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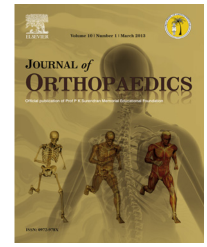

Original Article

Improving the accuracy of wide resection of bone tumors and enhancing implant fit: A cadaveric study

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ABSTRACT

Background/Aims: Customized three-dimensional (3-D) jigs have been shown to increase the accuracy of skeletal tumor resection in comparison to freehand techniques. However, the utility of these jigs in subsequently enhancing the fit of endoprosthetic implants has yet to be determined. We hypothesized that custom jigs would improve implant fit compared to freehand resection.
Methods: Nine matched pairs of cadaveric femurs were scanned by CT. The images then had 'virtual' tumors positioned on the distal medial femoral condyle and preoperative resection plans were generated. Custom implants were designed to fit into the resected spaces and 3-D printed. Similarly, customized 3-D jigs were designed and printed for half of the femurs. Resections were then performed using the jigs or freehand. The implants were positioned in the resected femurs and the accuracy-of-fit was quantitatively assessed by re-scanning the resected femurs and calculating the deviation from the implant (in degrees) for each of the 3 cutting planes. The results were then compared between jig and freehand resections.
Results: For the first plane, the jig resulted in less deviation than the freehand cut, but it did not achieve statistical significance. However, for the 2nd and 3rd planes, the jigs deviated 1.78° and 2.20° from the implants compared to 4.41° and 7.96° for the freehand cuts, both of which were statistically significant improvements ($p = 0.038$ and $p = 0.003$).
Conclusion: In summary, customized 3-D jigs were shown to improve the accuracy-of-fit between implants and host bone, moving this technology closer to clinical implementation.

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1. Introduction

One of the most significant advances in orthopedic oncology in the past few decades has been the ability to safely perform limb-sparing surgery for primary bone sarcomas without compromising oncologic results in the vast majority of cases.[1–5] However, limitations in reconstruction techniques and endoprosthetic implant technology often translate into multiple revision surgeries in a patient's lifetime for failures of the reconstruction.[6] Customized three-dimensional jigs have been used successfully in total knee arthroplasty[8,9] and it has recently been demonstrated that the utilization of computer-generated three-dimensional (3-D) custom jigs can greatly improve the accuracy of bone tumor resection.[7] Use of such technology not only allows surgeons to more reliably achieve negative margins, but also has great potential to allow surgeons to spare nearby critical anatomic structures, which may result in significant functional and reconstructive advantages for the patient. Although several detailed studies have demonstrated that such custom jigs can improve the quality of orthopedic oncology resections, the use of such jigs in improving orthopedic oncology reconstructions has not yet been well described in the literature. We surmised that the vastly increased accuracy afforded by the custom jig technology might also help improve a surgeon's ability to reconstruct skeletal defects left after bone tumor resection.

In this study, we specifically focused on reconstructions involving prefabricated custom implants. In this type of reconstruction, the surgeon typically works with an engineering design team from a given manufacturer to design a custom shaped metallic implant that is designed to replace a given skeletal defect. We hypothesized that a technique utilizing custom jigs would result in more accurate fit between a custom implant and host bone compared to the traditional freehand technique.

2. Material and methods

Nine pairs of skeletonized cadaveric femurs were utilized for this study. The workflow used to design and manufacture the cutting guides and implants was similar to prior studies conducted in our laboratory[7] with some minor modifications (Fig. 1). The femora were first imaged using a clinical CT scanner (GE VCT) running a standard bone algorithm with a 0.625 mm slice thickness, 0.5° pitch, and small field of view (FOV). The images were then exported from the PACS server as DICOMS and imported into In Vesalius (Brazilian Sciences and Technology Center, Brazil) to transform the files into stereolithography (STL) files. The STL files were then imported into Geomagic (3D systems, Morrisville, NC) and transformed into 3-D CAD models. Finally, the resulting 3-D files were imported into SolidWorks (Dassault Systèmes S.A., Vélizy, France).

At this point, virtual bone tumors (10 mm × 10 mm × 25 mm ellipsoids) were positioned on the distal medial metaphases (Fig. 2). Surgical resection plans designed to satisfy the Enneking principles of ''wide resection'' for high-grade bone sarcomas[2] were then outlined virtually on the computer by the surgeon. While the resection plans were unique to each femur, they all had approximately the same shape and dimensions. The shape was trapezoidal with an ~40 mm base on the medial cortex, beginning ~40 mm from the end of the distal condyle. The sides angled in 15° to the top which was ~25 mm from the base. Hemi-metaphyseal resections were planned to go full thickness through the femora on the anterior-posterior axis.

