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SUMMARY

The aim of this study was to evaluate the effectiveness of the injectable Guna Collagen MDs regarding pain, functioning and recovery of periarticular tissues of the shoulder.

In patients with Partial Thickness Tear (PTT) of the Rotator Cuff (RC). Musculoskeletal ultrasonography (US) is an approved imaging technique for diagnosis of the RC pathology and for therapy monitoring.

This study included 22 patients with painful shoulder and sonographically proven PTT of the RC.

Clinical assessment included demographic and clinical data, a Visual Analog Scale (VAS) for pain (0-100) and Shoulder Function Assessment (SFA) scale (0-70) at baseline, at 30 and 60 days.

Evaluations of the efficacy according to the patient and the physician were performed. All patients had US of both shoulders with Mindray M5 scanner with multi-frequency linear transducer (7.5-10 MHz).

It was applied a combination of Guna Collagen MD-Shoulder and Guna Collagen MD-Muscle into the subacromial space; the total course of treatment consisted of 8 weeks.

Physical therapy was not administered during the follow-up.

Pain was significantly reduced. There was a statistically significant improvement of the SFA Index.

73% of patients assessed efficacy as very good / good, which coincided with the opinion of the physician. At the third visit, 77% of patients had either a complete recovery or showed improved structure of the RC, as proven by sonography.

Injectable collagen is an innovative approach with regenerative effect in the treatment of PTT of the RC.

Guna Collagen MDs significantly reduced pain and increased functional activity of the shoulder, thereby increasing the quality of life. No adverse effects were registered during the treatment.

KEY WORDS

ROTATOR CUFF SYNDROME, PAIN, COLLAGEN MEDICAL DEVICES, COLLAGEN MD-SHOULDER, COLLAGEN MD-MUSCLE

CLINICAL AND SONOGRAPHIC ASSESSMENT OF THE EFFECTIVENESS OF GUNA COLLAGEN MD_s INJECTIONS IN PATIENTS WITH PARTIAL THICKNESS TEAR OF THE ROTATOR CUFF

INTRODUCTION

The aim of this study was to evaluate the effectiveness of the injectable Guna Collagen MDs regarding pain, functioning and recovery of periarticular tissues of the shoulder in patients with Partial Thickness Tear (PTT) of the Rotator Cuff (RC).

The purpose of the local administration of collagen is essentially structural, in order to provide **mechanical support**, to **replace, strengthen, structure** and **protect** the **treated area**.

Thanks to its low dose (300 mcg), collagen is particularly active, changing extracellular matrix and leading to activation of cellular functions.

– Musculoskeletal ultrasonography (US) is an approved imaging technique for diagnosis of the RC pathology and for therapy monitoring.

METHODS

We enrolled **22 patients** with painful shoulder and PTT of the RC proven by sonography. Including and excluding criteria are presented in **TABLE 1**.

Clinical assessment included demographic and clinical data, a Visual Analog Scale (VAS) for pain (0-100) and Shoulder Function Assessment (SFA) scale (0-70) at baseline, at 30 and at 60 days. The SFA test has 2 items concerning pain during movement and at rest; 4 items for shoulder function in daily activities; and 3 objective ROM (Range of Motion) measures.

The SFA consists of 2 Visual Analog Scales (VAS, pain at rest and during movement), 4 multiple choice questions about daily activities (dressing, combing hair, washing opposite axilla, and using the toilet), and 3 measures for ROM (to-

Inclusion criteria	Exclusion criteria
1. Age: 18-80 years	1. Joint inflammatory and rheumatic autoimmune diseases/infections
2. Clinical diagnosis: shoulder periarthritis	2. Degenerative arthropathy, traumas, shoulder surgery, full thickness tear of the RC
3. Duration of the symptoms: up to 7 days	3. Physiotherapy and topical corticosteroids application the month before and during monitoring
4. VAS for pain: > 25mm	4. Other diseases: diabetes mellitus, neurological diseases, including brachial plexitis, and peripheral neuropathy
5. PTT of the RC proven by sonography	5. Cancer, chemotherapy, radiotherapy

TABLE 1

Inclusion and exclusion criteria.

tal active abduction and 2 combined movements asking the patient to place the hand on the head with the elbow forward and backward).

The overall score ranges from **0** (worst shoulder function) to **70** (best shoulder function).

Evaluations of the efficacy according to the patient and the physician were performed at the third visit.

