Failure of VariAx® Distal Radial Locking Plate: Fractographic Analysis and Report of Two Cases

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Abstract: We describe two cases of atraumatic fracture of VariAx® distal radial locking plate following its use in distal radial osteotomies. The plates fractured through an unused screw hole at the level of the osteotomy. Scanning electron microscopy was used to evaluate the fracture surfaces. This confirmed that there had been fatigue failure and did not find evidence of abnormal composition or structure of the metal. These cases are important because they highlight that this new and innovative implant can be prone to failure, and demonstrate the requirement for adequate surgical technique and metalwork protection following surgery.

Keywords: Distal radius, osteotomy, locking plate, implant failure.

INTRODUCTION

Various implants, including a spectrum of locking plates, are now available for distal radial fracture fixation and reconstructive wrist surgery, with recent design innovations intended to improve fixation and reduce complications. Low profile designs, pre-contoured plates and options of poly axial locking systems make them the preferred implants for complex fracture fixations and osteotomies [1]. There are very few reports of broken locking plate systems [2,3]. We present two cases of failure of a distal radial locking plate (Stryker® VariAx, Stryker, Mahwah, NJ, USA) with fractographic studies of the failures. The VariAx®Distal Radius Locking Plate is a relatively new pre-contoured titanium alloy locking plate with options of polyaxial screws allowing variable insertion angles through the plate.

PATIENTS AND METHODS

Case-1

A 76-year-old patient was referred with wrist pain and stiffness following a distal radial fracture sustained 2 years ago. She had initially been treated non-operatively and did not respond to a period of aggressive physiotherapy. Radiographs showed a malunited distal radial fracture with shortening of about 14 mm and dorsal angulation of 25 degrees (Figure **1**). Patient was not on any medication including corticosteroids.

Figure 1: Pre-operative anteroposterior and lateral wrist radiographs of case 1, showing malunited distal radial fracture with shortening and dorsal angulation.

She underwent a distal radial dorsal opening wedge corrective osteotomy with iliac crest bone grafting and stabilisation with a dorsal VariAx distal radial locking plate with 3 proximal and 5 distal screws. The plate was contoured in the volar direction to allow close apposition to the osteotomy site and supported with cortico-cancellous bone graft from iliac crest. The fixation was stable and intra-operative images confirmed satisfactory correction of the deformity (Figure **2**). The arm was immobilised in plaster for 2 weeks, following which she had physiotherapy with intermittent use of a splint.

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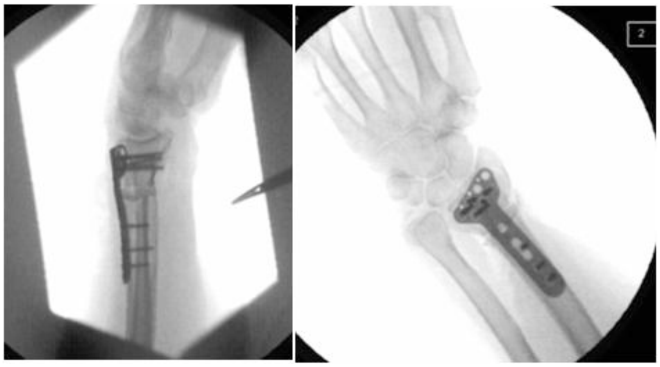

Figure 2: Intra-operative fluoroscopic images of case 1, demonstrating correction of deformity and fixation with VariAx dorsal distal radial locking plate.

However, she presented at 6 weeks with spontaneous onset of wrist pain and radiographs showed implant failure through the unfilled screw hole at the osteotomy site (Figure **3**). She underwent revision surgery with retrieval of the broken implant and re-fixation with a standard non-locking plate (Synthes GmbH, Solothurn, Switzerland).

Figure 3: Radiographs demonstrating broken VariAx distal locking plate at the level of the unfilled screw hole (case 1).

The harvested broken plate was sterilised and examined visually for manufacturing defects and its thickness measured using a digital Vernier calliper. It was then imaged by scanning electron microscopy (SEM) and the metal alloy composition examined by Energy-Dispersive X-ray analysis (EDX).

Case-2

Another 49-year-old patient presented with a malunited distal radial fracture following a conservatively treated distal radial fracture one year previously. Radiographs showed malunion with shortening of 8 mm and dorsal angulation of 20 degrees (Figure **4**). She had wrist pain and loss of palmar flexion and hence a corrective osteotomy was planned.

Figure 4: Pre-operative anteroposterior and lateral radiographs of the wrist (case 2) showing malunited distal radial fracture.

She underwent distal radial dorsal opening wedge corrective osteotomy and iliac crest bone grafting and fixation with a dorsal VariAx distal radial locking plate. Intra-operatively good correction of deformity was achieved with a stable fixation, using three proximal and five distal screws (Figure **5**). In this case, the VariAx plate was contoured as a single manoeuvre. Post-operatively she was recovering well, but 3 months later presented with non-traumatic wrist pain and radiographs showed that the plate had fractured through an unfilled screw hole at the osteotomy site (Figure **6**).

