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Hindfoot Alignment in Surgical Planning for Total Knee Arthroplasty

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Numerous biomechanical factors, including malalignment of the lower limbs, are associated with increased force across the joints leading to higher incidence and progression of OA of the knee and ankle.[1] Traditionally, this mechanical axis deviation has been measured from the center of the femoral head to the center of the ankle and is called the conventional mechanical axis deviation (MADC). However, numerous studies have indicated that a more accurate measurement of the actual weightbearing axis would also account for hindfoot malalignment distal to the ankle, including the subtalar joint.[2-6] This axis can be measured from the center of the femoral head to the ground reaction point and is called the ground mechanical axis deviation (MADG).

The relationship between knee OA and hindfoot deformity has been examined in the literature. Though no predictable relationship between knee and hindfoot malalignment has been found, it is known that a significant number of patients with knee OA will also have some degree of hindfoot deformity.[6-7] The importance of precise alignment for knee implant success cannot be underestimated, as even a minor deviation can lead to increased edge loading, polyethylene implant wear, early failure and subluxation.[8] As such, a more accurate measurement for operative planning that accounts for alignment distal to the ankle, such as MADG, is desirable. We designed a dynamic computer model to compare measures of malalignment using MADC and MADG. We hypothesized that there would be a significant difference between estimates using MADC and those where MADG was used. We will now bring our focus to the biomechanics laboratory where we aim to compare load transmission applied at the femoral head using MADC and MADG on a cadaveric model. We hypothesized that MADG would prove a superior method for predicting actual weightbearing axis of the lower extremity.

Methods

Sample lower extremity x-rays combining standard AP radiographs with hindfoot alignment views were compared for estimated MADC and MADG. (Figure 1) Computer simulation free-body diagrams of single leg stance, double leg stance, toe off and heel strike were drawn and geometrically compared using MADC and MADG. Length of tibia (286.5 mm), femur (353.5 mm) and the height of foot (70.6 mm) were derived from anthropological data of an average adult male.[9] Guichet et al.'s predicted trigonometry equation was coded in MATLAB and used to derive MADC and MADG for each stance over a range of foot-tibial angles and genu valgum angles at the knee.[3] By convention, valgus deviations were considered positive and varus deviations were considered negative. A 3D graph was plotted to illustrate the differences between

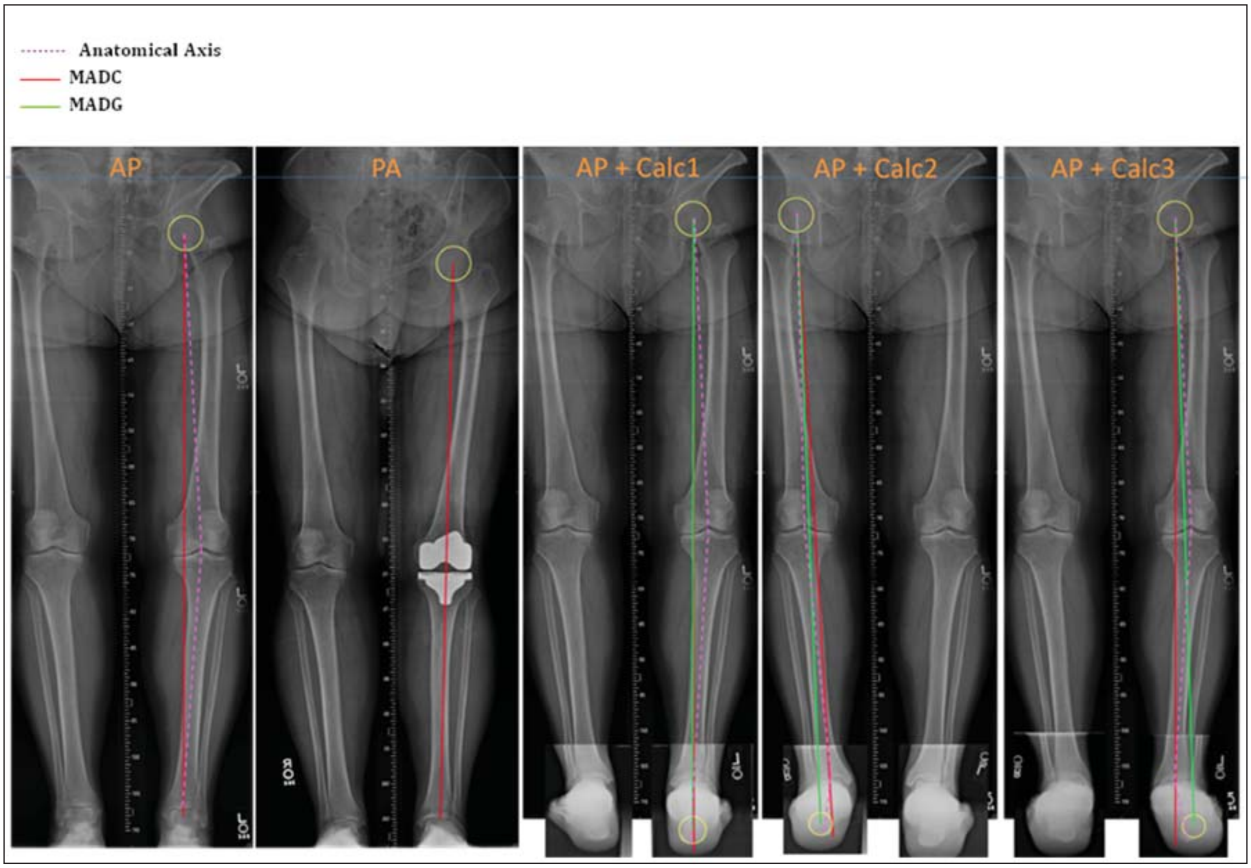

FIGURE 1.