All patients were examined with the real-time equipment Mindray M5 (China) using a 7.5-10 MHz linear phased array transducer. A standard scanning protocol including multiplanar, dynamic and bilateral evaluation was followed in order to avoid missing the assessment of one or more anatomic structures of the shoulder. MSU assessment was performed at baseline (first visit) and at 60 days (third visit).

To objectify the MSU evaluation, two trained and experienced MS sonographers with at least 5 years experience in MSU scanned together each patient and reached consensus on the US findings.

Physical therapy was not administered during the follow-up period.

– It was administered to each patient the combination of **1 Collagen MD-Shoulder + 1 Collagen MD-Muscle** into the subacromial space, a total of 20 vials, 2 vials for each application, according to the following scheme: for 2 weeks, 2 applications/weekly; for 6 weeks, 1 application/weekly.

The overall treatment lasted 8 weeks. Statistical analysis:

For VAS and SFA assessment it was used repeated measures analysis; for the assessment of Bursitis, it was used χ^2 analysis.

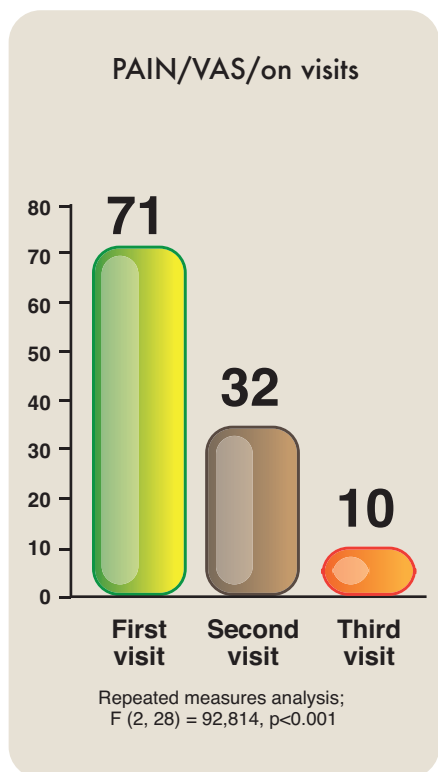


Figure 1

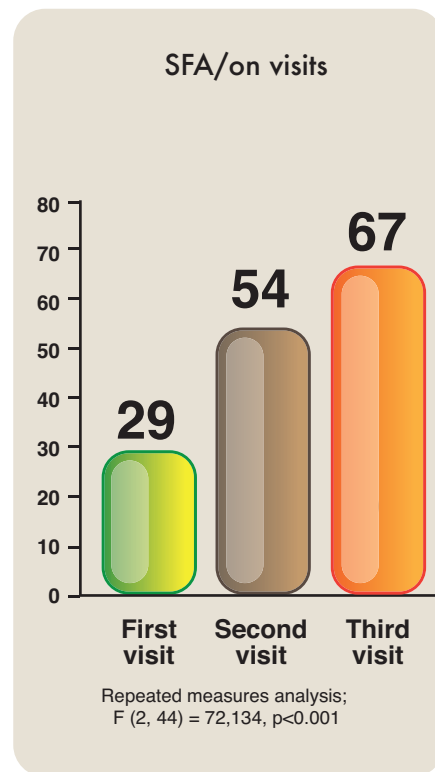


Figure 2

RESULTS

VAS for pain was significantly reduced: threefold at the second visit and continued to reduce till the third visit, **7 times** compared to the first visit (FIGURE 1).

The SFA index had a statistically significant improvement of all criteria, which correlated with an increasing of 25 points. The improvement continued till the third visit with 38 points more compared to the first visit (FIGURE 2).

73% of patients assessed efficacy as **very good/good**, which coincided with the opinion of the physician (FIGURES 3, 4).

77% of patients had a **complete recovery** or improved structure of the RC on the third visit, proven by sonography (MSU assessment) (FIGURE 5).

