	30	F

AOFAS scale for Hallux

*VAS: Visual Analog Pain Scale

** MR: Movement range of the first metatarsophalangeal joint in degrees (°)

Tabela 3. Descriptive analysis of the collected parameters.

	Age (years old)	Time of follow up (unit)	AOFAS# pre	AOFAS# 6m	AOFAS# current	VAS* pre	VAS* 6m	VAS* current	Mr** pre (degrees)	Mr** 6m (degrees)	Mr** current (degrees)
Mean	51.909	3.727	32	82.454	77.272	6.636	1.545	0.727	4.545	43.636	21.818
St. deviation	1.065	0.140	0	1.574	0.787	0.152	0.281	0.194	1.574	2.787	2.634
Median	52	4	32	87	75	7	1	1	0	50	20
Mode	53	4	32	87	75	7	1	1	0	50	20
St. deviation	3.534	0.467	0	5.222	2.611	0.504	0.934	0.646	5.222	9.244	8.738
Variance	12.490	0.218	0	27.272	6.818	0.254	0.872	0.418	27.272	85.454	76.363
Curtose	-0.062	-0.763	#DIV/0!	-2.444	-2.444	-1.964	4.750	-0.207	-2.444	3.933	3.523
Assimetry	-0.074	-1.189	#DIV/0!	-0.212	0.212	-0.660	2.088	0.291	0.212	-1.833	-1.507
Interval	12	1	0	10	5	1	3	2	10	30	30
Minimum	46	3	32	77	75	6	1	0	0	20	0
Maximum	58	4	32	87	80	7	4	2	10	50	30
Sum	571	41	352	907	850	73	17	8	50	480	240
Count	11	11	11	11	11	11	11	11	11	11	11
CVP	6.808	12.531	0	6.333	3.379	7.602	60.448	88.917	114.891	21.184	40.052

AOFAS scale for Hallux

*VAS: Visual Analog Pain Scale

** MR: Movement range of the first metatarsophalangeal joint in degrees (°)

Table 4. p values for the analysis of variables by Friedman and Dunn test.

		AOFAS	VAS	MR
FRIERMAN + DUNN	global	P<0.0001	P<0.0001	P<0.0001
Non parametric	pre x 6m	P < 0.001	P < 0.05	P < 0.001
	pre x current	P < 0.05	P < 0.001	P < 0.05
	6m x current	P > 0.05	P > 0.05	P > 0.05

The results show significant improvement of the three parameters evaluated in this study, both for global analysis for comparisons as well as to pre-and postoperative isolated comparisons. A comparative analysis of each variable in postoperative periods of six months and current - three to four years after surgery - show no statistically significant difference, indicating the maintenance of parameters during this interval. Figures 1 and 2 show the post-operative lateral and front X-ray profile of patient number six.

DISCUSSION

The hállux osteoarthritis is the most common form of degenerative joint disease of the foot and ankle, with annual prevalence of 2-10%^{1,2} in the population above 50 years with predominance in the female gender.³⁻¹⁰

Upon failure of non-surgical treatment, there are several options of surgical procedures discussed in the literature.

The optimal surgical treatment for patients with a Hállux Rigidus diagnosis is that which allows improvement of painful symptoms, restores the normal motion arc and joint alignment, keeps the length of the first ray and allows return to normal function of the foot and march. The metatarsophalangeal joint arthroplasty procedure is designed to meet these factors.

Most discussion in the literature is regarding the replacement or joint fusion for the treatment of stages II and III of the Kravitz classification system. Comparative studies have found greater satisfaction of patients undergoing arthrodesis compared with hállux arthroplasty.^{16, 23} The first metatarsophalangeal arthrodesis is a procedure that leads to effective pain relief and restores the patient's function.⁷ However, due to loss of mobility, it may not be tolerated by most active patients, particularly young one, besides presenting complication rates up to 10%.^{26,27} Raikin *et al.*⁹ showed hemiarthroplasty ("metallic" Bio Pro) and arthrodesis with clinically similar results; they identified that arthrodesis



Figure 1. Profile X –Ray of the load bearing foot of patient #6 after 24 months surgery.



Figure 2. Frontal X –Ray of the load bearing foot of patient #6 after 24 months surgery.

postoperative evolution is more predictable in relieving symptoms and that most failures due to the choice of arthroplasty occur in the first two years postoperatively. Konkel *et al.*³¹ describe the successful use of hemiarthroplasty (“Futura Hemi-Great Toe”), with minimal radiolucency at the base of the

implant during the radiographic follow-up, and lack of material failures in a mean follow-up period of eight years. In our series we did not identify flaws in arthroplasties during an average of 3.72 years.

Hasselmann e Shields³² describe the use of metallic implant to cover the first metatarsal head (HemiCAP), performed with minimal bone resection, without changing the joint gleno-sesamoid articulation or interfere with the balance of the flexor and hállux extensor mechanisms, keeping the plate plant intact. The follow-up period of patients was 20 months, with an average gain range of motion of 42 degrees and average postoperative AOFAS score of 82.1 points.

