ICRS 2013 International Cartilage Repair Society
ELECTRONIC POSTER SYSTEM
Izmir- Turkey | September 15 -18, 2013
Geistlich Surgery

Safety and efficacy of chondrotissue® for the treatment of knee cartilage defects: clinical results after 12 and 24 months

e-Poster: P195

Congress: ICRS 2013

Type: Electronic Poster

Topic: Clinical Research / Clinical outcome

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MeSH:

Polyglycolic Acid [D25.720.728.780]

Cartilage Diseases [C05.182]

Joint Diseases [C05.550]

Keyword: Cartilage implant, chondrotissue®, microfracture, cartilage defects, clinical study

1. Abstract

Purpose: The cartilage implant chondrotissue® is used for cartilage repair in degenerative and traumatic changes of the synovial joints. To evaluate the safety and efficacy of chondrotissue® in microfracture treatment of local femoral knee cartilage defects, a randomized multicentre open-label study versus microfracture was initiated.

Patient cohort: Twelve patients with 12-24 months follow-up were included in an interim evaluation of the clinical outcome. Therein, the efficacy of the chondrotissue® treatment (7 cases) compared to microfracture (5 cases) and to the pre-operative situation was evaluated at 3, 12 and 24 months post-operatively by VAS pain score, IKDC and KOOS. To evaluate defect filling and covering, magnet resonance imaging of the defect area was performed pre-operatively and at 12 months follow-up. Additionally, clinical safety data were recorded.

Results: The chondrotissue® treatment led to a significant reduction in pain (VAS pain score) and a significant improvement of knee function and symptoms (IKDC score) compared to the preoperative situation. In contrast to that, the microfracture group showed no significant changes. Furthermore, chondrotissue® led to a significant improvement in all subcategories of the KOOS score at 12 and 24 months post-operatively, when compared to the pre-operative situation. In contrast to that, the microfracture group showed no significant increase in KOOS. Comparison of delta KOOS between both groups showed that the improvement in the chondrotissue® group was significantly higher in the subcategories pain, symptoms and activity of daily living. Concerning the safety evaluation of the chondrotissue® treatment, no complications or revision surgeries were indicated during the observation period of 24 months. For evaluation of defect covering and filling, MRI evaluation at 12 months after implantation of chondrotissue® showed a good defect covering and filling in comparison to the pre-operative situation.

Conclusion: First results of this randomized, comparative open-label study show that the chondrotissue® treatment for cartilage repair effectively improves the patients' situation, while there is no significant improvement after microfracture treatment.

2. Purpose

The cartilage implant chondrotissue® is a mechanically stable one-step product, which is used for cartilage repair in degenerative and traumatic changes of the synovial joints. To evaluate the safety and efficacy of chondrotissue® in microfracture treatment of local femoral knee cartilage defects, a randomized open-label study versus a microfracture control group was initiated in five European study centers.

3. Methods and Materials

For an interim evaluation of the clinical outcome data of 12 patients with 12-24 months follow-up were analyzed. Therein, the efficacy of the chondrotissue® treatment (7 cases) compared to microfracture (5 cases) and to the pre-operative situation was evaluated at 3, 12 and 24 months post-operatively by VAS pain score, IKDC and KOOS. To evaluate defect filling and covering, magnet resonance imaging of the defect area was performed pre-operatively and at 12 months follow-up. Additionally, clinical safety objectives and side effects were recorded after microfracture treatment with or without application of chondrotissue®.

4. Results

The chondrotissue® treatment led to a significant reduction in pain (VAS pain score; Fig. 1A) and a

significant improvement of knee function and symptoms (IKDC score; Fig. 2A) compared to the preoperative situation. In contrast to that, the microfracture group showed no significant changes (Fig. 1/2 B). Furthermore, chondrotissue® led to a significant improvement in all subcategories of the KOOS score at 12 and 24 months post-operatively, when compared to the pre-operative situation (Fig. 3 A). In contrast to that, the microfracture group showed no significant increase in KOOS (Fig. 3 B). Comparison of delta KOOS between both groups showed that the improvement in the chondrotissue® group was significantly higher in the subcategories pain, symptoms and activity of daily living (Fig. 4). Concerning the safety evaluation of the chondrotissue® treatment, no complications or revision surgeries were indicated during the observation period of 24 months. MRI evaluation at 12 months after implantation of chondrotissue® (Fig. 5 B) showed a good defect covering and filling in comparison to the pre-operative situation (Fig. 5 A).

