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Joint preservation in revision arthroplasty and intercalary tumour implants using custom stem solutions

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Abstract

Background Off-the-shelf stems offer a wide variety of fixation methods for revision arthroplasty and intercalary tumour implants. However, in extensive defects or needed resection with minimal bone stock left, solid fixation is often not feasible with these implants. Custom-made stem solutions (CSS) offer a viable alternative in these cases to achieve joint preservation.

Methods Between 2017 and 2024 14 patients (15 implants) were treated in a single-centre study. CSS were indicated if the remaining bone stock was deemed insufficient for normal stem fixation due to tumour resection or previous operations. Postoperative analysis was conducted to evaluate the functional outcome as well as revision rates.

Results Implantation was possible in all cases, during the follow-up of 30 (SD 18; 6–66) months revision was needed in five cases; with one aseptic loosening, one screw loosening and three PJI cases. Mean MSTS score was 24 (SD 5; 17–30).

Conclusion Custom-made stem solutions show promising results in extreme cases. Especially as a preservation of the joint is possible, this treatment algorithm should be considered on a case-by-case basis.

Keywords rTKA, rTHA, Intercalary implants, Revision arthroplasty, Custom implants, Tumor endoprosthesis

Introduction

In recent years, custom-made orthopaedic implants have emerged, especially for extensive acetabular defects, these implants have proven to be a viable alternative compared to off-the-shelf implants and often the last viable option preventing a girdlestone situation [1]. However, extra-acetabular individual implant usage, particularly in revision arthroplasty is sparse. As re-revision rates continue to rise, the need of megaprosthesis reconstruction is becoming more prevalent [2]. In addition, insufficient bone stock to support standard stem solutions is increasing. Typically, in these cases, prosthesis conversion to a complete bone replacement, e.g. a total femur or humerus replacement, was the only option [3].

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As known, these implants suffer from high complication rates, often resulting in a secondary amputation [4]. However, as implant surfaces as well as CAD-CAM manufacturing becomes more prevalent, new techniques are available [5]. While only few custom-made stem solutions stem (CSS) have been published, most often for tumour cases, acceptable revision rates and promising outcomes are reported [6]. Especially in intercalary implants, highly porous short stems (HPSS) show promising results [7]. Adapting the fixation methods established in these cases as well as taking into consideration the special requirements in revision arthroplasty setting solutions for joint and limb preservation in revision and tumour settings were developed. Especially as the remaining bone stock encountered in older patients and in revision arthroplasty is expected to be worse. The aim of this study was to evaluate the functional outcome as well as the complication rate in these cases and establish a design algorithm for this treatment option.

Materials and methods

Between 2017 and 2024 a consecutive cohort of 14 patients with 15 custom-made stems were included as a single-centre study at a referral arthroplasty centre. In eight cases a custom-made highly porous stem was combined with an intercalary implant for tumour cases as either a primary ($n=3$) or revision solution ($n=6$). In four cases a custom-made stem was combined in a revision arthroplasty setting ($n=2$ rTKA, $n=1$ revision shoulder / elbow arthroplasty). Manufacturing was conducted by two companies (Implantcast, Buxtehude, Germany; Waldemar Link, Hamburg, Germany). In four patients the implant was planned for the upper, in 10 for the lower extremity (UE, LE). Indications for CSS were periprosthetic joint infection (PJI) ($n=4$), aseptic loosening ($n=4$), tumour resection ($n=6$) and one pathological fracture. Perioperative antibiotic prophylaxis was administered as a single- or double-shot depending on the time of surgery. In PJI cases the perioperative antibiotic therapy was based on the pathogens found and continued afterwards in a standard therapy regime. The baseline mean data were as followed: Age 49 (SD 20; 15–83) years, Charleson Comorbidity Index 4 (SD 3; 2–11), previous operations 2.6 (SD 1.8; 0–7). To evaluate the algorithm a follow-up of 6 months was deemed to be sufficient to assess early loosening and complications. No patient was lost to follow-up. Detailed patient data are shown in Table 1. Ethical approval was obtained prior to the investigation from the local ethics committee (reference number 21-10438-KOBO) for patients treated with the C-FIT 3D System, otherwise single individual consent was obtained.

