Is Humeral Segmental Defect Replacement Device A Stronger Construct than Locked IM Nailing?

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Abstract Intramedullary (IM) nailing is currently the most common method for treating patients with impending pathologic humeral fractures; however, this treatment is associated with known complications primarily owing to violation of the rotator cuff during insertion. A better option is needed. To determine if a humeral segmental replacement prosthesis would provide a stronger construct compared with an IM nail in this setting, we compared the mechanical properties of these two devices in a cadaver model simulating an impending pathologic fracture. In each of nine matched pairs of fresh human humeri one was randomly selected to undergo a 50% lateral middiaphyseal defect simulating an impending pathologic fracture and subsequent fixation with an IM nail and bone cement. The contralateral humerus underwent fixation using a humeral segmental defect prosthesis. We determined T-scores using DEXA. Each specimen subsequently was tested in torsion to failure. Peak torque and peak rotation at failure were greater for the prosthesis specimens whereas torsional stiffness was greater for the IM nail specimens. We found a

linear relationship between peak torque and T-score for each device with the slopes of the lines suggesting the construct with the prosthesis can withstand greater forces than the IM nail and the differences between devices were greater in weaker bones.

Introduction

Greater than 1.3 million people are diagnosed with carcinoma each year in the United States, and greater than 50% eventually will have bone metastases develop [16]. Many patients live for extended periods after the diagnosis of bone metastases [16]. Thus, proper orthopaedic care has become extremely important to minimize pain and help patients maintain a high quality of life.

With the exception of the femur, the humerus is the most common long bone affected by bone metastases [4]. Although parameters defining impending fractures of long bones have been variously described, a 50% cortical defect generally is believed to indicate a long bone is at high risk [1, 2, 10, 12, 15, 17, 18]. Some authors have recommended prophylactic treatment of impending long-bone fractures as it is thought prophylactic treatment is technically easier and associated with less morbidity for the patient compared with treatment of a completed fracture [1, 2, 10, 12, 13, 15, 17, 18].

Methods for treating impending humeral fractures include plate and screw fixation and flexible and locked IM nailing [2, 12, 20, 22, 23]. Each of these methods of treatment can be augmented with polymethylmethacrylate bone cement to fill the tumor defect. The most frequently used treatment of an impending pathologic humeral fracture is locked IM nailing [12, 20, 22]. Compared with other methods, locked IM nailing provides superior strength [8].

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Furthermore, locked IM nails protect the entire bone through a relatively small surgical exposure. Frequently reported complications associated with the use of locked humeral nails, however, include chronic shoulder pain, weakness, and decreased range of motion [5, 11], which occur because insertion of the nail requires violation of the rotator cuff. Despite these complications, locked nails have remained the mainstay of treatment of completed pathologic fractures and impending pathologic fracture of the humerus.

Locked IM nails provide a stronger construct compared with plates and screws and flexible IM nails in a model of an impending pathologic fracture from metastatic disease of the humerus [8]. However, one mechanical study suggested a humeral segmental defect replacement (SDR) prosthesis provides a stronger construct than a humeral nail in a segmental defect model [14]. Furthermore, Chin et al. [6] found humeral SDR prostheses mechanically superior to other fixation methods in a model simulating a pathologic fracture of the humerus.

Owing to the known complications associated with humeral nails, a better method of treatment is desired for patients with metastatic disease and impending pathologic fractures of the humerus. A better method should be at least as strong as an IM nail for this indication, but preferably would not violate the rotator cuff. Although locked humeral nails are currently the most common method of treatment for these patients, some surgeons have used humeral SDR prostheses [9].

We asked the following questions: (1) Does a humeral SDR prosthesis provide a stronger construct compared with a locked IM nail in a model simulating an impending pathologic fracture of the humerus secondary to metastatic disease? (2) Does a humeral SDR prosthesis provide a stiffer construct compared with a locked IM nail in a model simulating an impending pathologic fracture of the humerus secondary to metastatic disease? (3) Is there a relationship between bone density and the ability of these devices to prevent mechanical failure of the bone? Finally, (4) What will be the modes of failure of each of these methods of reconstruction?

Materials and Methods

We obtained nine matched pairs (18 specimens) of fresh-frozen cadaver humeri, and using DEXA, determined bone density for each. Humeri then were randomized so that one specimen in each pair would undergo placement of a SDR prosthesis whereas the other would undergo fixation of a simulated impending pathologic fracture with a locked IM nail and bone cement. Mechanical testing to failure in torsion then was performed. Statistical analysis was

performed to check for differences in the strength and stiffness of the two constructs and to evaluate a possible effect of bone density on the strength of the two constructs.