MADC and MADG for a given angle of deformity in each stance.

In the laboratory, baseline measurements of anatomic axis, MADC and MADG will be recorded for 14 cadaveric lower extremity specimens. We have designed and are building a biomechanical testing jig to apply load to the specimens. The jig will be constructed using a hydraulic jack to apply load to the femoral head at an angle calculated to simulate physiologic loading. We will measure the load transmitted through the medial and lateral knee joint, the center of the ankle joint and the ground reaction point of the calcaneus. Loads measured at the center of the ankle and the ground reaction point will be compared to determine which more accurately estimate actual load transmission. Deformities at the level of the hindfoot will then be created by an orthopaedic surgeon to simulate typical physiologic malalignments. Load transmissions at the knee, ankle and hinfoot will be measured to determine the weightbearing axis in the setting of hindfoot deformity.

Results

Using the computer model, the two evaluative methods, MADC and MADG, produced greatly varying results. MADG significantly exceeded MADC values, which stresses the severity of the malalignment. Higher angles of hindfoot deformity were associated with greater MADG from anatomical axis. In future studies using the cadaveric model, we expect to find that load measured at the ground reaction point is closer to the actual force applied when compared with load measured at the center of the ankle. This difference between measured load transmission at the center of the ankle and the ground reaction point should be greater for each specimen after hindfoot deformity has been simulated. Based on our computer model findings, we also expect that knees implanted using MADC to plan realignment will demonstrate more uneven loading at the medial and lateral knee joint when compared to those implanted using MADG for surgical planning.

Conclusions

The results of this analysis so far illustrate that the incorporation of hindfoot deformity into calculation of mechanical axis deviation creates a more dynamic model. MADG results for each stance appeared much wider than MADC, which suggests possible errors due to the limited number of parameters used for MADC. Where MADC accounts for only length of tibia, length of femur and genu-valgum angle, MADG also considers height of foot, valgus angle of foot and theta (angle between the line joining the sole of the foot to the knee and the femur) in addition to these conventional parameters.

In conclusion, it is essential to accurately evaluate limb mechanics. Planning for knee and ankle surgery and arthroplasty requires the evaluation of the conventional mechanical axis alignment as well as hindfoot malalignment. Precise and comprehensive evaluation will reduce the risks of postoperative malalignment, early failure of osteotomies and increased wear of polyethylene components in knee arthroplasty. Future work will include application of our findings to a cadaveric model.

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Distal Interphalangeal and Thumb Interphalangeal Joint Arthrodesis with New Generation Small Headless, Variable Pitch Fixation Devices

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Distal interphalangeal (DIP) joint and thumb interphalangeal joint (IP) arthrodeses are well-accepted procedures for the treatment of painful or unstable joints. Numerous techniques for accomplishing fusion have been described in the literature, using methods of fixation including Kirschner Wires (K-wires), interosseous wiring,[1] standard bone screws,[2-4] bioabsorbable implants,[5] plates,[6] external fixators,[7] and headless variable pitch screws such as Herbert (Zimmer, Warsaw, Indiana)[8-12] or Acutrak (Acumed USA, Hillsboro, OR)[13-16] screws. An arthroscopic-assisted technique has been described as well.[17]

Implant size plays an important role in fixation of DIP joint arthrodeses, in light of the small size of the distal phalanx, especially in the small finger. Wyrsch et al[18] noted that the average dorsopalmar diameter of the distal phalangeal neck (3.55mm) was smaller than the diameter of the lagging threads of the Herbert screw (3.90mm). In 10 of 15 male cadaveric specimens and 15 of 15 female specimens, these threads penetrated either the volar or dorsal cortex. In those penetrating dorsally, this lead to apparent nail matrix injury.

There are commercially available headless variable pitch devices now available in smaller sizes than previous implants (Table 1). These devices should theoretically decrease the risks of nail injury and distal phalanx fracture, be more technically forgiving, and permit a greater bone-to-bone contact area at the fusion site. We present a retrospective case series summarizing our experience with smaller, headless, variable pitch implants for DIP and IP joint arthrodeses along with our technique and observed complications.

Materials And Methods

Patients were located by querying our billing database for CPT codes 29860 or 29862. Between July 2007 and January 2012 there were 57 fusions in 36 consecutive patients treated with arthrodesis of the DIP or thumb IP joint with either the Acutrak Micro or Fusion (9 digits in 9 patients) or AcuTwist (48 digits in 28 patients)*. Revision arthrodeses were excluded.