Observed indicators

Due to the heterogenous study group, functional outcome was measured using the Musculoskeletal Tumour Society (MSTS) Score. Scores were collected at the latest follow-up. To evaluate the treatment algorithm, all cause as well as infection-related revisions were recorded. Additionally, radiographic osseointegration was assessed in cases where highly porous stems were used.

Data analysis was performed using the Statistical Package for Social Sciences Software (IBM SPSS Statistics Version 24, Chicago, IL). Descriptive statistical results were recorded to describe comorbidities, complications, previous procedures. Shapiro-Wilk test was performed to determine non-normal/normal distribution. Due to the heterogenous study group and small sample size, statistical tests for significant risk factors were not conducted.

Implant design

In all patients a thin-slice CT scan was conducted preoperatively to determine bone stock, defect volume, anatomic landmarks and possible additional fixation methods (e.g. screws or flanges). Two-stage exchange was chosen in cases where (I) an infection, (II) a fracture risk due to tumour growth or (III) metal artifacts reducing the planning safety were present. After the CT-Scan a CAD/CAM model was assembled by an engineer, afterwards in a close cooperation with the head surgeon, a 3D model was conducted based on the fixation needs. All implants were produced as a titanium aluminum vanadium alloy (TiAl6V4) using electron beam melting technology (EBM®). Highly porous surfaces were manufactured by both companies in an additive manufacturing process, similar to the surface used in "off-the shelf" implants with the following parameters: (I) Epore® (Implantcast) Porosity 61% ± 8%, Specific E-Module 3.1 GPa±0.6 GPa, Rod diameter 360 µm±50 µm, (II) Trabeculink Porosity 70%, Pore diameter 610–820 µm. The implant design philosophy consisted of several steps as shown in the treatment algorithm flowchart in Fig. 1.

The principles were as followed: (I) Osseointegration was the main aspect, therefor uncemented fixation was planned if possible. (II) If native bone marrow with a diameter of at least 20 mm was present, e.g. in tumour cases after primary resection and spacer implantation, hollow stems were planned, otherwise solid octahedron shaped stems were planned (III) To ensure best possible fixation, flanges were added in the later designs with the option of combined flange – stem screw fixation. We consider these especially vital in HPSS (≤6 cm) (IV) Additional screw fixation was conducted to reduce rotational forces (V) Highly porous structure was added in all cases where bone contact was present, including the flange backside. If bone resection was planned, additional patient specific instruments (PSI) were planned to ensure

Table 1 Detailed patient data

Patient	Age	Indication	Surgical procedure	Implant	Custom-made part	Stem length	Flanges	Screws	Revision	Follow-up (months)	MSTS Score
1	66	PJI	Two-stage	rTKA: DFR and PTR	HPS tibial	75	0	1	Amputation	66	n/a
2	59	Tumour (primary)	Two-stage	ITP	HPSS tibial	10	2	2	Amputation	14	n/a
3*	33	Tumour (primary)	Two-stage	ITP	HHPS tibial	50	2	2	Screw removal	50	28
4*	76	Tumor (metastasis)	One-Stage	ITP	HPSS tibial	55	0	0	No	6	n/a
5*	83	Tumor (metastasis)	One-Stage	ITP	HHPS tibial	42	0	2	No	/	n/a
6	15	Tumour (primary)	Two-stage	IHP	2x HPSS humeral	35 / 25	1/2	2/4	No	46	30
7	63	Aseptic loosening	One-Stage	IFP	HHPS femoral	65	2	3	No	41	25
8	62	Aseptic loosening	One-Stage	Reverse tumour shoulder prosthesis	Humeral stem with screw fixation	80	0	3	No	37	17
9	56	Tumor (metastasis)	One-Stage	IHP	HPSS humeral	25	2	4	Repositioning	36	27
10	51	Aseptic loosening	One-Stage	rTKA: DFR	HPS femoral	70	1	2	No	26	22
11	64	PJI	Two-stage	Revision total elbow prosthesis	HPS humeral	70	1	2	No	19	19
12	36	PJI	Two-stage	rITP	HHPS tibial	45	2	3	No	15	19
13	36	PJI	Two-stage	rTKA: DFR	Cemented femoral stem	120	0	2	No	10	27
14	33	Aseptic loosening	One-Stage	rIFP	HPS femoral	95	2	6	No	8	29

ITP: Intercalary tibial prosthesis; IHP: Intercalary humeral prosthesis, IFP: Intercalary femoral prosthesis, HPS: Highly porous stem, HPSS: Highly porous short stem, HHPS: Hollow highly porous stem, DFR: Distal femoral replacement, PTR: proximal tibial replacement

* Patient died

optimal resection. A variety of the planned reconstructions is shown in Fig. 2.

