A retrospective follow-up of ankle fracture patients treated with a biodegradable plate and screws

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1. Introduction

Fractures of the distal fibula (lateral malleolar fractures) are the most common ankle fractures requiring surgical treatment. Unstable fractures of the lateral malleolus are typically treated with a one-third semitubular or locking metal plate fixed by metal screws to the fibula. These metal implants provide strong fixation during bone healing but remain in the patient’s body permanently unless subsequently surgically removed. Although metal implants do not cause any significant problems to most patients, in the USA a secondary procedure for hardware removal after open treatment of lateral malleolar fracture is carried out in 16% of cases during the first postoperative year [1].

Biodegradable materials have been used for years in orthopaedic surgery and traumatology [2,3]. Pins and screws manufactured from these materials have been used with good results in the treatment of ankle fractures [3–11]. Biodegradable plates have been successfully used in the treatment of cranio-maxillofacial and mandibular fractures and osteotomies [12–19], and are currently also being used in many countries in Europe in the treatment of ankle fractures.

Although the idea of treating lateral malleolar fractures with a biodegradable plate is justified as it could make plate removal unnecessary, thereby saving health care resources [6,20,21], only limited clinical data is available on its safety and efficacy in the treatment of fractures of weight-bearing bones [22–25].

The aim of this study was to retrospectively follow-up ankle fracture patients treated with a biodegradable plate and screws, and to evaluate clinical outcome and occurrence of complications in these patients.

2. Materials and methods

2.1. Subjects

After ethical committee approval 57 ankle fracture patients treated with a biodegradable plate and screws (Inion OTPS™, Inion Oy, Tampere, Finland) between March 2004 and September 2006 were invited for a follow-up visit at a private outpatient clinic.
Clinical outcome at follow-up was evaluated using the classification described by Cedell and the final fracture reduction achieved was rated as anatomical. Preoperative radiographs, X-rays taken the day after the operation, the original procedure and the follow-up date were reviewed. Each patient’s complications, or additional medical visits between the day of the operation and the follow-up date were noted.

2.4. Follow-up evaluation

The follow-up included a review of each patient’s medical records for any remarks regarding perioperative or postoperative complications, or additional medical visits between the day of the original procedure and the follow-up date. Each patient’s preoperative radiographs, X-rays taken the day after the operation, 6 weeks postoperatively and at the follow-up visit were reviewed, and the final fracture reduction achieved was rated as anatomical, good and poor according to the classification described by Cedell [26] (Table 1). Clinical outcome at follow-up was evaluated using the functional scoring scale of Olerud and Molander (0–100) [27]. In addition, the duration until return to work and normal daily activities were elicited from each patient.

3. Results

A total of 50 patients (21 female, 29 male) gave informed consent to participate in the study. There were 36 lateral malleolar fractures (2 with syndesmosis rupture) and 14 bimalleolar fractures (3 with syndesmosis rupture). The average age of the patients was 45 years (SD ± 14, range 18–65) and average weight was 80 kg (SD ± 18, range 45–150).

No perioperative complications occurred. Average follow-up time was 17 months (SD ± 6.2, range 7–36). All fractures healed and final fracture reduction was classified as anatomical in 49 patients and good in 1 case (Fig. 2). The mean Olerud and Molander ankle score was 86 (SD ± 20, range 15–100). The patient with the lowest score (15) is on disability pension due to her other previous disabilities (unrelated to the ankle fracture). The mean duration before return to work was 2.8 months (SD ± 1.3, range 1.5–6); and the mean duration before return to normal daily activities 3.1 months (SD ± 1.3, range 1.5–6). Eight patients had postoperative complications. These included one delayed wound healing (Fig. 3), 3 cases of deep-vein thrombosis (diagnosed by Doppler ultrasound and treated uneventfully), and four subcutaneous implant-degradation related soft tissue reactions.