Sample size calculations were based on paired t-tests for the primary end points (peak torque, torsional stiffness, and rotation). These calculations assumed the Type I error rate would be controlled at 5% and the desired power is 80%. Assumptions regarding the expected differences (and standard deviations [SD]) between the SDR prosthesis and the IM nail were based on the results of a similar study by Henry et al. [14]; the assumed effect sizes were 18 Nm (SD = 5) for peak torque, 0.5 Nm/° for torsional stiffness (SD = 0.5), and 7.4° for rotation (SD = 7.5). The resulting sample size calculations suggested nine pairs of humeri likely would provide sufficient power for the three end points of interest.

Specimens were stored at −20°C. All of the humeri underwent evaluation by dual-emission x-ray absorptiometry (DEXA). The average T-score obtained from the DEXA scan was −2.5 9 (range, −3.8—−0.7). In each pair, one humerus was chosen randomly to undergo a 50% lateral middiaphyseal cortical defect simulating an impending pathologic fracture as described by Damron et al. [8]. These humeri (IM group) were fixed with a locked humeral IM nail (Stryker Orthopaedics, Mahwah, NJ) augmented with bone cement. A 5-cm segmental defect was created in the contralateral humerus (SDR group) in each pair, which was fixed with a humeral SDR prosthesis (Stryker Orthopaedics) (Fig. 1).

Each humerus of the IM group was thawed at room temperature for creation of the defect and placement of the humeral nail. Each humerus was measured and subsequently marked at the middiaphysis. Calipers were used to measure the anteroposterior and mediolateral dimensions of the humerus at the marked point. A standardized 50% lateral middiaphyseal cortical defect was created using a power burr. Saline solution was used to keep the specimens

Fig. 1 A photograph shows a matched pair of cadaver humeri with a SDR prosthesis in the right humerus and a locked IM nail augmented with bone cement fixing a simulated impending pathologic fracture of the left humerus.

moist during the procedure. Using the instrumentation provided by the manufacturer, the entry portal for the IM nail was created medial to the greater tuberosity using a rigid reamer. Flexible reamers were used to ream the humeral canal to a diameter of 10 mm. The length of the humeral canal was measured. The appropriate length 9-mm humeral nail was placed using the provided insertion guide. Two proximal locking screws were placed using the provided guide. The holes were drilled and measured, and the appropriate length screws were placed. One distal-locking screw was placed under guidance of a C-arm fluoroscope gaining bicortical purchase. Position of all of the hardware was confirmed under a C-arm fluoroscope. The 50% cortical defect was packed with Simplex® bone cement (Stryker Orthopaedics) prepared according to the manufacturer's instructions.

Each humerus in the SDR group was thawed for placement of the SDR device. A 5-cm segmental defect was created using a saw. Marks were placed on the anterior surface of the proximal and distal segments to indicate proper rotation for the reconstruction. The middle segment then was discarded. The proximal and distal aspects of the humeral canal were reamed up to 11 mm using flexible reamers. A facing reamer then was used on both fragments. The proximal and distal canals were dried using sponges. Using a cement gun, the proximal and distal bone fragments were filled retrograde with Simplex® bone cement prepared according to the manufacturer's instructions. The cement was pressurized, and the prosthesis was inserted into each fragment, taking care to maintain appropriate rotational alignment. The prosthesis is modular, consisting of variable-length body segments and multiple stem lengths. For this study, a 5-cm body length was used with a 100- × 9-mm stem proximally and a 75- × 9-mm stem distally. The two halves of the prosthesis were assembled using two screws according to manufacturer's recommendations. Excess cement was removed, and the entire construct was held still until the cement hardened. The specimens were imaged with a C-arm fluoroscope to ensure proper implant placement.

All specimens were individually potted at both ends in cylindrical testing fixtures with potting cement. The fixtures were designed with the Pro/ENGINEER® software package (Parametric Technology Corp, Needham, MA) and then custom manufactured. The IM nail fixation specimens had clay placed over proximal protrusions of the locking screws to avoid being affected by the potting cement. Each specimen was tested in torsion to failure on an MTS Mini Bionix® II (MTS Systems Corp, Eden Prairie, MN) torsional materials testing system at a rate of 30° per second as described in previous studies [8, 14]. A zero force was maintained during testing using the load control capabilities of the MTS. Load control minimized

any effect of compression, tension, or bending. Along with a universal joint, load control ensured only torsion was applied to the specimens.