Individual instructions were assembled for each case, showing detailed images of the necessary bone preparation as well as optimal screw positioning and length. The implants where than combined with off-the shelf intercalary and joint implant solutions. The reconstruction length as well as the axis and rotation was planned on the preoperative conducted CT scan to ensure best possible anatomical reconstruction. Postoperative X-rays were conducted to determine implant positioning, in cases where a sufficient assessment was not feasible, CT scans were conducted. If the implant position was deemed sufficient, postoperative full weight bearing was allowed for the lower extremity, in upper extremity cases weightlifting was prohibited for 6 weeks postoperatively.

Results

Implantation was possible in all cases with a mean operation time of 170 (SD 58; 83–252) minutes. One- and two-stage algorithm was carried out in seven cases each. In one case the CSS was used as an extremity salvage procedure to preserve the lower leg, the remaining cases were indicated as a joint preservation procedure. Twelve highly porous stems, and three cemented stems were implanted. In eight cases, due to the massive bone loss, HPSS (≤6 cm) were needed, hollow-stem design was used in four cases. Flanges were present in ten cases ($n=1$ cemented), consisting of one- ($n=3$) and two- ($n=7$) flange designs. Mean stem length was 57 (SD 29; 10–120), with 47 (SD 26; 25–80) mm in the upper and 62 (SD 30; 10–120) mm in the lower extremity. The mean diameter 19 (SD 7; 10–30) mm, with 14 (SD 4; 10–20) in the upper and 23 (SD 7; 10–30) in the lower extremity. Remaining bone length was 71 (SD 34; 20–140) mm [UE: 60 (SD 17; range 45–86); LE: 77 (SD 39; 20–140). Resulting in a stem length to remaining bone fixation length