In this series, the surgical technique allowed maintenance of the sesamoid joint with the first metatarsal head as well as the extensor and flexor hállux balance mechanisms, the average gain in MR was found to be 16.3 degrees and postoperative AOFAS average score observed was 77.27 points.

Sorbie e Saunders¹⁰ designed a prospective study with use of cemented hemiarthroplasty and observed improvement in the AOFAS score from 57 to 88 points, with follow-up ranging from 34-72 months, concluding that hemiarthroplasty improves pain symptoms, joint motion, bending force and joint alignment. The authors found no signs of osteolysis or loosening of the prosthesis. These data corroborate the results observed in the present series.

Cook *et al.*¹⁹ reported in a meta-analysis that evaluated arthroplasties of the first metatarsophalangeal, patient satisfaction from 85.7% to 94.5%, with an average follow up period of 61.48 months. The significant improvement of the three parameters evaluated in this study are similar to those published by Cook *et al.*¹⁹

Carpenter *et al.*³³ found similar results, in the medium-term, by replacing the head of the first methatarsal (“HemiCAP”), and for arthrodesis on the treatment of Hállux Rigidus, with a mean follow up period of 27 months - 89.31 AOFAS score for HemiCAP against 83.8 for artrodesis.⁹

Despite little experience accumulated by our group that designed this study, analysis of clinical outcomes, with follow-up longer than three years, may contribute to the knowledge of the technique in our country and motivate prospective comparative and randomized trials.

CONCLUSION

The hemiarthroplasty of the 1st metatarsophalangeal is a reproducible and safe option for the surgical treatment of Hállux Rigidus II and III, with significant improvement in articular range of motion, functional AOFAS scale and decreased pain by VAS score for the population studied.

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Annex 1. Postoperative protocol.

There is no need to drain installation. At the end of the procedure the surgical wound is covered with a sheet of non-adherent dressing (Adaptic®) and a layer of absorbent dressing (Zobec®). Tubular mesh keeps the bandage in its place on the wound. Then, rapping the foot with orthopedic cotton and crepe bandage is done; tubular mesh covers the bandage, and finish of the dressing is made with tape. All toes should remain visible for free inspection through the anterior opening of this dressing made primarily for postoperative protection. The pneumatic tourniquet-garrot is deflated, and the reperfusion of the fingers is checked. The postoperative analgesia is achieved by peripheral nerve block guided by ultrasonography. One percent ropivacaine is used. Final postoperative radiographs are obtained at this point. Accelerated postoperative protocol rehabilitation aims to prevent joint stiffness and increase the gain of movement, while minimizing the complications associated with poor surgical wound healing, edema and pain. From the first postoperative day, deambulation is encouraged, as long as it is tolerated by the patient. The orientation is progressively unload the patient's body load on the operated foot, protected by postoperative sandals provided with a firm sole, up to the limit of the patient's tolerance. Active movement of the fingers (flexion-extension of the hallux) is allowed since the first postoperative day, and the hospital discharge also occur on the next day after surgery. To minimize swelling and pain after surgery, the patient is instructed to keep the leg elevated at the hips level in the early days when not walking. In two weeks the stitches are removed. Upon healing of the surgical wound, passive flexion-extension mobilization exercises of the joint are allowed. The patient is instructed that his articulation will be mobilized up to the extent that he feels pain, then he must report such occurrence to the physiotherapist. These exercises are performed slowly until reaching the maximum motion range in extension or dorsiflexion whose pain is well tolerated by the patient, at this point, the joint is submitted to a slightly greater tension, stimulating the gain in motion range. The joint is held in this position for ten seconds. At the end of this period the majority of the patients report accommodation to the pain feeling, after this period, the movement in the opposite direction is initiated. Likewise, the maximum extent dorsiflexion which pain is tolerated by the patient is reached; at this point, once again, the joint is subjected to a slightly greater tension, stimulating the gain in motion range, now in the opposite direction. The joint is held in this position for ten seconds, and the movement in the other direction is resumed. Twenty repetitions of this passive exercise are slowly done. When the patient is capacitated, he is trained to do it alone. Once trained, he is instructed to maintain a routine exercise repetition of twenty repetitions four times a day. During deambulation, at this stage, the joint is protected with firm sole sandals until completing six weeks. After this period, the use of conventional shoes is allowed. Once the patient is able to use conventional shoes, the return to the day-to-day and sports activities are allowed as tolerated.

Annex 2. The Data Harvesting Protocol.

· Age	· Surgical time
· Gender	· Tourniquet time
· Comorbidities	· Anesthesia time
· Habits and addictions: alcoholism, smoking	· Intra-operative complications
· Laterality	· Immediate and late postoperative complications
· Preoperative Imaging - Classification of Hallux Rigidus	· Time elapsed until load bearing
· Current image exams - Position of prosthetic component, component loosening signs	· Time tracking in standardized rehabilitation protocol
· Implant Numbering	· Immediate and late complications.