A clinician-run 3D-printing laboratory for orthopaedic preoperative planning: an illustrative case series

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Abstract

Background

Orthopaedic surgery often benefits from innovation in biomedical engineering, with 3D printing being one of the latest examples. Proving cost-effectiveness and improved clinical outcomes remains challenging. Because of the reduced cost and increased accessibility, it has been possible to start an orthopaedic 3D-printing laboratory in a South African tertiary hospital, exploring the place for this emergent technology in orthopaedic practice. This case series aims to illustrate the clinical use of 3D-printed anatomical models and investigate the time and cost involved in their manufacture.

Methods

The design and manufacturing process is discussed, and a retrospective descriptive case series is presented of all models manufactured from January 2020 to April 2021. Using three illustrative cases, we elaborate on two main usage situations: intraoperative reference models (haptic maps) or rehearsal and templating (simulation models).

Results

In the study, 3D-printed anatomical models were manufactured for 16 patients. For 12 patients, these were simulation models, and for the other four patients, haptic maps were made. The mean time for manufacture was 33 hours (range 8–62), and the median cost per patient was ZAR 3 257.62 (range ZAR 927.17 to ZAR 7 177.09).

Conclusion

Considering the decreasing cost and ease of using 3D-printing technology, starting a clinician-run orthopaedic 3D-printing laboratory at a South African training hospital has become possible. In this series we illustrate how 3D printing has been used at our unit for planning and rehearsal of a wide range of orthopaedic cases, and we establish a baseline of time and cost expenditure. The cost-effectiveness of implementing 3D-printing technology in everyday orthopaedic practice warrants further investigation.

Level of evidence: Level 5

Keywords: additive manufacturing, 3D printing, orthopaedic preoperative planning, orthopaedic surgery

Introduction

Orthopaedic surgery has often benefitted from innovation in biomedical engineering, with additive manufacturing (AM) and 3-dimensional printing (3DP) being some of the most recent advances. AM refers to the process that builds 3D geometries by successive addition of material, with 3DP being one of the employed production techniques.[1,2] New technologies are often expensive and technically inaccessible, progressively becoming more affordable and user friendly as refinements and developments occur.[3] In the field of AM, this process has been accelerated by foundational patents having lapsed in the 2000s, drastically reducing costs.[4]

Improved accessibility and the intuitive knowledge that having a 3D model of the patient's anatomy will aid the understanding of the pathology has resulted in many orthopaedic surgeons exploring 3DP.[5-7] Clinical applications have included anatomical models for preoperative planning and surgery rehearsal, production of patient-specific instrumentation, manufacture of patient-specific implants and bioprinting.[8,9] In their 2015 review of 3DP in medicine, Tack et al. reported on 227 papers that included 270 cases. In 45% of these cases, 3DP was used to produce patient-specific implants and anatomical models for planning orthopaedic surgeries. Most articles (72%) reported improved clinical outcomes, although quantitative data supported only 10% of these reports. Interestingly, 33% of studies mentioned an increased associated cost, while 64% of studies did not report cost at all, reiterating that cost is still an essential factor to consider.[10]

In 2018 we founded an in-house orthopaedic 3DP laboratory in collaboration with the Institute of Biomedical Engineering (IBE) at Stellenbosch University (SU) to explore the place for this emergent technology in orthopaedic practice and training. Since inception, we have identified several ways that 3DP could improve the

planning of surgical procedures, the way we evaluate orthopaedic pathology and how we train future orthopaedic surgeons by adding haptic perception to traditional visual-only planning techniques.

This retrospective, descriptive case series aims to illustrate the clinical use of 3D-printed anatomical models and investigate the time and cost involved in their manufacture.

Methods

Design and manufacturing process

The primary surgeon proposed cases, usually because they faced new clinical situations and wanted to augment their established planning techniques or rehearse the case in the lab to compare different plans. They would then discuss the pathology and their surgical plan with our biomedical engineering team member. To create an anatomical 3DP model, high-quality volumetric imaging (CT/MRI scans) is required. All images were anonymised using the Philips Picture Archiving and Communication System (PACS) viewing software package (Philips iSite; Philips Healthcare, Andover, MA, USA) and assigned a unique patient identifier code. Institutional ethics approval was obtained before creating any models.

Images were then imported into software for segmentation. Image segmentation refers to the process of creating a digital shape (surface mesh) from the scan data using a set of digital tools. Both open-source software, like 3D Slicer (Slicer Community) and licenced software, like Rhino3D Medical (Mirrakoi SA, Switzerland), were used for image processing.