Fig.1A

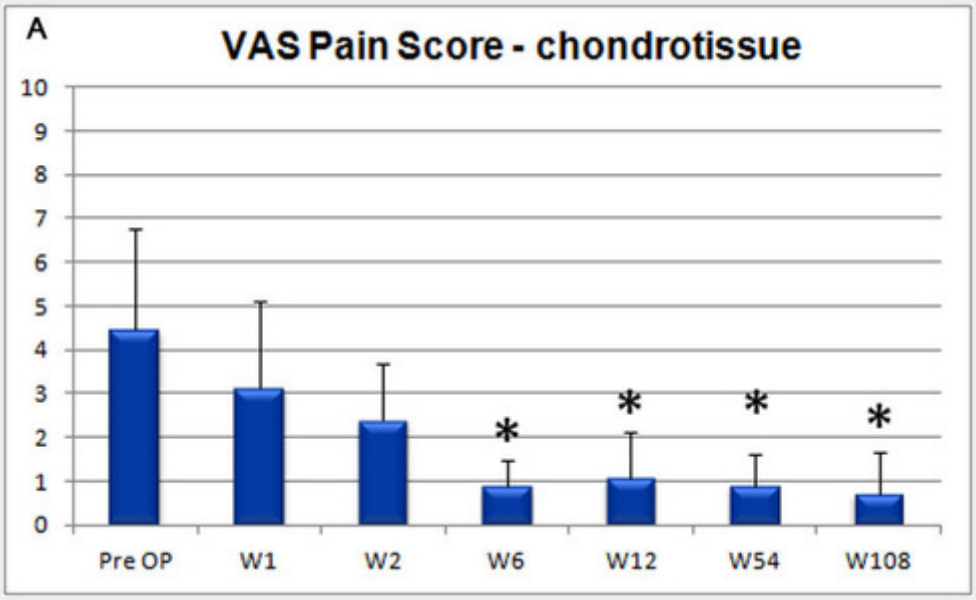

Fig. 1B

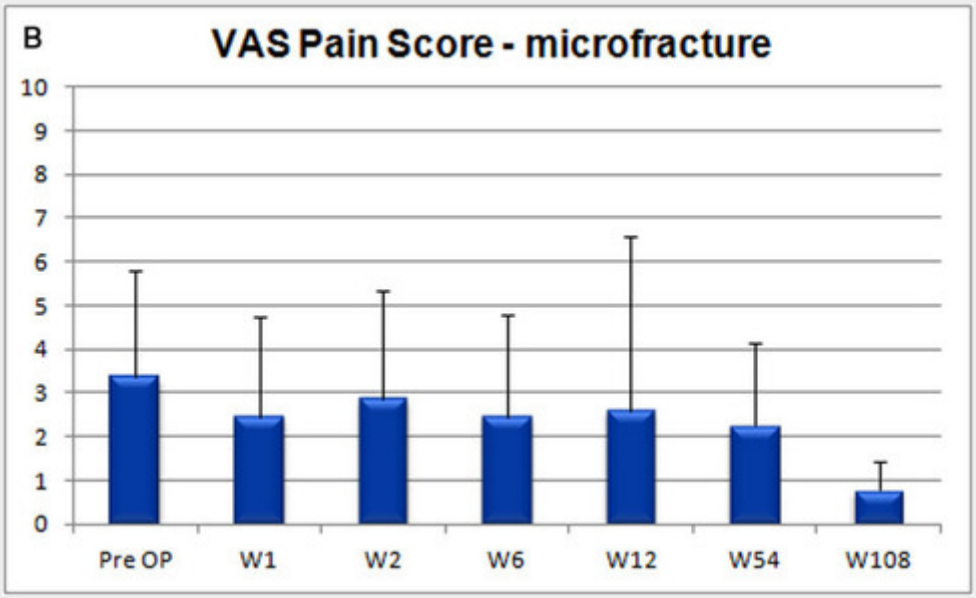

Fig. 1: Pain significantly reduced at week 6, 12, 54 and 108 after chondrotissue® treatment compared to pre-operative situation (A) whereas the microfracture group showed no significant changes (B).

