

CaReS®-1S

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

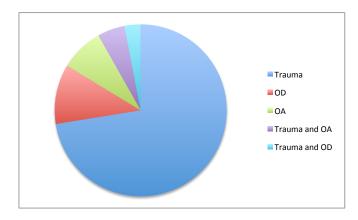




Average patient age: 35 years

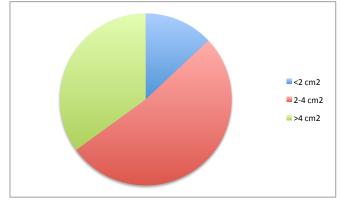
Diagnosis

Trauma	71 %
Osteochondrosis dissecans (OD)	11 %
Osteoarthritis	8 %
Trauma and osteoarthritis	5 %
Trauma and OD	3 %



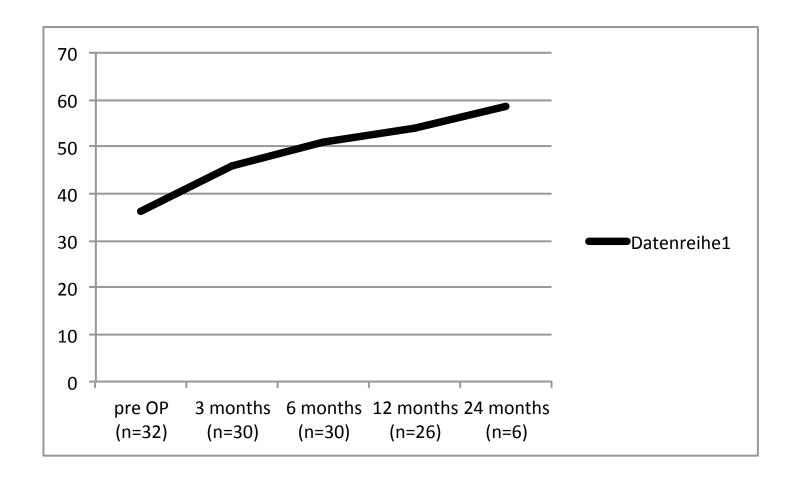
Defect Size

<2 cm ²	13 %
2-4 cm ²	52 %
>4 cm ²	35 %
average size	4 cm ²



IKDC Score

(International Knee Documentation Committee Subjective Knee Form)



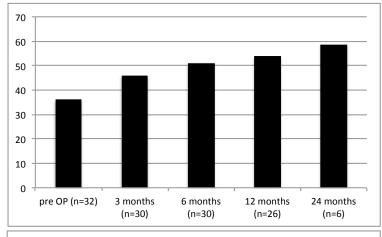


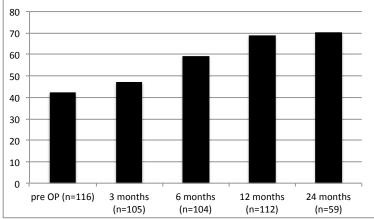
IKDC Score

(International Knee Documentation Committee Subjective Knee Form)

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)







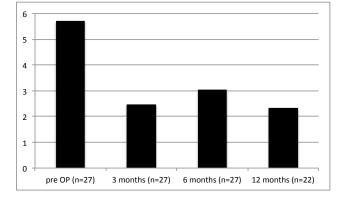
CaReS®-2S (MACI)

VAS Score

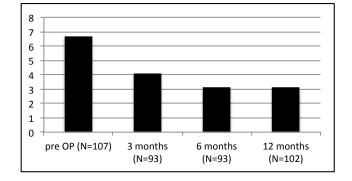
(Visual Analogue Scale)

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 Cell free



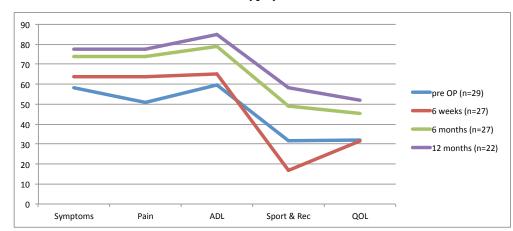
CaReS®-2S (MACI)

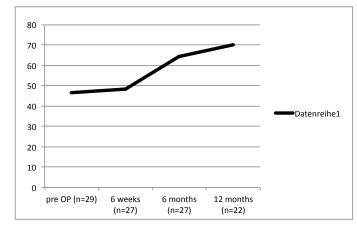


KOOS Score

(Knee injurie and Osteoarthritis Outcome Score)

KOOS consists of 5 subscales: Pain, other Symptoms, Function in daily living (ADL), Function in Sport and recreation (Sport/Rec) and knee related Quality of life (QOL)





Average score

Subscales

FIRST RESULTS - SUMMARY



Patient data:

- The average age of the patients is 35 years
- The average defect size is 4 cm².
- 87% of the defect sizes were larger than 2 cm², 35% even larger than 4 cm² (up to 8 cm²)

IKDC score:

- Between 2011 and 2013 a total of 32 patients were included in the study. 30 patients had 3 months, 30 patients 6 months, 26 patients 12 months and 6 patients 24 months results.
- The overall IKDC score in the present analysis significantly improved from 36.2 preoperatively to 58.8 after 2 years (to 53.8 after 1 year). 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 score in this first analysis are identical than the results of a multicenter study with the MACI product CaReS. The study design was identical in both studies, the starting point in the CaReS-1S study was even worse.

VAS score (the score was collected only at the Hospital of the University of Marburg):

- Between 2011 and 2013 a total of 27 patients were included in the study. 27 patients had 3 months, 27 patients 6 months and 22 patients 12 months results.
- The VAS score in the present analysis significantly improved from 5.69 preoperatively to 2.32 after 1 years. Already after 3 months there is a clear improvement of the VAS score with further progress at 12 months. The VAS score in this first analysis are identical than the results of a multicenter study with the MACI product CaReS. The study design was identical in both studies.

KOOS score (the score was collected only at the Hospital of the University of Marburg):

- Although the KOOS score is not an ideal score for cartilage defects, it reflects the subjective feeling of the patients after knee surgeries.
- Between 2011 and 2013 a total of 29 patients were included in the study. 27 patients had 3 months, 27 patients 6 months and 22 patients 12 months results.
- The overall KOOS score in the present analysis significantly improved from 46.5 preoperatively to 70.05 after 1 years. Already after 6 months there is a clear improvement of the overall KOOS score with further progress at 12 months.
- The same course is also reflected in the individual assessment. The KOOS score for symptoms, pain and function in daily life show the same improvement. The KOOS scores for sports and recreation and quality of life show after 6 weeks also a clear improvement. After 3 month both scores are below or on the same level compared with the preoperative situation. The reasons is in the rigid rehabilitation program.



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