In vitro evaluation of a custom cutting jig and custom plate for canine tibial plateau leveling

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Objective—To design and manufacture custom titanium bone plates and a custom cutting and drill guide by use of free-form fabrication methods and to compare variables and mechanical properties of 2 canine tibial plateau leveling methods with each other and with historical control values.

Sample Population—10 canine tibial replicas created by rapid prototyping methods.

Procedures—Application time, accuracy of correction of the tibial plateau slope (TPS), presence and magnitude of rotational and angular deformation, and replica axial stiffness for 2 chevron wedge osteotomy (CWO) methods were assessed. One involved use of freehand CWO (FHCWO) and screw hole drilling, whereas the other used jig-guided CWO (JGCWO) and screw hole drilling.

Results—Replicas used for FHCWO and JGCWO methods had similar stiffness. Although JGCWO and FHCWO did not weaken the replicas, mean axial stiffness of replicas after JGCWO was higher than after FHCWO. The JGCWO method was faster than the FHCWO method. Mean ± SD TPS after osteotomy was lower for FHCWO (4.4 ± 1.1°) than for JGCWO (9.5 ± 0.4°), and JGCWO was more accurate (target TPS, 8.9°). Slight varus was evident after FHCWO but not after JGCWO. Mean postoperative rotation after JGCWO and FHCWO did not differ from the target value or between methods.

Conclusions and Clinical Relevance—The JGCWO method was more accurate and more rapid and resulted in more stability than the FHCWO method. Use of custom drill guides could enhance the speed, accuracy, and stability of corrective osteotomies in dogs. (*Am J Vet Res* 2008;69:961–966)

Sliding and closing wedge osteotomies are routinely used to change the shape of bones in dogs and humans, particularly in the proximal portion of the tibia.[1,2] Most osteotomies in humans and dogs rely on freehand cuts made with oscillating saws or osteotomes.[3,4] Custom cutting jigs have been used, particularly to perform osteotomies of the proximal portion of the tibia and distal portion of the femur for corrective osteotomies and total knee replacements.[5–7] Custom jigs increase the accuracy of corrective osteotomies.[5] Custom drill guides have also been used for craniofacial and dental surgery.[8–13] Chevron (V-shaped) osteotomies have been used as an alternative to flat osteotomies in humans because of their perceived improvements in stability and healing rate.[14] Chevron osteotomies have been experimentally used for corrective osteotomies of the proximal portion of the canine tibia.[15]

Abbreviations

CNC	Computer numeric control
CT	Computed tomography
CWO	Chevron wedge osteotomy
EBM	Electron beam melting
FFF	Free-form fabrication
FHCWO	Freehand chevron wedge osteotomy
JGCWO	Jig-guided chevron wedge osteotomy
TPS	Tibial plateau slope

Stabilization of bone fragments after corrective osteotomies most often relies on commercially available bone plates. Custom bone plates are sometimes used for fixation of bone fragments in geometrically complex regions and in patients with bone defects.[16,17] However, little is known about the potential benefits of custom cutting jigs, custom drill guides, or patient-specific bone plates with regard to speed, accuracy, and stability of corrective osteotomies.

The purposes of the study reported here were to design a patient-specific cutting jig, drill guide, and bone plate for fixation of a CWO of the proximal portion of the tibia in dogs and to assess the impact of the cutting jig on the geometry and mechanical properties of the corrected bones. The study included the design and

Received September 14, 2007.
Accepted November 20, 2007.
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Supported by a research initiation grant of the Society of Manufacturing Engineers (No. 4006).
The authors thank Dr. Harvey A. West II, Brian Deaton, and Jess Bardin for technical assistance.
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FFF of a patient-specific custom cutting jig and drill guide and EBM-made titanium alloy bone plate. These were used on canine tibial replicas identical to the replicas used to assess the features of several corrective osteotomies of the proximal portion of a canine tibia in another study[15] conducted by our laboratory group. We hypothesized that use of custom titanium plates would increase the accuracy of correction and axial stiffness of plated replicas after CWO, the JGCWO procedure could be completed faster and more accurately than the FHCWO procedure, and the resulting construct would be stiffer. To test these hypotheses, we compared the plated replicas after JGCWO and FHCWO with each other and with results for a historical control group of CWOs performed earlier by the same surgeon on identical replicas by use of identical osteotomy methods.

