Reconstruction with 3D-printed pelvic endoprostheses after resection of a pelvic tumour

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Aims
The aims of this retrospective study were to report the feasibility of using 3D-printing technology for patients with a pelvic tumour who underwent reconstruction.

Patients and Methods
A total of 35 patients underwent resection of a pelvic tumour and reconstruction using 3D-printed endoprostheses between September 2013 and December 2015. According to Enneking’s classification of bone defects, there were three Type I lesions, 12 Type II+III lesions, five Type I+II lesions, two Type I+II+III lesions, ten type I+II+IV lesions and three type I+II+III+IV lesions. A total of three patients underwent reconstruction using an iliac prosthesis, 12 using a standard hemipelvic prosthesis and 20 using a screw-rod connected hemipelvic prosthesis.

Results
All patients had an en bloc resection. Margins were wide in 15 patients, marginal in 14 and intralesional in six. After a mean follow-up of 20.5 months (6 to 30), 25 patients survived without evidence of disease, five were alive with disease and five had died from metastatic disease.

Complications included seven patients with delayed wound healing and two with a dislocation of the hip. None had a deep infection. For the 30 surviving patients, the mean Musculoskeletal Society 93 score was 22.7 (20 to 25) for patients with an iliac prosthesis, 19.8 (15 to 26) for those with a standard prosthesis, and 17.7 (9 to 25) for those with a screw-rod connected prosthesis.

Conclusion
The application of 3D-printing technology can facilitate the precise matching and osseointegration between implants and the host bone. We found that the use of 3D-printed pelvic prostheses for reconstruction of the bony defect after resection of a pelvic tumour was safe, without additional complications, and gave good short-term functional results.

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order to assess the feasibility of this technology in manufacturing prostheses for pelvic reconstruction, we performed a retrospective study of patients who underwent resection of pelvic tumour and reconstruction using a 3D-printed pelvic endoprosthesis.

**Patients and Methods**

A total of 35 patients with a pelvic tumour underwent reconstruction with a 3D-printed pelvic prosthesis between September 2013 and December 2015. The demographic and oncological data are summarised in Table I with further details in Supplementary Table i. There were 20 men and 15 women with a mean age of 36.9 years (12 to 65). The diagnosis and staging of the tumours is shown in Table I. The nine with a diagnosis of “other” included two giant cell tumours, two haemangiopericytomas, one synovial sarcoma, one liposarcoma, one undifferentiated pleomorphic sarcoma and two metastatic renal cancer. All the patients with a stage III tumour had an osteosarcoma. Of these, two had pulmonary metastases and one had tumour embolism in the vena cava. All 17 patients with an osteosarcoma and a Ewing’s sarcoma received neo-adjuvant chemotherapy.

**The principles and design of the 3D-printed pelvic endoprostheses.** We have previously described an extensive experience of the use of modular hemipelvic prostheses, which showed a three-year prosthesis survival as 81.8% and a mean Musculoskeletal Tumour Society 93 (MSTS-93) score as 57.2% in a cohort of 100 patients. The three kinds of 3D-printed pelvic prostheses which were used in this study were made from titanium alloy by electronic beam melting technology. The fundamental characteristic is the porous nature of the implant-bone interface allowing osseointegration, as has been shown in in vitro and in vivo studies. In order to provide more flexibility at the time of the reconstruction, the prostheses were modular with each component having three sizes.

The iliac prosthesis (Aikangyicheng Co., Beijing, China) (Fig. 1b) was designed for type I and type I + IV resections to be placed between the sacrum and the roof of the acetabulum. Its shape matches that of the inner wall of the ilium and it has two screw holes for fixation to the sacrum and acetabulum. It also has a polyaxial screw on the back for connection to the lumbar pedicle screws. There are several holes on the outer and inner edges for attachment of the soft tissues.
The 3D-printed standard hemipelvic endoprosthesis (Aikangyicheng Co.) (Fig. 2d) was used after type II/II+III resections. Its design evolved from the previous hemipelvic prosthesis with modifications on the contour of iliac aspect, the direction of the screw holes and structure of the implant-bone interface.

