RESEARCH

The use of a biodegradable mesh plate to augment grafting of an acetabular defect

LABORATORY INVESTIGATION AND CLINICAL PILOT STUDY

We used a biodegradable mesh to convert an acetabular defect into a contained defect in six patients at total hip replacement. Their mean age was 61 years (46 to 69). The mean follow-up was 32 months (19 to 50). Before clinical use, the strength retention and hydrolytic in vitro degradation properties of the implants were studied in the laboratory over a two-year period. A successful clinical outcome was determined by the radiological findings and the Harris hip score.

All the patients had a satisfactory outcome and no mechanical failures or other complications were observed. No protrusion of any of the impacted grafts was observed beyond the mesh. According to our preliminary laboratory and clinical results the biodegradable mesh is suitable for augmenting uncontained acetabular defects in which the primary stability of the implanted acetabular component is provided by the host bone. In the case of defects of the acetabular floor this new application provides a safe method of preventing graft material from protruding excessively into the pelvis and the mesh seems to tolerate bone-impaction grafting in selected patients with primary and revision total hip replacement.

Acetabular defects are encountered in both primary and revision total hip replacement (THR). In a revision the defects can be divided into uncontained (segmental) and contained (cavitary) or combinations of these.1,2 Reconstruction of the bone stock is one of the main goals of revision and often requires an uncontained to be converted into a contained defect. Additionally, dysplastic hips often show varying degrees of defect of the rim. Bulk femoral autograft incorporates reliably into the host bone, but it can only be used at a primary procedure. In revisions the long-term results of using allograft bone chips by impaction grafting using a technique established in the early 1980s have been favourably reported.3-5

One of the more common methods of converting an uncontained into a contained defect has been to use a metal mesh fixed by metal screws into the host iliac bone.3 This reconstruction is strong enough to hold the impacted bone grafts in place until they incorporate into the host bone. However, reinforcement devices made of metal have several disadvantages. First, the sharp edges of the metal mesh and/or screws may irritate the soft tissues and cause complications, especially if displaced into the pelvis during impaction. Secondly, shaping them to conform to the cavity is difficult and time-consuming and the mesh may also cause perforations in surgical gloves with a risk of contamination. Finally, post-operative imaging of the grafted site is difficult when the graft is surrounded by a radio-opaque mesh.6,7 Furthermore, in the case of revision, the removal of a previously implanted metal mesh may be difficult.

Radiolucent plates of biodegradable mesh have been developed to avoid the problems described above. Biodegradable implants can be shaped easily and cut as desired after immersion in a bath of sterile warm water. They do not obstruct any type of post-operative imaging, they do not cause stress shielding or release metal ions and should avoid secondary complications such as migration, discomfort, pain or infection after the implants have degraded.8-11 However, although biodegradable implants have been successfully used in various orthopaedic indications,10-13 we are unaware of any clinical data on their safety and efficacy as graft-containment devices in hip joint replacement.

Our aims were first to determine the retention of strength and degradation properties of biodegradable mesh plates and screws during hydrolytic in vitro degradation and secondly to introduce a new surgical technique for...
converting an uncontained defect in the acetabular bone into a contained defect to allow bone-impaction grafting. We have followed up prospectively patients with THR who had been treated by the new technique to evaluate the clinical outcome and occurrence of complications.

**Patients and Methods**

**In vitro experiments.** Before clinical use we studied the effects of hydrolytic degradation on the retention of strength and degradation properties of the biodegradable mesh plate and screws over the course of two years (Fig. 1). After immersion in a warm water bath (70°C (69° to 71°)) for one minute according to the manufacturer’s instructions, 110 samples of a biodegradable mesh plate (0.7 mm thick Inion OTPS Mesh Plate; Inion Oy, Tampere, Finland) were stored at 37°C (36° to 38°) in individual containers filled with phosphate-buffered solution (pH 7.4 (7.2 to 7.6)). The solution was changed and the pH measured every second week. In addition, 110 biodegradable screws (Inion OTPS 3.1 mm Screw) were treated identically. The mechanical strength, inherent viscosity and loss of mass of implants were determined at zero (i.e. 24 hours) and at 4, 8, 12, 16, 20, 26, 40, 52 and 104 weeks of hydrolytic in vitro degradation.

