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*ORIGINAL STUDY*

# An alternative treatment method for defective pseudoarthrosis ; evaluation of eight patients treated with Artelon + Kryptonite

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**Pseudoarthrosis with bone loss is one of the most challenging orthopaedic problems for surgeons. Bone loss usually leads to technical difficulties during surgery due to instability in the fracture area.**

**Eight patients with pseudoarthrosis of different long bones were operated on by the same surgeon. The median age was 53 years (25-61), and the median time period after the index operation was 21 months (12-72 months).**

**Radiographic union was achieved in all patients in 3.62 months (2-5 months). Efficient healing with new bone formation was observed in all of the patients. The result of the current case series is promising.**

**This treatment method can be used for the treatment of pseudoarthrosis without increasing morbidity. Long-term follow-up and larger case series are needed for evidence of the adequacy and reliability of this method of treatment.**

**Keywords** : Nonunion ; grafting ; Kryptonite.

## INTRODUCTION

The management of pseudoarthrosis is one of the most challenging orthopaedic problems for surgeons, and physically and psychologically demanding for patients. In particular, atrophic nonunion with bone loss creates a major biological and technical problem, with no guarantee of a satisfactory outcome.

Bone loss usually leads to technical difficulties during surgery, due to instability in the fracture area especially when the compression is not possible. While autologous bone grafting is widely accepted as the gold standard for treating aseptic nonunions and bone defects, this method has some serious drawbacks, such as inflammation, increased infection risk, prolonged operation time, and donor site morbidity (*3,7*).

Calcium triglyceride bone cement (Kryptonite™ ) is a biocompatible polymer derived from castor oil. It has permission to use in human by U. S. Federal Drug and Food Administration (*12*). It has been reported to possess osteoconductivity, adhesive properties and to have a modulus of elasticity very similar to bone (*11*). The porous network within the product allows osteointegration with the host bone over time, making it a successful void filler (*5*). Artelon® is a synthetic material that acts as tissue reinforcement with excellent biocompatibility. In

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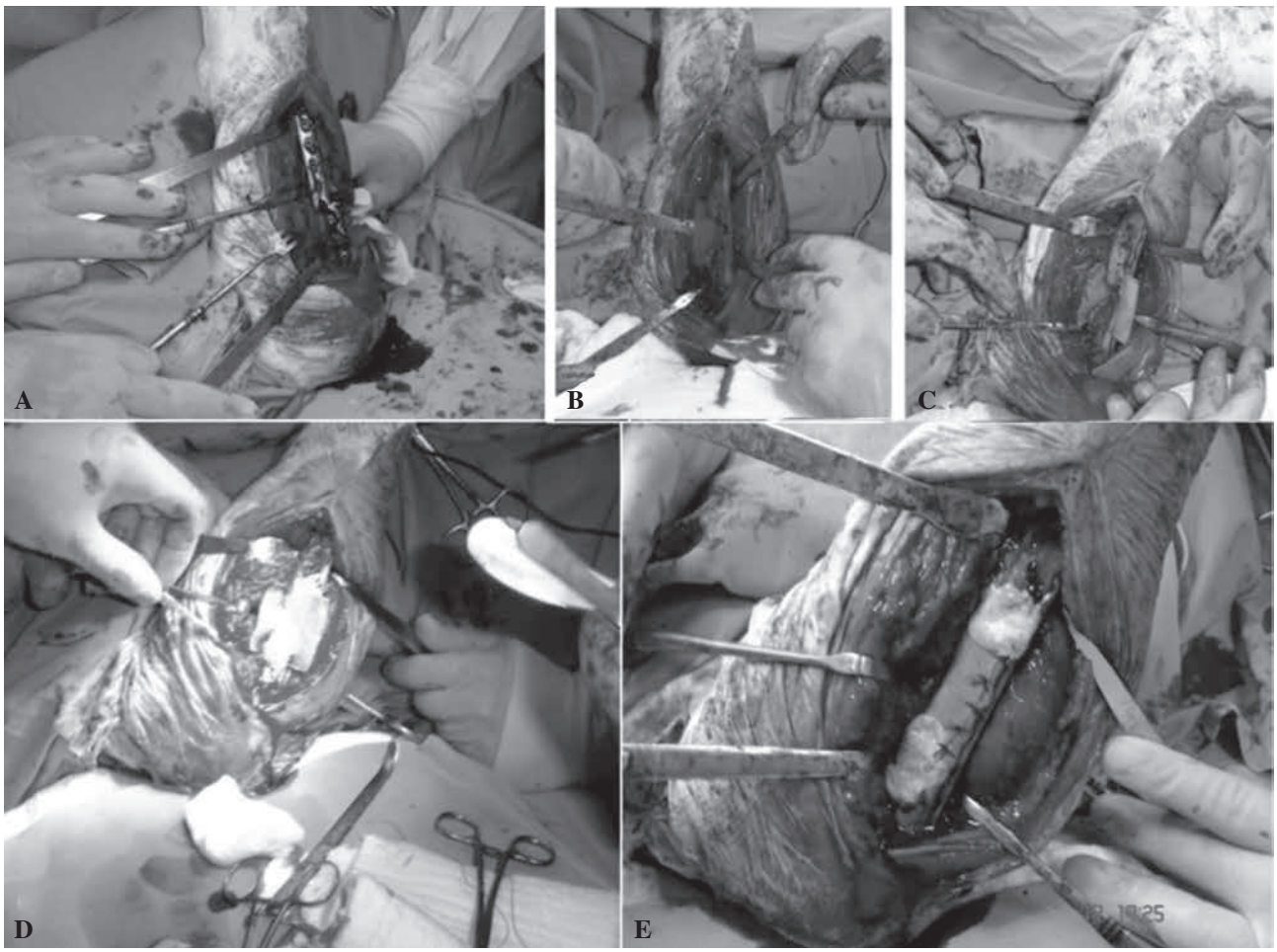