The subcutaneous soft tissue reactions were noted as swelling at the implantation site 8–18 months postoperatively (Fig. 4). In 3 cases, the patients felt that the swelling was minor and painless, they did not complain and would not have consulted a doctor on their own initiative but the reactions were observed by the researchers at the follow-up visit. In all 4 cases, the swollen area was surgically explored under spinal anesthesia. When the incision was made, fluid reminiscent of sour milk was found under the skin. The plate was observed to have degraded by 18 months but some screw head remnants could be identified inside granulomatous tissue in all cases. The granulomatous tissue and implant remnants were removed, and samples were collected for microbiological and histopathological evaluation. The results revealed that no bacterial infection was present but macrophages and giant cells seen microscopically suggested a non-specific foreign body reaction. After surgical debridement the wounds were closed in normal fashion and healed uneventfully. The subcutaneous soft tissue reactions observed did not impair wound or bone healing in any of the cases. All fractures had already healed before the reactions occurred.

4. Discussion and conclusions

According to the results of this retrospective study, the biodegradable plating system used, when used in conjunction with postoperative cast immobilization, provides successful healing of lateral malleolar fractures. This finding clinically verified the previous assumptions based on the biomechanical results of...
Sjöblom et al. [unpublished data] and Väänänen et al. [28]. Sjöblom et al. showed in their human cadaver study that the biodegradable plate provides initial fixation stability similar to that of conventional metallic fixation implants and Väänänen et al. found in their in vitro degradation study that the plate withstands simulated physiological cyclic loading and maintains its initial fixation stability for 12 weeks, suggesting that the biodegradable plating system is suitable for the treatment of lateral malleolar fractures in conjunction with postoperative cast immobilization. In addition, the biodegradable screws and pins used provided successful healing of the syndesmosis and medial malleolar fractures in our study.

Eitenmüller et al. previously investigated the suitability of biodegradable poly-\(\alpha\)-lactide screws and plates for the treatment of ankle fractures [22]. In their study, 19 ankle fractures were fixed with 3 mm thick plates and 5.5 mm (\(\varnothing\)) screws made of block-polymerised PLLA with high molecular weight. Fractures healed within 6 weeks, but 52% of the patients experienced an aseptic soft tissue problem caused by delayed clearance of the degrading polylactide particles. Prompted by these problems, the authors treated 7 patients with volume reduced 2 mm thick plates and screws with flat heads, and none of the patients experienced any soft tissue reactions. The authors concluded that the use of biodegradable plates and screws is acceptable for the fixation of ankle fractures, and soft tissue inflammatory reactions can be avoided by using implants with reduced volume of biodegradable material [22].

The biodegradable implants used in the present study are made of co-polymers composed of \(\alpha\)-lactide, \(\beta\)-lactide and trimethylene carbonate (TMC). The plates are 1.2 mm thick and the 2.8–3.1 mm (\(\varnothing\)) screws have flat low-profile heads. The co-polymer material has been found in sheep to become soft in 6–12 months and to degrade completely by 24 months without any harmful inflammatory or foreign body reactions [29]. However, in the present study, subcutaneous implant-degradation related soft tissue reactions were found in four patients (three mild and painless, and one more severe reaction, i.e., 2–8% occurrence rate) 8–18 months postoperatively. We performed surgical debridement in all 4 cases in this study although only the patient with more severe swelling complained and expressed a desire for treatment. It is not known whether the three milder reactions would have cleared up over time even without surgical treatment.

![Fig. 2. Radiographs of a bimalleolar fracture preoperatively (A) and postoperatively (B). The biodegradable implants are not visible in X-rays but the screw holes can be identified.](image)