The 3D-printed screw-rod connected hemipelvic endoprosthesis (Chunli Co. Beijing, China) (Fig. 3) was used after resection of both the acetabulum and sacroiliac joint. This new prosthesis has improved design features compared with the previous screw-rod connected hemipelvic prosthesis. It includes a sacral component and an acetabular ring which are linked by a double-axle mechanism. The vertical part of the sacral component has three holes for sacral fixation and two polyaxial screws for connection to the lumbar pedicle screws. The inner surface of the sacral component is porous and the angle of the acetabular ring is adjustable.

**Type I resection and reconstruction.** For patients with an iliac tumour with or without involvement of the sacral ala, the operation can be performed at a single stage using an extended ilioinguinal approach followed by dissection of the retroperitoneal space and mobilisation of the iliac vessels and femoral nerve. The glutei are mobilised to expose the sciatic notch and sciatic nerve. Then two Gigli saws are introduced through the greater sciatic notch to allow osteotomy through the ilium and sacral ala or sacroiliac joint, after which the tumour is removed.

A 3D-printed iliac endoprosthesis of suitable size is selected following measurement of the defect. In order to fix the prosthesis, two cancellous screws are passed through the holes in the upper aspect of the prosthesis into the S1 or S2 vertebral body. Another two screws are passed into the pubis and ischium respectively. One or two pedicle screws are introduced through the ipsilateral pedicles of L5 and/or L4. Finally, fixation is reinforced posteriorly by connecting to the pedicle screws with a titanium rod (Figs 1b and 1c).

**Type II+III resection and reconstruction.** Resection of the acetabulum and obturator foramen is undertaken and has been previously reported. After removal of the tumour, a 3D-printed modular hemipelvic endoprosthesis of suitable size is selected to fit for the contour of residual ilium. Before fixation, the angle of the acetabular ring is adjusted and two long cancellous screws are introduced through the screw holes across the sacroiliac joint into the vertebral body of S1 or S2 with fluoroscopic guidance. Another two or three cortical screws can be used to strengthen the fixation. Finally, high viscosity bone cement containing gentamicin is used to augment the prosthesis, and the hip is restored as in a conventional total hip arthroplasty (THA). (Figs 2d and 2e).
Type I+II/I+II+III/I+II+III+IV resection and reconstruction. En bloc resection of the acetabulum, ilium, and/or obturator foramen, and/or partial resection of the sacral ala is undertaken as previously described.3,18 A structural graft is harvested from the femoral head and fixed to the residual sacrum. Sometimes the prosthesis can be fixed to the residual sacroiliac joint without an autograft. The 3D-printed screw-rod connected hemipelvic prosthesis is then fixed to the graft using two long cancellous screws which are passed into the vertebral body of S1 or S2. Then two screws are introduced into the pedicles of L4 and L5 and connected to the polyaxial screws of the prosthesis using two titanium rods (Figs 3 and 4c to 4d). The angles of abduction and anteversion of the acetabulum can be adjusted by the two
undertaken at each follow-up, and bone radionuclide imaging would be administered every six months. Oncological status (recurrence or metastasis) and prosthetic status (radiolucent lines, heterotopic ossification, implant breakage, loosening, infection etc) would be assessed by above radiological studies during each follow-up by senior orthopaedic surgeons (TJ and WG). At the latest follow-up, the patients’ survival status and the MSTS-93 lower extremity score was determined through telephone contact by the authors (YW and YZ).

Statistical analysis. Survival was analysed using Kaplan-Meier curves. The overall survival of patients with reconstruction using a screw-rod hemipelvic prosthesis was compared with that using a standard prosthesis with log-rank testing. A p-value of < 0.05 was considered to be significant. Statistical analysis was performed using the Statistical Package for the Social Science (SPSS) software version 16.0 (SPSS Inc., Chicago, Illinois).

Results

Operational outcomes. En bloc resection was achieved in all patients with satisfactory surgical margins in 29 (82.9%, wide in 15 and marginal in 14). Satisfactory margins were not obtained in six patients (17.1%) (Table II). Two of these patients had an osteosarcoma with tumour invading the pre-sacral venous system, the internal iliac vein and with an embolus of tumour in the vena cava, which was discovered at the time of surgery. The tumours in the other four patients, including two Ewing’s sarcomas, one chondrosarcoma and one osteosarcoma, were all very large and invaded the sacrum.