***Fig. 1.*** — A. Failed implant. B. Bone defect after debridement. C. Rigid fixation with Arthelon sheet. D. Bone defect filled with Kryptonite. E. Ends of the Arthelon sheet were sutured.

our practice, we use Artelon to prevent the spread of Kryptonite to the surrounding tissue.

This retrospective study evaluates the results of using Kryptonite calcium triglyceride bone cement and Artelon tissue reinforcement as a primary grafting material on healing aseptic nonunions with implant failure.

## PATIENTS AND METHODS

This observational study was undertaken at Turgut Ozal University Department of Orthopaedics and Traumatology between November 2010 and January 2013, with the approval of the local ethics committee. Eight patients with nonunion of different long bones were operated on by the same surgeon. All of the patients had undergone previous surgery after the initial trauma, which resulted in implant failure with pseudoarthrosis. In those previous surgeries, bone grafts were used in three patients, and the defects after debridement were too large to be filled with autologous bone grafts in four patients.

The median age of the patients was 53 years (25-61). Five patients were male and three patients were female. The median time period after the index operation was 21 months (12-72 months). Three of the fractures were in the distal humerus, and there was one each in the proximal humerus, the shaft of the ulna, the shaft of the femur, the distal femur, and the distal tibia. There were three open fractures and five closed fractures. Two of the patients had undergone two previous surgeries, and six had undergone one surgery. In the previous surgeries,