Fig.2A

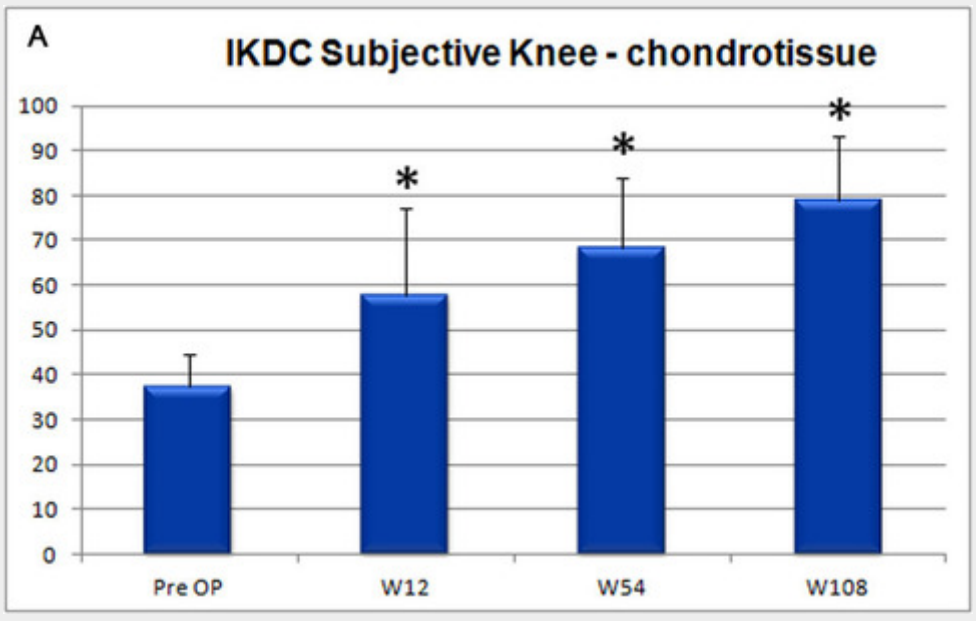

Fig.2B

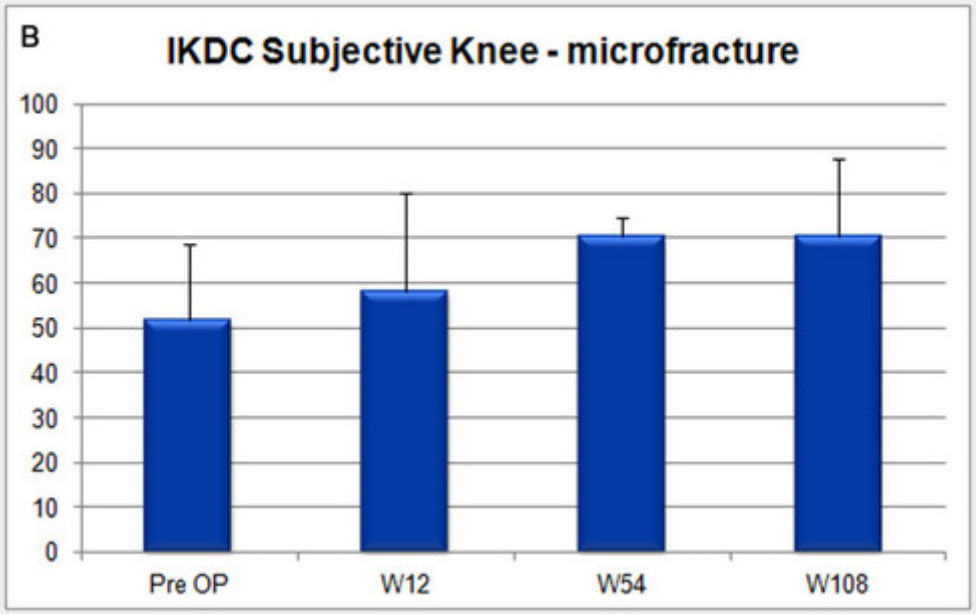

Fig. 2: Activity and absence of symptoms significantly increased at week 12, 54 and 108 after chondrotissue® treatment compared to pre-operative situation (A) whereas the microfracture group showed no significant changes (B).

