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CASE REPORT

Designing patient-specific solutions using biomodelling and 3D-printing for revision lumbar spine surgery

Ganesha K. Thayaparan[1,2] · Mark G. Owbridge[3] · Robert G. Thompson[3] · Paul S. D'Urso[1,3]

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Abstract

Purpose Despite the variety of "off-the-shelf" implants and instrumentation, outcomes following revision lumbosacral surgery are inconstant. Revision fusion surgery presents a unique set of patient-specific challenges that may not be adequately addressed using universal kits. This study aims to describe how patient-specific factors, surgeon requirements, and healthcare efficiencies were integrated to design and manufacture anatomically matched surgical tools and implants to complement a minimally invasive posterior approach for revision lumbar fusion surgery.

Methods A 72-year-old woman presented with sciatica and a complex L5–S1 pseudoarthrosis 12 months after L2–S1 fixation surgery for symptomatic degenerative scoliosis. Patient computed tomography data were used to develop 1:1 scale biomodels of the bony lumbosacral spine for pre-operative planning, patient education, and intraoperative reference. The surgeon collaborated with engineers and developed a patient-specific 3D-printed titanium lumbosacral fixation implant secured by L2–L5, S2, and iliac screws. Sizes and trajectories for the S2 and iliac screws were simulated using biomodelling to develop a stereotactic 3D-printed drill guide. Self-docking 3D-printed nylon tubular retractors specific to patient tissue depth and bony anatomy at L5–S1 were developed for a minimally invasive transforaminal approach. The pre-selected screws were separately sourced, bundled with the patient-specific devices, and supplied as a kit to the hospital before surgery.

Results At 6-month follow-up, the patient reported resolution of symptoms. No evidence of implant dysfunction was observed on radiography.

Conclusion Pre-operative planning combined with biomodelling and 3D printing is a viable process that enables surgical techniques, equipment, and implants to meet patient and surgeon-specific requirements for revision lumbar fusion surgery.

Keywords Biomodelling · Lumbosacral · Patient specific · Revision · 3D printing

Introduction

Lumbar fusion procedures have evolved to treat the neurological symptoms caused by degenerative disease of the lumbar spine. Current surgical techniques, with open and minimally invasive variations, allow near-circumferential access to the lumbar spine [1, 2]. Each surgical technique and implant for lumbosacral stabilization require a set of device-specific tools for instrumentation. This expansion of surgical tools and implants has partly contributed to a considerable increase in the rates of lumbar fusion surgery over the last two decades with a proportional increase in lumbar revision rates [3, 4].

Meticulous pre-operative planning is paramount to determine a revision strategy from a variety of approaches, techniques, and equipment. Subsequently, the decision to offer surgical correction is influenced by the suitability of the patient to a particular surgical technique, which may exclude a patient from surgery.

Recently, the adaptability of additive manufacturing techniques combined with biomodelling and pre-operative planning allows the development of implants and surgical tools to complement, adapt, or replace existing surgical methods to suit patient and surgeon-specific requirements [5, 6]. In this report, we present a process where patient-specific

✉ Ganesha K. Thayaparan
ganesha.thayaparan@gmail.com

[1] Department of Neurosciences Epworth Healthcare, Richmond, Victoria, Australia

[2] The Epworth Centre, Suite 7, Level 8, 32 Erin Street, Richmond, Victoria 3121, Australia

[3] Anatomics Pty Ltd, St Kilda, Victoria, Australia

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implants and surgical tools were designed and manufactured using biomodelling and 3D printing (3DP) for a patient requiring revision lumbosacral fusion surgery.

Case history

A 72-year-old lady initially presented with a history of chronic lower back pain, left sciatica, and abnormal gait. Her history was significant for osteoarthritis with bilateral knee replacements, osteopenia with previous stress fractures in her right ankle, previous C4–6 anterior cervical discectomy and fusion, hysterectomy, and hypertension. Lumbar imaging revealed a scoliotic spine with grade 1 degenerative spondylolisthesis with severe canal stenosis at L4–5 and L3–4, disc prolapse at L2–3 with severe canal stenosis, and severe left L5 nerve root compression.