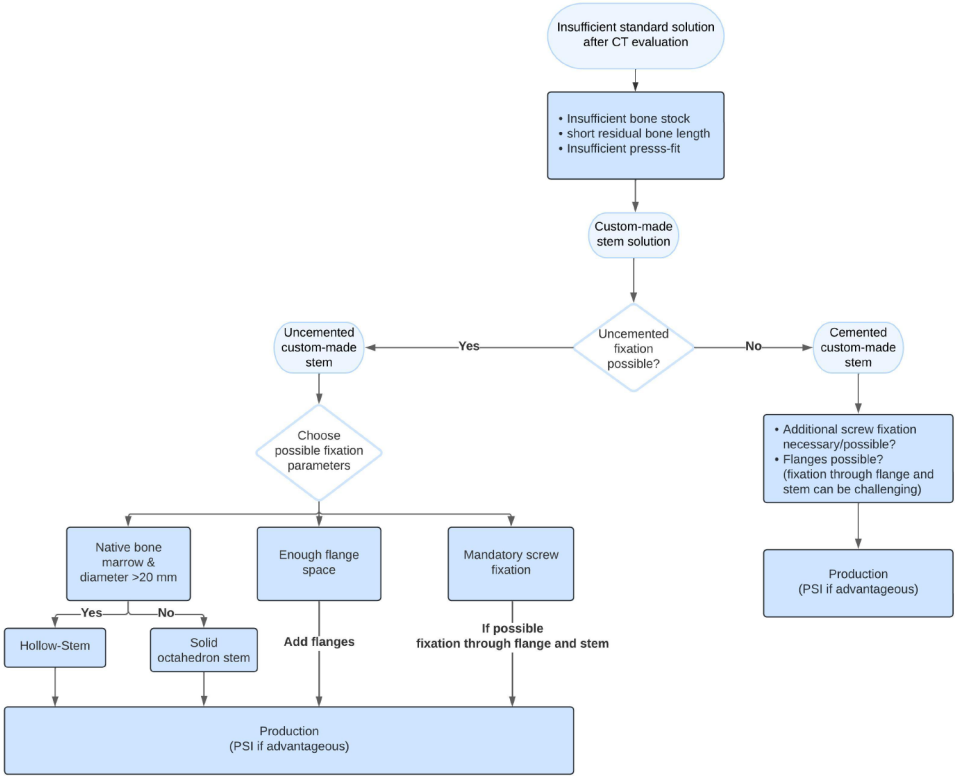

Fig. 1 Treatment algorithm for custom-made stem solutions

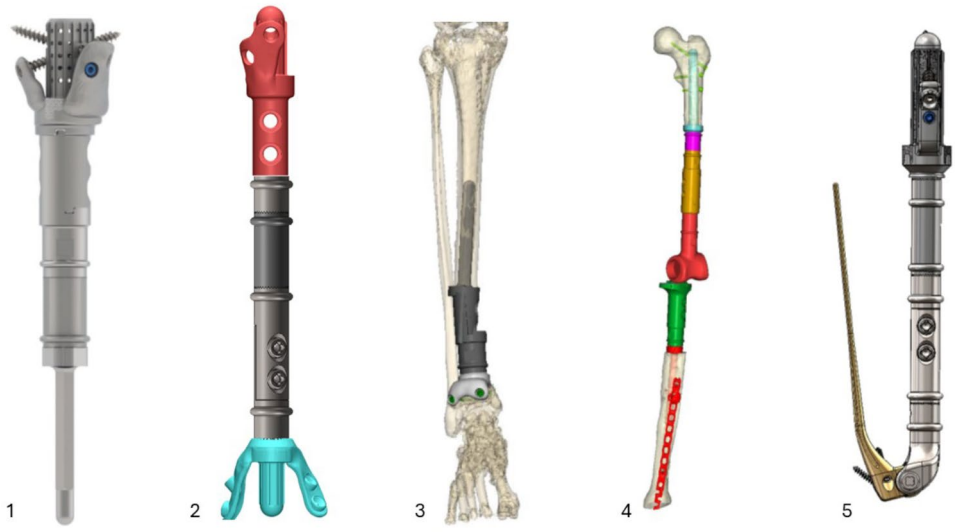

Fig. 2 Various custom-made stem solutions; Image **1**: Hollow tibial stem with additional flange fixation; Image **2**: Solid humeral octahedron stems with flanges and angular stable screws; **3** ultra-short tibial stem with additional flange fixation; **4** cemented proximal femoral stem with additional screw fixation in a rTKA; **5** custom-made octahedron stem with an additional flange in a combination with a custom-made elbow prosthesis

ratio of 0.7 (SD 0.16; 0.4–0.9) [UE: 0.6 (SD 0.2; 0.4–0.8); LE 0.8 (SD 0.1; 0.5–0.9). Additional screw fixation was carried out in 14 CSS with 3 (SD 1; 1–6) screws. The metallic prosthesis reconstruction length was 160 (SD 50; 80–260) mm. Mean manufacturing time after implant finalization was 21 (SD 10; 14–35) days.

In a mean follow-up of 30 (SD 18; 6–66) months with no patient lost to follow-up, revision was conducted in five cases (35%). In three cases (21%) revision was conducted due to periprosthetic infection with no recurrent infection, in one case this could be treated successfully with a DAIR procedure, the remaining two cases

ultimately ended in a lower leg amputation. Aseptic revision was needed in two cases (14%), $n=1$ screw loosening with isolated screw removal (lower extremity), $n=1$ repositioning of the implant as aseptic loosening occured after extensive force was applied by the patient when working with highly vibrating machines (upper extremity). In all other cases, no implant loosening could be observed, additionally no radiolucent lines were recorded in the last x-rays. MSTS score could be obtained in 10 patients with a mean of 24 (SD 5; 17–30). There were no differences in the outcome based on the manufacturing company. The detailed results are shown in Table 1. Exemplary cases are shown in Figs. 3 and 4.

During the follow-up two patients died due to the primary tumour diagnosis, one patient died postoperatively due to a multiorgan failure related to the primary tumor diagnosis.