The mechanical strength of the mesh plate and screws was determined by a shear test using a Zwick Z020/TH2A universal materials-testing machine (Zwick GmbH, Ulm, Germany). At each study interval, five mesh plate and screw samples were loaded at a constant speed of 5 mm min in metal shear fixture in water at 37°C (SD 1) until breakage of the implant occurred. The maximum shear strength (MPa) to failure was determined.

In addition to strength testing, the inherent viscosity (dl/g) and loss of mass (mg) were determined by studying the hydrolytic degradation properties of the implants in vitro. The inherent viscosity of the mesh plate and screw samples was characterised using a Schott Ubbelohde capillary viscometer (Schott Instruments GmbH, Mainz, Germany). At each testing point, the flow-time of the diluted samples from three mesh plate and three screw samples was compared with that of pure chloroform at a temperature of 25° (24° to 26°). The samples for the inherent viscosity measurements were prepared by dissolving 20.0 mg (19.6 mg to 20.4 mg) of the implant’s material to 20.0 ml (19.9 ml to 20.1 ml) of chloroform. The initial dry mass of the mesh plate and screw samples was measured on a Mettler Toledo AX205 DeltaRange balance (Mettler Toledo Inc., Columbus, Ohio) and at each follow-up interval three samples of the plates and screws were extracted from their containers. They were weighed for water absorption and then dried in a vacuum for four days, after which they were re-weighed and the loss of mass determined.

**Operative technique and clinical pilot study.** After approval of the Ethical Committee seven patients signed informed consent forms to participate in the study. They were selected so that filling of the bone defect was not critical for the stability of the implant since the main objective of the pilot study was to confirm the biocompatibility of this material for patients with THR which has been seen in other applications. The in vitro results suggested that the biodegradable mesh plate should not lose its strength before the implant had acquired stability. The inclusion and exclusion criteria of the patients recruited are shown in Table I. One patient died two months post-operatively of causes unrelated to the operation, leaving six to be followed up (Table II). There were two men and four women with a mean age of 61 years (46 to 69) at the time of the operation.

At induction each patient received a single dose of cefuroxine (3 g) intravenously. The operations were performed with the patient in the lateral decubitus position and using a posterolateral approach. The patients had either mild dysplasia of the acetabulum at primary THR or an acetabular defect associated with revision in which treatment of the defect was not critical for the stability of the implant, but supported the philosophy of restoring the bone stock. The defects were classified peroperatively according to the classification system of Paprosky and Magnus.

The biodegradable mesh plate was used to manage the acetabular defect located either peripherally at the rim of the acetabulum or in its floor. Before fixation, the mesh was cut to a suitable size and then placed in the warm water bath to make it temporarily malleable and to allow contouring according to the shape of the defect (Fig. 2). Since the mesh retained some of its inherent flexibility even after
Table I. Inclusion and exclusion criteria for the study