Materials and Methods

Sample population—Tibial replicas of a 6-year-old castrated male Labrador Retriever with cranial cruciate ligament disease and a TPS of 29° were created by use of rapid prototyping and rapid tooling methods as described in another study[15] conducted by our laboratory group. Computed tomography of a pelvic limb was performed by use of helical CT with a 512 × 512 resolution and 0° gantry tilt.[a] The CT image was retroreconstructed into 1-mm slices with a pixel size of 0.59 mm. The CT image was converted by a software program[b] into a 3-dimensional computer model of the cortical bone and a model of the cancellous bone. The computer models were exported as STL files and used as input files for the stereolithography process.[c] Stereolithography uses a UV laser to cure thin layers of an epoxy-based photopolymer 1 layer at a time. Stereolithography models of the cancellous and cortical bone were used as patterns when creating room temperature vulcanizing silicon rubber molds. The cancellous bone core was cast by use of polyurethane foam. The cortical bone was then cast around the foam core by use of a mixture of epoxy, bone powder, and shredded fiberglass. Each replica had surface markers (4-mm-diameter hemispheres) on the cranial aspect of the tibial shaft, medial and lateral aspect of the tibial plateau, and cranial and caudal aspect of the tibial condyle. A 10-mm-diameter hole was drilled in a craniocaudal direction at the base of the replicas. A 15-cm-long bolt was placed through that hole and secured with nuts. The markers and bolt were used to assess axial, coronal, and sagittal plane alignment before and after osteotomy. Ten replicas were created, and 5 were randomly assigned to each of 2 groups (FHCWO and JGCWO).

Custom plate design and fabrication—The plate design was based on the helical CT images of the Labrador Retriever used to make the tibial replicas.[15] The CT images were imported into an image-editing software program[b] for manipulation and conversion into a 3-dimensional model. The model was exported as an STL file and imported into a reverse engineering program.[d] The STL file was then converted into nonuniform rational B spline surfaces and exported as a STEP file, which was directly imported into a computer-aided design program[e] and manipulated to develop a solid computer model for custom design of the bone plate. Chevron wedge osteotomy was performed on the model, and a bone plate was extruded from the bone surface (**Figure 1**). Six screw holes were extruded from the plate, and edges of the plate were smoothed. Ten titanium alloy (Ti6Al4V) bone plates were created by use of EBM, which is an additive direct-metal fabrication technology. The EBM machine spread a 100-µm-thick layer of titanium powder on a stainless-steel substrate that was heated to 750°C. A 4.8-kW electron beam was used to selectively melt the first cross section (layer) of the object. The substrate was then lowered 100 µm, and the process was repeated until the object was completed[18,f] (**Figure 2**).

FHCWO method—Geometry of the FHCWO was identical to that for a CWO reported in another study[15] conducted by our laboratory group. An FHCWO was performed on each of 5 replicas by placing a template on the surface of the bone and making 2 V-shaped cuts (intersection angle of 24°; the cuts intersected on the caudal tibial cortex) by use of an electric oscillating cordless saw.[g] The 2 bone fragments were reduced. Six 3.5-mm cortical bone screws[h] were inserted (**Figure 3**).Two screw holes adjacent to the osteotomy were drilled eccentrically to provide interfragmentary compression.

Custom jig design and fabrication—The custom jig was designed with computer-aided design software by use of surface knitting, then thickening (**Figure 4**). Geometry identical to that of the CWO used for the custom plate design was imported. The custom cutting jig was extruded from the bone surface. Screw holes in the cutting jig were created by cutting the custom plate in half, affixing it to the proximal and distal portions of the tibia, positioning drill holes in the custom jig by use of the custom plate, and extruding the holes from the cutting jig surface. The custom cutting jig was built in arylonitrile butadiene styrene plastic by use of a fused deposition modeling FFF system[i] (**Figure 5**). The fused deposition modeling system heats and melts a thin acrylonitrile butadiene