Discussion

In this study, we are able to present 15 custom-made stem solutions for cases with extreme bone loss due to revision arthroplasty or tumour resection with various stem designs. As known from pelvic tumour cases or, in the recent years, more and more published data about custom-made rTHA acetabular designs, individual implants provide a viable alternative in extensive cases with promising results. While the data about acetabular implants, e.g. tri- or monoflange designs is becoming profound, custom-made stem solution data is still sparse [1]. However, several cohorts have been published for tumour cases in intercalary implants. Streitbuerger et al. reported usage of 17 custom-made stems ($n=7$ femur, $n=10$ tibia) in a cohort of 28 patients treated for intercalary bone defects [6]. During a follow-up of 75 months for the whole study group, 4 revisions due to aseptic loosening where conducted in the CSS group. The same research group published usage of complete custom-made intercalary implants with highly porous surface for soft tissue adhesion in 4 cases, with a mean MSTS Score of 23.5 at a follow-up of 21 months [7].

In a similar manner, Zhu et al. reported 17 patients with femoral intercalary implants with a median follow-up of 25 months, using a combination of a proximal CSS and a distal 3D printed interface with screw fixation [8]. During the follow-up only one revision was conducted due to screw loosening, the mean MSTS score was 28.

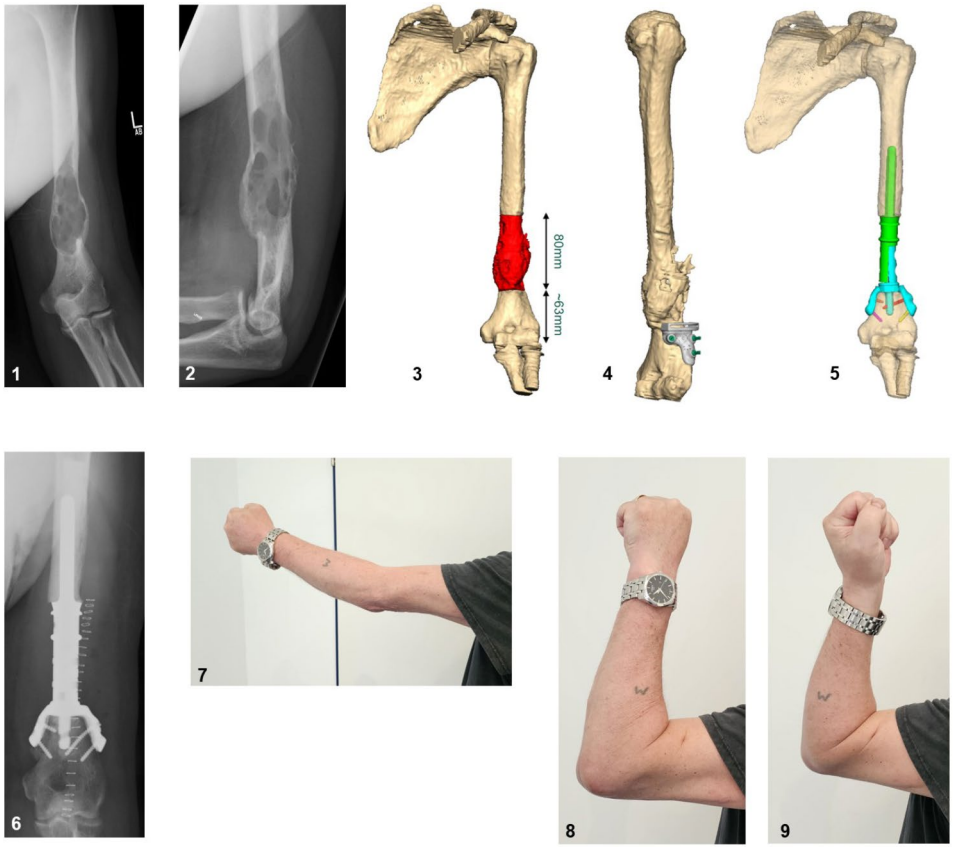

Fig. 3 56-year-old patient with a plasmacytoma of the left humerus; Image 1 and 2: preoperative images; Image 3: planned resection; Image 4: PSI guidance for the resection; Image 5: Planned reconstruction; Image 6: postoperative outcome; Image 7–9: Functional outcome at a 32 month follow-up, the patient received a repositioning after 26 months due to aseptic loosening