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria*</th>
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<tbody>
<tr>
<td>Patient informed consent signed</td>
<td>Participation in concurrent trials</td>
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<tr>
<td>Age over 45 years</td>
<td>Participation in previous trial within three months</td>
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<tr>
<td>Bone defect associated with acetabular component loosening or liner wear (type I to IIC defect where the dimensions of the defect are such that the use of biodegradable mesh plate is not crucial for implant stability but acts as bone-stock restoring procedure), or mild dysplasia causes cranial bone defect after implantation of the acetabular component in primary arthroplasty and where bone defect filling is not crucial for implant stability but acts as bone-stock restoring procedure</td>
<td>Subjects with HIV, Hep, CMV, syphilis</td>
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<td>Alcohol and drug (medication) abuse</td>
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<td>Poor general state of health as judged by the researcher</td>
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<td>Known allergy to penicillins and genta-Malignancy micin (or presence of multiple severe allergies)</td>
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<td>Existing acetabular rim mesh in previous operation</td>
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<td>Any concomitant painful or disabling disease of the spine, hips or lower limbs that would interfere with evaluation of the afflicted hip</td>
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<td>The patient agrees to participate in a strict rehabilitation protocol and follow-up programme</td>
<td>Any clinically significant or symptomatic vascular or neurologic disorder of the lower extremities</td>
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<td>Chronic use of anticoagulants</td>
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<td>Uncontrolled diabetes</td>
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<td>Current diagnosis of osteomyelitis</td>
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<td>A blood test showing liver enzymes (SGOT, SGPT, alkaline phosphatase) of more than two times the upper limit of normal or any other result that in the clinical investigator’s mind is important clinically</td>
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<td>CRP level greater than 10 mg/ml</td>
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* HIV, human immunodeficiency virus; Hep, hepatitis; CMV, cytomegalovirus; SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase

Table II. Details of the six patients and the clinical results

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (yrs)</th>
<th>Acetabular defect</th>
<th>THR*</th>
<th>Chamley class**</th>
<th>Follow-up (mths)</th>
<th>Final acetabular component stability</th>
<th>Final graft status</th>
<th>HHS† (pre-operative/post-operative)</th>
<th>Other findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>46</td>
<td>Dysplastic cranial defect</td>
<td>Primary A</td>
<td>50</td>
<td>6</td>
<td>Stable</td>
<td>Autograft partially resorbed</td>
<td>59/100</td>
<td>No osteolysis</td>
</tr>
<tr>
<td>2</td>
<td>56</td>
<td>Dysplastic cranial defect</td>
<td>Primary B</td>
<td>37</td>
<td>8</td>
<td>Stable</td>
<td>Autograft fully incorporated</td>
<td>42/86</td>
<td>No osteolysis</td>
</tr>
<tr>
<td>3</td>
<td>64</td>
<td>Type IIC</td>
<td>Revision A</td>
<td>40</td>
<td>6</td>
<td>Stable</td>
<td>Allograft fully incorporated</td>
<td>100/100</td>
<td>No osteolysis</td>
</tr>
<tr>
<td>4</td>
<td>69</td>
<td>Type IIA</td>
<td>Revision A</td>
<td>27</td>
<td>8</td>
<td>Stable</td>
<td>Allograft resorbed 89/89</td>
<td>No osteolysis</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>67</td>
<td>Type IIC</td>
<td>Revision B</td>
<td>21</td>
<td>8</td>
<td>Stable</td>
<td>Allograft fully incorporated</td>
<td>98/95</td>
<td>No osteolysis</td>
</tr>
<tr>
<td>6</td>
<td>65</td>
<td>Type IIC</td>
<td>Revision C</td>
<td>19</td>
<td>10</td>
<td>Stable</td>
<td>Allograft fully incorporated</td>
<td>65/73</td>
<td>No osteolysis</td>
</tr>
</tbody>
</table>

* THR, total hip replacement
† HHS, Harris hip score
cooling, an exact match with the defect was not necessary. The shaped mesh plate was fixed in place by the biodegradable screws and the defect packed with autograft or allograft bone chips. These were allowed to make direct contact with the mesh. In all cases an uncemented porous-coated acetabular component was then introduced.

Post-operative regimen. On the first post-operative day the patient began a rehabilitation programme under the supervision of a physiotherapist. The extent of weight-bearing and the use of crutches were determined individually according to the stability of the reconstruction. The time to full weight-bearing in each patient is shown in Table II.

