Re-operated Clavicular Non-Union Treated with OP-1 and Electrical Stimulation

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Abstract

Fracture of the clavicle is a common injury and usually heals with non operative treatment. Non-union is rare and is usually managed in symptomatic patients with surgery. We present the successful management of two patients with persistent clavicular non-union following previous attempts of internal fixation. The technique described combines traditional internal fixation with advanced bone biology techniques of a recombinant osteogenic protein (OP-1) and electrical stimulation.

Introduction

Clavicular fractures are common and non-union of un-operated mid shaft fractures is rare with a reported incidence between 1% and 4% (7,12,19). These reports are predominantely in adults but non-union has also been described in children (20) Several factors have been hypothesised to increase the risk of non-union developing. They include: inadequate immobilisation (22), severity of trauma (1), re-fracture (13), location of fracture (19), degree of displacement (13) and primary open reduction (23). The rate of non-union following primary internal fixation is quoted to range from 0.1% to 4% (19) but in one group has been quoted as high as 13% (23).

Management of patients who have symptomatic non-union has involved use of various surgical techniques, the most common being either intramedullary fixation (21) or rigid internal fixation with plates (16,18). There has been a report of achieving 100% union at 10 weeks postoperatively using open reduction and internal fixation with bone grafting (15). However Jupiter reported on clavicular non-unions treated surgically with a success rate of 90% in achieving union (13).

The two cases presented had persisitent symptoms of non-union even after previous internal fixation and bone grafting. The majority of such cases in the literature have been treated by repeating the initial operation and using iliac crest bone graft (13). There is one report of the successful use of a vascularised fibular graft in such a situation (17). This technique is technically demanding and in particular requires microvascular expertise.

Cases

A twenty-four year old life-guard sustained a comminuted fracture in the mid shaft of his non dominant clavicle following a ski-ing accident. He was placed in a figure of eight bandage for two weeks and then gently allowed to mobilise. At 9 months following the fall he still had pain at the fracture site. On examination by the senior author (J.A.G.) he was found to have a painful and mobile fracture with a full range of shoulder movements.

Non-union was confirmed with a CT scan. He underwent open reduction and internal fixation with a 3.5mm pelvic reconstruction plate with six screws and iliac crest bone graft. He was immobilised in a broad arm sling for two weeks only performing pendulum exercises. At six weeks he commenced gentle range of movement exercises. Unfortunately he failed to attend his subsequent appointment.

He re-attended five months post operatively complaining of clicking and pain, and denying any injury. An x-ray confirmed that the plate was fractured . He was reluctant to consider further surgery and was therefore kept under observation. By one year post operatively his fracture was still mobile and tender. A CT scan confirmed non-union. Therefore open reduction and internal fixation was carried out using an AO DCP plate (Synthes, Switzerland) with iliac crest bone graft. A chevron type osteotomy was performed at the non-union site to allow maximum apposition at the fracture site (Figs 1 and 2). However on this occasion surgery was combined with OP-1 (Stryker Biotech,Michigan, U.S.A.) and an electrical stimulator (Osteogen Bone Growth Stimulator, E.B.I., Biomet, New Jersey, U.S.A.) was inserted. He was allowed to carry out pendulum exercises whilst in a broad arm sling for the first six weeks. Then gentle mobilisation was commenced. A CT scan at three months post operatively confirmed that the bone was uniting and therefore he was allowed to carry out full activities. At one-year post operatively full union had been achieved and the metalwork and stimulator were removed with no complications.

The second case was a thirty year old courier who sustained a comminuted fracture of the mid-shaft of his dominant clavicle following a fall from a mountain bike. He was immobilised in a broad arm sling for six weeks. At four months following injury he underwent open reduction and internal fixation without any bone graft at another institution. Radiographs revealed distraction at the fracture site following this surgery. Three months post operatively the plate broke without any trauma. He underwent a repeat internal fixation and this time iliac crest graft was used. He was told that it was safe to cycle again, but unfortunately fell,

breaking the second plate three months after its insertion. He continued to cope with this painful non-union until he was seen by the senior author (J.A.G.) two and a half years following the original accident. This examination confirmed a persistent and painful non-union with a broken plate. He too underwent internal fixation with a A.O. DCP plate, iliac crest graft, OP-1 and an electrical stimulator (Fig. 1). His post-operative recovery was identical to the previous case, with union confirmed by CT at three months and all metalwork removed at one year, with no adverse events.

Discussion

Symptomatic non-union of midshaft clavicular fractures are usually treated surgically with either an intramedullary device or plate fixation, and often combined with iliac crest bone graft. Success in achieving union ranges from 89% to 100% (13,15). There is little written about the subsequent management of those who do not unite with this surgery. Both of these cases fall into this category i.e. they had failed to achieve bony union following internal fixation with an AO plate and iliac crest bone graft.

Bone defects that do not heal are frequently treated with bone graft harvested from the iliac crest. However, the supply of autograft bone is limited and has a risk of donor site morbidity (4). Allograft has several attractions but has limited osteoinductive capacity (10) and a limited capacity to incorporate (11,23). More recently osteoinductive materials such as bone morphogenic proteins have been shown to induce new bone formation (25), these are part of the transforming growth factor-B superfamily. Whilst recombinant human osteogenic protein-1 (OP-1) combined with type-1 collagen has been shown to promote the healing of segmental bone defects in animals (5).

Electrical stimulation has been used with mixed acceptance for a long time, with some reports of success over 150 years ago (14). However, because of inconsistent results its use dwindled. It was re-popularised following Fukuda and Yasuda’s report of inducing bone growth (9).

Further clinical studies have advocated its use but without fully understanding the mechanisms (8). Use of electrical stimulation in the clavicle for the treatment of non-union by pulsed electromagnetic fields has been described (2,6). More recently Brighton et al. (3) have demonstrated clear biochemical confirmation of a proliferative response of bone cells to electrical stimulation.

Conclusions

The two cases presented have both had previous attempts at obtaining bony union using open reduction, internal fixation and iliac crest grafting. Unfortunately both failed to unite and required further surgery. However, by combining further internal fixation and iliac crest bone graft with OP-1 and electrical stimulation bony union was achieved. Review of the medical literature has demonstrated that, besides one report of using vascularised fibular bone graft, there are no other reports of using this type of technology to obtain bony union in this difficult situation. We accept that this is a small series and purely a presentation of two cases but would strongly recommend the technique to promote union, particularly in a revision situation.

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FIGURE 1 - SURGICAL TECHNIQUE

(a) chevron osteotomy at non union site

(b) application of Bone Growth Stimulator

(c) application of dynamic compression plate

FIGURE 2

(a) non union fractured clavicle with failure of fixation

(b) post operative union