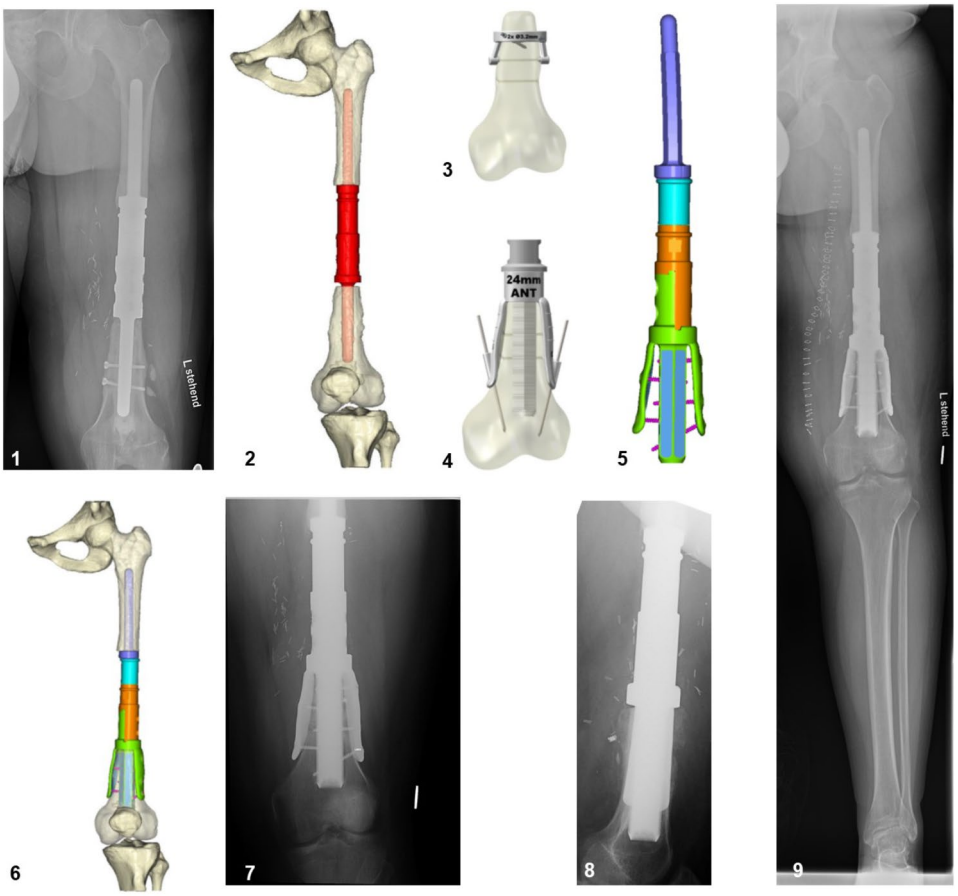

Fig. 4 32-year-old patient presenting with an aseptic loosening of an intercalary implant due to a primary osteosarcoma after 6 years; Image 1: Preoperative x-ray; Image 2: generated 3D model; Image 3 and 4: Planned PSI; Image 5: Planned implant; Image 6: Planned reconstruction; Image 7 and 8: Follow-up at 6 months; Image 9: Postoperative lower extremity x-ray

Wang et al. published a highly porous stem design for femoral and tibial bone defects, reporting an osseointegration of 100% at 42 months mean follow-up [9].

In contrast, published literature for custom-made stems combined with revision arthroplasty is nearly non-existent and mainly focussed on individual metaphyseal augmentation techniques. Burastero et al. published the usage of 8 tibial cones in 11 patients with a mean follow-up of 26 months [10]. While showing a low rate of complications ($n=1$) only reporting a functional outcome in 3 patients (OKS; 41;43;38). Using similar treatment approach Savov et al. reported results in 10 patients with 9 custom-made tibial cones, showing a low complication rate ($n=2$) in a mean follow-up of 21 months, though no functional outcome parameters were reported [11]. Li et al. published a study using a similar method in 7 patients with a good functional outcome in a follow-up of 25 months (HSS postoperatively 78 (70–83) ($p<0.01$)) [12].

As in every highly porous implant choice, periprosthetic infections remain a lifelong risk, as seen here in three patients, while a DAIR might be a viable option to maintain infection control, risk of amputation is high, as in two out of the three PJI in our cohort [13].