When the desired areas of bone had been separated from the surrounding soft tissue, the surface meshes were exported as surface geometry files (*.stl or *.obj) and imported into 3D-modelling software, e.g. Meshmixer (Autodesk Inc., San Rafael, Calif) or Blender (Blender Foundation, Amsterdam, The Netherlands), to smooth and mark the 3D model with the pre-generated patient identifier codes.

When the models were ready for printing, they were uploaded into a slicing software package specific to the 3D printer that was going to be used (e.g., Simplify3D [Simplify3D, Ohio, USA] or Z-SUITE [Zortrax, Poland]). Two 3D printers are currently being used in our laboratory, both acquired through institutional equipment grants: the Leapfrog Bolt Pro (Leapfrog Co., Alphen aan den Rijn, Netherlands) and the Zortrax M300 Dual (Zortrax SA, Olsztyn, Poland). Both use fused deposition modelling (FDM) technology, creating an object by layering melted plastic filament. The choice of printing material largely depended on the intended applications of the model, with some materials being tougher and more resistant to heat and chemicals than others. The final part of the workflow was post-processing, consisting of cleaning the newly printed models and preparing them for use (e.g. removing support material, ethylene oxide gas sterilisation and packaging). *Figure 1* illustrates the design and manufacturing workflow.

In manufacturing and using the models, we identified two distinct usages that influence how the models were designed: models for reference only and models for surgical simulation. We refer to models intended for intraoperative reference as haptic maps. The exterior surface of these models was the primary priority, while the internal architecture of the bone could be ignored during the segmentation process. In these instances, care was taken in choosing the material and the sterilisation process as some materials deform when subjected to the high temperatures and pressures in an autoclave.

