PRELIMINARY RESULTS OF A NEW INJECTABLE AND DRILLABLE BONE VOID FILLER IN THE TREATMENT OF TIBIA PLATEAU FRACTURES
A First Case Review

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Abstract
Norian® Drillable is a biocompatible, injectable, Bone Void Filler based on the successful Norian® SRS. We evaluated the outcome and clinical experience of 16 patients presenting with tibia plateau fractures, each treated according to the AO techniques of reduction and fixation using Norian Drillable Bone Void Filler. Nine physicians performed the surgeries at 6 different hospitals located in The Netherlands (Nieuwegein, Tilburg), Norway (Tønsberg), Spain (Madrid, Sevilla), and Sweden (Uppsala). In 8 cases, Norian Drillable was injected prior to hardware fixation (“reduce-fill-fix”) and in 6 cases vice versa (“reduce-fix-fill”). In 2 cases both procedures were used. Surgeons were “very satisfied” with the performance of Norian Drillable in 10 cases, and “satisfied” in the remaining 6 cases. No cracking of Norian Drillable was observed during drilling or screw insertion and no intraoperative complications occurred. Furthermore, all surgeons indicated they would use Norian Drillable again for the same procedure. Review of this case series suggests that Norian Drillable is an effective and reliable Bone Void Filler with substantial advantages compared to conventional grafting materials. Particularly useful is the possibility to choose between the “reduce-fill-fix” and the “reduce-fix-fill” approach according to the patient’s needs. In addition, Norian Drillable allows early load bearing and is associated with a good clinical outcome.

Indications
Norian Drillable is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. The product provides a Bone Void Filler that resorbs and is replaced with bone during the healing process. Norian Drillable can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable is intended to be placed in bony voids either before or after final fixation.

Contraindications
The safety and effectiveness of this device for use in the spine has not been established. Use of this device is contraindicated in the spine, including use in the pedicle, as this could be associated with leakage of the device material into the bloodstream, which could cause serious adverse events, including death.

Norian Drillable should not be used in the presence of active or suspected infection.

Norian Drillable is not for screw augmentation.

Norian Drillable is not for use in:
• Patients with traumatic open injuries that are predisposed to infection
• Stress-bearing applications
• Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware
• Patients with compromised health (eg, abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site
• Patients who are skeletally immature
• Vertebral compression fractures
• Intra-articular space (ie, material injected into the joint space)

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.
Introduction

The treatment of choice for tibia plateau fractures involves internal fixation and reduction to restore the plateau surface. The process of reduction frequently results in the formation of cancellous bone defects, which require bone graft substitutes in order to achieve anatomical fixation.

A common material used for filling tibia plateau defects has been autologous bone graft harvested from the iliac crest. On the whole, though, this has not been a satisfying solution. While autologous bone grafts do support integration and generation of new bone, the initial stability imparted is insufficient and harvesting of the material is a painful procedure associated with significant donor site morbidity.

Hydroxyapatite preparations have also been applied to fractures of the tibia plateau. These types of void filler provide more primary stability than autologous grafts but they are somewhat brittle and require preshaping. This is a considerable drawback as bone defects can be complex and irregularly shaped, making preshaping difficult. Therefore, hydroxyapatite preparations are also unsatisfactory for fixation of tibia plateau fractures.

Polymethyl methacrylate cement has been extensively used for augmenting fixation following bone fractures. However, while this acrylic cement does have the important characteristic of being moldable and can be suitable for some fracture types, its use is limited due to cytotoxic and exothermic effects that adversely affect healing.

Beginning about 10 years ago, a new type of Bone Void Filler came into use that addressed many of the concerns associated with products available at the time. Norian Skeletal Repair System (SRS), a fast-setting calcium phosphate cement, can be injected through a minimally invasive technique to fill cancellous bone defects, resulting in improved absorption and distribution of compressive energy. The material delivers 10 MPa of compressive strength after 10 minutes and fully cures within 24 hours.

Norian Drillable is composed of 3 main components: calcium phosphate powder, bioresorbable fibers, and sodium hyaluronate solution. Calcium phosphate has been widely used in clinical applications for decades. There are many publications and clinical cases available that demonstrate its effectiveness and safety in addressing bone regeneration. After injection, Norian Drillable hardens in vivo to form carbonated apatite, closely resembling the mineral phase of bone. This gradually resorbs and is replaced with bone during the healing process via osteoclastic resorption and osteoblastic new bone formation.

The bioresorbable polylactide/glycolide (82/18) copolymer fibers are uniformly distributed within the material and provide an increase in toughness that reduces crack propagation and allows the material to be drilled and tapped.

Materials & Methods

Sixteen patients presenting with a tibia plateau fracture were included in this prospective analysis. Fractures were classified according to AO classification.

In accordance to the AO techniques of reduction and fixation it was proposed to accesses the plateau via a lateral parapatellar, longitudinal incision and that the fracture should be exposed by elevation of the lateral meniscus. Following reduction, fractures were filled with Norian Drillable Bone Void Filler and then fixed, or fixation was first performed, followed by the filling of voids with bone cement. Norian Drillable Injectable bone cement was applied to fill bone voids in all cases. The material begins to harden within 10 minutes and reaches its full compressive strength of approximately 35 MPa within 24 hours.
The liquid component, sodium hyaluronate, is a pH-neutral solution that increases viscosity, leading to improved mixing and flow properties. Sodium hyaluronate occurs naturally in the fluid of joints\textsuperscript{19} and in the viscous humor of the eye.\textsuperscript{20} Norian Drillable uses sodium hyaluronate from a bacterial source, which minimizes the risk of disease transmission.

