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# Systematic Review and Meta-Analysis of the Clinical Evidence Supports the Use of AMIC® in the Ankle Joint

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The first meta-analysis of pain and functional outcomes following AMIC® Chondro-Gide® treatment of osteochondral lesions of the talus (OCL) demonstrated significant improvement compared to baseline.

## Systematic Literature Search

48 publications identified in systematic searches in PubMed and Embase databases.



Studies were included (PRISMA guidelines) if they had primary measures of clinical outcomes, a minimum of 1-year follow-up, and included more than 5 patients.



- > **Qualitative analysis: 15 studies / 492 patients**
- > **Quantitative analysis: 12 studies / 323 patients**
- > Mean age: 36 (range, 12–68) years
- > OCL size varied from 1–2.4 cm<sup>2</sup>
- > Different surgical approaches and bone marrow stimulation techniques
- > Mean follow-up: 33 (range, 12–60) months

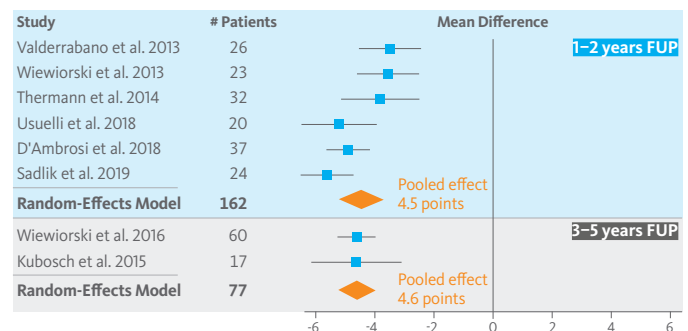
## Statistical Methods for Quantitative Analysis

- > The meta-analysis compared the pain VAS, the American Orthopedic Foot and Ankle Score (AOFAS), and the Foot Function Index (FFI) between baseline and follow-up of 1–2 and 3–5 years.
- > A random effects model was used to evaluate the changes. Results were displayed using forest plots which show the effect of the **individual studies** (■) with a 95% confidence interval, as well as the **pooled effect** (◆).
- > The vertical line through 0 indicates no effect: a big distance to the 0-line and a narrow 95% confidence interval for the effect size of an individual study indicate a significant effect and conclusive data.

## Improvement in pain following AMIC

- > From baseline to 1–2 year follow-up (FUP), the forest plot shows a clinically and statistically significant improvement (reduction) in mean pain of 4.5 points (light blue area).
- > From baseline to 3–5 year FUP, mean pain reduced significantly by 4.6 points (light grey area).

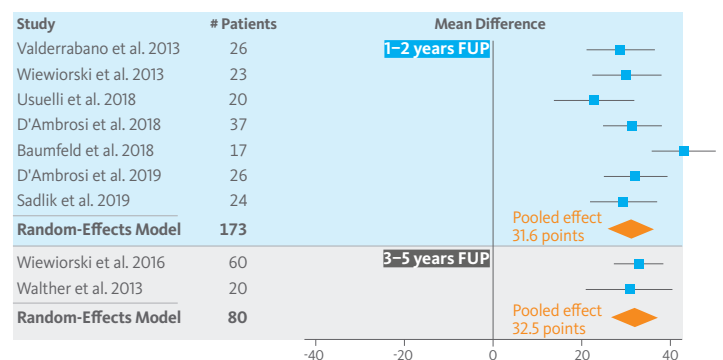
Fig. 1: Improvement in pain compared to baseline



## Improvement in joint function following AMIC

- > From baseline to 1–2 year FUP, the forest plot shows a significant improvement in mean AOFAS of 31.6 points (light blue area).
- > From baseline to 3–5 year FUP, significant improvement was observed for the mean AOFAS by 32.5 points (light grey area) and for the mean FFI by 31 points (not shown).

Fig. 2: Improvement in AOFAS compared to baseline



## CHONDRO-GIDE® LITERATURE HIGHLIGHT

The bilayer collagen membrane is an established product for cartilage therapies with 20 years of clinical use. AMIC® Chondro-Gide®, a technique that combines bone marrow stimulation with the use of a collagen membrane, has been used for over 15 years. Based on pre-clinical and clinical evidence, AMIC® was included in the treatment recommendations for cartilage lesions of the talus, knee and hip by the respective committees of the German Society for Orthopaedics and Trauma (DGOU).

Recently, the intended use of Chondro-Gide® was extended to augment meniscal repair by wrapping the membrane around the sutured meniscus. The corresponding meniscus wrapping technique is registered as AMMR™.

This literature highlight addresses important aspects of the evidence for the use of Chondro-Gide®.

## Conclusions

- > The **AMIC Chondro-Gide** procedure for treatment of OCL of the talus provided clinically relevant and **significant improvement** in ankle joint **pain** and **functional outcome** scores **up to 5 years** after surgery.
- > There were **no reported adverse events** or **complications** directly **related** to the **AMIC procedure**. Within the follow-up period, 6 of 492 treated patients (1.2%) required revision surgeries due to persistent pain caused by arthrofibrosis or hypertrophic scar tissue or because of progressive degeneration.
- > None of the patients required conversion to ankle fusion or arthroplasty.
- > Surgical approach and bone marrow stimulation technique were not related to clinical outcome.

For details of the study refer to the original article:

### Is there clinical evidence to support autologous matrix-induced chondrogenesis (AMIC) for chondral defects in the talus? A systematic review and meta-analysis

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#### ABSTRACT



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- > Chondro-Gide®, the original AMIC® membrane<sup>1</sup>
- > One-step procedure for cartilage regeneration techniques<sup>1,2,3</sup>
- > With more than 10 years of clinical experience<sup>4</sup>



- 1 Geistlich Pharma AG, data on file
- 2 Schiavone Panni, A. et al. Good clinical results with autologous matrix-induced chondrogenesis (Amic) technique in large knee chondral defects. Knee Surg Sports Traumatol 2018 Apr;26(4):1130-1136. doi: 10.1007/s00167-017-4503-0. (Clinical study)
- 3 Niemeyer, P. et al. Significance of Matrix-augmented Bone Marrow Stimulation for Treatment of Cartilage Defects of the Knee: A Consensus Statement of the DGOU Working Group on Tissue Regeneration. Z Orthop Unfall 2018; 156(05): 513-532. doi: 10.1055/a-0591-6457
- 4 Kaiser, N. et al. Stable clinical long term results after AMIC® in the aligned knee. Arch Orthop Trauma Surg. 2020 Aug 13. doi: 10.1007/s00402-020-03564-7.