Radiographic healing of the arthrodesis site was defined as bridging callus on two or more cortices on plain radiographs. All procedures were performed by one of two attending hand surgeons within a tertiary referral academic practice in a metropolitan setting. Hospital charts were reviewed for clinical data and radiographs were evaluated for alignment and healing.

*Note: One patient had IF, MF, RF, SF arthrodeses with Acutwist devices and a T arthrodesis with an Acutrak Fusion device.

TABLE 1. Selected Commercially Available Cannulated Headless Screws

Implant	Leading Thread Diameter (mm)	Trailing Thread Diameter (mm)
AcuTwist	1.5	2.0
Acutrak Micro	2.5	2.8
SBI AutoFix	2.0	3.0
Synthes 2.4mm Cannulated Headless Screw	2.4	3.1
Zimmer Herbert Mini	2.5	3.2
Acutrak Mini	2.8	3.2
Synthes 3.0mm Cannulated Headless Screw	3.0	3.5
Zimmer Herbert Screw	3.0	3.9

Surgical Technique

The technique for Acutrak micro screws is similar to the technique described by Brutus et al.[13] The technique for the Acutwist is described below.

Patients were positioned supine utilizing a hand table. Pre-operative antibiotics were administered. A transverse incision was made at the level of the DIP joint. This was carried down sharply through skin and extensor tendon to the bone. The flap was not undermined distally so as to protect the germinal matrix. After exposing the DIP joint any remaining cartilage was curetted out and osteophytes were removed with a rongeur. The bone was contoured at this point, if necessary, to correct any coronal or sagittal plane deformities, but the overall shape of the two opposing surfaces was maintained except for correcting angular deformity and exposing deep to the subchondral bone. A small K-wire was used to penetrate the subchondral surfaces of the surface of the distal phalanx in areas of dense sclerotic bone.

Then, a 0.045-inch diameter double tipped wire was advanced in an antegrade fashion through the flexed distal phalanx, exiting through the tip of the finger in the midline, just volar to the nail plate. This was then advanced until the tip was just proximal to the surface of the distal phalanx. The finger was then reduced to a position of neutral coronal plane alignment and 0-10 degrees of flexion, and the wire was advanced proximally into the middle phalanx. Positioning was confirmed on anteroposterior and lateral mini-C arm fluoroscopy. The skin was incised at the tip to a 2mm opening. The length was then measured, either with a supplied depth gauge or with a second guide wire and ruler. Next, while holding the reduction, the wire was removed and the tract tapped (when necessary); in our series tapping was used only when the surgeon felt the bone was particularly dense. The appropriate length Acutwist device was inserted inserted taking care to maintain the reduction of the arthrodesis site to allow the screw to follow the proper wire tract. Once seated to the desired depth, the implant placement and clinical alignment were again confirmed. The device was then toggled in the anteroposterior and mediolateral planes while securing the arthrodesis site. The shaft of the device then would break off from the screw at the machined "snap-off groove". Final fluoroscopic images were then taken. Bone grafting was used at either at this point or prior to the final placement of the implant depending on surgeon preferences. Wounds were then irrigated and typically closed with 5-0 or 6-0 nylon sutures. Soft bandages and a finger cap splint were placed, leaving the PIP joint completely free.

Sutures were removed at 10-14 days post-operatively. Hand therapy was not typically deemed necessary, unless required for any concomitantly performed procedures. Patients were followed with interval clinical visits and radiographs until bony and clinical union occurred.

Results

There were 7 males and 29 females. Average age was 58.3 years (range 33-84) at the time of surgery. Average duration of follow up was 321 days. 2 patients were lost to follow up at a time period before radiographic union would have been expected (0 days and 35 days). The primary diagnosis was osteoarthritis in 23, trauma in 4, Lupus in 3, Mallet/Boutonniere deformity in 3, and there was one case each of Dupuytren's, post infectious arthritis, and neuromuscular disorder. There were 7 thumbs, 17 index fingers, 12 long fingers, 9 ring fingers, and 12 small fingers included. 21 patients (58%) had other associated procedures performed concomitantly.

There were no cases of nail deformity, significant skin sloughing, or clinically significant malalignment. There were no cases of implant breakage intra-operatively at another site than the planned site. There was one case of prominent hardware at the volar pulp requiring hardware removal following union. This patient was asymptomatic at the most recent follow up. There was one intraoperative distal phalangeal fracture that occurred in the small finger of a patient with lupus. This was noted on final fluoscopic imaging; however, the arthrodesis site was noted to be stable. The fracture healed uneventfully and the arthrodesis site went on to union.

Radiographic union was noted in 50 of 55 fingers (91%). [2 fingers in 2 patients were lost to follow up]. Local autograft (typically from the dorsal osteophytes) was used in 27 of 57 digits. In 2 cases, bone graft from a distant site (e.g. distal radius) was used.