Three patients had reconstruction with an iliac prosthesis, 12 with a standard hemipelvic prosthesis and 20 with a screw-rod connected hemipelvic prosthesis. The mean intra-operative blood loss was least in solitary type I resections (1200 ml, SD 223) and most in type I + II/I + II + III/I + II + IV/I + II + III + IV resections (2660 ml, SD 919). Likewise, the mean operating time was shortest for type I resections (three hours 20 minutes, SD 15 minutes) and longest for resections including type I + II (four hours 40 minutes, SD 23 minutes) (Table II). Temporary occlusion of the aorta with a balloon to control bleeding during surgery was used in 21 patients, mainly for type I + II + III and I + II + IV resections. The mean duration of occlusion was 106 minutes (60 to 150). No patient died of peri-operative complications.

Oncological outcomes. The mean follow-up was 20.5 months (6 to 30), at which time 25 patients (71.4%) were alive without evidence of disease, five (14.3%) were alive with disease and five (14.3%) had died of metastatic disease at a mean of nine months (6 to 12) post-operatively (Table II and Supplementary Table i). Those with a standard hemipelvic prosthetic reconstruction had a higher overall rate of survival than those with a screw-rod connected reconstruction (p = 0.048) (Figs 5 and 6).

Post-operative functional status. The mean MSTS-93 score of the 30 surviving patients was 19.1 (9 to 26). A total of three
patients with an iliac prosthesis had a mean MSTS-93 score of 22.7 (20 to 25). Those with type II + III resections and a standard hemipelvic prosthesis had a mean score of 19.8 (15 to 26), while those with screw-rod connected prosthesis reconstruction had a mean score of 17.7 (9 to 25) (Table II).

Complications. A total of seven patients had delayed wound healing and required debridement; and two (5.7%) had a dislocation of the hip. No patient had a deep infection. Radiographic examinations were undertaken every three months post-operatively as mentioned previously, and showed no evidence of bone resorption or osteolysis at the prosthesis-bone interface. There were no radiolucent lines, heterotopic ossification, loosening, breakage or displacement of the components. Fusion was seen between the graft and sacrum in the 18 patients whose operation included a femoral head autograft.

Discussion
With the improvements of surgical techniques and adjuvant therapy, the oncological outcomes of patients with a pelvic tumour have improved, but a more durable reconstruction is still required.3,20-22 Although various techniques for internal pelvectomy have been described,1,3-9,18,19 the rate of complications remains high with limited long-term functional outcomes. The use of 3D-printing technology in Orthopaedic Surgery allows greater freedom of prosthetic design and the fabrication of more complex shapes including a porous surface with pre-determined pore sizes. This increases the accuracy of the reconstruction, reducing the rate of post-operative complications and potentially improving stability in the long-term.13-16,23 In this study, we reported three novel designs of 3D-printed prostheses for different types of defects after resection of a pelvic tumour, which showed satisfactory outcomes in terms of surgical technique and peri-operative safety with good short-term survival and functional outcomes.

Reconstruction for type I/I+IV resection. Resection of tumours involving the ilium, sacrum or sacroiliac joint can cause pelvic disruption and discontinuity. Although it has been suggested that reconstruction after type I/I+IV resection is not necessary,24 an unreconstructed sacroiliac defect can allow superior migration of the acetabulum, leg length discrepancy and scoliosis.7,24,25 Iliosacral arthrodesis with autografts or allografts has been attempted but with only fair functional outcomes (mean MSTS-93 score: 51% to 57%)7,8,24 and with significant disadvantages including prolonged immobilisation and a high rate of nonunion, infection, fracture or arthrodesis and secondary scoliosis. As a result, instrumented reconstruction, mainly sacro-iliac screw-rod fixation, has been used with bone grafts. This allows early mobilisation and gives satisfactory functional scores (mean MSTS 93 score: 57% to 75.4%).7,8,25-27 The combined biological and instrumented methods of reconstruction, however, increase operating time and there remain risks of infection, nonunion, aseptic loosening and fracture.

