



Cartilage Regeneration System – One Step



Multicenter Study CaReS®-1S

Multicenter clinical trial using a cell-free collagen matrix (CaReS®-1Step)

to treat focal cartilage defects in knee joint -

first analysis

Patients included by: PD Dr. T. Efe, Department of Orthopaedics, Hospital of the University of Marburg; Prof. Dr. Ch. Heiß, Dr. J. Mika, Department of Traumatology,
Hospital of the University of Giessen; Dr. M. Friedrich, Dr. M. Blaser, Orthoclinic Rottweil

February 18, 2013

Patient Data

Included patients:

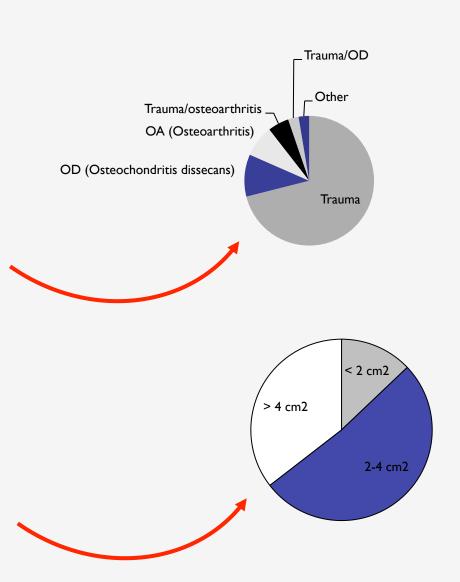
▶ Pre-OP: 37
 ▶ 3 months: 34
 ▶ 6 months: 26
 ▶ 12 months: 13
 ▶ 24 months: 2

Diagnoses:

➤ Trauma:
➤ Osteocondrosis dissecans (OD):
➤ Osteoarthritis
➤ Trauma and osteoarthritis
➤ Trauma and OD:
3%

Defect sizes:

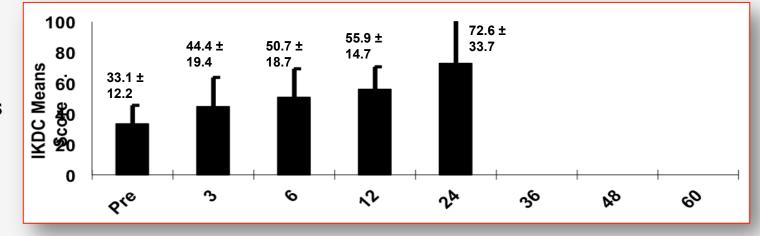
 $ightharpoonup <2 cm^2$ 13% $ightharpoonup 2-4 cm^2$ 52% $ightharpoonup >4 cm^2$ 35%



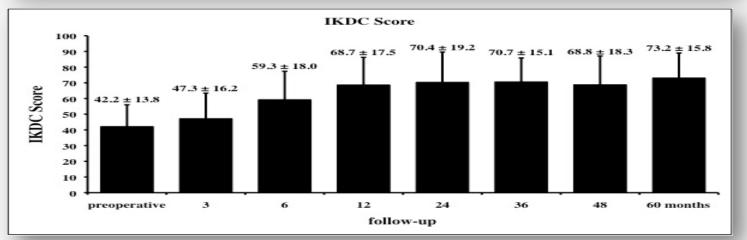
IKDC Score

IKDC score compared with data obtained by a multicenter trial with the MACI product CaReS® (A Prospective Multicenter Study on the Outcome of Type I Collagen Hydrogel–Based Autologous Chondrocyte Implantation (CaReS) for the Repair of Articular Cartilage Defects in the Knee Ulrich Schneider, Lars Rackwitz, Stefan Andereya, Sebastian Siebenlist, Florian Fensky, Johannes Reichert, Ingo Löer, Thomas Barthel, Maximilian Rudert and Ulrich Nöth; *Am J Sports Med* 2011 39: 2558 originally published online October 7, 2011)

CaReS®-1S Cell free



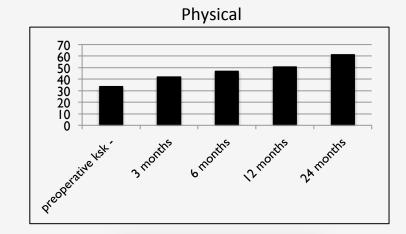
CaReS®-2S (MACI)