There were five non-unions. One was in an osteoarthritic patient who underwent 3 simultaneous DIP/IP arthrodeses, all with AcuTwist devices, which resulted in loss of fixation of the thumb IP arthrodesis site around 6 months post-operatively. This was treated with revision to an Acutrak Fusion screw with distal radius autograft and a supplementary 26-gauge interosseous wire, progressing to union at 4 months after the revision surgery. Another patient underwent ring finger DIP joint arthrodesis for post-traumatic arthritis did not demonstrate radiographic union at a 7 month follow up visit, but he was asymptomatic at that time.

There was one case of a deep infection occurring prior to bony union. This required implant removal. The patient was left with a flail joint, but was pain free in an orthosis and declined further operative intervention. The remaining non-union occurred in a patient with lupus who underwent arthrodesis of the thumb, index, and long fingers. The thumb and long figers healed uneventfully; the index did not. No further operative intervention has been performed, although she does report discomfort at this site.

Our major complication (nonunion, deep infection) rate was 10.5% and our minor complication (intraoperative fracture, symptomatic hardware) rate was 3.5%.

Conclusions

Arthrodesis of the DIP/IP joints is proven and effective for dealing with a myriad of painful and deforming ailments of the DIP and IP joints. In this setting, headless variable pitch screws have many theoretical benefits compared to other potential fixation methods. Unlike K-wires they are buried deeply and avoid having a potential conduit for deep infection. This may explain the low instance of either deep or superficial infections seen in this series. Unlike standard bone screws, they are completely intraosseous and avoid having a prominent screw head situated in the sensitive volar pulp region. This may account for the lack of complaints of tip sensitivity and the limited need for hardware removal in our series.

Our results compare favorably to prior reported series. In 1992, Stern and Fulton[12] published a series of 181 arthrodeses of DIP and IP joints. Their major complication rate was 20% (infections, non-unions, etc) and their minor complication rate was an additional 16% (skin necrosis, prominent hardware, paresthesias, etc). They reported non-unions in 21 (12%), however, 13 of these were pain free. A variety of techniques were employed.

Several case series have documented usage of headless variable pitch screws, which have the theoretical benefit of being completely intraosseous to avoid hardware prominence while providing inter-fragmentary compression. Faithfull and Herbert[9] noted 100% union and no complications in 11

DIP joints in their early series using Herbert screws. In Stern's[12] subgroup of Herbert screws, a major complication rate of 19% and minor complication rate of 44% was documented in 27 cases. More recent case series have documented variable results. El-Hadidi and Al-Kdah[8] documented fusion in 14 of 15 digits. They had one case of poor screw placement causing pain. Lamas Gomez et al[11] had fusion in 19 of 20 digits with one case of amputation related to dorsal skin necrosis. They recommended using the mini-Herbert screw to facilitate placement. Brutus et al[13] utilized mini-Acutrak screws and noted nonunions in 3/22 (14%), infection in 4/22 (18%), and nail bed injury in 3/22 (14%). They noted the difficulty of using the mini-Acutrak screws, especially in the small finger.

The smaller diameter of these devices is more appropriate for the tight confines of the distal phalangeal medullary canal. Perhaps due to this sizing, we had no instances of nail plate deformities due to penetration of the dorsal cortex of the distal phalanx as seen in the biomechanical study by Wyrsch et al.[18]

While our case series is larger than any other series utilizing headless variable pitch screws for DIP/IP arthrodeses, there are several limitations worth noting. Its retrospective nature makes it difficult to make direct comparisons with other studies. Our radiographs were obtained at non-standardized intervals, thus making a determination of time to healing unreliable. Our patients had a broad array of diagnoses, which limits the ability to elucidate different subgroup characteristics. We also were unable, given the low complication rate, to determine the relative complication rates for DIP/IP arthrodeses for these differing diagnoses. One of the nonunion cases was in a thumb IP joint and this patient went on to heal with a larger diameter implant. As the distal phalanx of the thumb is typically significantly larger then the other digits, larger implants may be preferable. The authors have switched to using larger diameter implants for arthrodesis of the thumb IP joint. We were unable to determine the role or effect of autogenous bone grafting.

Reliable fusion rates were achieved with a modest complication rate. Insertion of these implants is perhaps more technically forgiving than with prior generations of larger implants. These devices seem to be an improvement over prior generations of headless variable pitch screws.

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Time to Union as a Measure of Effectiveness

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Time to fracture union is commonly reported in orthopaedic clinical research even though there is no accepted reference standard for the radiological diagnosis of union, and radiographic diagnosis of union has not been shown to be reliable or precise. Studies have noted inconsistent definitions and measure of union both in orthopaedic scientific publications[1] as well as in a survey of orthopaedic traumatologists.[2] Several studies have also questioned the intra- and inter-observer reliability of radiographic diagnosis of union for various fractures.[3-7] The growing consensus that time to union is an unreliable and imprecise measure of the effectiveness of fracture treatment would be corroborated by identification of variance in the average time to union in studies of comparable fractures similarly treated.

In this study we catalogue the last 10 years' studies that use time to union as an outcome measure, recording diagnostic criteria and comparing mean time to union for comparable fractures with comparable treatment.