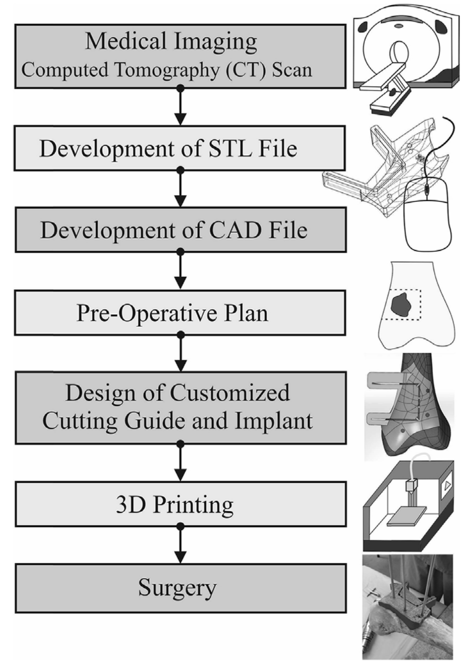

Fig. 1 – Workflow for cutting guide fabrication. This figure illustrates the workflow that is used in the fabrication of cutting guides and implants. It begins with a CT scan of the patient that is converted into an STL and then a CAD file. The resulting 3-D representation is used to craft a pre-operative plan and design a cutting guide and implant. The guide and implant are then 3-D printed and used for surgery.

Cutting guides were then designed for one femur from each pair (alternating left and right) using SolidWorks. The undersurface of each guide was designed to match the anterior surface of the femur and the top was a flat surface with a slot to guide a saw blade in accordance with the preoperative plan. In order to facilitate proper placement of the guides, the distal edges were designed to align with the superior ridge of the medial femoral articular surface and three holes were placed to attach the guides to the bone. Implants corresponding to each of the resection plans were also designed. The guides and implants were then 3-D printed in acrylonitrile butadiene styrene (ABS) using a Cube 2nd Generation 3-D printer (3D Systems, Rock Hill, SC).

A single senior orthopedic resident performed the resections in two separate sessions and alternated between cutting guides and freehand in order to minimize the role of experience. The femora were stabilized in the operative field

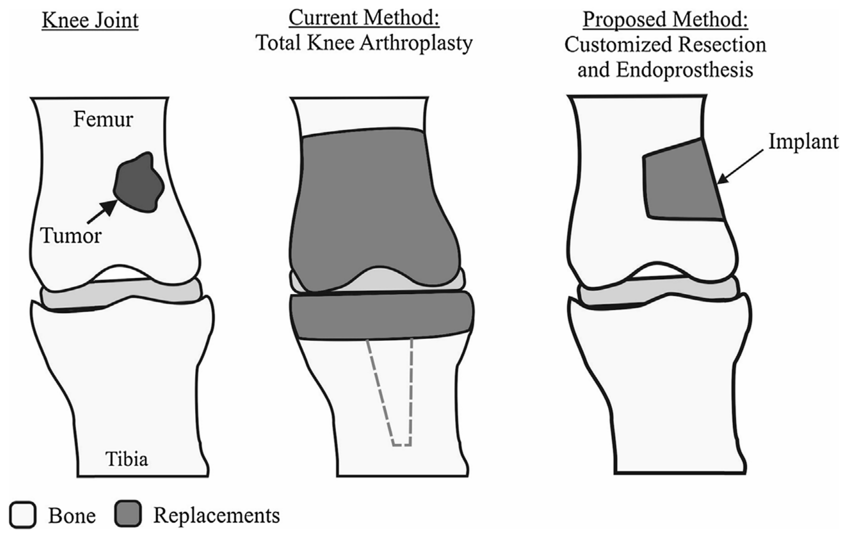

Fig. 2 – Methods for tumor resection. This schematic representation shows, from left to right, a hypothetical tumor on the medial aspect of the distal femur; the current method of treatment by complete resection of the distal femur followed by total knee arthroplasty; the proposed method of treatment by cutting guide-assisted resection followed by implantation of a customized endoprosthesis.