![Fig. 3. Delayed wound healing was observed in one patient 6 weeks postoperatively when the cast was removed. The biodegradable implants (the plate and a screw head) were visible in the wound. The patient was treated with antibiotics but the implants were not removed. The wound healed in 4 months without further complications.](image)
All biodegradable implants induce a subclinical (i.e., non-symptomatic) but histopathologically recognizable non-specific foreign body type of tissue response. According to Rokkanen et al. this seems to be a phenomenon inherent in the degradation and absorption processes of these polymers in the tissues [3]. This is expected and normal as long as it does not cause any clinical symptoms. The process of biodegradation of a polymer implant begins with the polymer chains being broken into smaller fragments by hydrolysis. The molecular weight of the implant decreases first. Thereafter, the mechanical strength of the implant decreases, allowing subsequent mechanical fragmentation and absorption of the implant to begin. Actual mass loss of the implant then occurs through the release of soluble degradation products, phagocytosis by macrophages and histiocytes, intracellular degradation, and finally, metabolic elimination through citric acid (Krebs) cycle to carbon dioxide and water occur, which are expelled from the body via respiration and urine [30–32]. Regarding the phagocytic and clearing capacity of the tissues, the most demanding phase is the decomposition stage, when the gross geometry of the implant is rapidly lost. At this time, the production rate of polymeric debris particles may exceed the critical limits of tissue tolerance [33]. This may occur especially if there is poor vascularity at the implantation site or if there is only a thin soft tissue layer covering the implants [33] like when implants are placed on the lateral malleolus. Local accumulation of released monomers may lower the local pH of the tissue [34], which may in turn lead to increased osmotic pressure resulting in a temporary local sterile fluid accumulation. The patient notices this reaction as swelling which can be painful if severe [33]. However, such soft tissue reactions do not usually impair bone healing because with the currently used materials they are unlikely to occur during the first 6 months after implantation.

When conventional metallic fixation implants are used, the need for secondary hardware removal is typically not considered to be a complication although it is done routinely due to or to avoid problems such as pain and discomfort [35]. According to the PearlDiver Patient Records Database, a database of 4.2 million orthopaedic patients and their records between 2004 and 2006 collected from a consortium of insurance companies in the United States, a secondary procedure for hardware removal after open treatment of lateral malleolar fracture is carried out in 16% of cases during the first postoperative year [1]. Although the use of biodegradable implants does not seem to completely eliminate the need for secondary hardware removal, the observed occurrence rate of tissue reactions is clearly lower than the frequency of surgical hardware removal after use of conventional metal implants. Considering that screw head remnants were found inside all tissue reaction induced swellings in our study, it will be interesting to see whether the occurrence of degradation-related tissue reactions can be reduced by using a recently introduced second generation biodegradable plating system which allows removal of the screw heads after screw insertion.

Controversy continues with regard to the optimal postoperative care after open reduction and internal fixation of ankle fractures [36]. In 2003, Lehtonen et al. published their Level I prospective, randomized clinical study of the long-term outcome of patients treated with a below-the-knee cast compared with those treated with a functional ankle brace in the first 6 weeks following internal fixation of lateral malleolar fractures with conventional metal implants [36]. The authors concluded that the long-term functional outcome after postoperative treatment of an ankle fracture with a cast and that after use of a functional brace are similar. Although early mobilization using a functional ankle brace may have some theoretical beneficial effects, the risk of postoperative wound complications associated with this treatment approach is considerably increased compared with that after conventional cast treatment [36]. When biodegradable fixation implants are used, a below-the-knee cast must be used postoperatively. In addition, patients should be co-operative and agree to follow the instructions regarding postoperative immobilization and non-weight bearing. When we first started using biodegradable implants years back in time, we did not realize the importance of postoperative immobilization, restricted weight bearing and patient selection, and experienced mechanical failures in two non-compliant...
patients who started full weight bearing too soon after the operation. However, the fact that no mechanical failures were observed in the current study shows that such complications can be avoided by using appropriate plaster cast immobilization and by instructing and selecting suitable patients properly to ensure restricted weight bearing during the healing period.

Our study has some limitations which need to be considered. First, this was a retrospective study. A prospective study should be conducted to verify the findings of this study. Second, we did not have any control group (i.e., direct comparison to conventional metal fixation) in our study and this limited our ability to compare the results with those provided by permanent hardware. However, our study material, postoperative treatment and evaluation methods were fairly similar to those of Lehtonen et al. [36] (Table 2) allowing inter-study comparison of the results. As can be seen in Table 3, the biodegradable implants used in our study provided fracture healing and functional results comparable to those previously obtained with conventional metallic fixation devices by Lehtonen et al. Moreover, the occurrence of postoperative complications was similar between the groups treated with a cast postoperatively.

In conclusion, according to the results of this retrospective study, the biodegradable implants used, when used in conjunction with postoperative cast immobilization, provide successful healing of ankle fractures and functional results similar to those previously reported after conventional metal fixation. These findings justify further clinical use and research of the biodegradable fixation system. The treatment of ankle fractures with biodegradable implants does not completely eliminate the need for secondary hardware removal but seems to decrease the frequency. A proper prospective randomized controlled study with long-term follow-up is needed to determine how much the hardware removal rate can ultimately be reduced by using biodegradable implants and to verify the potential effects on overall health care costs compared to conventional permanent hardware in the treatment of ankle fractures.