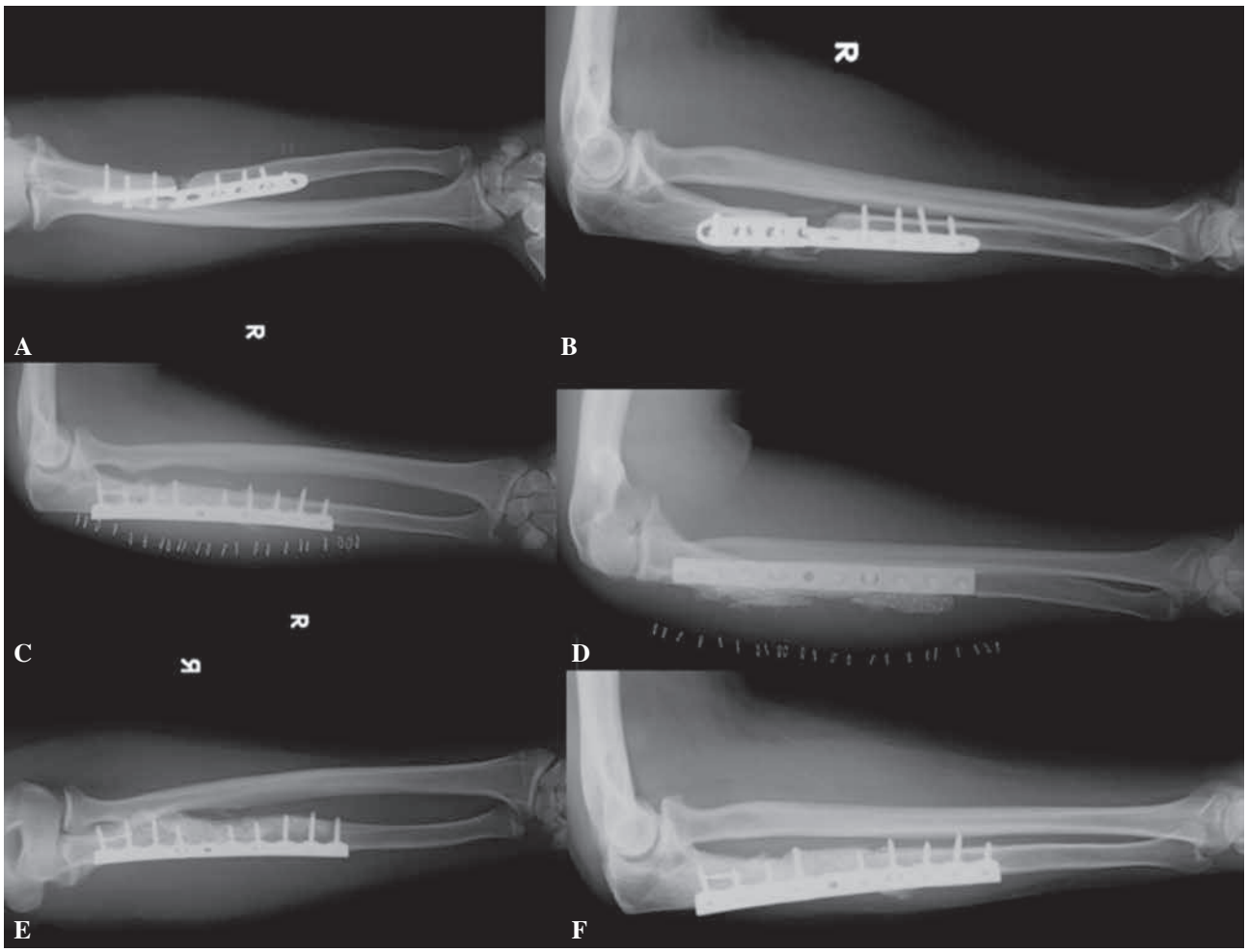


***Fig. 2.*** — A and B. Preoperative X-rays of ulna pseudoarthrosis with failed implant. C and D. Forearm X-rays at the first postoperative day. E and F. Forearm X-rays 18 months after surgery.

seven patients had plates installed, and one patient had an intramedullary nail installed (in the proximal humerus). One patient had suffered axillary nerve damage, two had experienced shortness, and one had a history of infection.

Kryptonite bone cement (Doctors Research Group Inc, Southbury, CT) is a biocompatible polymer derived from castor oil. The adhesive bonds, specifically and directly, to bone, and within 24 hours, results in rigid bone fixation and stability. The porous network within the product allows osteointegration with the host bone over time (*5,6,8*). Artelon (Artimplant AB, Göteborg, Sweden) is a tissue reinforcement composed of polyurethane urea.

**Surgical techniques**

With the patient under general anesthesia, exposure of the pseudoarthrosis was achieved. The failed implant was removed, and after meticulous debridement, the fracture ends were shortened if necessary. The fracture ends were reduced and covered with Artelon, and the fracture was fixated with a plate of sufficient length. Then, the Kryptonite was prepared. It was an injectable liquid for up to 8 minutes after mixing and became adhesive at 8-15 minutes ; it was then shaped for use. The gap between the fracture ends and around the near cortex was

Table I. — Demographic data of the patients

| Case No | Age (years) | Gender | Localization | Previous Surgical Technique/ Graft | Principal Surgical Technique/Graft | Union Time (month) | Follow-up Time (month) | Defect Size (mm) |
|---|---|---|---|---|---|---|---|---|
| 1 | 55 | Female | Distal humerus | Plate / - | 90-90 plate / Kryptonite-Artelon | 3 | 34 | 18 |
| 2 | 51 | Female | Proximal humerus | Intramedullary nail (Twice) | Locked plate / Kryptonite-Artelon | 4 | 21 | 6 |
| 3 | 29 | Male | Distal humerus | Plate / autogenous bone graft | 90-90 plate / Kryptonite-Artelon | 3 | 12 | 8 |
| 4 | 56 | Female | Distal tibia | Plate / autogenous bone graft | Intramedullary nail / Kryptonite-Artelon | 3 | 46 | 16 |
| 5 | 61 | Male | Distal femur | Plate / autogenous bone graft | Locked plate / Kryptonite-Artelon | 4 | 53 | 12 |
| 6 | 56 | Male | Distal humerus | Plate / - | 90-90 plate / Kryptonite-Artelon | 5 | 58 | 10 |
| 7 | 25 | Male | Shaft of ulna | Plate / Autogenous bone graft | Locked plate / Kryptonite-Artelon | 2 | 24 | 14 |
| 8 | 42 | Male | Shaft of femur | Plate / autogenous bone graft following external fixation | Intramedullary nail / Kryptonite-Artelon | 5 | 14 | 15 |