Methods

Pubmed was searched for English Language articles published during the 10-year period between 1997 and 2007 using the following terms: "time to union," time AND union, time AND bony AND healing, time AND fracture AND healing, time AND unite AND fracture, time AND bone AND unite. Exclusion criteria were (1) nonhuman studies, (2) studies of the treatment of ununited fractures, osteomyelitis, or peri-prosthetic fractures (3) case reports and (4) pediatric fractures.

The papers were evaluated in three ways. First, the following data were extracted: the method for diagnosing union; mean and range of "time to union"; the number of patients; fracture site and treatment; and the statistical methods used to evaluate time to union. Second, in order to evaluate variations in average "time to union" for comparable treatments of nearly identical fractures at identical anatomic sites, we selected sets of three or greater papers evaluating similar fracture treatment. Finally among all papers providing enough data to perform statistical comparisons, the average time to union was evaluated for statistically significant differences across studies using one-way analysis of variance. P values <0.05 were considered significant. For each statistically significant difference, post-hoc pair wise comparisons of the selected studies were performed using the Tukey test.

Results

One hundred twenty-seven studies met the inclusion criteria. Because of the number of studies and many anatomical areas, the areas were categorized by AO location. The following anatomical areas were involved: Ankle (3 studies); calcaneus (1); clavicle (3); distal femur (2); distal radius (1); tibial pilon (5); distal femur (21); floating knee (1); forearm (9); hip (13); humerus (10); long bones (2); mallet finger (1); metacarpal (1); metatarsal (1); proximal phalanx (1); scaphoid (6); segmental tibia (2); talus (1); tibial shaft (39), tibial plafond (4) and 1 trans-scaphoid perilunate fracture-dislocation.

Diagnosis of Fracture Union

There was variation in the diagnostic criteria for fracture union as follows: Bridging callus (39 studies), bridging callus at three different cortices (30), bridging callus in two different views (25), and bridging callus or obliteration of the fracture line (13), presence of callus (2), absence of osteonecrosis (1), absence of displacement (1), and hardware failure or loosening (1). The diagnostic criteria were not clearly stated in 27 studies.

Variation in Reported Time to Union for Specific Fractures

Most studies don't mention the interval time between follow-up appointments. Others have a monthly interval for follow-up, and some have a two-weekly follow-up. Ten specific fracture types had three or more studies addressing time to fracture union, comprising a total of 66 studies. The anatomical regions covered included: Upper extremity fractures: Clavicle (3); Forearm (3); Humerus (6) and Scaphoid (4); Lower extremity fractures: Distal Tibia (6); Femur (9); Hip (12); Tibia (8); Tibial plafond (3), and open tibia fractures. (12) There was substantial variance in mean time to union for all fractures.

Upper Extremity Fractures

The average mean time to union was 12.8 ± 2.6 weeks (range 9.6 – 16.4 weeks) among the three studies of clavicle fractures; 10.9 ± 2.7 weeks (range 7.8 – 16 weeks) among the six studies addressing humeral fractures treated with nailing or plating; 13.6 ± 5.2 weeks (range 6.4 – 20 weeks) among the three studies addressing forearm fractures; and 12.0 ± 5.0 weeks (range 6.1 – 18.2 weeks) among the four studies addressing operative management of scaphoid fractures.

Lower Extremity Fractures

The average mean time to union among seven studies addressing operative treatment of intertrochanteric femur fractures was 14.0 ± 3.1 weeks (range 10.2 – 19.5 weeks). The average mean time to union among three studies of the operative management of subtrochanteric femur fractures was 14.9 ± 0.7 weeks (range 14 – 15.7 weeks). The average mean time to union among nine studies of operative treatment of diaphyseal femur fractures was 18.2 ± 7.1 weeks (range 11.4 – 39.4 weeks).

The average mean time to union among three studies addressing tibial plafond fractures was 19.9 ± 2.6 weeks (range 16.5 – 22.8 weeks). The average mean time to union among eight studies addressing diaphyseal tibia fracture was 18.5 ± 3.6 weeks (range 13.6 – 25.7 weeks). The average time to union among 12 studies addressing surgical treatment of open diaphyseal tibia fractures was 32.1 ± 7.4 weeks (range 19 – 47.8 weeks). Among six studies addressing distal tibia fractures, the average time to union was 20.9 ± 5.8 weeks (range 14.7 – 35 weeks).

Statistical Comparison of Time to Union for Specific Fractures

Among studies that provided sufficient data to perform a statistical comparison, there were statistically significant differences in average time to union among two studies evaluating plate fixation of clavicle fractures[8,9] (mean 11.5 ± 1.8 weeks; $p=0.03$), three studies evaluating unreamed nailing of femur fractures (mean 25.9 ± 10.0 weeks, $p < 0.01$; Post hoc Tukey--all significantly different from one another), and three studies evaluating reamed nailing of femur fractures (mean 19.3 ± 7.0 weeks, $p < 0.01$; Post hoc Tukey--all significantly different from one another). There were no differences in four study groups evaluating plate and screw fixation of intertrochanteric femur fractures (mean 10.9 ± 0.6 weeks, $P=0.29$), three studies describing plating of distal tibia fractures (mean 20.0 ± 0.6 weeks; $p=0.92$), or three studies comparing intramedullary nailing of femur fractures (mean 17.1 ± 3.0 weeks; $p=0.23$).