However, the indications greatly differ, CSS are mainly a possibility for limb and especially joint preservation as seen in all our cases. Therefor alternative surgery methods are mainly limited to extensive megaprosthesis reconstruction, e.g. total bone replacements or proximal tibial replacements. As known, limited functional outcome and high revision rates can be expected from these implants, ranging from 15 up to 30% for PJI and up to 50% for all cause revision rates [13–15]. Compared to these limited outcomes, the described treatment algorithm seems promising, especially as salvage treatment options remain a valid choice after a failed CSS.

Nevertheless, indication for a CSS has to be discussed thoroughly with each patient on a case-by-case basis as several factors have to be considered. As the individual implants have to be manufactured, urgent operations do not qualify for this treatment concept. Additionally in tumour cases the resection has to be carried out on a set date due to the treatment algorithm, therefor two-stage approaches might be feasible and have to be discussed

with the patient. However, alternative treatment options, e.g. joint replacement of the initial preserved joint or amputation still remains possible after the CSS.

Stem design and fixation is the key factor for solid long-term survival, as advised in the flowchart in this manuscript. We are able to report only one case of aseptic loosening in our cohort, all other implants remain stable up until the latest follow-up with fully achieved osseointegration in all uncemented cases. Adapting the lessons learned from custom-made partial pelvis replacement, we favour highly porous surfaces which have shown to achieve superior osseointegration [16]. Additionally, solid flange fixation, while only adapted in the later designs, provides a secondary stabilization, especially for rotational forces and therefor should be planned if possible. Cemented fixation should only be conducted, if necessary, to optimize fixation, additional screws should be implanted. While this technique can be demanding, PSI screw guidance, similar to the techniques used for individual acetabular implants, can be helpful [17, 18].

There are some limitations which have to be mentioned for the study. As this analysis was conducted as a single-center study, the indications as well as the fixation methods are heavily influenced by the department philosophy. In addition, the number of patients is sparse due to the rare indication. Nevertheless, as re-revisions seem to be increasing it is expected that surgeons will be more and more confronted with these insufficient stem reconstruction methods. The follow up presented in our cohort is relatively low, especially compared to primary arthroplasty studies. Due to the rare indication as well as the challenging, time-consuming treatment requirements, the authors would like to emphasize the special focus on early complications, e.g. loosening, and therefore a minimum follow-up of six months is justifiable. Additionally, comparable studies report a similar follow-up [7, 19]. Therefore, a multi-centre study seems necessary to further establish standardized treatment algorithms and diagnostic approaches while simultaneously increasing the number of patients and the follow-up. Additionally, custom-made implants, especially for rTHA, become more common, thus transmission to other arthroplasty indications is expected and will enable larger studies. Besides the surgical as well as patient parameters, costs must be considered. Regardless of the manufacturer, an increased cost compared to an off-the shelf stem can be expected. However, as the joint replacement is not needed, the overall costs are reduced.

Conclusion

Joint preservation via custom-made stems in revision arthroplasty and tumour cases proves to be a promising treatment strategy. As only a minimal residual anchorage distance appears to be required, even severe cases can be treated with this reconstruction method. Especially as the viable alternative treatment options often include extensive megaprosthesis reconstruction, the outcome with a mean MSTS Score of 24 emphasizes that a joint preservation using 3D printed custom-made stems should be considered. Therefor the lessons learned in individual implant solutions for acetabular reconstruction could be adapated to other orthopaedic fields.

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Author contributions
Y. Hanusrichter, MD: Conceptualization, Data curation, Investigation, Methodology, Formal analysis, Resources, Validation, Writing – original draft C. Gebert, Prof: Conceptualization, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft S. Frieler, MD: Investigation, Validation, Writing – review & editing O. Somberg, MD: Investigation, Validation, Writing – review & editing M. Dudda, Prof.: Supervision, Validation, Writing – review & editing A. Streitbuerger, Prof: Conceptualization, Writing – review & editing J. Hardes, Prof.: Supervision, Validation, Writing – review & editing M. Wessling, MD: Conceptualization, Data curation, Formal analysis, Investigation Methodology¸ Validation, Writing – original draft.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Essen-Duisburg, Essen, Germany (Date: 29.03.2022; reference number: 21-10438-KOBO). All patients agreed to participate in the study, giving informed consent and permission.

Consent to participate
Informed consent was obtained from all individual participants included in the study.

Consent for publication
Consent to publish was obtained from all individual participants included in the study.

Competing interests
The authors declare no competing interests.

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