A two-stage operation was performed to correct scoliosis with interbody cages implanted at L2–3, L3–4, and L4–5 using a lateral technique (XLIF, Nuvasive, San Diego, CA, USA). A polyether ether ketone (PEEK) interbody cage combining autologous bone with bone morphogenic protein (Infuse Medtronic, Memphis, TN, USA) was implanted at L5–S1 using a minimally invasive left-sided transforaminal approach (MIS TLIF). Minimally invasive laminectomies and rhizolysis were performed on the right at L3–4 and bilaterally at L4–5. Pedicle screws and rods were inserted to connect L2 to S1.

Post-operative radiographs at 1 and 4 months were satisfactory. Despite the resolution of lower back pain, her left sciatica persisted. At 12 months, a computed tomography (CT) scan demonstrated a pseudoarthrosis and coronal collapse at L5–S1 with a loose S1 screw trapping and irritating the left L5 nerve root (Fig. 1). The sacral promontory had collapsed underneath a grade 1 spondylolisthesis of the L5 vertebra (Fig. 2). Revision surgery was proposed to decompress the L5 nerve root, to minimize movement across the L5–S1 segment without instrumenting S1, and to promote bony fusion across the L5–S1 segment.

Materials and methods

The design process is summarized in Fig. 3.

Biomodelling

The patient underwent a helical CT scan. Digital Imaging and Communications in Medicine (DICOM) data were transferred to a workstation running AnatomicsPro software (Anatomics, St Kilda, Australia) for processing prior to manufacture of a 1:1 stereolithographic biomodel of the osseous spine (Fig. 4) from polymerized transparent layers of ultraviolet light-cured acrylic resin. The biomodel allowed the treating surgeon to examine patient anatomy, appreciate surgical pathology, rehearse the surgical procedure, and formulate a surgical plan in conjunction with standard clinical imaging.

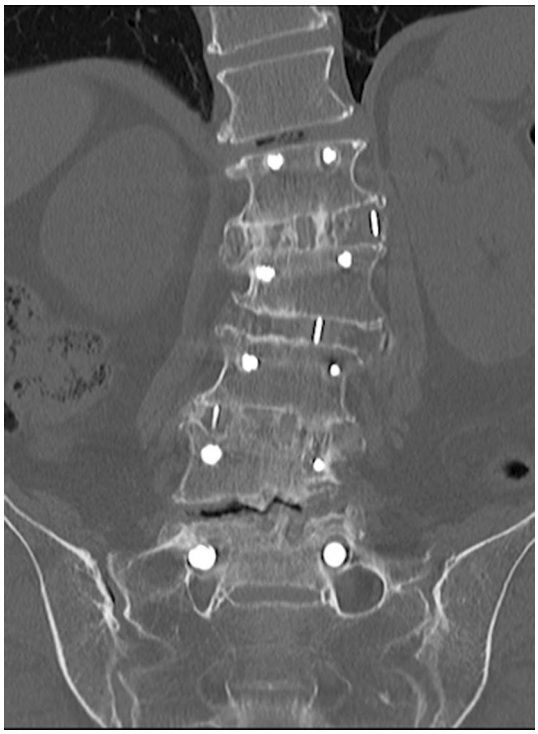

Fig. 1 Coronal computed tomography image demonstrating a pseudoarthrosis at L5–S1, loosening of the left S1 screw, and coronal imbalance

Pre-operative planning

Using AnatomicsC3D software (Anatomics, St Kilda, Australia), the surgeon collaborated with biomedical engineers to formulate a list of design specifications for the patient-specific posterior fixation construct (Table 1). The specifications allowed engineers to develop a software model of the fixation construct by simulating the required pedicle screws, connecting rods, and interbody cage. In this case, a patient-specific contoured iliolumbar implant spanning L2 to pelvis with a pelvic anchor was designed to provide stabilization (Fig. 4). The porous ventral surface of the anchor was contoured to complement the ilium.

Suitable entry points, sizes, and trajectories for the S2 and iliac screws were simulated in software. An interbody cage was sized and selected using the software and biomodel. Stereotactic drill guides were designed using planned pedicle screw positions for intraoperative use with fluoroscopy (Fig. 5). A self-docking tubular retractor specific to patient tissue depth and bony anatomy at L5–S1 was designed for a MIS TLIF technique (Fig. 6).