We used to use a pedicle screw-rod fixation method to obtain immediate stability,19,26 but the incidence of these complications encouraged us to seek more stable and durable methods. We therefore designed the iliac prostheses made possible by 3D-printing technology. With appropriate screw holes, a one-stage reconstruction of an iliac defect was possible, allowing a normal pattern of the transfer of load through the posterior pelvic ring (Fig. 1). Posterior pedicle screw-rod fixation would add stability and the abductor muscles could be re-attached using the holes in the edge of the prosthesis. The reconstructive procedures were relatively straightforward, with a mean operating time of three hours 20 minutes and mean intra-operative blood loss of 1200 ml, which was comparable with those previously reported for other techniques.8,27 The porous
surface of the implant increased the potential for bony ingrowth and long-term stability. The functional outcome in the short-term was excellent (mean MSTS-93 score: 22.7% to 75.6%) without evidence of mechanical failure. One patient could walk independently without a Trendelenburg gait six months later and started swimming nine months post-operatively.

**Reconstruction for type II/II+III resections.** The highlight of reconstruction for type II/II+III resections has always been restoration of a functional stable hip. Although biological reconstruction including iliofemoral arthrodesis, ischiofemoral arthrodesis, pseudarthrosis and a flail hip have all been reported to yield good function (mean MSTS-93: 58% to 62%), drawbacks such as prolonged immobilisation, leg length discrepancy, and limited movement of the hip warranted improved techniques. The re-implantation of devitalised autografts with THA had also shown excellent functional outcomes (mean MSTS-93: 75%) but could not be used in patients with large tumours. Prosthetic reconstruction is therefore a reasonable choice after type II/II+III resections.

Saddle prostheses were described for reconstruction after resection of a peri-acetabular tumour but had a high incidence of complications (dislocation: 2% to 22%; disassociation of the components: 0% to 12%; superior migration: 25%; iliac fracture: 30%; heterotopic ossification: 35%). The failure of this type of prosthesis suggested that a THA with secure fixation of the acetabular component should be a fundamental principle for the design of a hemi-pelvic prosthesis. Various types of hemipelvic prostheses have been reported. They usually differed from each other in the design of the method of anchorage. Good function has been reported after the use of custom-made hemipelvic prostheses but with limited survival. In 1996, Windhager et al described 21 patients with a peri-acetabular sarcoma who underwent different kinds of reconstruction. A total of nine involved a custom-made prosthesis; this gave better function than a combination of a saddle prosthesis and allograft. In 2002, Ozaki et al described 12 patients with custom-made hemipelvic prostheses, all of which were designed with computer-assisted technology based on pre-operative images. At a mean follow-up of 57 months, survival of the prosthesis was 42% and the major complication was deep infection. In 2009, Witte et al described the use of the Modular Universal Tumour and Revision System custom-made hemipelvic prosthesis in 40 patients, which showed a mean post-operative MSTS-93 score of 50% but with a rate of complications of 75% after a mean follow-up of 24 months.

The ‘pedestal cup’, also called the ‘ice-cream cone’ prosthesis due to its shape, showed disappointing early results. Bus et al described its use in 19 patients with peri-acetabular malignancies. A total of three had recurrent dislocation, three had aseptic loosening, nine had deep infection and two had local recurrence, with an overall implant survival at five years of 50% and a mean MSTS-93 score of 49%. The Royal Orthopaedic Hospital in Birmingham also reported the outcome of a similar prosthesis in 27 patients treated between 2004 and 2009 with a rate of complications of 37% including four dislocations (14.8%) and three deep infections (11.1%). Recently Bus et al described a modified pedestal acetabular component prosthesis, which was used for peri-acetabular reconstruction and showed improved survival with a rate of failure at five years of 17.3% for mechanical reasons and 9.2% for infection, and better functional status, with a mean MSTS-93 of 70% in 47 patients.

In 2007, we described the use of a modular hemipelvic prosthesis in 28 patients and six years later we reported the mid-term outcome of 100 patients with this prosthesis who had a mean MSTS-93 score of 57.2% three years post-operatively. The mean survival was 81.8% at this time with a rate of deep infection of 15%, a rate of wound-healing problems of 18%, a rate of dislocation of 9% and of breakage of 5%. This modular prosthesis had the advantages of technical convenience. It allowed the normal transfer of load and was stable in the short-term.