by a tabletop vise (Fig. 3A). For specimens in the cutting guide group the guide was aligned to the superior ridge of the articular surface, seated, and held in place by three bicortical 5 mm Steinmann pins (Fig. 3B). An oscillating sagittal saw (Stryker, Kalamazoo, MI) equipped with a 0.89 mm sagittal saw blade was used to perform the resection through the slots in the jig. Once the resection was completed, the pins and guide were removed. For the freehand resection group, the surgeon was given a printout of the preoperative plan showing the distances of each osteotomy line from major palpable and identifiable landmarks (e.g., medial epicondyle, articular surface). The surgeon then used a ruler and marking pen to draw the preoperative plan on the femur. The region was then resected manually with the sagittal saw. Upon completion of each resection, the surgeon attempted to press-fit the implant into the resulting defect. In those cases when the defect was too small, the surgeon was allowed to make additional improvements until a satisfactory implant fit was achieved.

The femurs were re-scanned after surgery using the same scanner and settings. The images were then imported into SolidWorks, as previously described, to quantitate the accuracy of implant fit. This was done by comparing the directions of vectors normal to cut planes of the resected bone to their corresponding vectors on the sides of the implant. First, each of the three planar surfaces of the implant was defined by a normal vector *nx*, where *x* represented the number of the surface (Fig. 4A). The surface of the implant corresponding to the proximal cut plane was labeled **1**, the sagittal plane **2**, and the distal plane *3*. Each value for *nx* was obtained by determining the cross product of the vectors defined by points P_1–P_2 and P_1–P_3 that defined each plane. Based on the preoperative plans, the ideal angle for these vectors was 15° for n_1 and n_3, and 0° for n_2, with respect to the *Z*-axis.

Second, the respective vectors for the resected femora were calculated. Due to a variety of factors (e.g., saw vibration, tissue anisotropy, surgical technique), these surfaces were not completely planar. The analysis was restricted to the exposed cortical surfaces because of the natural deviation from planarity of cancellous bone as well as the compressibility of cancellous bone during implant impaction. Therefore, for each surface, **1**, **2**, and **3** planes were defined from hundreds of points positioned along the cortex (Fig. 4B) and used to define normal vectors (n_x).

Finally, these normal vectors were then compared to the vectors for the implants and the differences (γ) were calculated. All of the values of γ for each plane were then averaged to obtain the mean and standard deviation. The values calculated for γ included both positive and negative numbers, limiting the importance of a comparison of means. Therefore, the absolute values of the differences between n_x and γ were calculated for each resection plane. These values were then averaged by resection plane within each of the two groups and compared with paired *t*-tests using SPSS (Ver.19, SAS Institute, Cary, NC) at an alpha of 0.95.

3. Results

After the implants had been press-fit into the resected femurs, a qualitative assessment implant fit was made by visually examining digital photographs taken of the anterior and posterior surfaces (Fig. 5). Implant fit in the cutting guide group appeared better than the freehand group for the majority of pairs. Moreover, while several specimens from the freehand group had large gaps (>5 mm) between the implant and the bone, no large gaps were seen in the cutting guide group.

