



ONE-YEAR FOLLOW-UP OF PATIENTS TREATED FOR RHIZARTRHOSIS WITH THE REGJOINT™ IMPLANT

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ABSTRACT

Rhizarthrosis is the second most common degenerative disease of the hand, associated with pain, function disability, and impaired quality of life. The literature describes various operative techniques for the treatment of rhizarthrosis, but the outcomes of the effectiveness of RegJoint™ implant are still scarce.

Purpose: The aim of this study is to determine the effectiveness of using the RegJoint™ implant in the operative treatment of rhizarthrosis and the subsequent recovery.

Material and methods: In the period 2019-2023, a total of 48 patients diagnosed with rhizarthrosis (46 women and 2 men) of average age 61.4 (± 3.2) years went for treatment through the clinical bases of UMHAT "Kaneff" - Ruse and UMHAT "SOFIAMED" - Sofia. All of them were operated with the bioabsorbable implant - RegJoint™, after which the thumb was immobilized using a fixation splint for 6 weeks. Their average hospital stay was 3.2 (± 1.3) days, after which they underwent rehabilitation procedures for 6 months.

Results: Functional capacity was assessed using the DASH test, and thumb movements were tested using the Kapanji score three times - preoperatively and at the end of the 6th and 12th postoperative months. The results at the end of 6 months and 1 year period show a significant improvement in terms of pain, swelling and functional status of the operated hand.

Conclusion: The combined surgical intervention for the treatment of rhizarthrosis with a RegJoint™ implant, combined with adequate and timely physiotherapy, ensures a high-quality, fast and painless functional restoration of the thumb and the overall function of the hand.

Keywords: rhizarthrosis, RegJoint, thumb physiotherapy, physiotherapy program,

INTRODUCTION

Upper extremity disorder can limit the activities of sufferers and have negative effects on their quality of life [1]. Trapeziometacarpal joint osteoarthritis, or rhizarthrosis, is a disabling condition of the hand that causes pain, stiffness and weakness, resulting in impaired hand function, strength and dexterity. After distal interphalangeal joint osteoarthritis, it is the second most common degenerative disease of the hand. About one in four women (30% of post-menopausal women) and one in 12 men eventually show osteoarthritic changes on radiographs, although the vast majority are asymptomatic [2]. Thumb carpometacarpal arthritis contributes considerably to functional disability in the aging adult [3].

Trapeziometacarpal joint arthritis is a common cause of radial-sided wrist pain. A thorough history, physical examination, and radiographic evaluation are needed to diagnose the disease. The stage of arthritis is based on the radiographic image, but the severity of the symptoms determines the treatment. Nonoperative treatment consists of activity modification, exercise, splinting, nonsteroidal anti-inflammatory drugs, and corticosteroid injections. If conservative treatment fails, there are different surgical options available based on the disease's stage [4]. In an advanced stage, eliminating pain and restoring strength to the thumb are the priority goals of treatment [5].

In recent years, numerous operative techniques have been described that aim to eliminate pain and restore strength to the thumb [6]. However, there is still no gold standard in the surgical treatment of osteoarthritis of the basal joint of the thumb [7].

One of the most common procedures for the treatment of trapeziometacarpal osteoarthritis is trapeziectomy with ligament reconstruction and tendon interposition with the flexor carpi radialis tendon [8].

In recent years, as an alternative to the classic osteotomy, the use of a bioabsorbable implant - The RegJoint™ (Scaffdex Oy, Finland) has become necessary. In rhizarthrosis surgery, the bio-absorbable poly-L/D-lactide implant is used as a spacer between the first metacarpal and the trapezium and plays the role of a temporary support in the resected joints [9].

MATERIAL AND METHODS

In the period 2019-2023, a total of 48 patients diagnosed with rhizarthrosis (46 women and 2 men) of average age 61.4 (± 3.2) years went for treatment through the clinical bases of UMHAT "Kaneff" - Ruse and UMHAT "SOFIAMED"- Sofia.

All of them were operated with the bioabsorbable implant - RegJoint™, after which the thumb was immobilized by means of a fixation splint for 6 weeks and a k-wire. Their average hospital stay was 3.2 (± 1.3) days, after which they underwent rehabilitation procedures for 6 months.

The rehabilitation program includes anti-edema massage, anti-cicatricial massage, passive and active exercises of the thumb free joints and, the other fingers and the wrist. After the sixth postoperative week, exercises are included to restore thumb strength and coordination, as well as stretching and other specialized techniques to overcome existing contractures.