Three studies compared unreamed nailing

techniques in closed tibia fractures. There was no significant difference between the studies of Larsen and colleagues[10], Uhlin and colleagues[11], and Karladani and colleagues[12] (mean 21.2 ± 3.2 weeks; $p = 0.07$). There was a significant difference between the four studies reporting time to union in tibia fractures treated with reamed nailing (mean 15.8 ± 1.5 weeks; $p < 0.01$). Post hoc Tukey HSD analysis found a significant difference between Emami and colleagues[13] and Tigani and colleagues[14]; Larsen and colleagues[10] and Tigani and colleagues[14]; and between Braten and colleagues[15] and Tigani and colleagues[14].

Discussion

This study and prior structured reviews[1,16] note that there is no reference standard for the radiographic diagnosis of fracture union. Furthermore, our analysis demonstrated substantial variation in reported time to union for comparable fracture types with comparable treatments and statistically significant differences between several comparable studies that provided adequate data for statistical comparison. Combined with analyses that question the precision and reliability of the diagnosis of fracture union[2,3], these findings bring into question the role of time to union as a useful and meaningful measurement of treatment effectiveness in studies of fracture treatment.

The observed variations in average time to union are likely the result of multiple factors, including, but not limited to: (1) variations in diagnostic criteria for union; (2) intra- and interobserver variation in the diagnosis of union; and (3) variations in the details of management. One must also consider differences in the number, spacing, and regularity of the office appointments to assess fracture healing as well as differences in the statistical technique for evaluating union.

Until there is a consensus technique for the diagnosis of fracture union that is reliable and precise, it is misleading to report measurements of time to union. Other measures of successful fracture healing, such as the absence of loosening or failure of implants a minimum one year after surgery, may prove more valid and reliable for the diagnosis of fracture union and are probably more applicable and relevant. The imprecision of time to union as a measure of treatment effectiveness makes it particularly susceptible to bias and therefore inadequate for scientific investigation.

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Appendix A: Papers Used for Analysis

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Advances in Single-cell Tracking of Mesenchymal Stem Cells (MSCs) During Musculoskeletal Regeneration

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Musculoskeletal diseases are the most commonly reported health conditions in the United States.[1] These diseases include various forms of arthritis, congenital deformities and anomalies, fractures, and pain associated with the back, neck, or intervertebral disks.[1] Millions of surgeries are performed every year to correct musculoskeletal diseases, yet a high percentage fail to obtain a satisfactory outcome.[2-5] For example, only 64% of patients treated surgically for lumbar spinal stenosis reported good-to-excellent outcomes.[4] Treatments and lost wages due to musculoskeletal diseases are a significant burden on society, representing 7.7% gross domestic product (~$849,000,000,000) for 2002 to 2004.[1] Therefore, new therapies that reduce the cost and morbidity of musculoskeletal diseases are in great demand.

MSCs have been the focus of widespread attention in recent years, and are being studied in over one hundred clinical trials world-wide.[6] In addition to their obvious potential for treatment of musculoskeletal diseases, MSCs have demonstrated promise as a cell therapy in many pre-clinical and early-stage clinical trials for a range of diseases, including diabetes, cardiac disease, bone marrow transplant-associated GVHD, and osteogenesis imperfecta.[6,7] Although proven to be safe, efficacy in late stage clinical trials has not met expectations.[8,9] This has led some to develop strategies that can enhance the potency of MSCs before infusion, including activation or transfection of cells before infusion, and cell surface engineering.[10,11] A critical challenge in the development of these enhancement strategies is quantification of in vivo MSC homing and therapeutic efficiency. To address this challenge, we applied in vivo confocal and multi-photon microscopy, a powerful singe-cell detection and evaluation technique.

MSC use in pre-clinical and clinical models began with their discovery in the 1960's during bone marrow transplant experiments that led to the hypothesis that a cell type existed within the bone marrow that could differentiate into osteoblasts, aid in the development of sinusoidal structures, and support hematopoiesis in ectopic sites.[12] These skeletal stem cells were first purified from bone marrow based on adherence to tissue culture plastic and were re-named MSCs for their ability to differentiate into adipocytes, chondrocytes, and osteoblasts.[13,14] MSCs have been well characterized in vitro, and are defined as being tissue culture plastic adherent; positive for CD105, CD73, and CD90 antigens; negative for HLA-DR, and CD45, CD34, CD14, CD19 antigens; and able to differentiate into osteoblasts, adipocytes, and chondrocytes.[15] Recently, it has been suggested that MSCs are perivascular cells in vivo. This has raised many interesting questions about how pericytes and adventitial cells respond to acute bone injury and if perivascular cells in non-bone tissues are also MSCs.[16-18]

Our research describes the ability of in vivo confocal and multi-photon microscopy to quantify the behavior of exogenous engineered MSCs and evaluate endogenous perivascular cell response to bone injury. Our results contribute to our understanding of how exogenous MSCs interact with diseased tissue and how endogenous perivascular cells respond to musculoskeletal injury. These results may help improve current cell therapies and lead to the development of novel therapeutics.