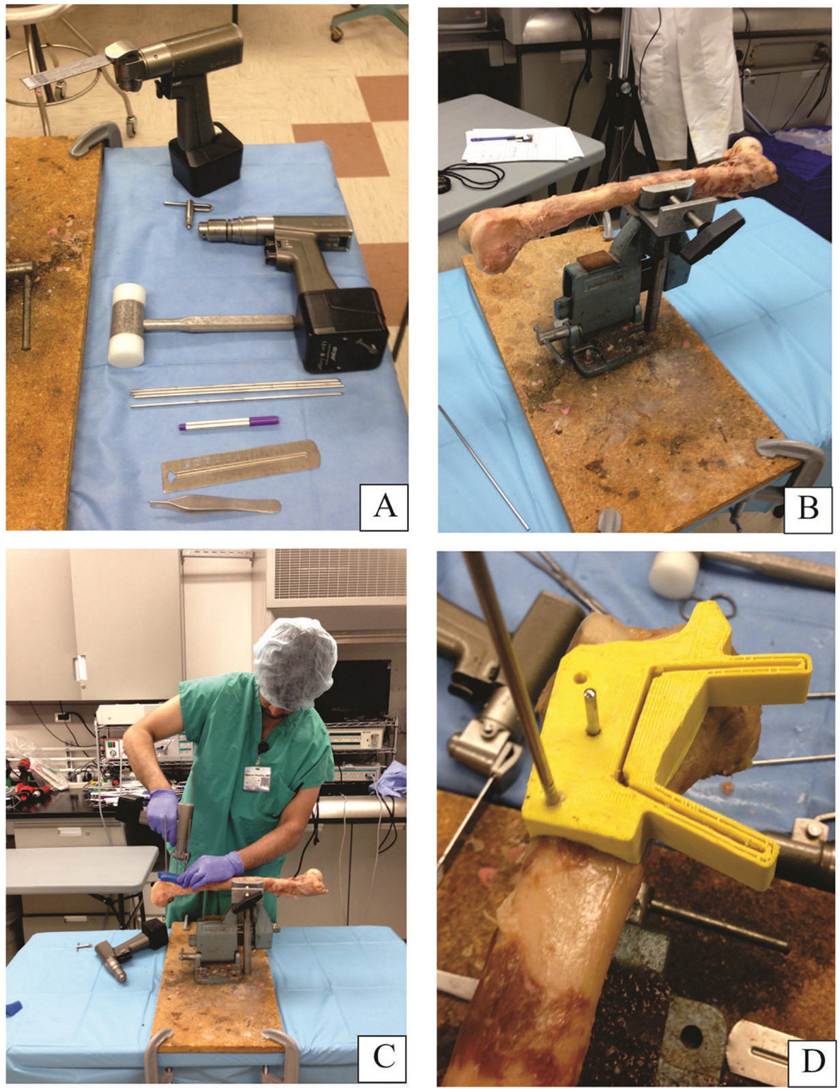

Fig. 3 – Cadaveric resection and implant positioning. Digital photographs showing: (A) The instruments used for the surgery; (B) A femur mounted in a vise for stability; (C) The surgeon fixing the cutting guide to the femur with a pin; (D) A close-up of the cutting guide positioned on the femur prior to resection.

Finally, it was observed that for both groups implant fit appeared better when viewed from the anterior side compared to the posterior side.

The quantitative analyses confirmed the visual analysis with the mean angles closer to the planned angles for all three planes in the cutting guide groups compared to the freehand group (Table 1). Comparison of the differences showed that for planes 2 and 3, specimens from the cutting guide group deviated from the preoperative plan significantly less than those in the freehand group, $p = 0.038$, and 0.003, respectively.

4. Discussion

This study builds upon prior work conducted in our laboratory to develop customized 3-D printed cutting guides as a viable method to improve clinical outcomes for orthopedic oncology patients.[7] Specifically, this series of experiments was performed to test the hypothesis that cutting guides can improve the accuracy-of-fit for customized endoprostheses when compared to traditional freehand resection.

The results were first assessed visually and it was apparent that the use of cutting guides resulted in smaller gaps between the implants and the host bone. Of the specimens that showed large gaps between the implants and the host bone, all were in the freehand group. Similarly, the specimens that had the best implant fit were all from the cutting guide group. The quantitative analysis supported the qualitative data with significantly less deviation from the preoperative plan seen for two of the three resection planes in the cutting guide group, indicating superior implant fit.