Fig. 3A

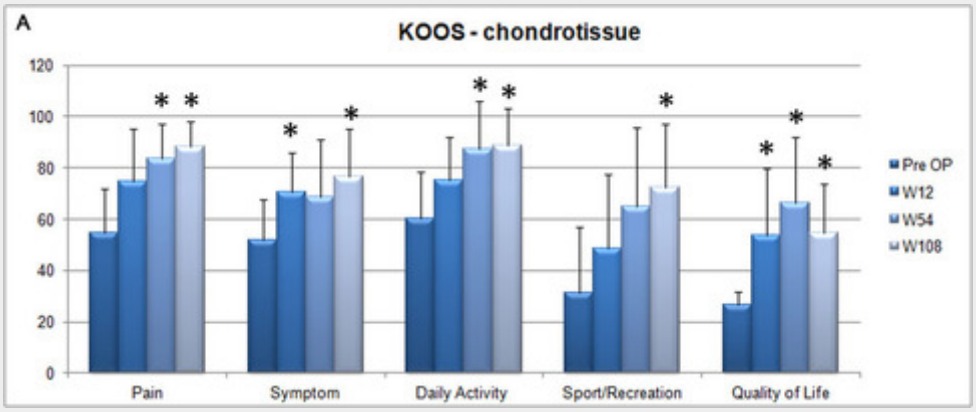

Fig. 3B

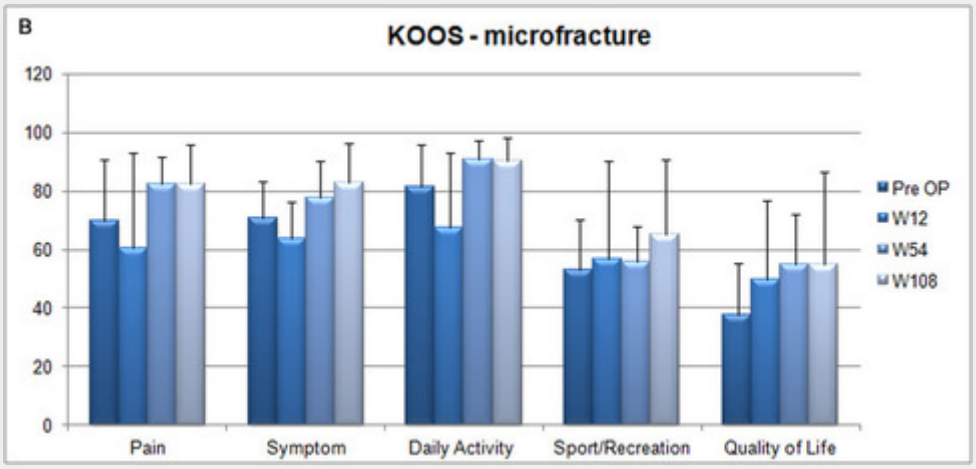

Fig. 3: chondrotissue® led to a significant improvement in all subcategories of the KOOS score at 12 and 24 months post-operatively, when compared to the pre-operative situation (A), whereas the microfracture group showed no significant increase in KOOS (B).