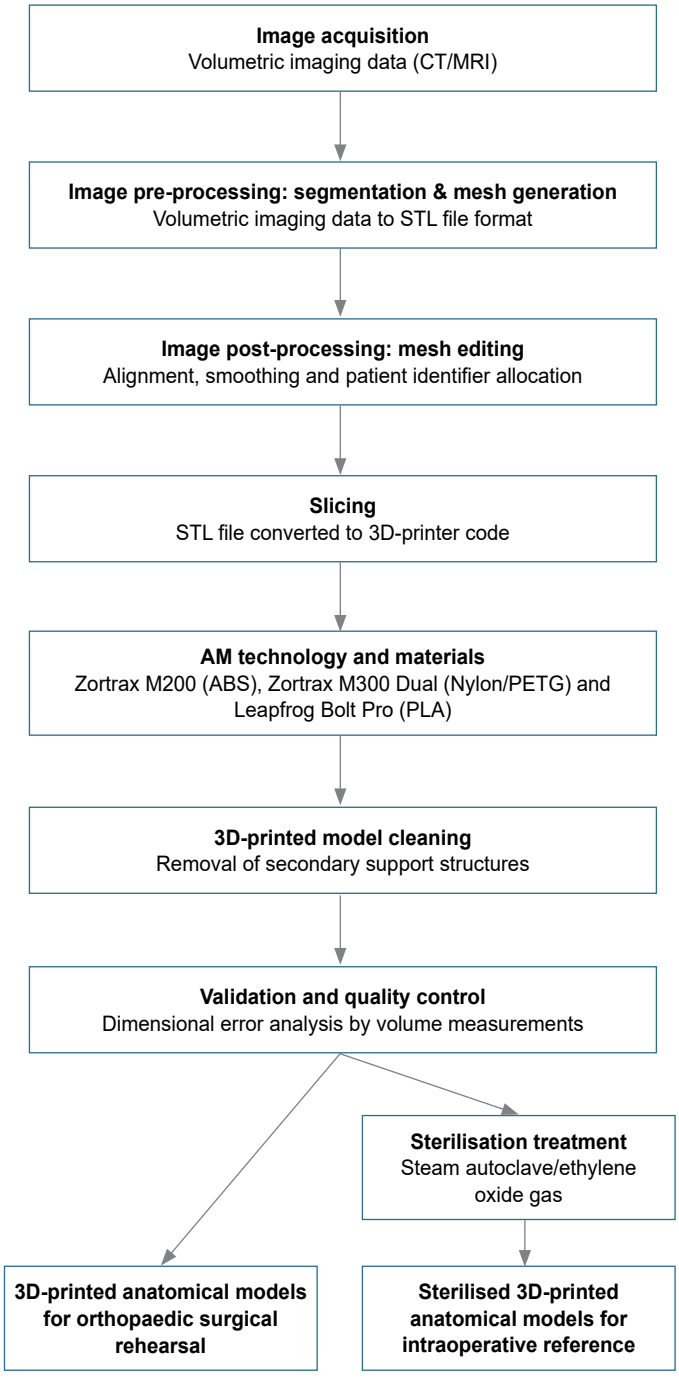

Figure 1. Flow diagram of the design and manufacturing process

In contrast, a simulation model was produced when surgical rehearsal was planned. In these cases, the model's internal architecture was critical to simulate a procedure realistically (e.g. broaching the femoral canal when simulating total hip replacement). Most filaments in use can be cut and reamed with power tools and standard orthopaedic instrument sets, allowing a situation to be realistically simulated using the instrument trays and trial implants planned for the definitive surgical procedure.

Data collection

A retrospective, descriptive review of cases between January 2020 and April 2021 was undertaken.

'Total manufacturing time' was calculated as the sum of 'labour time' (time spent on the segmentation process, slicing and post-processing) and '3D printing time'.

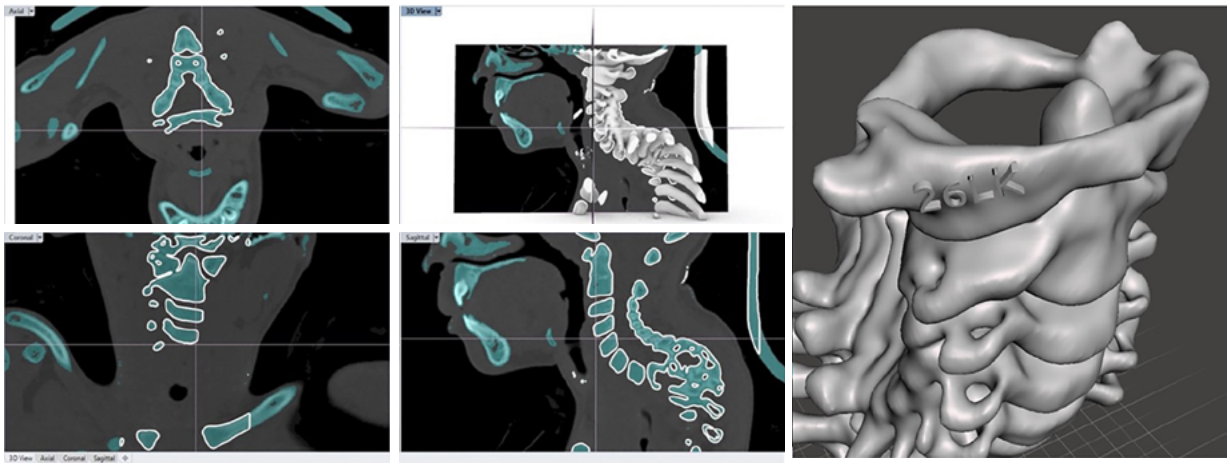

Figure 2. Segmentation process (left) using Rhino3D Medical (Mirrakoi SA, Switzerland) to create an initial surface mesh based on CT data. Finished surface mesh (right) modelled in Meshmixer (Autodesk Inc., San Rafael, Calif).