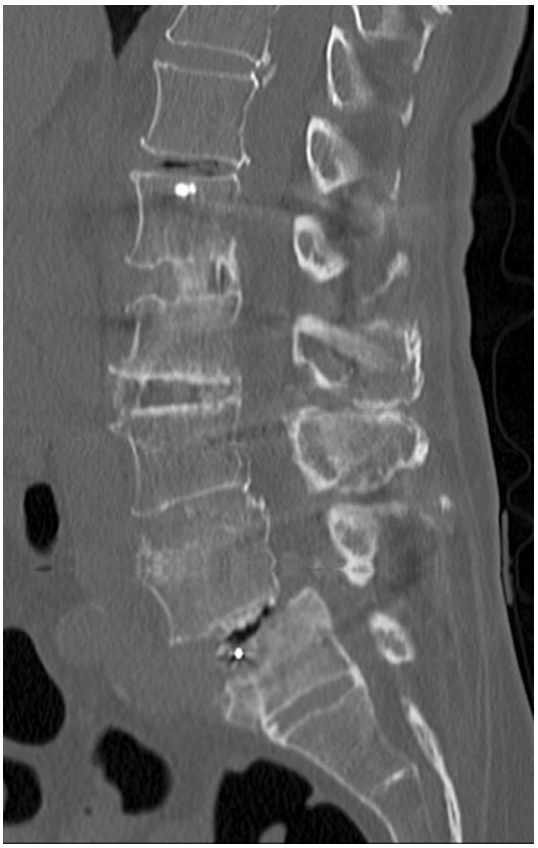

Fig. 2 Sagittal computed tomography image demonstrating a pseudoarthrosis at L5–S1 with a grade 1 spondylolisthesis

Verification

Technical specifications for the proposed fixation construct using the pre-selected implants were provided as a report to the surgeon.

The surgeon simulated the proposed solution using AnatomicsC3D software and specified design modifications to the engineers. A revised solution was communicated to the surgeon for verification. This process iterated until the surgeon confirmed the design and implant selection.

Additive manufacturing

After surgeon approval, the drill guides and tubular retractors were manufactured from nylon particles (PA-12) using an Eosint selective laser sintering printer (EOS GmbH, Krailling, Germany) at Anatomics (Anatomics, St Kilda, Australia). The patient-specific rods were fabricated from titanium alloy powder (Ti64) using an Arcam A1 EBM printer (Arcam AB, Mölndal, Sweden) at CSIRO Lab 22 (CSIRO, Clayton, Australia).

The printed equipment was post-processed at Anatomics where the parts were cleaned, polished, sterilized, and packaged for delivery to the hospital. The pre-selected screws and interbody cage were separately supplied. We chose an EIT Cellular Titanium® (Emerging Implant Technologies GmbH, Wurmlingen, Germany) interbody cage to replace the existing PEEK interbody cage at L5–S1.

Surgery

All pedicle screws and rods were removed via the previous para-median keyhole incisions. The patient-specific tubular retractor was secured to the spine using a temporary cannulated screw along the previous S1 screw trajectory. The existing L5–S1 interbody cage was replaced by the pre-selected 3DP titanium cage, and BMP (Infuse, Medtronic) was implanted. New pedicle screws were inserted at L2 to L5.

A 4-centimetre incision was made over each ilium to expose the bony surface. The sacroiliac drill guide was introduced to place two S2 screws and iliac pilot holes bilaterally under fluoroscopic guidance. The tulip of the lower left iliac bolt stretched the overlying skin and was removed. Consequently, the left iliolumbar rod was shortened intraoperatively (Figs. 5, 7). Operative and clinical performances are listed in Table 2. Our patient recovered well reflected by a reduction in her visual analogue score (VAS) and satisfactory post-operative radiographs (Fig. 7).

Discussion

Pathologies such as infection, stenosis, fractures, painful instrumentation, pseudoarthrosis, adjacent segment disease, post-operative deformity, or non-spinal causes may be individually or collectively responsible for late complications following instrumented lumbar fusion surgery. Depending on the patient-specific indications for revision surgery, a surgeon's plan for corrective surgery may be limited by available equipment and implants. The issues specific to this revision case are listed in Table 1.

"Off-the-shelf" kits for spinal instrumentation are designed for specific indications and can be adapted for revision surgery. For example, anterior approaches to the lumbar spine have been used to achieve a bony fusion after the development of a pseudoarthrosis following posterior lumbar fusion surgery [7]. However, an indirect decompression via an anterior approach may not relieve severe stenosis. Additionally, an anterior interbody cage is not suitable for this patient at L5–S1 due to a collapsed sacral promontory. Further, the patient's age, comorbidity, and previous abdominal surgery may complicate an anterior approach to the anterior vertebral surface.