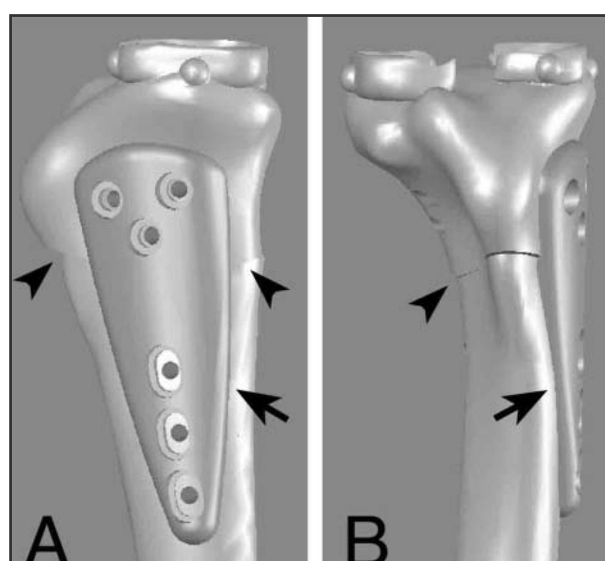

Figure 1—Three-dimensional renderings of the medial (A) and cranial (B) views of a canine tibia with an attached custom plate (arrows). The renderings were used to determine the CWO (arrowheads), match the osteotomy surfaces, and create a bone plate that would secure the bone fragments in place.

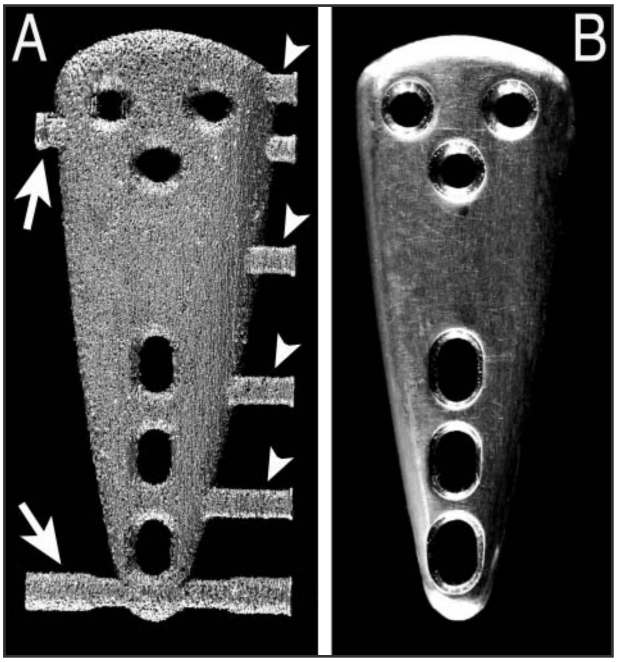

Figure 2—Photographs of a custom plate immediately after EBM fabrication (A) and after the plate was finished by use of CNC machining (B). Notice the rough surface of the custom plate before CNC machining. Four pegs (arrowheads) are used for plate support during EBM fabrication, and 2 pairs of opposing pegs (arrows) are used to secure the plate during CNC machining.

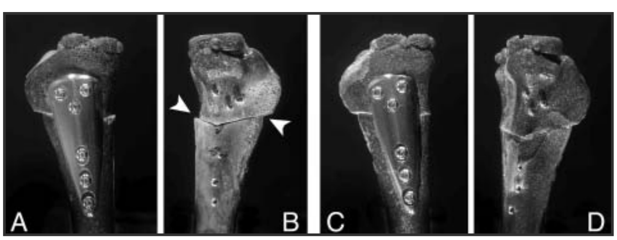

Figure 3—Photographs of tibial replicas on which an FHCWO (A and B) or JGCWO (C and D) has been performed and a custom plate used for repair. For the FHCWO, the medial (A) and lateral (B) views reveal that the osteotomy surfaces are approximately matched, with a small gap visible on the lateral aspect of the bone (arrowheads). In contrast, medial (C) and lateral (D) views for the JGCWO do not reveal a visible gap at the osteotomy site.

styrene filament and extrudes it onto a platform 1 layer at a time. The screw holes were positioned so that there would be 1 mm of interfragmentary compression when the screws were tightened.

JGCWO method—A JGCWO was performed on each of 5 replicas by placing the custom cutting jig on the bone, drilling the 6 screw holes, and making the 2 V-shaped cuts with an oscillating saw. The custom plate was secured to the bone by six 3.5-mm cortical bone screws.[h] Length of each screw was measured with a depth gauge before each screw was inserted.

Application time—The amount of time required for all corrective procedures was recorded from the beginning of the corrective procedure to the end of hand tightening of the bone screws on the replica. Final tightening of screws was performed immediately before mechanical testing.