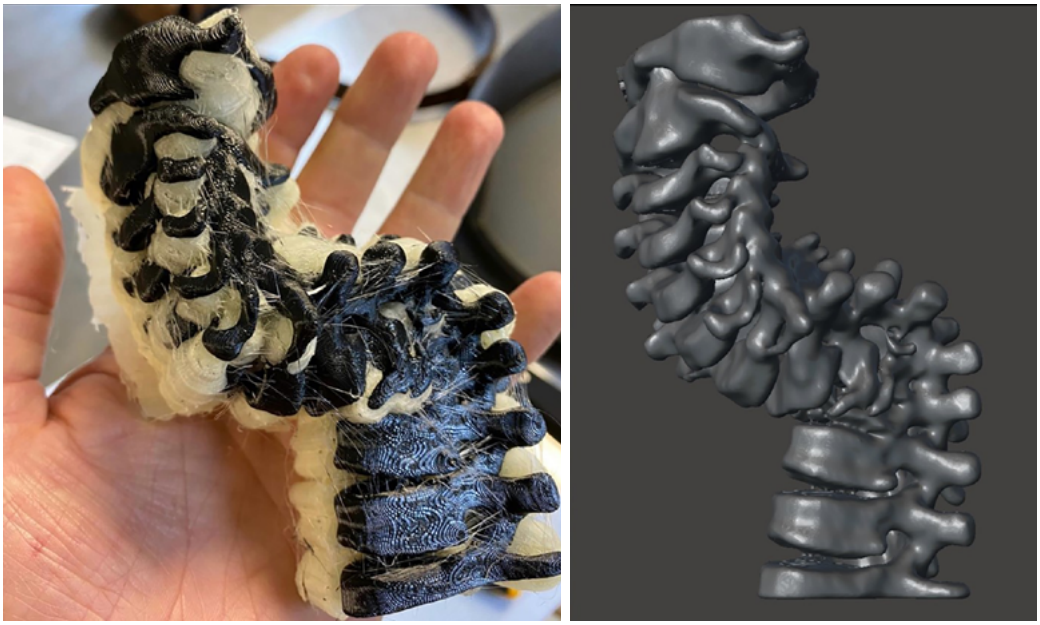

Figure 3. The final model manufactured in PETG (black) with water-soluble support material (white) shown immediately after manufacturing

Each case's 'total cost' was determined using a cost analysis model developed at our lab with the help of the IBE, according to the following formula:

$C_{total} = C_{lab} + C_{mat} + C_{mach}$

where C_{total} is the total cost; C_{lab} is the labour cost per hour (image segmentation, mesh processing, slicing and removal of secondary support structures); C_{mat} is the material cost per gram (3DP filament); and C_{mach} is the machine running costs per hour (calculated according to annual maintenance and depreciation rate).

Values for each of these variables change depending on: the operator doing the work (experienced vs inexperienced operator); 3D printer used (Leapfrog Bolt Pro vs Zortrax M300 Dual); and specific filament chosen and how much the filament cost at the time of purchase: acrylonitrile butadiene styrene (ABS) vs polylactic acid (PLA) vs polyethylene terephthalate glycol (PETG) vs Nylon. Values used for the different variables are shown in *Table I*. Time and cost were calculated per patient because, in some instances, multiple models were used to rehearse a case more than once.

Table I: Values to be substituted for variables in 'total cost' (C_{total}) calculation equation

Labour costs (C_{lab})	Senior lab technician/ experienced operator	ZAR 519.11 per hr (post level 5)
	Junior lab technician/ inexperienced operator	ZAR 300.92 per hr (post level 7)
Material costs (C_{mat})*	Wanhao PLA, 1.75 mm, natural	ZAR/g 0.35
	Wiiboox PLA, 1.75 mm, white	ZAR/g 0.41 (range ZAR/g 0.41 to ZAR/g 0.56)
	Zortrax ABS, 1.75 mm, white	ZAR/g 0.66 (range ZAR/g 0.50 to ZAR/g 1.10)
	Zortrax PETG, 1.75 mm, black	ZAR/g 0.82
	Zen Nylon, 1.75 mm, white	ZAR/g 0.47
Machine costs (C_{mach})	Zortrax M200 FDM	ZAR/hr 31.49
	Zortrax M300 Dual FDM	ZAR/hr 50.65
	Leapfrog Bolt Pro FDM	ZAR/hr 64.17

*Filament cost per gram (ZAR/g) can vary as prices fluctuate.

Table II: Detailed summary of 3DP anatomical models manufactured from January 2020 to April 2021