Results

In vitro experiments. The mean initial maximum shear strength, inherent viscosity and mass of the mesh plate were 71 MPa (SD 11), 1.3 dl/g (SD 0.0) and 5.83 g (SD 0.02), respectively. The corresponding values for the screws were 41 MPa (SD 2), 1.4 dl/g (SD 0.00) and 0.16 g (SD 0.0). During the hydrolytic in vitro degradation of 104 weeks the strength, inherent viscosity and mass of the implants decreased as shown in Figures 3 and 4. The mesh plate and

The follow-up examination regime was the same for each patient. Radiographs of the hip were obtained and an independent surgeon (JP) and the physiotherapist on duty recorded the Harris hip score (HHS) at two to three days and at two, six and 12 months post-operatively. The first radiographs were taken as anteroposterior (AP) and lateral views with a horizontal beam and subsequently AP and frog-leg lateral mediolateral views were obtained. The radiographs were taken using Siemens AXIOM Aristos FX Plus (Siemens AG, Erlangen, Germany) or Philips Digital Diagnost (Philips Electronics NV Eindhoven, The Netherlands) equipment. Each patient's radiographs were interpreted together in consensus by a musculoskeletal radiologist (AP) and an orthopaedic surgeon (JP), who were blind to the patients' clinical data. All the measurements were done using an Agfa Impax DS3000 workstation (Agfa-Gevaert NV, Mortsel, Belgium). The stability of the implant and the incorporation of the bone grafts as well as any complications were documented.

One year after the operation the patient joined the contemporary follow-up regimen of all THR patients carried out by the hospital. The radiograph and the HHS at the most recent follow-up were used for the final evaluation.

Graph showing the mean relative changes in the properties of the biodegradable mesh plate during hydrolytic in vitro degradation.

Graph showing the mean relative changes in the properties of the biodegradable screw during hydrolytic in vitro degradation.
screw samples had lost all their strength after 26 and 52 weeks, respectively, and could not be tested mechanically thereafter.

Clinical observation. The mean follow-up was 32.3 months (19 to 50). The pre- and post-operative HHSs are shown in Table II. No primary or late infections occurred. A successful primary clinical radiological outcome was achieved in all patients (Table II, Fig. 5). In four patients no resorption of the bone graft or any complications which could be related to the use of the biodegradable mesh plate were observed. In one (case 1) with a dysplastic cranial defect partial resorption of the autogenous graft occurred. In another (case 4) total resorption of the allograft at the peripheral area was observed. In four patients with defects of the medial wall which had received morcellised allograft bone remodelling was seen at final follow-up. No signs of osteolysis at the interface to the acetabular component were observed in any of the patients with defects of the floor. All the acetabular components appeared to be stable with no migration or change in position. Consequently, no protrusion of the impacted graft was observed beyond the mesh plate. One patient (case 4) with a rim defect was observed to have a grade-1 non-progressive osteolytic line in zone 1 of DeLee and Charnley.16

Compared with the metal mesh the biodegradable mesh plate was easy to shape with conventional scissors and left no sharp edges which could damage surgical gloves. Contouring of the biodegradable mesh for the recipient site mostly required repeated immersion in the warm water bath because of the short working time before hardening. The residual elasticity of the plate accommodated any remaining mismatch in shape when it was fixed into its final position by the biodegradable screws. It was a constant finding that both at the rim and on the acetabular floor area the mesh plate could tolerate the force transferred in the impaction grafting which was performed with the same effort as typically used with a conventional metal mesh.

Discussion

Encouraged by the results of our study in vitro on hydrolytic degradation, the biodegradable mesh plate was used as a graft-containment device in grafting defects of acetabular bone in carefully selected patients with THR. We do not believe that this technique has been described previously. Uncontained acetabular defects associated with revision arthroplasty have traditionally been converted into contained defects by using either metal mesh or bulk bone grafts.3,4

According to our observations of hydrolytic degradation in vitro, the biodegradable mesh plate retained most of its mechanical strength (>70%) for eight weeks and gradually lost it thereafter with complete loss by 26 weeks. The screws retained their strength longer, ensuring that the mesh plate remained fixed in place until it had lost its integrity. Less than 15% of the initial mass of the implants remained after two years of hydrolytic degradation in vitro.