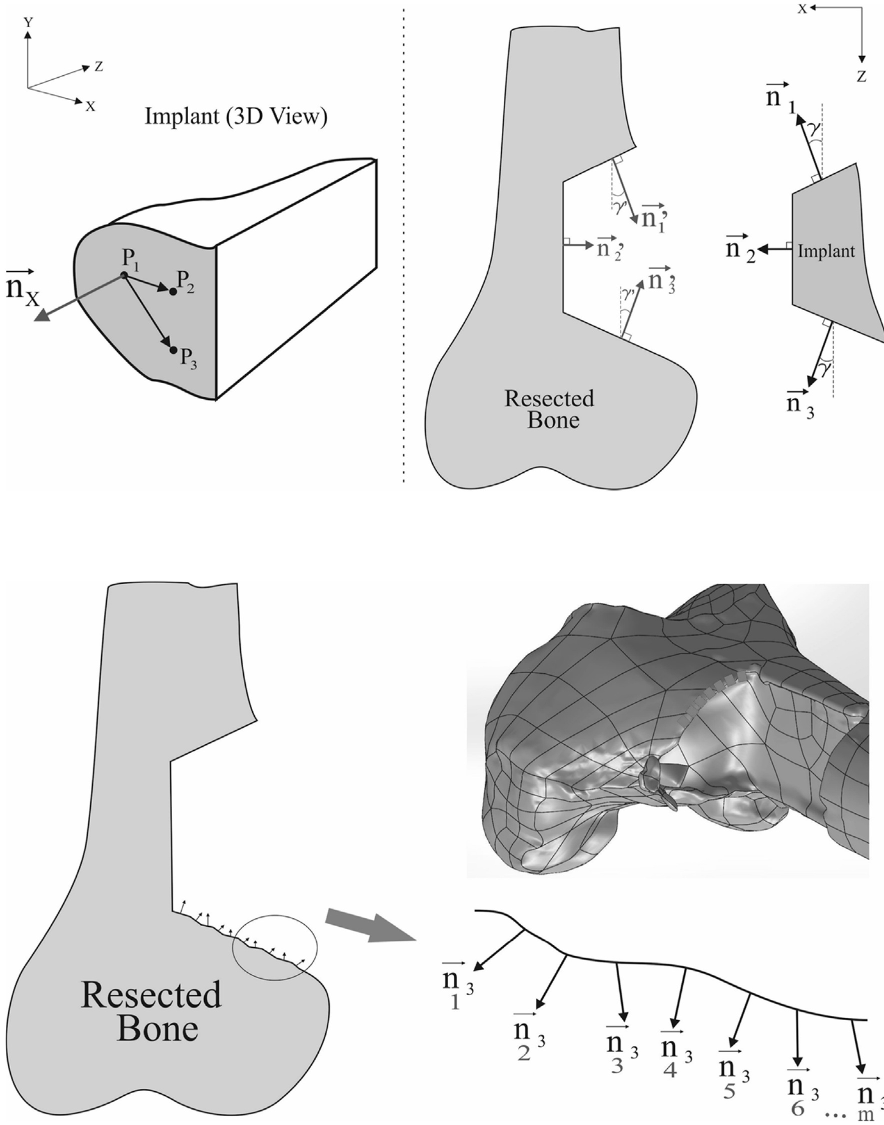

Fig. 4 – Quantitative assessment of implant fit. This figure illustrates the process by which implant fit was quantitated. (A) On the left is a schematic of an implant with the 3 points used to define the cut plane (P_x) and the angle normal to the plane (n_x) shown for the distal plane. On the right is a schematic showing how the cut planes and corresponding normal angles were compared between the resected bone and the implant in order to quantitate the accuracy of implant fit. (B) On the left is a schematic showing the three cut planes. The upper right shows a 3-D surface render CT scan of the same region from a resected femur. On the bottom right, a section of the distal cut plane is enlarged to show the angles normal to the surface (n_x) that were calculated along the plane and which correspond to the blue dot on the surface rendered image.

While this study offers strong support that customized cutting guides can improve the fit of endoprosthesis in skeletal tumor surgery, it does have several limitations. First, the positioning of the cutting guides with the femora still relied on the use of anatomic landmarks and this could contribute to error in alignment. Second, the resections were performed by a PGY 4 orthopedic surgery resident instead of a fellowship trained orthopedic oncologist. Therefore, it is possible that a more highly trained surgeon would have been better able to reproduce the preoperative plans using a freehanded technique. Third, the study was performed using skeletonized femora, which provided an expansive FOV. However, this exposure is likely to have benefitted both groups and may not have affected the comparisons being made in this study. Finally, the surgeon was allowed to refine the cuts in both groups to optimize implant fit. As in the large exposure, this is likely to have improved the results for both groups equally. The clinical utility of this study can only be generalized to patients with tumors that closely resemble our experimental model. For example, patients with lower grade malignant

Table 1 – Comparative results of implant fit.

	Planned angle	Cutting guide		Freehand		p-Value
		Mean angle (SD)	Difference (SD)	Mean angle (SD)	Difference (SD)	
Plane 1	15.00	15.36 (6.56)	5.30 (3.42)	12.23 (8.13)	7.16 (4.14)	0.358
Plane 2	0.00	1.78 (1.6)	1.78 (1.6)	4.41 (3.46)	4.41 (3.46)	0.038
Plane 3	15.00	15.69 (2.79)	2.20 (1.69)	19.23 (8.31)	7.96 (4.23)	0.003

Table shows the results of the quantitative assessment of implant fit. The first column identifies the cutting plane and the second shows the planned angle, followed by the columns for the specimens resected using the cutting guides and freehand. For each technique, the mean angle and standard deviation are shown. The mean of the absolute values of the differences from the planned angle is then shown. The final column shows the *p*-values from paired *t*-tests comparing the absolute values of the differences.