Fig. 4

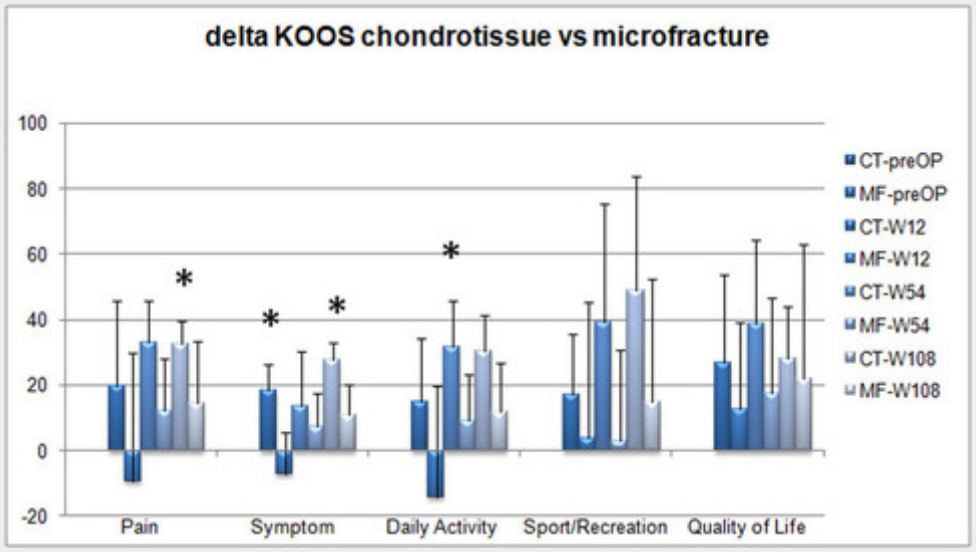

Fig. 4: Comparison of delta KOOS between both groups showed that the improvement in the chondrotissue® group was significantly higher in the subcategories pain, symptoms and activity of daily living.

Fig. 5

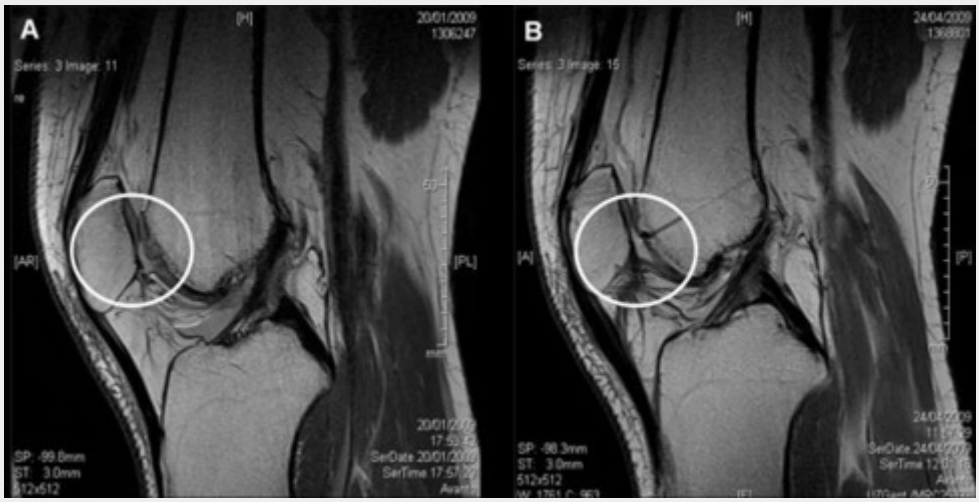

Fig. 5: MRI evaluation at 12 months after implantation of chondrotissue® (B) showed a good defect covering and filling in comparison to the pre-operative situation (A).

5. Conclusion

First results of this randomized, comparative open-label study show that the chondrotissue® treatment for cartilage repair effectively improves the patients' situation, while there is no significant improvement after microfracture treatment. Further patient data are needed to confirm the effectiveness of chondrotissue® and to show superiority of the chondrotissue® treatment over the microfracture treatment.

6. References

Zantop T, Petersen W. Arthroscopic implantation of a matrix to

cover large chondral defect during microfracture. Arthroscopy

2009;25:1354-60.

