Enhanced Implant Fixation in Patients with Poor Bone Quality

Sources:
1. DePuy Synthes test data on file, Windchill 0000268245.

The TFN-ADVANCED Proximal Femoral Nailing System is designed to advance hip fracture treatment with:

- Outcomes-based Design
- Reduced Procedural Complexity
- Comprehensive Surgical Options

To learn more about the future of hip fracture treatment, contact your DePuy Synthes Sales Consultant or visit: www.tfnadvanced.com

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Manufactured or distributed by:
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To order (USA): 800-523-0322
To order (Canada): 855-946-8999

Note: For recognized manufacturer, refer to the product label.
The TRAUMACEM™ V+ Augmentation System.

The first and only polymethylmethacrylate (PMMA) cement with specific indications for augmentation of a trauma device, allowing surgeons to inject a controlled amount of cement into the femoral head in patients with poor bone quality, reducing the risk of cut-out.

The TRAUMACEM V+ Augmentation System is exclusively offered for use with the TFN-ADVANCED® Proximal Femoral Nailing (TFNA) System and builds on the list of comprehensive surgical options that the TFNA System offers.

Demonstrated resistance to cut-out
- Augmented head elements have up to a 244% increase in resistance to cut-out in biomechanical testing.²

Enhanced surgical flexibility
- Sterile packed design allows for intra-operative decision to inject augmentation, after head element placement, for at risk patients.

Early clinical results
- Zero cut-outs and no unexpected head element migration observed in the first two prospective multicenter trials when using augmentation.³⁴

Disclaimer: Bench test results may not be indicative of clinical performance.
CUT-OUT AS A CLINICAL COMPLICATION

HIP FRACTURES ARE COMMON IN THE ELDERLY WITH OSTEOPOROTIC BONE, AND INCIDENCE IS EXPECTED TO RISE.⁵

CUT-OUT IS A LEADING CONTRIBUTOR OF CLINICAL COMPLICATIONS, AND HAS BEEN REPORTED AS HIGH AS 8%⁶, PRIMARILY LINKED TO THE PATIENT’S BONE QUALITY.

CLINICAL CASES

Case 1: 72-year old female > AO 31-A2.2 Fracture : Unstable pertrochanteric fracture
- This patient presented with osteoporosis and the surgeon elected to use the TRAUMACEM V+ Augmentation System. After insertion of the TFNA Helical Blade, peri-implant PMMA augmentation was applied to enhance bone anchorage of the implant. TRAUMACEM V+ Augmentation System was used in this patient due to their age and bone quality.

Case 2: 87-year old female > AO 31-A2 Fracture : Unstable pertrochanteric fracture
- This patient had an osteoporotic varus deformity of the femoral neck and shaft. In order to salvage the suboptimal placement of the TFNA Helical Blade, the head element was augmented to protect against cut-out.
DEMONSTRATED RESISTANCE TO CUT-OUT

By injecting a recommended 3 mL of TRAUMACEM™ V+ Injectable Bone Cement through cannulated implants and instruments into the femoral head, the risk of cut-out may be reduced as demonstrated through biomechanical testing.

Biomechanical test data shows that there is a significant increase in stability using the TRAUMACEM V+ Augmentation System.1,2

Withstand higher loads...
- Whether the head element is in the center or off-center position, augmented head elements withstand higher loads prior to failure.

...for more cycles
- Augmented constructs resist varus collapse for more cycles than non-augmented constructs.

Disclaimer: Bench test results may not be indicative of clinical performance.
ENHANCED SURGICAL FLEXIBILITY

Head element design enables intraoperative decision making

- Fenestrated head elements perform equivalent to solid head elements, thus enabling choice of augmentation with a single implant design.

Ready when needed

- Comprised of single use sterile implants and instruments, TRAUMACEM V+ Augmentation System enables surgeon choice following head element placement.

Controlled injection

- Inject a controlled amount of cement into the femoral head using a uniquely designed injection cannula and fenestrated head element, providing strong implant fixation.

Optimized cement

- Initial viscosity of TRAUMACEM V+ Injectable Bone Cement allows for cement injection immediately after mixing with no wait time.
- Cement working time begins immediately and lasts for up to 27 minutes at room temperature (68˚F).
- Radiopaque design enables visualization under fluoroscopy to detect cement flow.

Exclusively for TFNA System

- TRAUMACEM V+ Augmentation System is cleared exclusively for the TFNA System.
EARLY CLINICAL RESULTS
In two prospective multicenter trials when using augmentation:\textsuperscript{3,4}

Zero cut-outs
- 0 cut-outs and no unexpected head element migration observed.

No clinical complications related to the cement
- Clinically proven surgical technique reduces risk of cement extravasation into joints.
- 0 reported occurrences of heat-induced necrosis.

Author’s conclusions on augmentation
- Augmentation was used with the Proximal Nail Antirotation (PFNA) System\textsuperscript{*} with the authors concluding:

The augmentation of the blade gives the fixation construct much more stability due to a larger bone-implant interface.\textsuperscript{4}

Studies of the follow-up X-rays showed no unexpected blade migration such as cut-out or cutting through and no loosening of the blade in this series.\textsuperscript{4}

A safe and user-friendly tool for pertrochanteric fracture fixation. It prevents blade migration within the head-neck fragment and leads to good functional results.\textsuperscript{7}

PRODUCT ORDERING INFORMATION

TRAUMACEM V+ Injectable Bone Cement, Sterile (07.702.040S)
- 1 x TRAUMACEM V+ mixer with cement powder and sterilization lid
- 1 x Monomer glass ampoule
- 1 x Cement mixing and transferring lid

TRAUMACEM V+ Syringe Kit, 4 x 1 mL, 2 x 2 mL, Sterile (03.702.150S)
- 4 x Blue 1 mL syringes
- 2 x White 2 mL syringes
- 1 x One-way stopcock

TRAUMACEM V+ Injection Cannula, for TFNA System, sterile (03.702.121S)
- 1 x Side-opening cannula, with Luer-lock
- 1 x Plunger

Additionally required:
- 1-2 Syringes (6-10 mL) with Luer-lock
- Saline solution
- Radiographic contrast agent

*The PFNA System is a DePuy Synthes proximal femoral nail available outside the United States.