Posterior approaches using "off-the-shelf" kits are suitable but may not entirely address patient-specific factors,

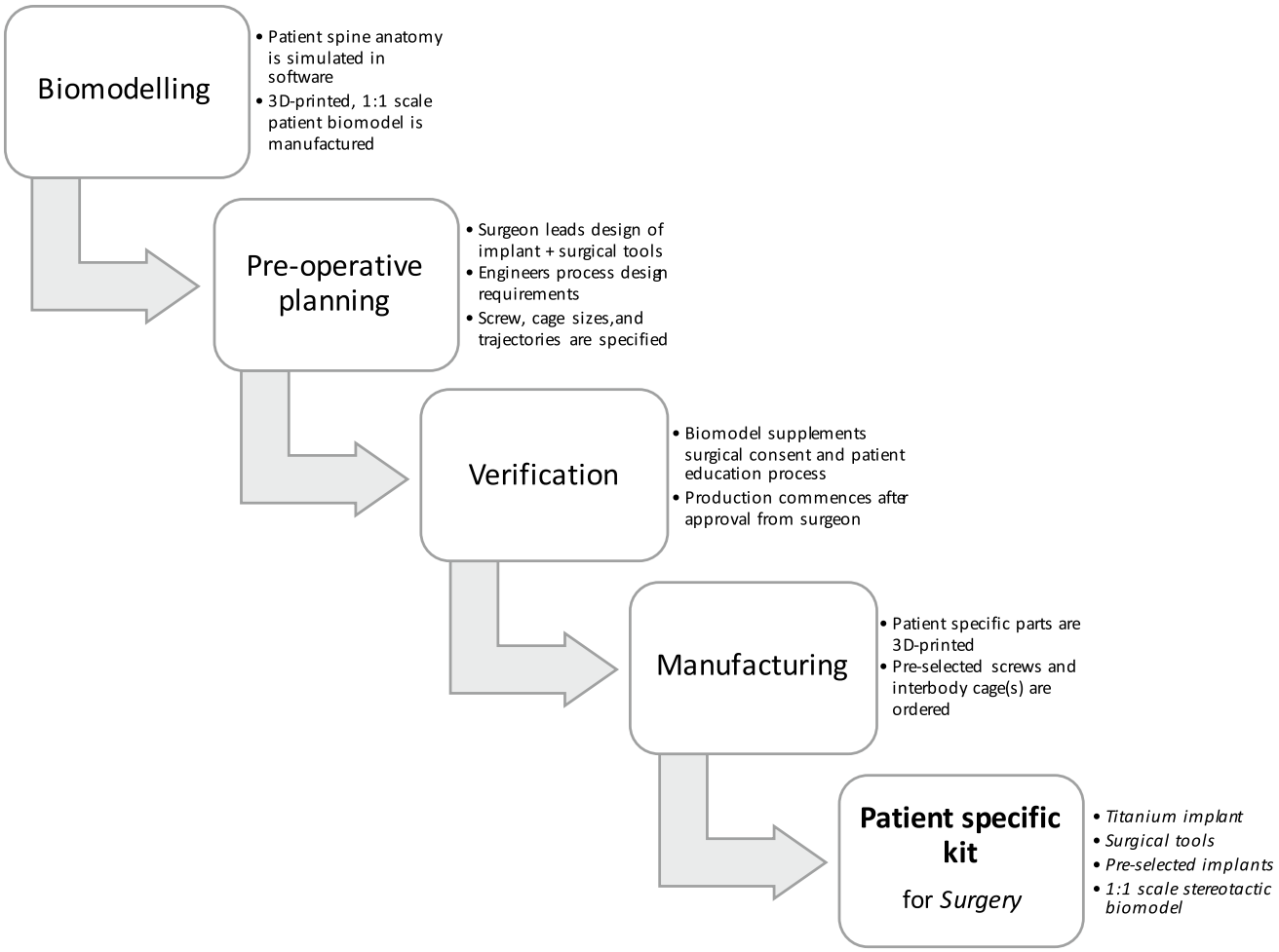

Fig. 3 Process flow diagram demonstrating the key steps in the design process

thereby compromising healthcare efficiencies [8, 9]. Several posterior techniques can adequately correct a pseudoarthrosis at L5–S1 and decompress the left L5 nerve root; we chose to use a minimally invasive transforaminal technique. However, this patient additionally needed the L2–S1 segments stabilized without re-instrumenting S1 as it was predicted replacement S1 pedicle screws would not find adequate purchase.

