

ARTICLE IN REVIEW:

Explant histology following ViviGen Formable® implantation

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TITLE: Clinical outcome and explant histology after using a cellular bone allograft in two-stage total hip arthroplasty

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STUDY DESIGN: Case report

RESULTS: Two patients underwent two-stage total hip arthroplasty (THA). ViviGen Formable was implanted at stage 1 to fill bone voids. A small portion of ViviGen was explanted at stage 2 to make room for the hip implant. Patient #1 was a healthy 48-year-old male with advanced osteoarthritis and a history of a femur fracture. Seven weeks after ViviGen implantation, he underwent the second stage of THA. Patient #2 was a 64-year-old female with type 1 diabetes, a history of pelvis fracture, and severe osteoporosis. Second stage of THA was performed 12 weeks after implantation. Neither patient experienced complications. Both demonstrated improved Harris Hip Scores post-operatively. Histological evaluation revealed extensive new bone formation in each explant. New bone formation in patient #2 was less mature than in patient #1, but still effective to support the new implant. These cases position ViviGen Formable as an alternative to autograft even in patients with multiple comorbidities.

New bone formation at 7 weeks:

Explants collected at 7 weeks from patient #1 displayed signs of new bone formation around the ViviGen® bone chips and between the demineralized bone fibers.

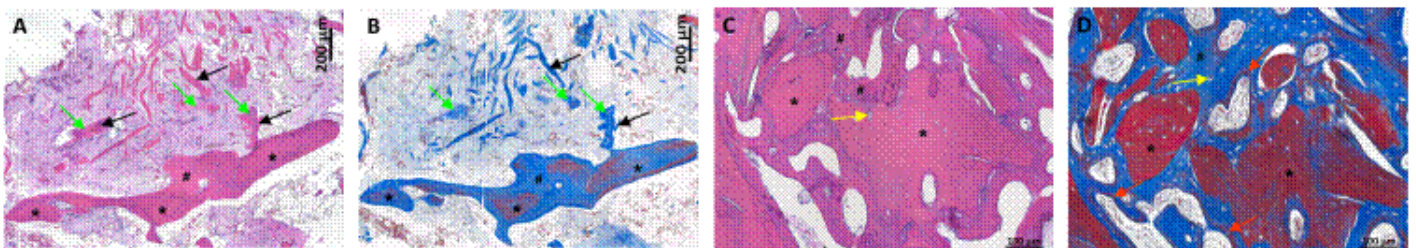
Early and rapid bone formation:

Over 100 µm of new bone was observed at week 7, which suggests direct participation in bone formation soon after implantation.

Achieved healing despite comorbidities:

Patient #2 had serious comorbidities which can slow new bone formation. While less extensive than patient #1 at week 7, indications of new bone were observed at week 12.

New bone formation in femoral explant at 7 weeks



H&E (A and C) or Masson's trichrome staining (B and D). Newly formed, collagen matrix (# and green arrows) was observed surrounding the implanted ViviGen Formable bone chips (*), as well as between the demineralized bone fibers (black arrows). New mineralization formed within the newly formed bone (red arrows, panel D). Yellow arrows indicate cells surrounded by matrix. Panels A&B: 10x; Panels C&D 20x.