After testing, all specimens were surveyed visually to inspect sites of fracture and modes of failure. Similar to the study by Henry et al., failure of the specimen was defined as fracture or 45° rotation without obvious fracture [14]. This degree of rotation was determined to represent gross loosening and thus failure of the prosthesis even in the absence of a fracture. Load cells collected data by converting mechanical forces (torsion) into load-deformation curves interpreted and displayed by the MultiPurpose TestWare® software (MTS Systems Corp). Peak torque at failure (Nm), maximum rotation at failure (°), and torsional stiffness (Nm/°) data were determined for all specimens. The torsional stiffness was calculated from the load-deformation curve as the steepest linear portion of the curve.

The end points of primary interest were the peak torque, peak torque per cross-sectional area, torsional stiffness, and rotation. Comparisons between devices were based on paired differences (differences between matched pairs of cadaver humeri). A two-sided, paired t-test was used to analyze each of the end points. A separate linear regression model was fit for each device. All analyses were performed using the R 2.7.0 software (R Foundation for Statistical Computing, Vienna, Austria) [19].

Results

The SDR prosthesis provided a stronger construct compared with the locked IM nail. The peak torque, peak torque per cross-sectional area, and peak angle all were larger for the SDR group than for the IM group in each pair of humeri (Fig. 2A–C). The mean peak torque for the SDR group was 25.75 Nm greater ($p = 0.00008$) than in the IM group (95% confidence interval [CI]: 17.66, 33.84) (Table 1). For peak torque per cross-sectional area, the mean for the SDR group was 6.64 Nm/cm² greater ($p = 0.00003$) than in the IM group (95% CI: 4.79, 8.49). The mean peak angle for the SDR group was 28.15° greater ($p = 0.00001$) than in the IM group (95% CI: 21.29, 35.01).

Conversely, the SDR group had a lower stiffness value than the IM group in each pair (Fig. 2D). The mean for the SDR group was 0.79 Nm/° smaller than in the IM group (95% CI: -1.17, -0.41; $p = 0.0001$).

The difference in the strengths of the two constructs depended on bone density. The mechanical advantage of the SDR prosthesis was greater in bones of lesser density. There was an approximate linear relationship between peak torque and T-score for each device (Fig. 3). The fitted

Fig. 2A–D (A) Peak torque, (B) peak torque per cross-sectional area, and (C) peak angle were greater for the SDR group, whereas (D) stiffness was greater for the IM group.

Table 1. Summary of the differences for each biomechanical variable

Biomechanical property	Mean difference (SDR – IM)	95% confidence interval	p Value
Peak torque (Nm)	25.75	17.66, 33.84	< 0.00008
Peak torque per cross-sectional area (Nm/cm ²)	6.64	4.79, 8.49	< 0.00003
Peak angle (°)	28.15	21.29, 35.01	< 0.00001
Stiffness (Nm/°)	–0.79	–1.17, –0.41	< 0.0001

SDR = segmental defect replacement; IM = intramedullary.

linear model is peak torque = $59.24 + 12.24 \times \text{T-score}$ for the IM devices (coefficient of determination, $R^2 = 0.80$) and peak torque = $69.24 + 5.55 \times \text{T-score}$ for SDR devices ($R^2 = 0.66$). The estimates of the slope parameters differed from zero for each group model (IM, $p = 0.0007$; SDR, $p = 0.0048$). These findings suggest there is an association between peak torque and bone density (as determined by T-score) for each device.

The modes of failure were recorded for each specimen. All of the humeri in the IM group failed through a fracture that communicated with the 50% lateral middiaphyseal cortical defect (Fig. 4). Six of the humeri in the SDR group

Fig. 3 A graph shows the peak torque versus DEXA T-score for each device, with linear regression lines. The mechanical advantage of the SDR prosthesis is greater in bones of lesser density.

failed through a fracture (Fig. 5), whereas three failed by rotation past 45° before fracture. Two of these failed at the bone-cement interface, and one failed by torsion of the implant stem.

Fig. 4 A photograph shows a fracture of a humerus in the IM group communicating with the 50% hemicylindrical defect and the distal locking screw.

Discussion

The most common method of treating patients with impending pathologic humeral fractures is IM nailing. Although IM nailing provides a strong construct, it is associated with chronic shoulder pain, weakness, and decreased range of motion primarily attributable to violation of the rotator cuff [5, 11]. A better method of treatment is needed for these patients. This method should provide a construct that is at least as strong as or stronger than IM nailing, but that does not violate the rotator cuff. We asked if a humeral SDR prosthesis (a method of treatment that does not compromise the rotator cuff) would provide a stronger construct compared with an IM nail in a model of an impending pathologic fracture. We also asked whether bone density has an effect on each device's ability to resist mechanical failure. The data suggest the humeral SDR prosthesis does provide for a stronger construct compared with an IM nail in this setting. Furthermore, the advantage of the SDR prosthesis is even greater in bones of lesser density.