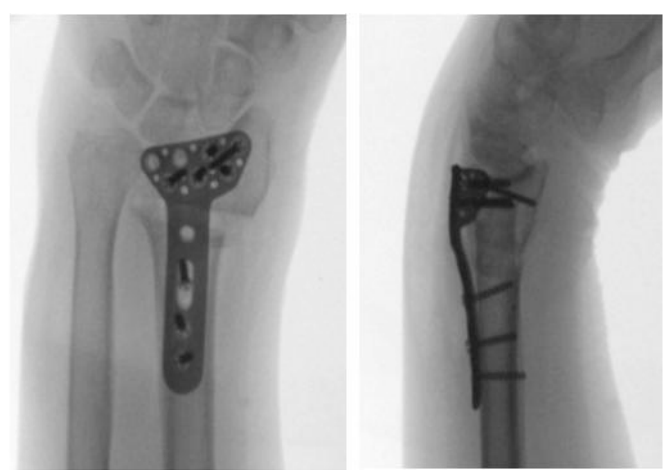

Figure 5: Intra-operative fluoroscopic images of case 2 demonstrating corrective osteotomy and fixation with dorsal distal radial VariAx plate.

Figure 6: Anteroposterior and lateral radiographs of the wrist (case 2) showing broken VariAx plate at the level of unfilled screw hole close to the osteotomy site.

As the patient continued to be symptomatic, the plate was removed and during surgery the osteotomy was found to be healed. She improved following a course of physiotherapy and at the latest follow-up visit, she was pleased with her recovery and was able to do all her activities of daily living without restrictions and was back at work. The harvested plate was also examined visually and by SEM.

RESULTS

The failures of the two plates were essentially identical. There had been a transverse fracture across the narrow bridges at the sides of the screw hole (Figure **7**). The plates had not undergone plastic bending deformation, but appeared to have fractured in a brittle manner, leaving matt fracture surfaces (Figure **8**). The thickness of the plates at the level of the fracture was equal to the thickness stated by the manufacturer at 1.5 mm.

Figure 7: Retrieved broken VariAx plate (case 2) demonstrating transverse fracture of the plate at the sides of the screw hole.

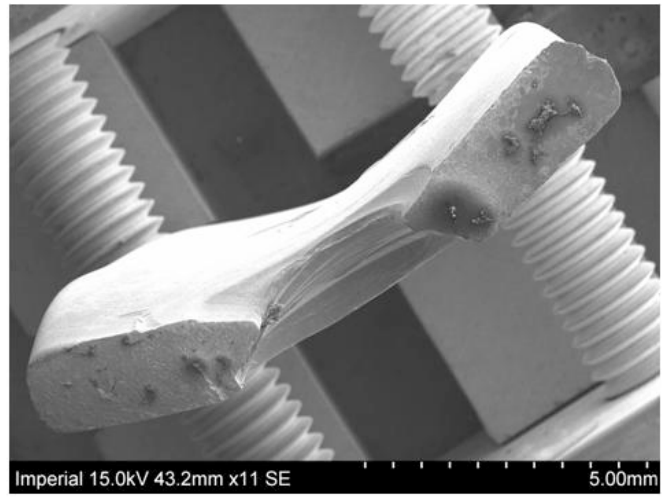

Figure 8: Scanning electron microscopy studies showing patterns suggestive of fatigue failure: End-view of fractured plate, with half of the screw hole in cross-section.

Microscopically, SEM revealed that the fracture surface had a brittle, crystalline morphology at low magnification (Figure **9**). At higher magnification, the grains of metal showed extensive areas of parallel

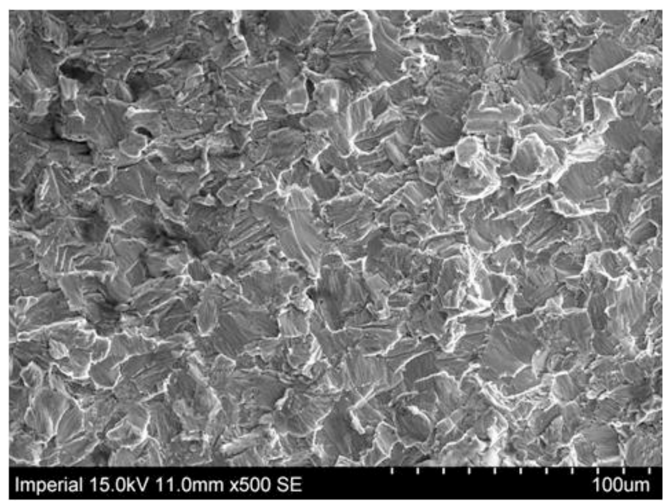

Figure 9: Scanning electron microscopy of the fracture surface, showing brittle granular fracture morphology, with numerous grains having fine striated patterns typical of a fatigue process.

striations across their surfaces. These observations are a classical appearance in fatigue failure. It is likely that such a failure would have started from an initiation site at the edge of the screw hole, and evidence of such a site was searched-for, but could not be identified on either plate. However, close to the presumed initiation sites, the metal at the edges of the screw holes of both of the plates had been deformed, and in one plate there was a crack running parallel to the fracture surface (Figure **10**). The EDX analysis found the typical composition of a titanium- 6% aluminium- 4% vanadium implant alloy. The fractography did not find evidence of porosity or other defect.