Week 1-6:

After the surgical intervention, the hand is placed in a rigid splint with the position of the thumb in slight abduction in the MCP and extension in the IPJ, which the patient wears until the 6th postoperative week. The splint is removed twice a day for an anti-edema massage and light passive movements. After removing the surgical sutures, an anti-cicatricial massage is also applied. During the entire period, active movements are performed for the wrist and other fingers, as well as for the MCP and IPJ of the thumb.

Week 7-12:

Warm compress and anti-edema massage are continued during this period. Passive movements of the thumb gradually turn into active ones. In the presence of a deficit in the range of motion of the joints of the thumb, muscle-relaxation techniques such as postisometric relaxation, reciprocal inhibition and low load prolonged stretching are applied. Resistive exercises with an elastic band are used to prevent muscle hypotrophy of the arm.

Week 13-24:

The normal performance of the activities of daily living is gradually restored. The emphasis of the physical therapy program is on restoring hand grip strength and eliminating functional deficits if any are still present. At the end of the period, all restrictions are removed.

RESULTS

All obtained results were processed with the SPSS computer program for statistical data processing. Means, standard deviations, and statistical significance were considered.

To establish the effectiveness of the surgical intervention and follow the course of recovery, the patients were tested several times. Functional capacity was assessed using the DASH outcome measure, and thumb movements were evaluated using the Kapanji score three times - preoperatively and at the end of the 6th and 12th postoperative months (Table 1).

Table 1. Functional capacity assessment.

test/score	before operation	after 6 months	after 1 year
DASH	86,71 (SD $\pm 7,52$)	29,17 (SD $\pm 5,28$)	24,16 (SD $\pm 4,43$)
Kapanji score	5,8 (SD $\pm 1,7$)	7,9 (SD $\pm 2,5$)	9,5 (SD $\pm 1,5$)

Preoperative DASH scores showed severely limited functional capacity of the hand affected by rhizarthrosis, with a mean test score of 86.71 (SD ± 7.52) at a statistical significance of 0.005. Postoperatively, at the sixth month, the DASH values showed a significant improvement in the functionality of the hand - 29.17 (SD ± 5.28) at $p=0.001$,

and after a year - 24.16 (SD ± 4.43) at $p=0.001$. The opposition of the thumb was also seriously affected, as preoperatively, the Kapanji score showed values of 5.8 (SD ± 1.7) at $p=0.001$, which at the sixth postoperative month showed a significant improvement in the opposition of the thumb - 7.9 (SD ± 2.5) at $p=0.05$, and after one year the recorded values were 9.5 (SD ± 1.5) at $p=0.00$.

Table 2. Wrist and Thumb Santimetry.

	operated hand - 6 months	operated hand - 1 year	unoperated hand
Wrist	18 (SD $\pm 1,7$)	17,5 (SD $\pm 1,5$)	17,5 (SD $\pm 1,5$)
CMCJ	8,5 (SD $\pm 1,3$)	8,1 (SD $\pm 1,6$)	8,1 (SD $\pm 1,6$)
IPJ	7,5 (SD $\pm 1,6$)	7 (SD $\pm 1,1$)	7 (SD $\pm 1,1$)

To measure the hand swelling after the surgery, circumference measurements of the hand at the level of the wrist, CMCJ and IPJ of the thumb were taken at 6 months and 1 year postoperatively and compared to the nonoperated

hand. Wrist circumference data showed a minor swelling of 0.5 cm at 6 months, which was completely reduced by the first year at $p=0.001$, and the same applies to swelling at the CMCJ and IPJ levels at $p=0.000$ (Table 2).

Table 3. Visual Analog Scale.

VAS	before operation	after 6 months	after 1 year
Rest	5,8 (SD ±2,4)	0,5 (SD ±0,2)	0 (SD ±0,0)
Motion	8,7 (SD ±0,6)	1,8 (SD ±1,2)	0 (SD ±0,5)

The degree of pain was recorded by VAS at rest and with movement immediately after surgery, at 6 months and after 1 year. The moderate to severe degree of pain at rest 5.8 (SD ±2.4) immediately after surgery was almost completely reduced by 6 months - 0.5 (SD ±0.2) and disappeared completely after 1 year 0 (SD ±0.0). As expected, the degree of pain during movement was stronger after the surgical intervention 8.7 (SD ± 0.6), which significantly decreased to a mild degree already at 6 months - 1.8 (SD ± 1.2) and disappeared completely by 1 year - 0 (SD ±0.5). The VAS results obtained are at $n=0.001$ (Table 3).