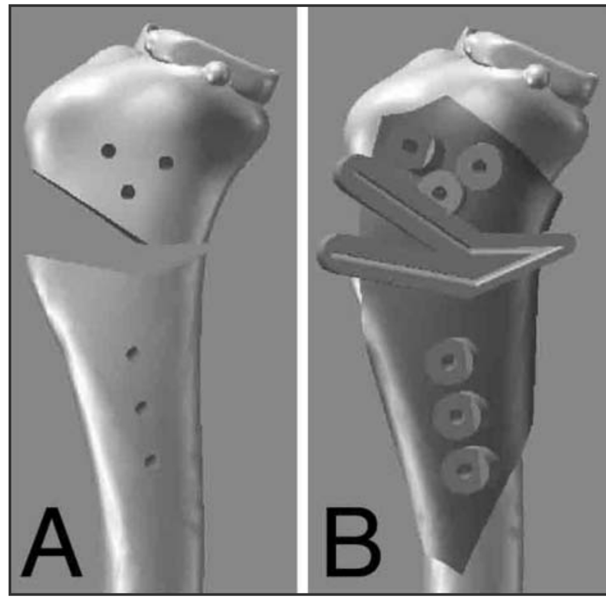

Figure 4—Three-dimensional renderings of the lateral views (A and B) of a canine tibia during design of the custom jig. The design process involved drawing the cut surfaces and screw holes on the 3-dimensional rendering that would correspond to those on a custom plate (A) and extruding the jig that would correspond to these cut surfaces and screw holes (B).

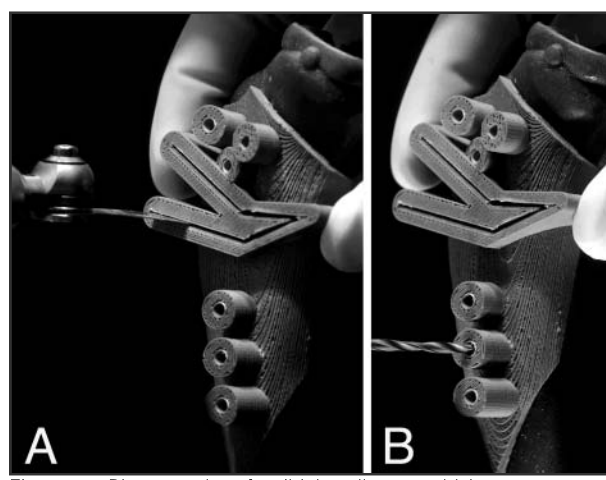

Figure 5—Photographs of a tibial replica on which a custom cutting and drill guide has been placed and is used to position the saw blade (A) and drill bit (B).

Geometric assessment—Target TPS for the FHCWO and JGCWO methods was identical to the target TPS of the CWO (8.9°) reported in another study[15] conducted by our laboratory group. Craniocaudal, mediolateral, and proximodistal digital images of replicas were obtained before and after osteotomy. Axes were drawn by use of image analysis software.[j] Each TPS was measured by comparing the orientation of a line tangential to the discrete, cranial portion of the medial tibial condyle to a line joining the intercondyloid eminence and a point equidistant to the cranial and caudal trochlear aspects of the talus.[19] Alignment of the coronal plane was assessed on craniocaudal images by comparing the position of markers on the medial and lateral aspect of the tibial plateau to the markers along the cranial aspect of the tibial shaft. Axial alignment was assessed on proximodistal images by comparing position of markers on the medial and lateral aspect of the tibial plateau to the direction of the bolt placed across the base of the replicas. All measurements were performed in a randomized order.

Mechanical testing—A solid aluminum replica of the femoral condyles was CNC machined from existing CT data, with a proximal coupling to a universal testing machine.[k] All tests were performed in randomized order with a crosshead speed of 5 mm/min with 3 preconditioning loads and data recorded on the fourth loading event. Each of the 10 replicas was axially loaded 4 times to 600 N before osteotomy.[20] Each of the 5 FHCWO and 5 JGCWO plated replicas was tested after osteotomy. The screws were tightened[21] to 1.13 N with a factory-calibrated torque wrench prior[l] to testing. The plated replicas were axially loaded 4 times to 300 N. We ensured that testing was nondestructive by comparing replica size and load displacement curves of the 4 loading events. Axial stiffness was calculated as a function of the terminal slope of the load displacement curve for replicas on the fourth loading event.