filled with Kryptonite. The Kryptonite was then covered by an Artelon sheet, and the ends of the sheet were sutured, side by side, after it began to solidify.

## RESULTS

Before surgery, six patients complained of loss of function in the affected extremity. After surgery, all of the patients were capable of full range of motion and partial weight bearing. No graft resorption was seen in any patient. Radiographic union was achieved in all patients within 3.62 months (2-5 months). After consolidation of the nonunion, all of the patients regained the use of their extremity within six months. One patient had transient radial nerve palsy. No infection, vascular injury, rotational deformity, or angulation developed. All of the patients showed excellent function and had no persistent pain, and all expressed that they were very satisfied with the outcome.

## DISCUSSION

Failed internal fixation may just necessitate more stability if there is biological potential for union. Improving stability may require more rigid implant or compression (*2*). In our patient group we used rigid implant fixation and kryptonyte as a void filler to improve stability (in cases 1,2,3,5,6 and 8). Kryptonite bonds specifically and directly to bone, and within 24 hours, results in rigid bone fixation and stability, acting as an optimum scaffold with its modulus of elasticity very similar to bone (*5,6,11*). In cases of 2 and 8 we need to stimulate fracture healing with bone grafting as they had two previous surgery. For both patients we used Kryptonite instead of autologous bone graft. We also need void filler to synchronize the bone length in forearm and cruris (in cases four and seven). There is no clinical study for use of long bones. This is the first study as we know. As Kryptonite has permission for use in humans we did not concern about its biological safety.

Ideal bone grafts must have osteoinductive and osteoconductive properties (*7,9,10*). While autogenous cancellous bone grafting is considered the gold standard for the treatment of nonunion and segmental bone defects (*4*), this technique also has some disadvantages. Major complications of harvesting autogenous cancellous bone grafts include infection, prolonged wound drainage, large haematomas, reoperation, pain lasting longer than six months, sensory loss, and unsightly scars (*3,4,7*). Younger

and Chapman reported a morbidity rate of 8.6% at the donor sites (*13*). In addition, autogenous bone grafts might be insufficient for filling large defects, or they might have to be harvested during an earlier surgery. In order to solve these problems, synthetic bone grafts have been developed. In nonunion defects, bone graft substitutes should provide structural integrity provided by rapid internal bone adhesion and a space-occupying effect, which allow load transfer for maintaining proper alignment and stability to enable adequate osteosynthesis (*1,9,10*).

Kryptonite bone cement, a biocompatible polymer derived from castor oil, is a non-toxic, ductile material that hardens with a low-energy exothermic reaction which may cause less soft tissue damage to the surrounding soft tissue. It has adhesive properties in dry conditions that may bond specifically and directly to bone. Therefore proper hemostasis should be obtained and all tissue fluids should be removed from the bone ends under tourniquet if possible. If appropriate conditions are provided, it achieves rigid bone fixation and stability within 24 hours, thereby allowing load transfer. For this reason a barrier like Artelon is needed to isolate bone with Kryptonite from the surrounding tissues and body fluids. Kryptonite has also osteoconductive properties due to its porous network, enabling osteointegration with the host bone over time (*5,6,8*).

All of the patients in this study had previously been treated with conventional treatment methods that failed ; all of the implants failed except one. Autologous bone grafting was not suitable in seven patients. After the surgery that incorporated Artelon and Kryptonite, efficient healing with new bone formation was observed in all of the patients, as well as a union rate of 100%, and all of the patients expressed satisfaction with the procedure. There was no wound infection or graft resorption. Although the number of the patients is not large enough to draw a conclusion, the results of the current case series are promising.

In conclusion, healing pseudoarthrosis treated with rigid internal fixation can be improved considerably by the addition of Kryptonite. This treatment method can be used as an alternative method for treating pseudoarthrosis without increasing morbidity. Early results are promising, but long-term follow-up and larger case series are needed to provide evidence of the adequacy and reliability of this method of treatment.

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