Case number	Anatomy	Diagnosis	Usage	3D printer	Material	3D printing time (hr)	Labour time (hr)	Total manufacturing time (hr)	Total cost (R)	Notes
No 1: 22JS	Right femur	Femoral non-union	Haptic map	Zortrax M200	Zortrax ABS filament 1.75 mm, white	32.73	9.97	42.70	4 267.94	Bridge of callus that needed resection; model for intraoperative reference
No 2: 24JB	Right scapula and humerus	Osteoarthritis of the shoulder	Simulation model	Zortrax M200	Wanhao PLA filament 1.75 mm, natural	18.22	21.77	39.98	7 177.09	Planned reverse total shoulder arthroplasty, concern about the amount of glenoid bone stock available
No 3: 21AM	Left and right; hemipelvis and femurs	Slipped capital upper femoral epiphysis	Simulation model	Zortrax M200	Zortrax ABS filament 1.75 mm, white	39.75	15.45	55.20	6 322.12	Severe slip of epiphysis, concerned whether hip was 'pinnable'; later used for surgical simulations by trainee surgeons
No 4: 26LK	C-spine and upper T-spine	TB spine	Haptic map	Zortrax M300 Dual	Zortrax PETG filament 1.75 mm, black	31.27	3.37	34.63	2 686.50	Destruction of multiple vertebrae; used in theatre as intraoperative reference
No 5: 27DS	Left proximal femur and hemipelvis	Developmental dysplasia of the hip	Simulation model	Zortrax M300 Dual	Zortrax PETG filament 1.75 mm, black	39.73	3.13	42.87	3 186.96	Planning of femoral and pelvic osteotomies
No 6: 28JJ	Left pelvis and proximal femur	Previous septic arthritis	Simulation model	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	25.42	5.23	30.65	3 328.29	Superior migration of acetabulum and destroyed femoral head; concern about support for the acetabular component
No 7: 29TD	Right hemipelvis and proximal femur	Developmental dysplasia of the hip	Simulation model	Zortrax M200	Zortrax ABS filament 1.75 mm, black	21.42	3.87	25.28	2 103.38	Planning of femoral and pelvic osteotomies
No 8: 30CR	Left radius, ulna and distal humerus	Radial clubhand, previous osteotomy	Simulation model	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	12.45	8.57	21.02	3 409.55	Previously implanted hardware was removed digitally. For planning new osteotomies and templating a new fixation device
No 9: 31AD	Right radius, ulna and distal humerus	Radial clubhand	Simulation model	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	12.53	3.02	15.55	1 743.15	For planning new osteotomies and templating a fixation device
No 10: 32NT	Left tibia	Adolescent Blount's disease	Simulation model	Zortrax M200	Zortrax ABS filament 1.75 mm, white	5.35	2.30	7.65	929.22	MRI was done to assess for bony bars across the growth plate; model manufactured to plan osteotomy
No 11: 33RV	Right foot, tibia and fibula ×2	Resistant clubfoot	Simulation model	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	56.37	5.25	61.62	5 424.45	A decision was made to treat with gradual frame correction; model used to pre-build the frame
No 12: 34RB	Right hemipelvis and proximal femur	Previous septic arthritis	Haptic map	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	24.42	2.12	26.53	2 348.43	Marked superior migration of acetabulum; used as intraoperative reference
No 13: 35CH	Right foot, tibia and fibula ×2	Residual clubfoot	Simulation model	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	29.05	5.20	34.25	3 587.27	A decision was made to treat with gradual frame correction; model used to pre-build the frame
No 14: 36ND	Distal humerus	Malunion of Milch-type lateral condyle fracture	Haptic map	Leapfrog Bolt Pro	Wiiboox PLA filament 1.75 mm, white	6.37	1.60	7.97	927.17	Both CT and MRI were available to aid in the design of the model; printed enlarged version (50% bigger)
No 15: 37TB	Right hemipelvis and proximal femur	Developmental dysplasia of the hip	Simulation model	Zortrax M300 Dual	Zen Nylon filament 1.75 mm, white	53.15	1.83	54.98	3 331.97	Planning of pelvic and femoral osteotomies
No 16: 39AE	Right scapula and humerus	Osteoarthritis of the shoulder	Simulation model	Zortrax M200	Zortrax ABS filament 1.75 mm, white	18.67	2.60	21.27	1 497.46	Planned reverse total shoulder arthroplasty; concern about glenoid bone stock