Statistical analysis—A randomized block design by use of randomization tables[22] was used to determine the order of osteotomy, testing, and geometric assessment. Application time, geometric assessment, and axial stiffness were assessed for all plated replicas. Normality of sample distribution was assessed before each test.[m] Replica stiffness before osteotomy was compared with stiffness after osteotomy for each method by use of 2-tailed Student *t* tests. Results were compared between methods by use of a 1-way ANOVA. Results were compared with historical target values (TPS, 8.9°; rotation, 0°; and angulation, 0°) by use of 2-tailed Student *t* tests for each group. Statistical significance was set at values of $P < 0.05$.

Results

Mean ± SD stiffness of the replicas was 811 ± 118 N/mm (**Table 1**). Initial replica stiffness did not differ significantly ($P = 0.087$; power, 0.4) for replicas used for JGCWO and FHCWO. The JGCWO method was significantly ($P = 0.003$) more rapid than the FHCWO method. Rotation after JGCWO did not differ significantly ($P = 0.924$) from the rotation after FHCWO. Rotation after JGCWO did not differ significantly ($P = 0.144$) from the target value, whereas rotation after FHCWO differed significantly ($P = 0.025$) from the target value. Mediolateral angulation after JGCWO did not differ significantly ($P = 0.210$) from the target value but differed significantly ($P = 0.015$) from mediolateral angulation after FHCWO. Mediolateral angulation after FHCWO differed significantly ($P = 0.003$) from the target value. The TPS after JGCWO differed significantly ($P = 0.022$) from the target value; the TPS after JGCWO also differed significantly ($P < 0.001$) from the TPS after FHCWO. The TPS after FHCWO also differed significantly ($P < 0.001$) from the target value. The stiffness of replicas after JGCWO did not differ significantly ($P = 0.783$) from preosteotomy stiffness. Replica stiffness after FHCWO also did not differ significantly ($P = 0.059$) from preosteotomy stiffness. Stiffness after osteotomy was significantly ($P = 0.035$) higher after JGCWO than after FHCWO.

Discussion

The purpose of the study reported here was to assess the impact of a custom cutting jig and a custom plate on the geometry and mechanical properties of the canine tibia. We used tibial replicas made with rapid prototyping and rapid tooling identical to the replicas described in another study[15] conducted by our laboratory group in which we compared 5 tibial plateau leveling methods.

Use of a custom cutting jig clearly enhanced results of corrective osteotomy; the osteotomy was more accurate and completed 36% faster, and the resulting construct was 16% stiffer. The increase in accuracy likely resulted from having a constrained saw blade during the cuts. The increase in speed likely resulted from the rapid placement of the custom jig on the replica, not having to double check alignment of the saw blade during osteotomy, and not having to use a sleeve when drilling holes for bone screws. The increase in stiffness likely resulted from the increase in accuracy of the CWO. Custom cutting jigs are not routinely used when performing corrective osteotomies in dogs or humans because of the cost and technical challenges involved in their design and construction. Preparation of the cutting jigs used in the study of this report required a total design time of 2 hours and fabrication and postprocess-

Table 1—Mean ± SD values for mechanical and geometric features after FHCWO and JGCWO methods were used for application of a custom bone plate on 5 tibial replicas each.

Variable	FHCWO	JGCWO	Overall	Target values
Replica stiffness				
Before osteotomy (N/mm)	874 ± 128	747 ± 170	811 ± 118	NA
After osteotomy (N/mm)	650 ± 140[a]	757 ± 153[b]	704 ± 129	NA
Change (%)	–24 ± 19	1 ± 10	–11 ± 20	NA
Application time (min)	12 ± 2[a]	8 ± 1[b]	10 ± 3	NA
Postosteotomy TPS (°)	4.4 ± 1.1*,[a]	9.5 ± 0.4*,[b]	7.0 ± 2.8	8.9
Postosteotomy rotation (°)†	2.1 ± 1.3*	1.9 ± 2.4	1.9 ± 1.8	0
Postosteotomy mediolateral angulation (°)‡	–4.8 ± 1.6*,[a]	–1.3 ± 1.9[b]	–3.0 ± 2.5	0

*Within a row, value differs significantly ($P < 0.05$) from the target value. †Positive values indicate external rotation. ‡Negative values indicate varus deformity.

NA = Not applicable.