In this study, we modified the previous modular prosthesis with 3D-printing technology. The extensive data from the CT scans of the previous cases were used in the modification of the contour of the iliac component and the site and directions of the screw holes within it. As a result, a perfect fit between the iliac component and the outer curved surface of the residual ilium with very precise screw paths from the implant through the sacroiliac joint into the body of S1 and S2 was guaranteed (Fig. 2e). This improved the stability and the transfer of load. We also used long cancellous as well as short cortical screws to further improve stability. The prosthesis-bone interface was produced as a porous structure with titanium alloy by 3D-printing, which could help facilitate bony ingrowth. The operations, at which this new hemipelvic prosthesis was introduced were straightforward and did not take extra time or involve increased blood loss. A mean MSTS-93 score of 19.8 (15 to 26, 66%) was achieved, which is better than for the previous prostheses.

**Reconstruction for type I+II resection.** Few kinds of prosthesis are suitable for reconstruction after a type I+II resection. The concurrent defects of the iliac wing, sacroiliac joint and acetabulum provide no anchorage for the prostheses which are mentioned above. We previously reported the use of a modular hemipelvic prosthesis with a structural autograft fixed to the residual sacrum after type I + II/I + II + IV resections. The functional result was fair (44.5%); breakage of the sacral screws was seen in long-term follow-up. Therefore, we developed the first generation of screwrod connected hemipelvic prostheses, which restore continuity between the pelvis and the spine while retaining the function of the hip. Patients could be fully weight-bearing and walk with or without assistance. This prosthesis, however, as we recently reported, still failed to provide sufficient stability of the spine, pelvis and sacroiliac joint. It also
added a risk of neuralgia from the use of screws in the lateral aspect of the lumbar vertebral bodies.

We modified the previous modular prosthesis to include rigid fixation to the sacrum while preserving the posterior pedicle screw-rod fixation (Figs 3 and 4). 3D-printing was also used to generate a porous interface for bony ingrowth. In this cohort, 15 patients with a type I + II resection underwent reconstruction with a screw-rod connected prosthesis and remained alive at the latest follow-up (Supplementary Table i) with a mean MSTS-93 score of 17.7 of 30, which is better than previous reports for other techniques.3,4,18 Moreover, no patient had neuralgia post-operatively and there was no evidence of bone resorption, osteolysis, loosening, migration or breakage at the latest follow-up. Nevertheless, further observation is required to assess fusion between the prosthesis and host bone.

Advantages of 3D-printing technology in reconstruction for pelvic defect. The advantages of these prostheses are as follows. First, the contours of the iliac prosthesis and the standard hemipelvic prosthesis were designed following extensive analysis of pelvic CT scans and they always matched the resection plane perfectly at operation. Second, the prostheses were still made with modular patterns in different sizes, not only to allow a more flexible osteotomy, but also to allow adjustment of the height and angles of the acetabular component. As a result, intra-operative navigation was not needed to guide the resection and it was possible to achieve precise matching of the implant to the host bone. Thirdly, the size and density of the pores on the surface of the components were determined from previous biomechanical studies which demonstrated bony ingrowth and long-term stability.13–16 No patient had a deep infection, which might due, in part, to the short operating time, the small sizes of the prostheses with good soft-tissue cover, wound drainage using two thoracic drainage tubes that minimised the risk of haematoma and a prolonged period of treatment with broad-spectrum antibiotics.

The main limitation of this study is the relatively short follow-up. Mechanical complications such as aseptic loosening and breakage of screws or rods might not occur until several years after the operation. Assessment of osseointegration in relation to these prostheses in the long-term will be required. Other complications and the survival and oncological outcomes will also need to be recorded with longer follow-up.

However, based on the results of these 35 patients, we can conclude that the use of 3D-printed pelvic prostheses for the reconstruction of defects after the excision of a pelvic tumour is possible and safe and gives good short-term functional results.

Take home message:
- The application of 3D-printed pelvic prostheses for reconstruction of the bony defect after resection of a pelvic tumour was safe, without additional complications, and gave good short-term functional results.

Supplementary material
A table showing the demographics of 35 cases with 3D-printed pelvic prosthetic reconstruction after resection of a tumour is available alongside the online version of this article at www.bjj.boneandjoint.org.uk

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