7. Author Information

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8. Mediafiles

Fig.1A

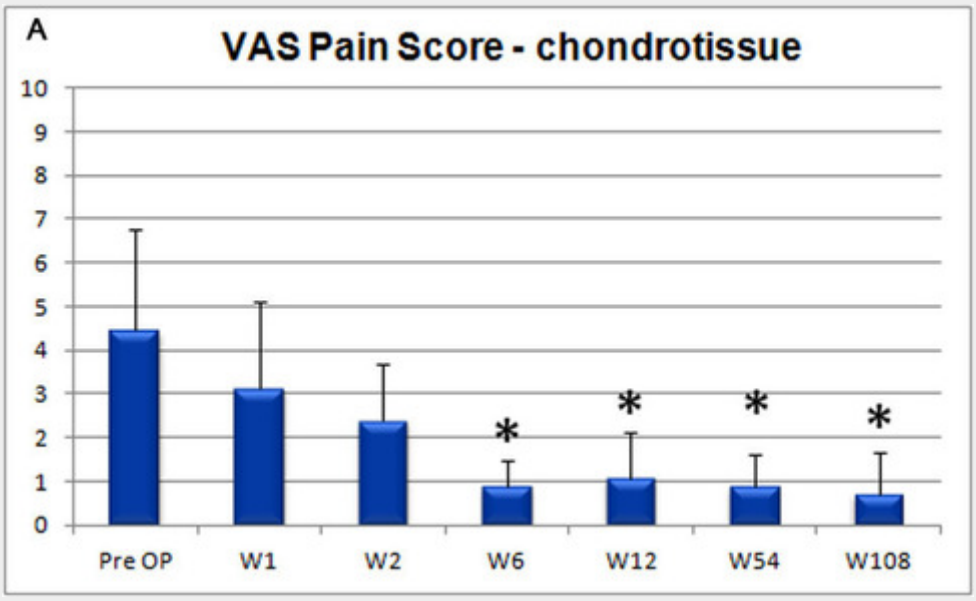


Fig. 1B

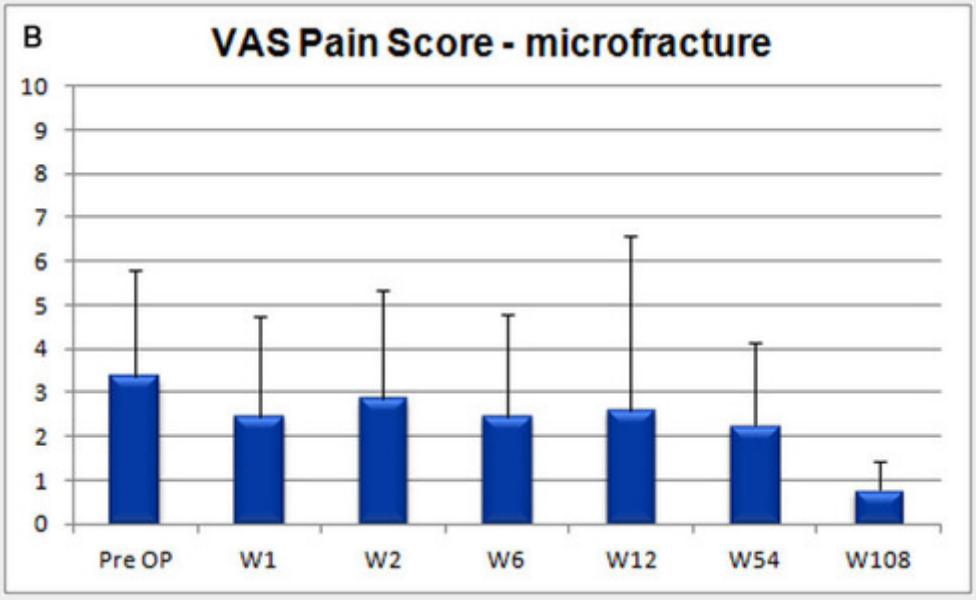
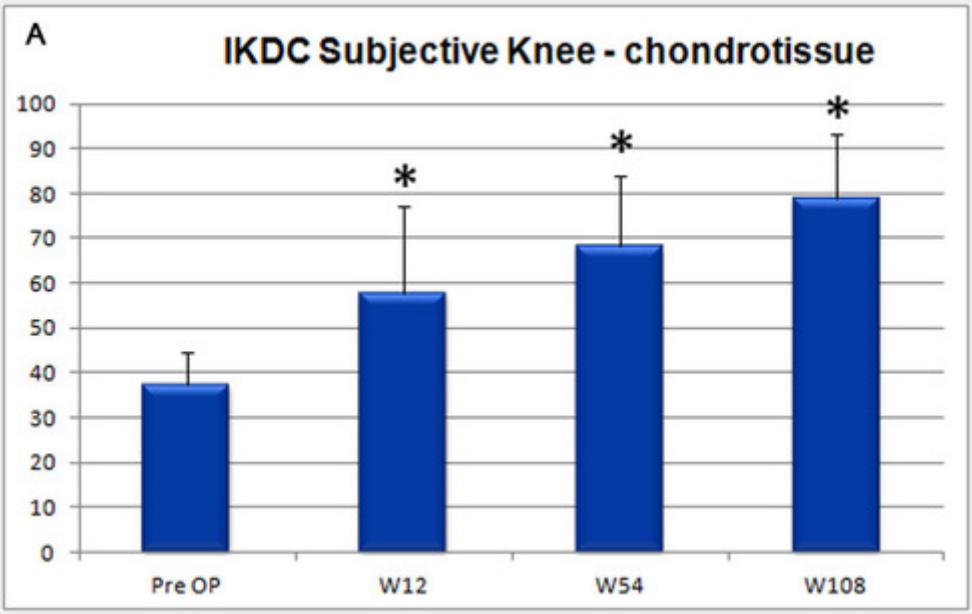