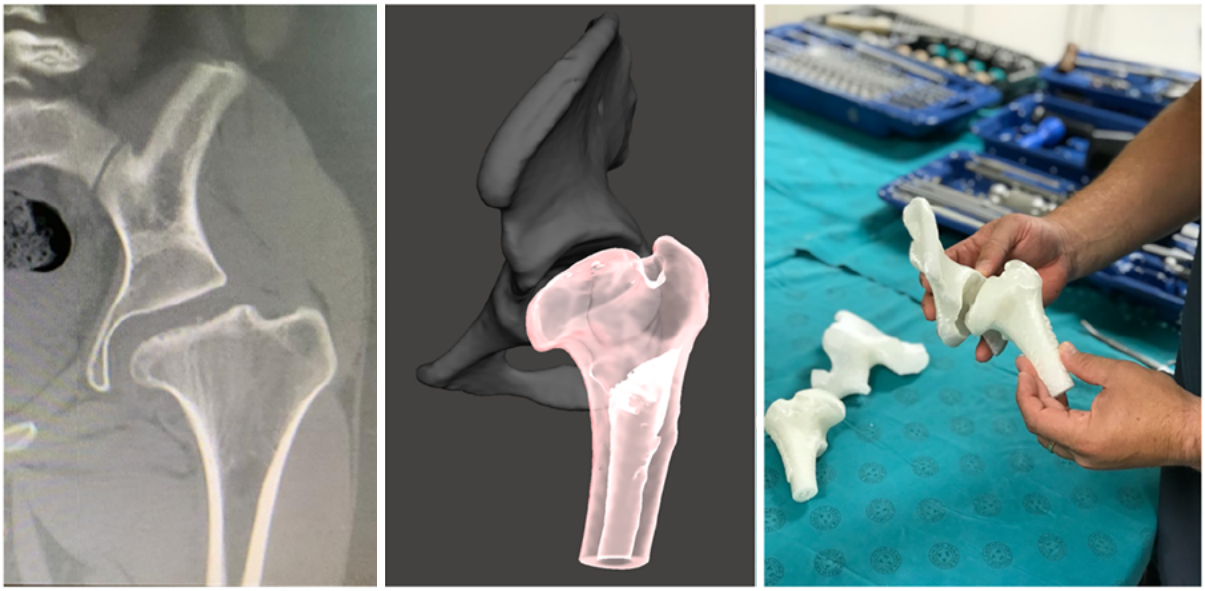

Figure 4. Design process of simulation models for pre-surgical rehearsal of THA. PLA 3D printing filament was used to produce the final product.

Results

From January 2020 to April 2021, 3D-printed anatomical models were manufactured for 16 patients. The series showed significant variation in pathology and anatomy. Most instances (n = 7, 44%) were paediatric reconstructive procedures, including four hip pathologies, two foot deformities and one post-traumatic elbow deformity case. When considering that both hand surgery cases, both hip arthroplasty cases and one limb reconstruction case was also for original paediatric orthopaedic pathology, it is clear that paediatric pathology dominated the indications for acquiring 3DP models. For 12 patients, these were simulation models, and for four patients, these were haptic maps (*Table II*).

The mean 'total manufacturing time' was 33 hours (range 8–62). The mean 'total manufacturing time' for the haptic map group was 28 hours (range 8–43), and for the simulation model group was 34 hours (range 8–62). The mean 'labour time' was 5.95 hours (range 1.60–21.77). There were two outliers in this group of 21.77 hours (case 24JB) and 15.45 hours (case 21AM) respectively, both 'simulation models'. In both cases the segmentation process was technically difficult and took longer than usual. Mean '3D printing time' was 26.68 hours (range 5.35–56.37). The variability in this group was primarily because of model size, complexity or the number of models required for repeated rehearsals.

The median 'total cost' per patient were ZAR 3 257.62 (range 927.17–7 177.09). The median 'total cost' for the haptic map group and the simulation model group was ZAR 2 517.46 (range 927.17–4 267.94) and ZAR 3 330.13 (range 929.22–7 177.09), respectively. Details regarding the time and cost involved in each case are listed in *Table II*.

Examples of unique usage

Example 1: Haptic map for TB spine with multilevel deformity

A 7-year-old patient presented with pronounced kyphosis secondary to multilevel vertebral body destruction in the upper thoracic spine. The diagnosis of TB spine was made, and reconstruction was planned after an initial period of skeletal traction. A haptic map was requested to augment the initial surgical planning, characterise the deformity better and take it to theatre as an intraoperative reference. *Figure 2* demonstrates the segmentation process (left) and the completed surface mesh (right). The model was designed

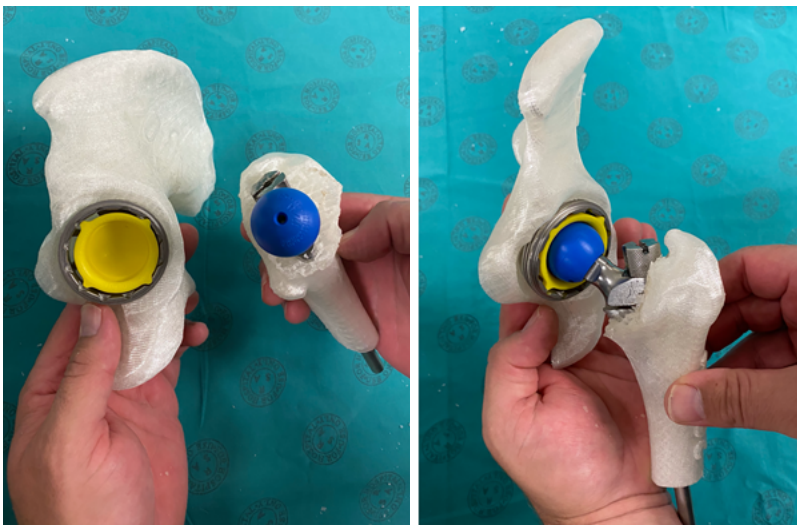

Figure 5. Simulation model of left hip from Figure 4 after rehearsal, showing trial implants in situ