Conflict of interest statement

One of the authors (J.T.N.) is employed by Inion Oy, Tampere, Finland. No funding was received for this investigator initiated retrospective study.

### Table 2
Comparison of the materials: the current study vs. the previous study of Lehtonen et al. [36].

<table>
<thead>
<tr>
<th>Study design</th>
<th>The current study</th>
<th>The study of Lehtonen et al. [36]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size at final follow-up (vs. initially)</td>
<td>Biodegradable fixation and cast</td>
<td>Prospective, randomized study</td>
</tr>
<tr>
<td>Age: mean ± SD</td>
<td>50 (57)</td>
<td>42 (50)</td>
</tr>
<tr>
<td>Weight: mean ± SD</td>
<td>45 ± 14 years</td>
<td>41 ± 13 years</td>
</tr>
<tr>
<td>Fracture type: uninamalleolar/bimalleolar/trimalleolar</td>
<td>80 ± 18 kg</td>
<td>82 ± 15 kg</td>
</tr>
<tr>
<td>Injured ankle: left/right</td>
<td>36/14/0</td>
<td>29/14/7</td>
</tr>
<tr>
<td>Postoperative treatment</td>
<td>Below-the-knee cast for 6 weeks</td>
<td>Below-the-knee cast for 6 weeks</td>
</tr>
<tr>
<td>Postoperative weight bearing protocol</td>
<td>Non-weight bearing for 2 weeks, thereafter half body weight bearing, and from the beginning of the 5th postoperative week gradually towards full weight bearing with pain restriction.</td>
<td>Non-weight bearing for 2 weeks, thereafter partial weight-bearing, and full weight bearing at 4 weeks postoperatively.</td>
</tr>
<tr>
<td>Average follow-up time</td>
<td>17 months</td>
<td>24 months</td>
</tr>
</tbody>
</table>

### Table 3
Comparison of the results: the current study vs. the previous study of Lehtonen et al. [36].

<table>
<thead>
<tr>
<th>Perioperative complications</th>
<th>The current study</th>
<th>The study of Lehtonen et al. [36]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture healing</td>
<td>Biodegradable fixation and cast</td>
<td>Metal fixation and cast</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Return-to-work—mean ± SD (range)</td>
<td>86 ± 20 (15–100)*</td>
<td>87 ± 8 (55–100)</td>
</tr>
<tr>
<td>Postoperative complications</td>
<td>2.8 ± 1.3 months (1.5–6.0)*</td>
<td>2.1 ± 0.4 months (0.6–3.3)</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>Totally 8 postoperative complications:</td>
<td>2.2 ± 0.6 months (0.3–4.4)</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>• 3 cases of deep-vein thrombosis (DVT)</td>
<td>Totally 33 postoperative complications:</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>• 1 delayed wound healing</td>
<td>• 16 superficial wound infections</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>• 4 soft tissue reactions</td>
<td>• 4 deep wound infections</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>Postoperative complications</td>
<td>• 3 cases of wound dehiscence</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>1.3 months (1.5–6.0)*</td>
<td>• 2 chronic skin irritations</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>Postoperative complications</td>
<td>• 3 cases of chronic dysesthesia of the skin</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>• 1 chronic skin irritation</td>
<td>• 1 local skin necrosis</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>Postoperative complications</td>
<td>• 1 chronic allodynia</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>• 1 chronic dysesthesia of the skin</td>
<td>• 1 loss of internal fixation</td>
</tr>
<tr>
<td>Olerud and Molander functional ankle score [27] at final follow-up—mean ± SD (range)</td>
<td>Postoperative complications</td>
<td>• 1 re-fracture of the lateral malleolus</td>
</tr>
<tr>
<td>Fracture healing</td>
<td>Postoperative weight bearing</td>
<td>• 1 postspinal headache</td>
</tr>
</tbody>
</table>

* One patient on disability pension due to her other previous disabilities (unrelated to the ankle fracture).

References