**Figure 1.**
Norian Drillable includes the 3 main components: calcium phosphate powder, biodegradable fibers, and sodium hyaluronate solution.

Data collected for each patient included: the name of the hospital where they were operated on, the name of the surgeon who performed the operation, fracture location and type according to AO criteria, age, gender, bone quality, surgical procedure used (either reduce-fix-fill or reduce-fill-fix), whether or not screws were placed through the Norian Drillable, duration of surgery, whether or not a tourniquet was applied and if so, for how long, whether or not satisfying results were achieved, any complications, and whether or not the surgeon would use Norian Drillable again for the same indication.
Sixteen patients underwent surgery for correction of tibia plateau fractures at 6 different hospitals located in The Netherlands (Nieuwegein, Tilburg), Norway (Tønsberg), Spain (Madrid, Sevillia), and Sweden (Uppsala). The surgeries were performed by 9 different physicians.

The majority of patients were female (6/10) and the age of patients varied from less than 40 to greater than 80 years of age.

Most patients presented with a fracture of the left tibial plateau (6/10). Patients’ bone quality and type of fracture presented are given in Tables 1 and 2. The most common type of fracture according to AO criteria was type B3.

Highlights of the case series include:
- Surgeons reported being “very satisfied” in 10, and “satisfied” in the remaining 6 cases
- No cracking of Norian Drillable during drilling and screw insertion
- No intraoperative complications
- All surgeons indicated they would use Norian Drillable again for this indication

### Table 1.
Patient Bone Quality

<table>
<thead>
<tr>
<th>Bone Quality</th>
<th>Patients</th>
</tr>
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<tbody>
<tr>
<td>Dense</td>
<td>5</td>
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<tr>
<td>Good</td>
<td>7</td>
</tr>
<tr>
<td>Poor</td>
<td>4</td>
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### Table 2.
Type of Fracture

<table>
<thead>
<tr>
<th>Type of Fracture</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>1</td>
</tr>
<tr>
<td>B3</td>
<td>8</td>
</tr>
<tr>
<td>C2</td>
<td>2</td>
</tr>
<tr>
<td>C3</td>
<td>5</td>
</tr>
</tbody>
</table>

1. According to AO criteria

Figure 2.
Radiographs illustrating the treatment, using LCP L-plate and Norian Drillable (reduce–fill–fix), of a female patient under 40 years of age who suffered a C3 tibial fracture and who had normal range of motion, no pain, and full weight bearing 3 months postop.
RESULTS

The mean duration of surgery was 115 minutes (±48 minutes). Ten patients required the use of a tourniquet and 5 patients were operated on without a tourniquet (unknown for 1 patient). When a tourniquet was used, it was removed before implantation in 4 cases and after implantation in 6 cases. The mean duration of tourniquet use was 97 minutes (±13 minutes).

The surgeon performed the injection of Norian Drillable prior to hardware fixation in 8 cases (“reduce-fill-fix”) and in 6 cases the hardware fixation was done before the injection of Norian Drillable (“reduce-fix-fill”). In 2 cases, the surgeon used both procedures.

Figure 3.
Used surgical technique

Figure 4.
Surgeon satisfaction with the use of Norian Drillable
RESULTS

Figure 5.
Radiographs illustrating the use of Norian Drillable for the treatment (reduce–fill–fix) of 50-60 year-old female patient with a tibia plateau C3 fracture who had full extension and 20 degree reduced flexion at 5 weeks postop. At 3.5 months postop, there was no limitation of motion and no pain.
Discussion

Review of this case series of 16 patients suggests that Norian Drillable is an effective and reliable bone void filler with several advantages over conventional grafting materials for filling of cancellous bone defects.

Perhaps the most significant innovation of Norian Drillable is the new possibility for surgeons to choose the surgical procedure that best fits a patient’s needs: surgeons can now fill bone voids before fixing the reduced fractures with screws or perform surgery with the traditional method of first fixing and then filling. The observation that the majority of surgeons in the present case series opted to fill before fixing the reduced fractures indicates that this innovation is useful and addresses a medical need.

The good clinical outcome in this case series can be at least partially attributed to the use of Norian Drillable. Based on multiple studies assessing donor site morbidity following harvesting of autologous iliac crest bone grafts, 6-15% of patients would likely have developed major complications5-10 if autologous bone grafts had been used, and 9-39% would have presented with minor complications.5-7 Similarly, hydroxyapatite preparations would likely have resulted in a longer period of invalidism due to initial instability of the graft11-13 and the use of acrylic cement can lead to reduced healing rates.14,15 Norian SRS would have been a viable alternative to the aforementioned graft materials but would not have allowed surgeons to freely choose the surgical procedure best fitting the patient’s needs: they would not have been able to fill before fixing.

Norian Drillable provides the unique possibility to fill reduced fractures before fixing. This is particularly beneficial for maintaining reduction in elderly patients with osteoporotic bone. One reason for this is that osteoporotic fractures are frequently complex and fragmented, requiring extensive reduction and multiple fixation screws. In addition, it is important that the period of invalidism is as short as possible for elderly patients.21,22 The high compressive strength of Norian Drillable (~35 MPa) enables the earliest possible weight bearing.

Conclusion

Norian Drillable offers the most advantages and the fewest drawbacks of available materials for filling bone defects. Key benefits of Norian Drillable are as follows:

- Allows the physician to choose the surgical technique that best fits the needs of the patient
- The product can be drilled, tapped, and screws can be placed through it
- Allows early load bearing
- Is associated with a good clinical outcome
References


(22) Schwab P, Klein RF. Nonpharmacological approaches to improve bone health and reduce osteoporosis. *Curr Opin Rheumatol*. 2008;20(2):213-7 or D

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