Fig.2A


A
IKDC Subjective Knee - chondrotissue
100
90
80
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50
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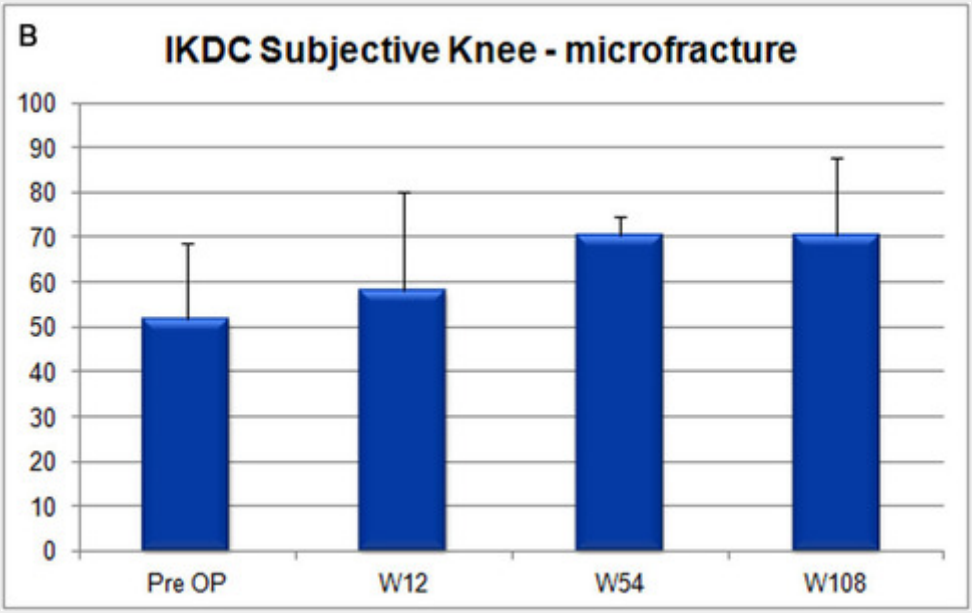
Pre OP
W12
W54
W108

Fig.2B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IKDC Subjective Knee - microfracture
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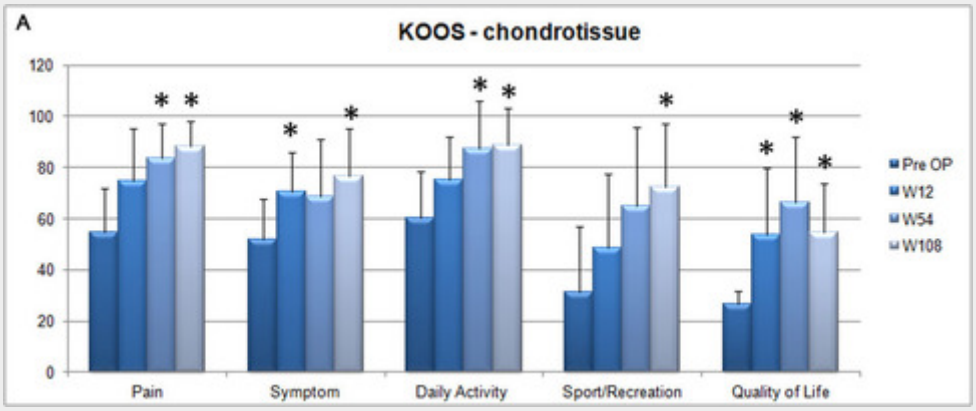
Fig. 3A