[a,b]Within a row, values with different superscript letters differ significantly ($P < 0.05$).

ing time of 7 hours. The use of more advanced software with a haptic interface would save steps and time during the design phase, which should decrease the design time to an estimated 30 minutes.[23,24] The use of custom bone-based or tooth-based dental cutting guides has been reported,[25,26] but there is a paucity of information in these reports on their specific benefits over conventional planning and drilling methods. Biocompatible rapid prototyping materials have been available for more than a decade but have had limited use in custom cutting and drill guides because of their mechanical properties.[27,28] New biocompatible materials with enhanced strength have been introduced for medical applications.[29,30] These materials have low concentrations of cytotoxins because of their manufacturing process or postmanufacturing detoxification. New FFF systems are considerably faster than the technology used for the materials in the study reported here.

Use of patient-specific, biocompatible drill guides could be considered in the future for specific clinical applications. Custom drill guides can increase drilling accuracy for dental applications.[12] It has also been proposed that use of computer-aided navigation can enhance the accuracy of osteotomies. Navigated freehand bone cutting enhances alignment of osteotomies during total knee arthroplasty,[7,31] but its long-term benefits are not yet known.[32] Robotic surgery can also improve the accuracy of osteotomies.[33,34]

Although the construct resulting from FHCWO was less accurate and less stable than the construct resulting from JGCWO, use of a custom plate in this report increased the speed of osteotomy (mean duration, 12 minutes), compared with CWO performed on identical replicas in our previous study[15] (mean duration, 24 minutes). Although these values are not directly comparable because the osteotomies for the 2 studies were performed several months apart and because the experience of the surgeon increased during that period, the increase in speed was likely attributable in part to the fact that plate contouring was not necessary for the custom plate. Similar replicas were used for the FHCWO in the study reported here and the CWO in our previous study.[15] Mean ± SD postoperative stability of the plated replicas in both studies was similar (FHCWO, 650 ± 140 N/mm; CWO, 637 ± 111 N/mm).

Custom metal implants have been used for many years for dental and orthopedic applications, including craniofacial reconstruction, joint arthroplasty, and limb-sparing surgery.[35–37] Creation of such custom implants has been made easier by the availability of software packages for medical editing.[b] Custom implants have been made by use of 3-, 4-, and 5-axis CNC machining.[38,39] The CNC machining is a time-consuming and costly process, particularly when cobalt-chrome or titanium is used.[40,41] Custom metal implants may be produced by the use of investment casting. This requires a wax pattern or suitable rapid prototyping pattern. Titanium is highly reactive and requires casting under vacuum, most often by use of a graphite mold.[42] Investment casting is also time-consuming and costly because of the steps involved. The EBM technique used in the study reported here may represent an alternative to other forms of custom plate manufacturing. Although the EBM machine is expensive in terms of capital cost, the machine has a low operating cost. Use of EBM FFF may become viable for implant fabrication because it is rapid and multiple implants may be manufactured simultaneously. More than 60 plates similar to the plates used in this project could be manufactured simultaneously in our EBM machine by use of its 300-mm-diameter base plate.

The study reported here had several limitations. Mechanical testing was limited to axial loading, and the tests were conducted on a limited number of replicas. This may have negatively impacted our ability to detect the full benefits of custom osteotomy for clinical patients. Also, our control group of CWO-stabilized replicas of noncustom plates was a historical control group of osteotomies performed in another study[15] under identical conditions. Because these surgeries were not performed in randomized order during the same time period, we avoided statistical comparisons of results for the historical CWO to results for the FHCWO. The potential benefits of custom plates with regard to the stability of the plated replicas would probably have been easier to appreciate had we included a noncustom group in the present study or used a surgical procedure with different specific geometric challenges. We chose these replicas and osteotomy procedures because we had a historical control group of CWOs performed on noncustom plates.

a. CT Sytec SRi, General Electric Co, Fairfield, Conn.
b. Mimics, version 9.1, Materialise, Leuven, Belgium.
c. SLA-190, 3-D Systems, Rock Hill, SC.
d. Geomagic Studio, version 8.0, Raindrop Geomagic, Research Triangle Park, NC.
e. Solidworks, version 2004–2005, SolidWorks Corp, Concord, Mass.
f. EBM S-12, Arcam AB, Mölndal, Sweden.
g. Stryker II, Stryker Instruments Inc, Kalamazoo, Mich.
h. Synthes Ltd, Paoli, Pa.
i. Dimension FDM, Stratasys, Eden Prairie, Minn.
j. Adobe Photoshop, version 8.0, Adobe Systems Inc, Mountain View, Calif.
k. ATS 1605C, Applied Test Systems Inc, Butler, Pa.
l. Sturtevant Richmont, Franklin Park, Ill.
m. JMP, version 7.0, SAS Institute Inc, Cary, NC.

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