Materials and Methods

Video-Rate Laser Scanning Confocal and Multi-Photon Hybrid Imaging System

Our video-rate laser scanning confocal and multi-photon hybrid imaging system is designed specifically for live animal cell-tracking and molecular imaging studies (Figure 1).[19] The system is equipped with three monochrome lasers and a Ti:Sapphire laser. The Ti:Sapphire laser can be tuned between 710-920 nm and can be used for two-photon microscopy. Enhanced Green Fluorescent Protein (EGFP) can be imaged by either confocal (λ_{ex} = 491 nm, 509-547 nm detection) or two-photon microscopy (λ_{ex} = 920, 505-575 nm detection). The system is designed to image EGFP and three other standard fluorescent channels: DsRed (λ_{ex} = 532 nm, 573-613 detection), DiD (λ_{ex} =633 nm, 667-722 nm detection), and DiR (λ_{ex} = 750 nm, >770 nm detection); as well as collagen/bone using Second Harmonic Generation (SHG, λ_{inc} = 880 nm, λ_{scat} = 440 nm). The Ti:Sapphire laser is used to excite both SHG and 2-photon

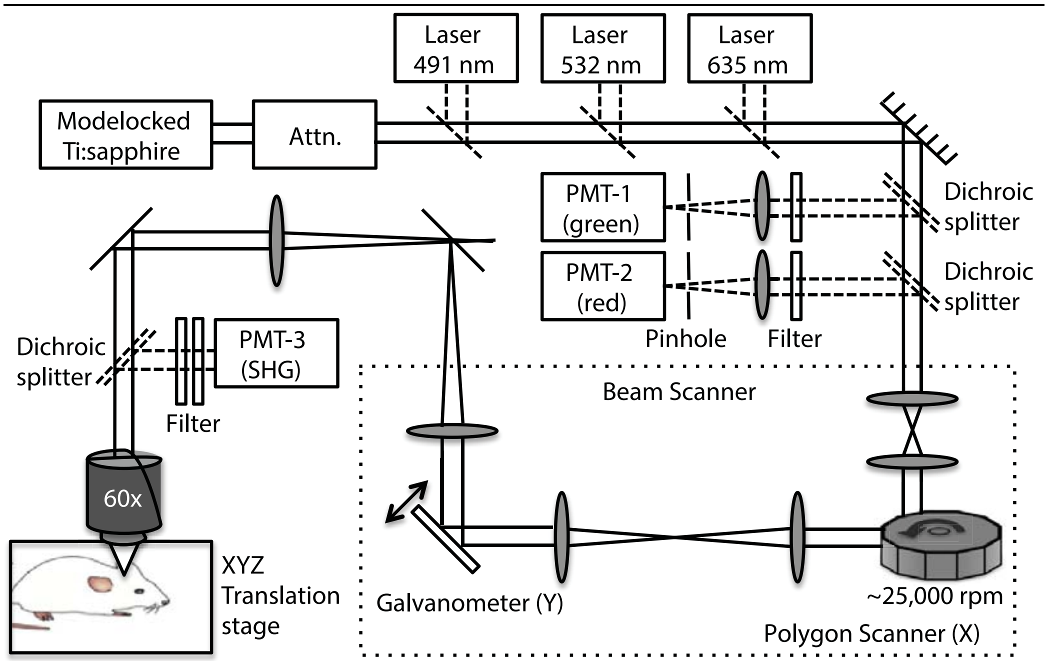

FIGURE 1. Schematic of in vivo confocal fluorescence and multi-photon microscope. A rotating 36-faceted polygonal mirror creates the X-scan and a galvanometer-mounted mirror creates the Y-scan. The mode locked Ti:sapphire laser provides wavelength-tunable multi-photon illumination. The anesthetized animal is placed under the objective in a heated 3D-translation stage, which has micron resolution.

imaging modalities since these are multi-photon processes that require high power and short pulse duration, ~100 fs. A rotating polygon mirror in series with a galvanometer mirror allows the x-y laser scan to be performed at video-rate (30 frames/sec).

Several aspects of this system allow us to track single-cells in real-time within inflamed tissue and calvarial bone marrow inside live animals. First, up to three confocal fluorescent channels or two confocal fluorescent and one two-photon channel can be recorded simultaneously. This allows us to image cells, blood vessels, and bone simultaneously (Figure 2A). Also, cells expressing specific markers can be visualized by infusing fluorescent antibodies intravenously or subcutaneously.[20] Second, we can probe skin to a depth of ~250 µm and calvarial bone marrow to a depth of ~150 µm. The spatial resolution is sufficient to determine distances between cells, bone surface, and blood vessels. This is particularly useful when defining the stem cell niche and observing extravasation of cells infused in the blood stream (Figure 2B).[10,21-23] Third, by utilizing the video-rate scanning capabilities, heartbeat and breathing artifacts are minimized, and it is possible to visualize circulating MSCs interacting with endothelium (Figure 2C). From these video-rate images, the rolling velocities of MSCs can be quantified.[11]