The biodegradable implants which we studied were made of copolymers composed of L-lactide, D-lactide and trimethylene carbonate. 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 loss of mass of the implant then occurs through the release of soluble degradation products, phagocytosis by macrophages and histiocytes and intracellular degradation. Finally, metabolic elimination occurs to carbon dioxide and water through the citric acid (Krebs) cycle.17-19

The reduction in inherent viscosity observed in vitro represents the reduction of the molecular weight of the material which takes place as the polymer chains of the mesh plate degrade. The loss of mass of the biodegradable polymer represents bioabsorption of the polymer which would take place in vivo. These changes result in a reduction in strength of the
mesh, but it must be noted that although hydrolytic degradation testing in vitro is widely used to study the degradation of biodegradable implants, complete elimination of the implant material cannot be achieved because the clearance effect of local vascularity and cells, mainly macrophages, is excluded.20 Therefore the in vitro last-phase debris cannot be fully cleared.21-23 Nevertheless, in several studies the degradation results obtained in vitro have been almost identical with the preclinical results of in vivo degradation.20,23-25 Nieminen et al20 have previously shown that the degradation behaviour of the copolymer material in this in vitro model is almost identical to that seen in vivo. They found that in sheep the copolymer material became soft in six to 12 months and degraded completely by 24 months without any harmful inflammatory or foreign-body reactions. Similar findings were found in a rabbit model with only minimal amounts of similar material remaining at 18 months after implantation.18 In reports on the use of the same copolymer in man it had totally degraded by 18 months post-operatively.13,14

The risk of post-operative adverse tissue reactions is always present when foreign materials are implanted in patients.9 All biodegradable implants induce an asymptomatic subclinical, but microscopically recognisable non-specific foreign-body type of tissue response.11 This is to be expected and is considered to be normal as long as it does not cause any clinical problem. Earlier publications have reported local accumulation of fluid, the presence of sterile abscesses and even local osteolysis in some patients treated by first-generation biodegradable materials typically at six to 24 months post-operatively.9 However, we did not observe any problems of this nature.

In a clinical setting the main function of the graft-containment device is to keep the graft in place until bone healing. Thereafter, the support of the device is no longer needed. Especially in the case of a defect of the acetabular floor there is always the risk of impacting the mesh intra-pelvically with potential complications related to the displaced metal mesh. No protrusion of the impacted graft was observed beyond the biodegradable mesh plate in the selected cases in our study but, in such a situation the absence of sharp edges would make damage to other tissues unlikely.

Remodelling was seen in all cases, but it was more pronounced in the patients with load-free rim defects in which the graft partially or totally resorbed. Although osteolysis due to fast-degrading first-generation biodegradable materials has been reported,8,26 the most probable explanation for the graft resorption in our study is the physiological remodelling27 because of lack of loading. Therefore, the observed graft resorptions may be considered to have been caused by the nature of our pilot study rather than by the biodegradable implants or material per se.

In our study the graft-containment device was located under the graft and subjected only to moderate stress. Although we encountered favourable results it must be recognised that the patients were carefully selected, had non-critical-size defects and the sample size was limited. Since our observations indicated permanent stability and physiological remodelling of the grafted area with a flawless interface we look very favourably on the use of this device. Long-term follow-up of these pilot cases will yield further information.

Our pilot study demonstrated that a biodegradable mesh plate could be used successfully for converting a non-critical-size uncontained acetabular bone defect into a contained defect to allow bone-impaction grafting. It provided adequate graft containment in carefully selected patients with THR in whom treatment of the defect was not crucial for the stability of the implant. These results justify further research to investigate the suitability of the biodegradable mesh for more demanding defects.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. However, two of the authors (PV, JTN) have been previously employed by Inion Oy.

References