Consequently, a pelvic anchor was required to secure a long patient-specific rod and provide the necessary stability for bony fusion. An open posterior approach may provide adequate visualization to contour rods but may cost the patient in terms of blood loss, post-operative pain, hospital stay, and rehabilitation time [10, 11]. Further, intraoperative rod contouring significantly reduces the fatigue life [12], especially when biomechanical cadaveric studies show increased strain in rods and S1 screws for long lumbosacral constructs [13]. Additional fixation by way of cross-linkages or "outrigger rods" [14] may overcompensate for biomechanical stability while potentially increasing complexity, operating time, and cost.

Alternatively, a surgeon's pre-operative plan can be combined with biomodelling and rapid manufacturing methods to design, test, and implant patient-specific solutions that address all issues indicating revision lumbar surgery. Biomodelling was used for pre-operative planning, patient education, and intraoperative reference [15] and allows stereotactic guides to be developed for intraoperative use to percutaneously place iliac bolts and S2 screws along predefined trajectories using only 2D fluoroscopy (Fig. 5).

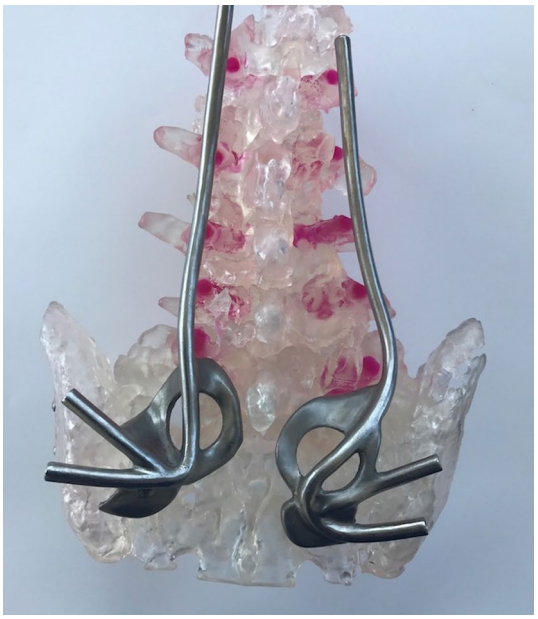

Fig. 4 1:1 scale biomodel of patient's spine with patient-specific 3D-printed titanium implants contoured to match the bony anatomy of the pelvis and desired spinal curvature for revision surgery

Fig. 5 1:1 scale biomodel of patient's spine with patient-specific drill guide designed to contour match the bony pelvis and guide placement of iliac bolts and S2 screws

Table 1 Patient- and surgeon-specific issues guiding design cues

Issue	Design cue
Osteoporosis; collapsed sacral promontory; previous abdominal surgery; L5 foraminal stenosis; L5–S1 pseudoarthrosis	*Approach*: Posterior MIS TLIF *Structural*: No pedicle screw to be placed in S1
Revise L5–S1 interbody cage Decompress S1 nerve root	*Exposure*: Custom self-docking tubular retractors specific to patient tissue depth to aid MIS S1 rhizolysis
Revise L2–S1 posterior fixation	*Structural*: MIS pedicle screw revision at L2, L3, L4, L5 bilaterally
Preserve scoliotic correction and anchor long segment construct to the pelvis	*Structural*: Connecting rods manufactured to planned curvature and continuous with a pelvic anchor
Reinforce long segment construct with a pelvic anchor	*Structural*: Custom pelvic contour matched anchor secured with bilateral S2 and iliac screws
MIS pelvic fixation	*Exposure*: MIS S2 and iliac screw drill trajectory guide

MIS minimally invasive surgery, *TLIF* transforaminal lumbar interbody fusion

The authors found the 3D-printed patient-specific biomodel, tubular retractor, and stereotactic drill guide particularly useful. Minimally invasive techniques typically limit visible patient anatomy. However, the biomodel improved our understanding of surgical anatomy by providing a scale visual and tactile frame of reference. The design of the tubular retractor matched the bony contours of the patient's spine and docked onto the bone, which removed the need for externally braced retraction systems to declutter the intraoperative workspace. Likewise, the contoured surface of the drill guide matched the patient's bony pelvic anatomy to simplify template positioning with minimal tissue dissection. The pre-planned trajectories were easily replicated intraoperatively to assist implantation of S2 screws and iliac bolts without the need for intraoperative image guidance systems.