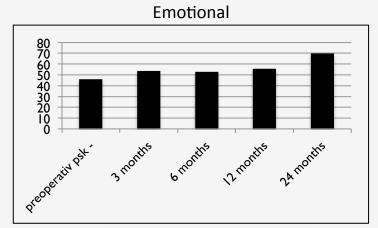


SF-36 Score

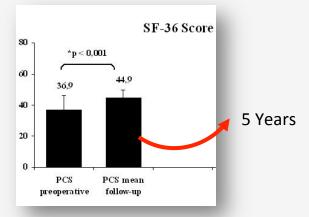
SF-36 score compared with data obtained by a multicenter trial with the MACI product CaReS® (A Prospective Multicenter Study on the Outcome of Type I Collagen Hydrogel–Based Autologous Chondrocyte Implantation (CaReS) for the Repair of Articular Cartilage Defects in the Knee Ulrich Schneider, Lars Rackwitz, Stefan Andereya, Sebastian Siebenlist, Florian Fensky, Johannes Reichert, Ingo Löer, Thomas Barthel, Maximilian Rudert and Ulrich Nöth; Am J Sports Med 2011 39: 2558 originally published online October 7, 2011)

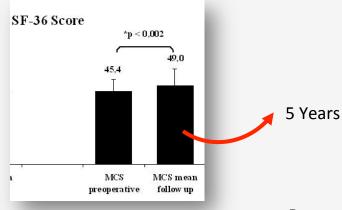
CaReS®-1S





CaReS®-2S (MACI)

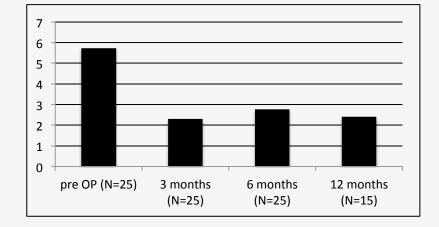


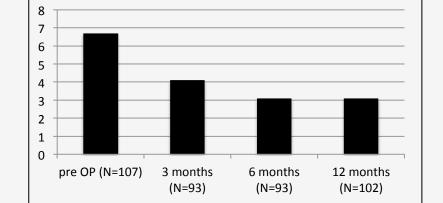


VAS-Score

VAS score compared with data obtained by a multicenter trial with the MACI product CaReS® (A Prospective Multicenter Study on the Outcome of Type I Collagen Hydrogel–Based Autologous Chondrocyte Implantation (CaReS) for the Repair of Articular Cartilage Defects in the Knee Ulrich Schneider, Lars Rackwitz, Stefan Andereya, Sebastian Siebenlist, Florian Fensky, Johannes Reichert, Ingo Löer, Thomas Barthel, Maximilian Rudert and Ulrich Nöth; Am J Sports Med 2011 39: 2558 originally published online October 7, 2011)

CaReS®-1S





CaReS®-2S (MACI)

First Results - Summary

Patient data:

- Between 2011 and 2013 a total of 37 patients were included in the study. 34 patients had 3 months, 26 patients 6 months, 13 patients 12 months, and 2 patients 24 months results.
- > 87% of the defect sizes were larger than 2 cm², 35% even larger than 4 cm². up to 8 cm².

IKDC Score:

The overall IKDC score in the present analysis significantly improved from 33.1 preoperatively to 72.6 after 2 years (to 55.9 after 12 months). Already after 3 months there is a clear improvement of the IKDC score with further progress at 24 months; there is no leak phase. The IKDC scores in this first analysis are identical or better than the results of a multicenter study with the MACI product CaReS® 2S. The study design was identical in both studies, the starting point in the CaReS®-1S study was even worse.

IKDC Current Health Assessment Form (SF-36 Score):

The PCS and the MCS both increased significantly from preoperative to the mean follow-up. Again the trend proves the similarity of the therapy of cartilage defects with CaReS®-1S and the MACI technique.

Conclusion:

This prospective multicenter investigation indicates that the use of CaReS®-1S leads to a successful regeneration of various, even large size cartilage defects.