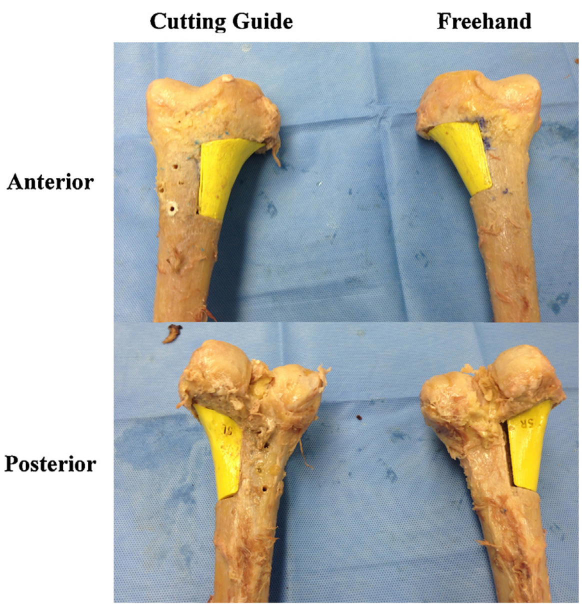

Fig. 5 – Qualitative assessment of implant fit. Anterior and posterior photos of a representative matched pair of femora following resection and implant placement. A cutting guide was used for the left femur while the right femur was operated on freehand.

lesions, which are caught early are confined to the boney compartment.

5. Conclusion

Overall, this study builds upon prior studies conducted on the development of customized cutting guides for skeletal tumor resections and shows that their use can result in improved fit of a customized endoprosthesis. Given the tremendous costs associated with ordering a customized endoprosthesis, it is vital that they can be precisely press-fit into the host bone. This is because a precise fit will result in more contact area to facilitate integration and a reduction of stress shielding to reduce the risk of peri-prosthetic fractures. The data presented in this study show that 3-D printed cutting guides have the potential to facilitate such precision by more accurately reproducing preoperative plans. A few remaining issues must be resolved prior to clinical utilization of these guides. These include optimizing guide design to ensure accurate positioning, minimizing the effects of soft tissue coverage, ensuring that the guides can work within a realistic surgical exposure, and accounting for all possible sources of error so that guide design will ensure that the tumors are resected with negative margins. If these issues can be resolved, this approach will significantly advance the state of the art in orthopedic oncology and improve patient outcomes in a cost-effective manner.

Conflicts of interest

The authors have none to declare.

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REFERENCES

1. Karakousis CP, Emrich LJ, Rao U, Krishnamsetty RM. Feasibility of limb salvage and survival in soft tissue sarcomas. *Cancer*. 1986;57:484–491.
2. Enneking WF, Dunham W, Gebhardt MC, Malawar M, Pritchard DJ. A system for the functional evaluation of reconstructive procedures after surgical treatment of tumors of the musculoskeletal system. *Clin Orthop Relat Res*. 1993;286:241–246.
3. Rougraff BT, Simon MA, Kneisl JS, Greenberg DB, Mankin HJ. Limb salvage compared with amputation for osteosarcoma of the distal end of the femur. A long-term oncological, functional, and quality-of-life study. *J Bone Joint Surg Am*. 1994;76:649–656.

4. Mankin HJ, Gebhardt MC, Jennings LC, Springfield DS, Tomford WW. Long-term results of allograft replacement in the management of bone tumors. *Clin Orthop Relat Res*. 1996;324:86–97.
5. Plotz W, Rechl H, Burgkart R, et al. Limb salvage with tumor endoprostheses for malignant tumors of the knee. *Clin Orthop Relat Res*. 2002;405:207–215.
6. Myers GJ, Abudu AT, Carter SR, Tillman RM, Grimer RJ. Endoprosthetic replacement of the distal femur for bone tumours: long-term results. *J Bone Joint Surg Br*. 2007;89:521–526.
7. Khan FA, Lipman JD, Pearle AD, Boland PJ, Healey JH. Surgical technique: computer-generated custom jigs improve accuracy of wide resection of bone tumors. *Clin Orthop Relat Res*. 2013;471:2007–2016.
8. Fitz W. Unicompartmental knee arthroplasty with use of novel patient-specific resurfacing implants and personalized jigs. *J Bone Joint Surg Am*. 2009;91:69–76.
9. Lombardi Jr AV, Berend KR, Adams JB. Patient-specific approach in total knee arthroplasty. *Orthopedics*. 2008;31: 927–930.