DISCUSSION

Davis TR, et al. followed the results of 76 women for the third month and the following year, operated for rhizarthrosis by trapezectomy or in combination with tendon interposition or ligament reconstruction. Comparative results obtained identical values in terms of pain relief, hand function and thumb strength. They concluded that tendon interposition and ligament reconstruction in trapezectomy are not effective, at least in the short term [10].

Lins RE, et al. performed a qualitative and quantitative evaluation of the outcome in 27 patients (30 thumbs) with arthritis of the base joint of the thumb who underwent ligament reconstruction and tendon interposition arthroplasty. They found after 42 months that there was no significant correlation between trapezius height maintenance and objective and subjective clinical outcomes. Although ligamentous reconstruction fails to restore trapezius height, similarly satisfactory primary and secondary clinical outcomes are reported after base joint arthritis [11].

Belcher HJ, et al. followed forty-three patients with trapeziectomy alone (control group) and with a ligament reconstruction and tendon interposition using an abductor pollicis longus tendon slip. At 13 months later, no significant differences in outcome were observed between the two treatment groups, and patients in both groups reported similar levels of satisfaction. They conclude that simple trapezectomy for rhizarthrosis is a reliable and effective intervention, and with regard to the addition of ligament reconstruction, no additional benefit was observed [12].

Gangopadhyay S, et al. conducted a study where 174 thumbs affected by trapeziometacarpal osteoarthritis were divided into three groups: one group underwent simple trapeziectomy, another group had trapeziectomy with palmaris longus interposition, and the third group underwent trapeziectomy with ligament reconstruction and tendon interposition using 50% of the flexor carpi radialis tendon. Following a review of 153 thumbs at a minimum of 5 years post-surgery (median 6 years, range 5-18 years), subjective and objective assessments were conducted on thumb pain,

function, and strength. The study's conclusion was that there seemed to be no long-term benefit from tendon interposition or ligament reconstruction [13].

Kennedy A, et al. recommended the use of RegJoint (Scaffdex Oy, Finland) implant in the base of thumb surgery as a spacer to prevent first metacarpal bone proximal migration. Kennedy A et al. consider the RegJoint a useful adjunct in the management of a select cohort of patients with base of thumb arthritis [9].

Sander AL, et al. described the results following the use of RegJoint™ in the surgical treatment of carpometacarpal (CMC) osteoarthritis of the thumb. They were reported in 21 patients with modified APL suspension interposition arthroplasty for the treatment of CMC joint osteoarthritis of the thumb. Results are comparable to better than other published procedures. They described the APL suspension technique as easy to perform, avoiding difficult bone tunneling and cutting of the FCR tendon and RegJoint™ interposition because the spacer prevents the first metacarpal base from impinging on the second metacarpal base or trapezius [5].

Three years after undergoing scaffold arthroplasty (RegJoint™) for trapeziometacarpal osteoarthritis, 23 patients experienced a notable reduction in pain, enhanced strength, and subjective improvement in function three years later. These positive outcomes were observed at the final follow-up when compared to the preoperative conditions, particularly in patients who did not require revision surgery.

Mattila S, et al. report adverse tissue reactions and osteolysis after partial trapezectomy for trapeziometacarpal osteoarthritis with RegJoint combination. In three patients, a revision procedure was also required after reporting a too high rate of adverse tissue reactions related to the process of implant degradation [14].

Marcuzzi A, et al. followed long-term patients who underwent poly-lD-lactic acid scaffold in patients with rhizarthrosis and found that there was an improvement in range of motion, strength and pain. They found radiographic collapse of the first metacarpal but nevertheless recommended the use of a poly-lD-lactic acid scaffold as a good alternative to classical trapezectomy [15].

In a comparative analysis of postoperative results between a group of patients undergoing arthroplasty with interposition of a bioresorbable spacer, suffering from rhizarthrosis of stage II-IV of the Eaton classification (42) and those who underwent a suspension arthroplasty according to Burton-Pellegrini modified (63) it is found, that the positive results obtained encourage the use of a reg-joint, especially in patients with Eaton stage II or III classification [16].

CONCLUSION

Despite the good results of the classic trapezectomy in the operative treatment of rhizarthrosis, the successful use of the RegJoint™ implant in this nosology is increasingly being introduced. Despite some of its established drawbacks, it has gained more and more support

for its use in recent years. The combined surgical intervention for the treatment of rhizarthrosis with a RegJoint™ implant, combined with adequate and timely physiotherapy, ensures a high-quality, fast and painless functional restoration of the thumb and the overall function of the hand.

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