Fig. 5 A photograph shows a fracture of a humerus in the SDR group.

Our study is not without limitations. First, the mechanical testing was performed only in one plane. It is possible the results could have differed if the specimens had been loaded differently, such as with four-point bending, axial loading, or combined loading. Torsion was chosen because this has become an established method to test long-bone defects [8, 14]. Torsional testing is believed to provide the most exact measurement of the effects of a cortical defect on the strength of a long bone [3, 8, 21]. Thus, we believed torsion would be the most clinically relevant mode of acute failure in a model of an impending pathologic fracture. Second, we tested only one size of prosthesis. Presumably, the mechanical advantage of the SDR prosthesis would increase with increasing size of the lesion up to the point that the lesion becomes a segmental defect, as tested by Henry et al. [14]. However, the results of the study by Henry et al. [14] cannot be extrapolated beyond the point

that the lesion is large enough that the SDR stem sizes would be shorter than those used for our study. Third, the mechanical testing was performed only in maximal load to failure. It is possible the results would be different with cyclic loading. Cyclic loading might be a clinically relevant mode of failure leading to loosening of the prosthesis at the bone-cement interface without catastrophic failure or fracture. Clinically relevant cyclic loading, however, is difficult to reproduce in the laboratory as it is impossible to account for the continuous bone remodeling that would occur in vivo in reaction to the cyclic stresses. Furthermore, many patients with metastatic carcinomas have a limited life expectancy, and thus, the number of cycles the prosthesis would have to withstand clinically would be limited. Finally, it would be difficult to estimate the average loads experienced clinically and the average number of cycles that these patients use their humeri on a daily basis. Therefore, we judged the maximal load to failure the most important parameter for testing.

Our data showed the peak torque and peak torque per cross-sectional area were larger for the SDR group than for the IM group. In one respect, these data confirm the results of Henry et al. [14], who reported a SDR prosthesis was stronger than a locked humeral nail combined with methacrylate or allograft in a segmental defect model. However, our study expands on that by Henry et al., by showing that the SDR prosthesis provides for a stronger construct not only in a segmental defect but also compared with an IM nail in a 50% defect model simulating an impending pathologic fracture. In our study the SDR prosthesis provided a stronger construct despite the fact that the IM group was aided by additional bone support.

The stiffness in the SDR group was less than that in the IM group. This is in contrast to the results of Henry et al. [14], who reported stiffness of the SDR group was greater than that of the IM nail group with methacrylate or the IM nail group with allograft. The difference in results most likely is attributable to the fact that the IM nail group in our study had more cortical support which could add substantial stiffness to the construct before failure. The implants in the SDR group likely underwent loosening at the bone-cement interface before gross failure resulting in lower stiffness values compared with the IM group in which the interface remained relatively stiffer until fracture.

Although our data showed a mechanical advantage of the SDR prosthesis over an IM nail in a model of an impending pathologic fracture, these data are insufficient to make definitive recommendations to change treatment algorithms. The SDR prosthesis provides an attractive option in that it is able to protect the entire humerus (Fig. 6), provide a construct that initially is stronger than

Fig. 6A–C Preoperative (A) AP and (B) lateral radiographs of the left humerus of a 61-year-old woman with metastatic lung cancer show an impending pathologic fracture. (C) A postoperative AP radiograph shows that multiple stem lengths of the modular SDR prosthesis allow the entire humerus to be protected.

an IM nail, and does not violate the rotator cuff. However, questions remain. A high rate of aseptic loosening of SDR prostheses has been reported [7] although these devices historically have been used to treat lesions with inherently poor prognoses such as very large tumors and those that would not be expected to respond to radiation, chemotherapy, hormones, or bisphosphonates. It is not known how well these prostheses would function compared with an IM nail in patients who have lesions with inherently better prognoses. It also is not known how other associated complications, such as infections and nerve injuries, would compare between the two devices.

Our data suggest a humeral SDR prosthesis provides superior strength compared with locked humeral IM nailing augmented with cement in a model of an impending pathologic fracture. The mechanical advantage of the SDR prosthesis is greater in bones of lesser density. It also is unknown whether this prosthesis will provide superior function or improved pain relief for patients with metastatic disease of the humerus compared with locked humeral nailing, and clinical studies in this area are warranted.

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