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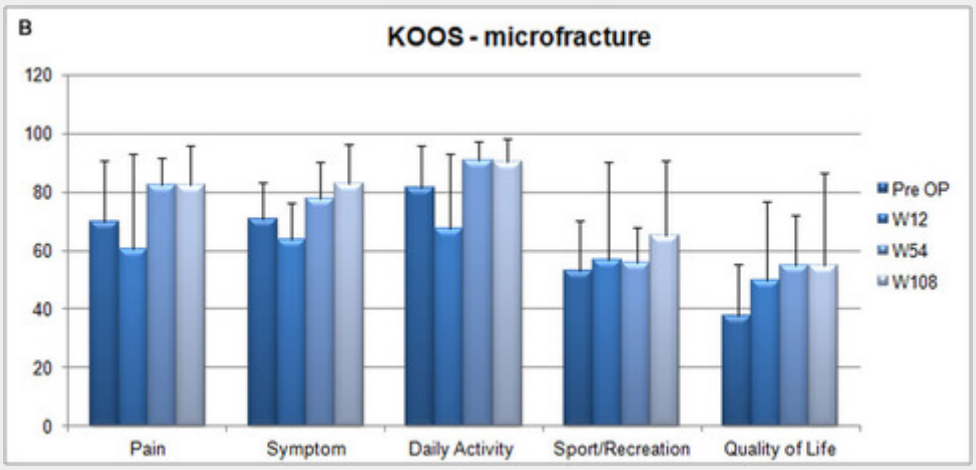

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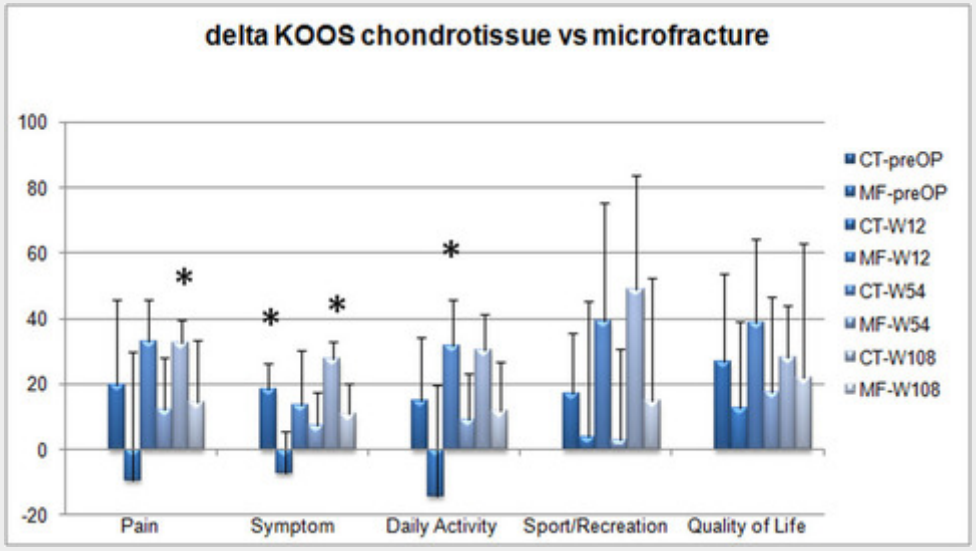

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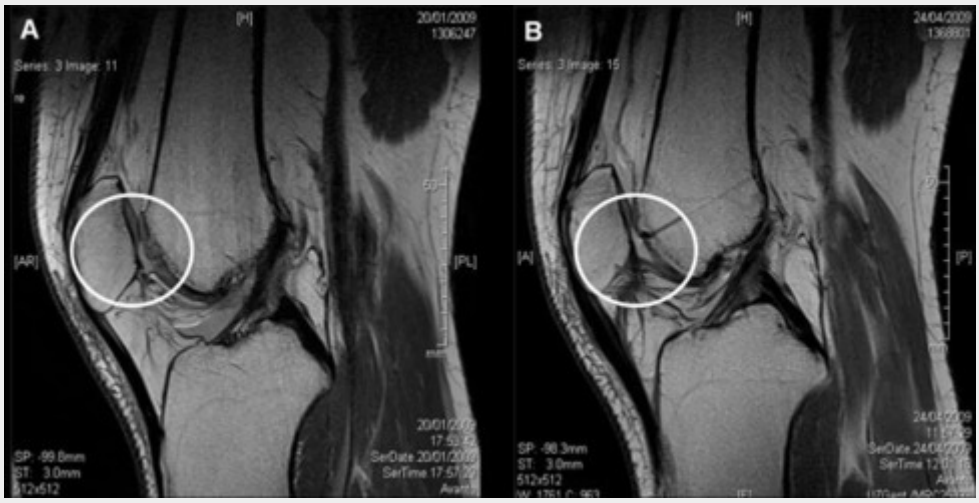
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