We present some sonographic images in transverse scan of SSP tendon showing PTT before treatment and recovered tissue of the tendon after the treatment with Guna Collagen MDs. PTT was presented as hypochoic zone

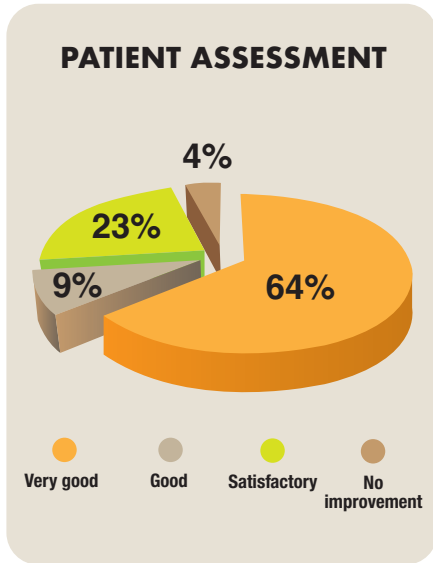


Figure 3

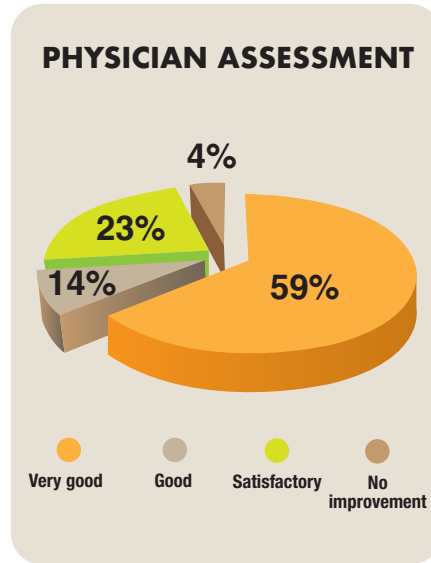


Figure 4

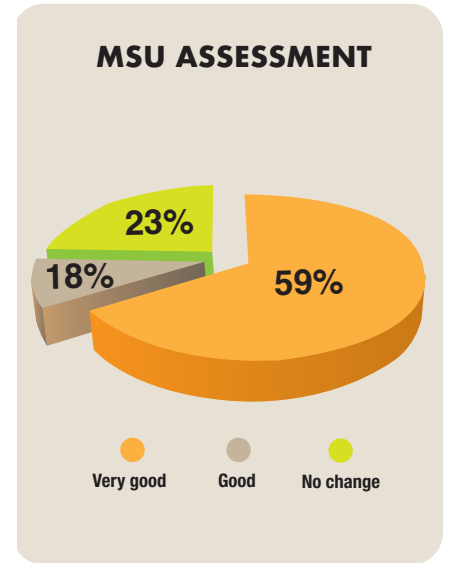


Figure 5

on the background of tendinosis. On the third visit (after treatment) there is no evidence of PTT (FIGURES 6, 7).

CONCLUSIONS

Guna Collagen Medical Devices in patients with shoulder periarthritis and PTT showed the following benefits:

1. High individual clinical response: VAS for pain, SFA, Patient assessment.
2. High objective clinical response: SFA, Sonographic assessment, Physician assessment.
3. Strengthening and restoring effect on collagen structures of the RC.
4. Increasing the patient's quality of life.
5. Total absence of adverse side effects.

The injections of Guna Collagen MDs are an innovative and effective approach with regenerative and analgesic effects in the treatment of shoulder periarthritis and PTT. Their easy application and total absence of side effects makes them a modern device of choice in the physician's daily practice. ■

Figure 6

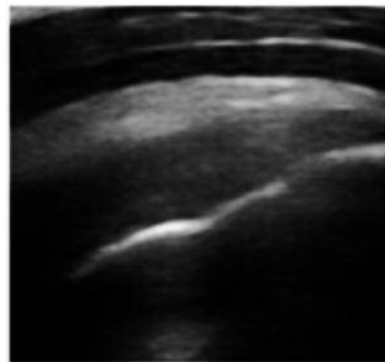
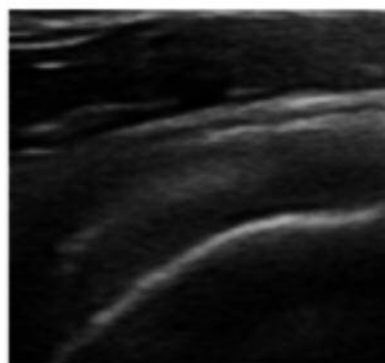
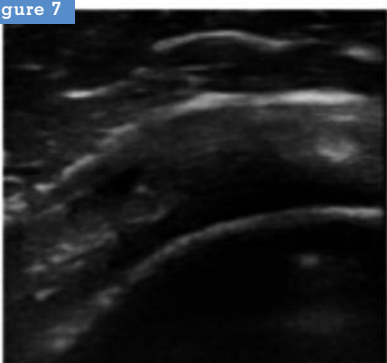


Figure 7



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