The performance of this process is measured by an operating time of 291 min, 59 s of fluoroscope screening time, no complications, no blood transfusions, and length of stay of 5 days with a reduction in patient-reported pain scores. In a retrospective review of 112 patients for posterior instrumented revision surgery, the operating time was 280 ± 62 min, 1.04 ± 1.17 units transfused, and a length of stay of 6 ± 2.4 days [16]. Radiation exposure was not reported in this series. However, another series of 40 patients undergoing first-time single-level MIS TLIF reported on average 55.2 ± 11.3 s of fluoroscopic screening [17]. The number of sterile trays used and waste generated is reported to benchmark this process so that healthcare resource allocation is also incorporated into the pre-operative planning process.

Fig. 6 A patient-specific tubular retractor for a minimally invasive transforaminal lumbar interbody approach that is designed to match the tissue depth and contours of this patient's posterior L5–S1 bony anatomy. The retractor is secured to the spine using a cannulated bone screw along the trajectory of the existing S1 pedicle screw

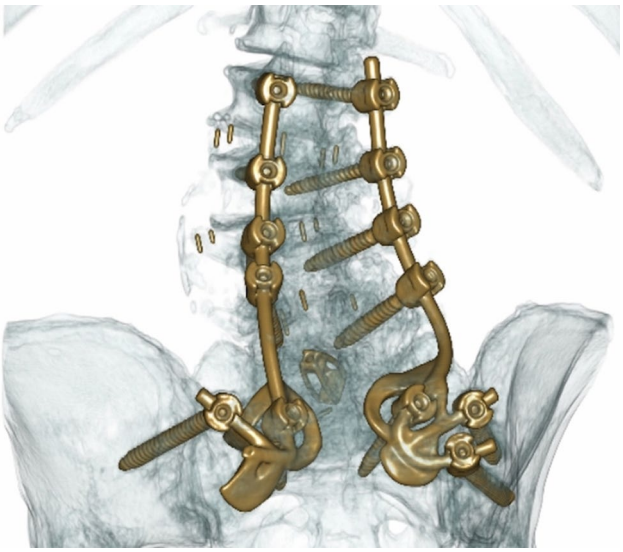

Fig. 7 3D reconstruction using post-operative computed tomography data demonstrating implant position. A second left-sided iliac bolt was not implanted as the tulip may have caused a pressure area. The respective segment of the patient-specific rod was intraoperatively shortened

Conclusion

For revision lumbar fusion surgery, "off-the-shelf" kits limit surgical solutions to a particular set of techniques, surgical tools, and implants, which can potentially compromise patient, surgeon, and healthcare-specific needs. As this single case history highlights, pre-operative planning combined with biomodelling and 3D printing is a viable process that enables the development of patient-specific implants and surgical tools suited to the needs of this clinical presentation. The next patient requiring lumbar revision surgery will present a different set of challenges. However, additive manufacturing techniques are adaptable, and so there is potential to tailor surgical solutions to optimally meet the needs of every patient needing revision lumbar fusion

Table 2 Patient characteristics and operative performance

Age (years)	72
BMI (kg/m^2)	25.4
Operative time (min)	291
Operative aids	Neural monitoring
Sterile trays	18
Contaminated OW (bags)[a]	0.5
Uncontaminated OW (bags)[a]	0.75
Fluoroscope screening time (s)	59
Total complications	0
Blood transfusion	0
Length of stay (days)	5
Pre-operative leg pain VAS	8
Post-operative leg pain VAS	5
Six-month follow-up leg pain VAS	2

BMI body mass index (kilograms per square metre), *OW* operative waste, *VAS* visual analogue score

[a]1 bag = 800 × 500 millimetres of 50 l capacity

surgery. Consequently, a patient's chance of resolving their chief complaint by revision surgery need not be dependent on their suitability to a limited set of techniques and implants.

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Compliance with ethical standards

Conflict of interest Mark Owbridge is an employee at Anatomics Pty Ltd. Robert Thompson is an employee at Anatomics Pty Ltd. Paul D'Urso is a director and shareholder at Anatomics Pty Ltd and has received funding from Stryker Corporation, Epworth Healthcare, and Anatomics Pty Ltd.

Ethical standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for this study was obtained from Epworth Healthcare Human Research Ethics and Research Governance Committees (HREC2017-254).

Human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent for surgery was obtained from all individual participants included in the study.

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