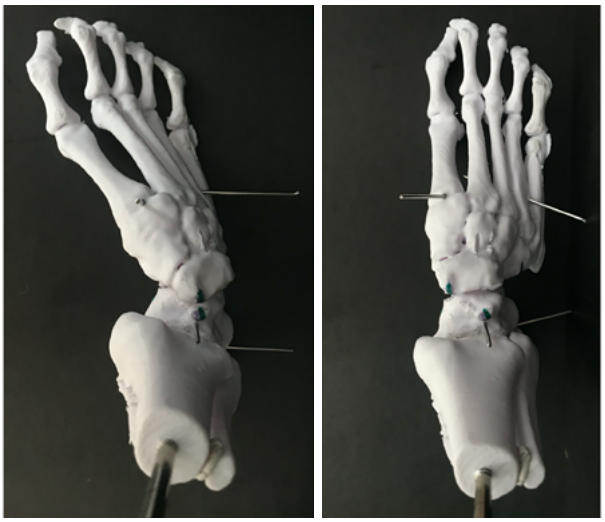

Figure 6. Simulation model to rehearse recurrent clubfoot correction. The model was designed to break apart at the level of the midfoot. K-wires indicate reference axes, and the amount of rotation required could be quantified accurately.

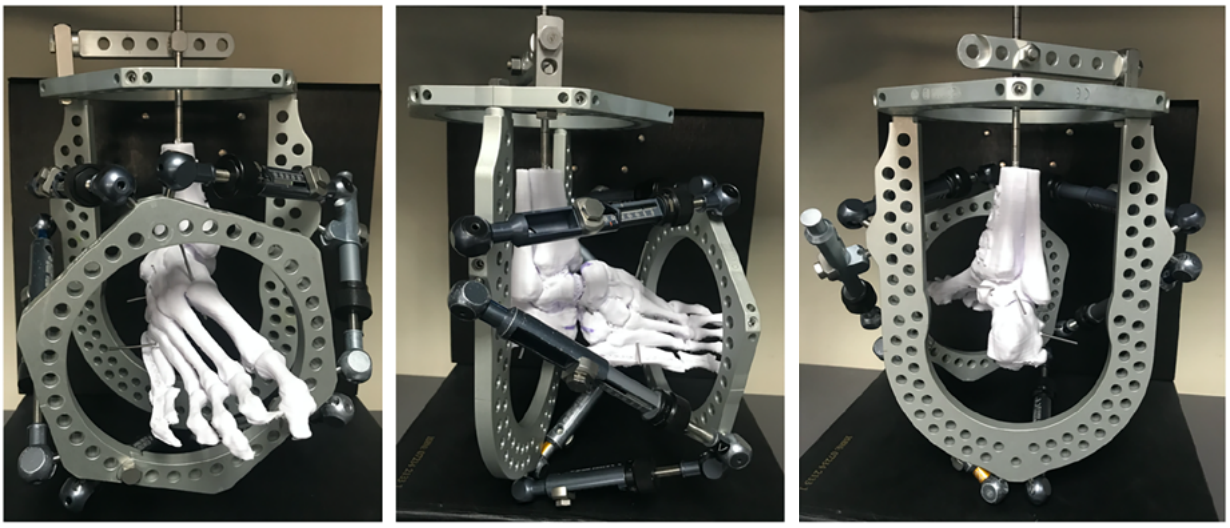

Figure 7. The model in Figure 6 being used to pre-build the butt frame for gradual correction

to be full scale and printed with PETG that is relatively heat resistant and could be sterilised. A white soluble support filament was used during printing to make post-processing time shorter (*Figure 3)*.

Example 2: Simulation models for rehearsal of total hip arthroplasty (THA) in achondroplastic dwarfism

An 18-year-old female known with achondroplastic dwarfism had developed arthritis of both hips. Considering the patient's small stature and the amount of dysplasia, there was uncertainty whether conventional arthroplasty implants would be appropriate or if patient-specific custom-made implants would be required, even after conventional digital planning was employed.

Two sets of simulation models, right and left, were manufactured to rehearse the procedures (*Figure 4*). The femoral canals were included in the design, and the hemipelvii were each designed so that putting them flat on a table simulated the patient lying in the lateral position. The ideal implant sizes and optimal implant positions could be determined preoperatively by rehearsing the procedure with the manufacturer sets and trial implants in the 3DP lab (*Figure 5*). This confirmed that patient-specific custom-made implants were unnecessary, reducing the potential cost of the operation.