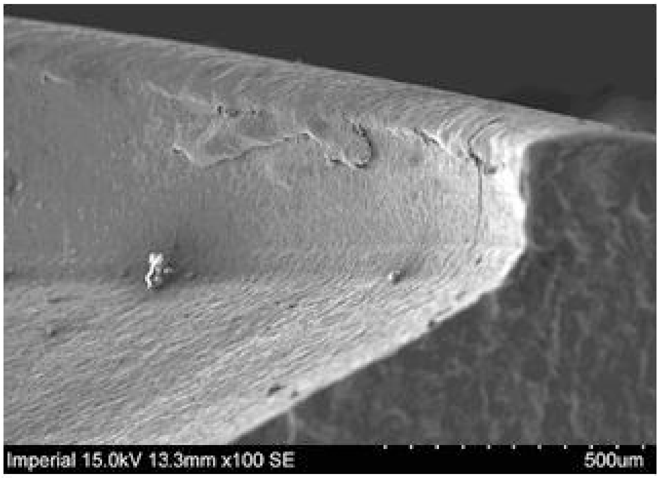

Figure 10: Scanning electron microscopy demonstrating damaged edge of screw hole at the top, with deformed metal and a crack near to the fracture surface, which is the dark area at bottom, right. The area at the centre, left of the picture is the countersink, where the screw head sits when inserted fully.

DISCUSSION

Locking plates have various advantages over conventional plates, with a lower incidence of loss of reduction secondary to screw toggling and improved bone healing due to the reduced disturbance of the periosteal blood supply [4]. They are also particularly useful in osteoporotic bones, providing optimal hold and fixation [1]. Many studies have confirmed excellent clinical results with the use of locking plates for distal radial fractures [5-7]. However, implant fracture is a recognised complication following fracture fixation and osteotomies [2,3]. Mechanical failure of plates may be due to brittleness or may follow plastic deformation, but it is more likely to be caused by fatigue failure in response to the cyclic loads borne in-vivo. Inadequate or inappropriate surgical insertion is another cause.

In this study, the dorsal locking plate failed through the unfilled screw hole at the level of the osteotomy site in both the patients. This appeared to have been a fatigue failure in both cases, presumably due to the cyclic bending moment in-vivo causing unsustainable stresses. We acknowledge that though the plates are pre-contoured, additional contouring in corrective osteotomies may be needed to ensure the plate is seated well against the bone. Surgeons need to be aware that this may lead to increased risk of implant failure. Many studies have shown that plates are more prone to fatigue failure at the level of the screw holes [8]. A smooth round hole in a wide plate causes a stress concentration factor of x3 [9], but that factor will be lower in this relatively narrow plate. The addition of a screw or locked screw plug into a redundant hole at the level of the osteotomy is unlikely to prevent the plate being susceptible to bending failure, if the loads on the plate are the same.

If the osteotomy has much lower stiffness than the plate construct, then most of the wrist load will pass from the distal fragment through the plate, rather than directly to the proximal fragment via the bone graft. The bending moment on the plate, from the wrist joint force vector, which passes volar to the plate at the level of the osteotomy would enhance that effect. One solution would be to increase the thickness of the plate as the bending strength is proportional to the thickness cubed [3]. For example, with the current plate thickness of 1.5mm, the stress due to a given bending moment will be 78% higher than if the plate were 2mm thickness. Also, full anatomical correction of the distal radial malunion may not be achieved by corrective osteotomy, and this can lead to increase in load transfer through the radius and the plate.

The length of time until motion is commenced following surgery is variable and surgeon dependant. Early mobilisation following surgery is always preferable and it was normal in our practice to protect the plate for approximately 2 weeks. Following these complications, we have adopted a less optimistic technique and now protect the wrist for 6 weeks following this type of surgery.

These are the first cases in the literature of this multiaxial locking plate failing in this manner. We recommend that, if these plates are used to stabilise a dorsal osteotomy, they should be protected by more cautious mobilisation of the wrist than in other cases. Changes to the plates themselves, such as thickening them and/or narrowing them with elimination of the screw hole, which was at the osteotomy site, may also reduce the likelihood of implant failure. However, the design and use of this type of device entails judgement and compromises between conflicting demands, such as strength versus bulk. We feel that progressive clinical demand for low profile implants, when combined with more rapid mobilisation may potentially lead to early implant failure.

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