Example 3: Simulation models for preoperative frame application in recurrent clubfoot deformity

A 16-year-old patient presented with a recurrent clubfoot deformity and was treated with soft-tissue procedures. After a second recurrence, gradual correction with an external fixator was planned. A simulation model was manufactured to characterise the deformity better and establish the rotation needed to realign the foot (*Figure 6*). The model was designed so that the midfoot could be broken apart at the level of the talonavicular and calcaneocuboid joints to simulate movement at the joints. The model was then used to pre-build a hexapod circular external fixator butt frame optimally and ensure that the minimum strut exchanges would be needed during the correction (*Figure 7*).

Discussion

Because of the reduced cost and increased accessibility, it has become possible to make 3DP part of practice and training in the orthopaedics department of a South African tertiary hospital. The current literature discusses various potential uses in orthopaedic surgery, from improved communication with patients and simulating basic procedures to sub-specialist surgeons' planning and rehearsal of advanced pathology.[10-12] Our study focuses on the use of 3DP anatomical models to plan and simulate critical steps in a surgical procedure, taking a part of the embodied learning experience out of the high-stress environment of the operating room.[13]

Proving cost-effectiveness and improved clinical outcomes will remain challenging due to the complexity of the cases for which 3DP is typically used. Advanced pathology and abnormal anatomy necessarily mean limited case controls for comparison and imply multiple factors that affect the traditional measures like theatre time, fluoroscopy use, blood loss and hospital stay. Even so, in their 2019 systematic review about the applications of 3DP in orthopaedic trauma, Morgan et al. collated data from 17 studies, representing a dataset of 922 patients.[11] The most consistently measured outcomes were surgical time, intraoperative blood loss and fluoroscopic exposure. Overall, they found a 20% reduction in theatre time, a 25% reduction in intraoperative blood loss and a 28% reduction in fluoroscopic usage.[11]

In the same review the reported costs varied widely from $2 (ZAR 30) to $330 (ZAR 4 951). The range in our lab varied from ZAR 927.17 to ZAR 7 177.09. The likely cause for this wide variation in the literature is a lack of standardisation regarding cost calculation and reporting. The lower values in the ranges are likely only to include filament cost, and the higher values are likely to incorporate a range of factors, including labour cost. These inconsistencies in the literature complicate an assessment of cost-effectiveness and limit comparison with our lab. The total manufacturing time (3D printing time and labour time combined) in our lab was 8–62 hours and is comparable to the reviewed studies, where times ranged from 5–72 hours, even though it is likely that similar inconsistencies regarding calculation and reporting are present.[11]

Regarding the use of 3DP in orthopaedic surgical planning specifically, there has been a gradual increase in publications since 2015, especially single case studies.[12] A recurrent theme in these articles is the need for close communication between the clinicians and the engineers providing the design and manufacturing service. This paper illustrates how the process could be streamlined by developing the capacity to design and manufacture these models in-house. Since starting the lab, we have identified the need to differentiate the models for planning (collectively referred to as anatomical models in some publications) into simulation models and haptic maps, each with a different design philosophy.[10] Their applications are illustrated in the three case studies above.

Limitations of this series include its retrospective nature and the fact that no intraoperative metrics on the effect of 3DP models

during surgery were recorded. This is partly because these cases had advanced pathology without obvious case controls for comparison. This article also did not discuss the potential of creating patient-specific instrumentation in the form of drill and cutting guides. Continuing research in our lab focuses on validating the design and manufacturing process, ensuring that the shapes and sizes of the models remain accurate after sterilisation.

Conclusion

Considering the decreasing cost and ease of using 3D-printing technology, starting a clinician-run orthopaedic 3DP lab at a South African training hospital has become possible. In this series we illustrate how 3DP has been used at our unit for planning and rehearsal of a wide range of orthopaedic cases, and we establish a baseline of time and cost expenditure. The cost-effectiveness of implementing 3D-printing technology in everyday orthopaedic practice warrants further investigation.

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Ethics statement

The authors declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Ethical approval for this study was obtained before the commencement of data collection from the Health Research Ethics Committee (HREC) of Stellenbosch University: S20/08/190.

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Declaration

The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

Author contributions

RGV: conceptualisation, study design, preparation of case studies, data analysis, manuscript preparation and manuscript review

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