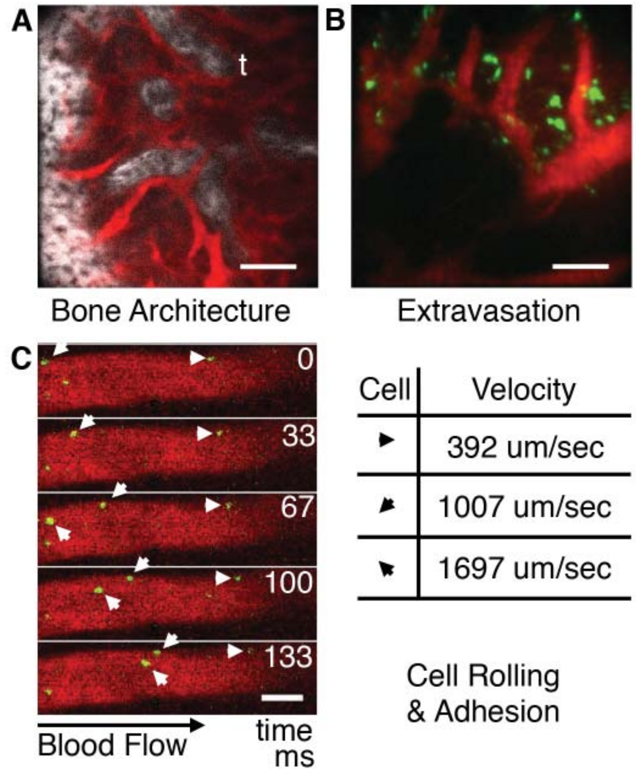

FIGURE 2. Basic capabilities of in vivo microscope. (A) Calvarial bone microstructures (white) and blood vessels (red); t = trabecula. (B) Visualization of MSC (green) extravasation in bone marrow. (C) Images of MSCs flowing through blood vessels acquired at 30 frames/second can be used to quantify cell velocity for cell rolling and adhesion studies. Bar = 100 µm.

MSC Homing

MSCs have the ability to home to bone marrow and sites of inflammation/injury. To assess homing, we used two methods of in vivo imaging, i.e. bone marrow and inflamed ear imaging. Studies were performed in accordance with US NIH guidelines for care and use of animals under approval of the Institutional Animal Care and Use Committees of Massachusetts General Hospital, Children's Hospital Boston, and Harvard Medical School. Intravital imaging of bone marrow and inflamed ears was performed as previously described.[10,24] For delineation of vasculature during imaging, fluorescent-conjugated dextran (2 x 106 Da; Invitrogen) was infused intravenously just prior to imaging. For bone marrow MSC homing studies, 106 DiD (Invitrogen) labeled MSCs were infused intravenously twenty-four hours prior to imaging. For inflamed ear MSC homing studies, inflammation was induced via injection of E. coli lipopolysaccharide (LPS) into the ear pinna of the right ear, while the left ear received saline as a control. Twenty-four hours after induction of inflammation, 106 MSCs were infused intravenously. Imaging was then performed 24 hours after MSC infusion.

Perivascular Cell Proliferation and Migration After Osseous Injury

To reliably image perivascular cells in vivo requires markers that have high specificity to pericytes and adventitial cells in the tissue of interest. CD146 antigen, nestin, and alpha-smooth muscle actin (SMA) are the most specific candidates characterized in bone marrow.[21,26,27] To observe pericyte and adventitial cell proliferation, migration, and homing during osseous regeneration, we imaged calvarial defects created in transgenic mice expressing EGFP under the SMA promoter. In these mice, SMA-EGFP cells are found in perivascular locations within mouse calvarial bone marrow. Figure 4A shows a large area map of the calvarial bone in which perivascular cells are associated with sinusoidal microvessels within the parasagittal bone marrow regions. In this mouse model, vascular smooth muscle cells can be visualized wrapped around arterioles (Figure 4A, arrowheads). Non-critical osseous defects were created in parasagittal bone marrow containing regions using a dental drill (Figure 4A, white boxes) and characterized using SHG imaging (Figure 4B). Briefly, the scalp was surgically retracted and calvarial defects were created using a dental drill. Between daily time-lapse imaging sessions, the scalp was sutured and mice were allowed to fully recover from anesthesia.

Results and Discussion

MSC Homing

As shown in Figure 3, high numbers of MSCs can be observed in bone marrow and inflamed ears (Figures 3A & 3B), but not in saline treated ears (Figure 3C). Images from these experiments were evaluated using ImageJ software (NIH). Thousands of MSCs per mm3 were found in calvarial bone marrow and inflamed ear tissue, while only ~22 MSCs per mm3 was observed in saline treated ears (Figure 3D).

After homing to damaged tissues, MSCs may secrete trophic factors or supply cell types that are necessary for tissue regeneration.[25] Increasing the numbers of MSCs that home to injuries could potentially increase the efficacy of MSC therapies.[10] We have developed methods to coat the surface of MSCs with homing ligands typically expressed on leukocytes, e.g. Sialyl Lewis X or SLeX. Our imaging methods demonstrated that engineered MSCs exhibit increased homing to inflamed tissue and slower rolling velocities on inflamed endothelium and (Figure 3E).[11]

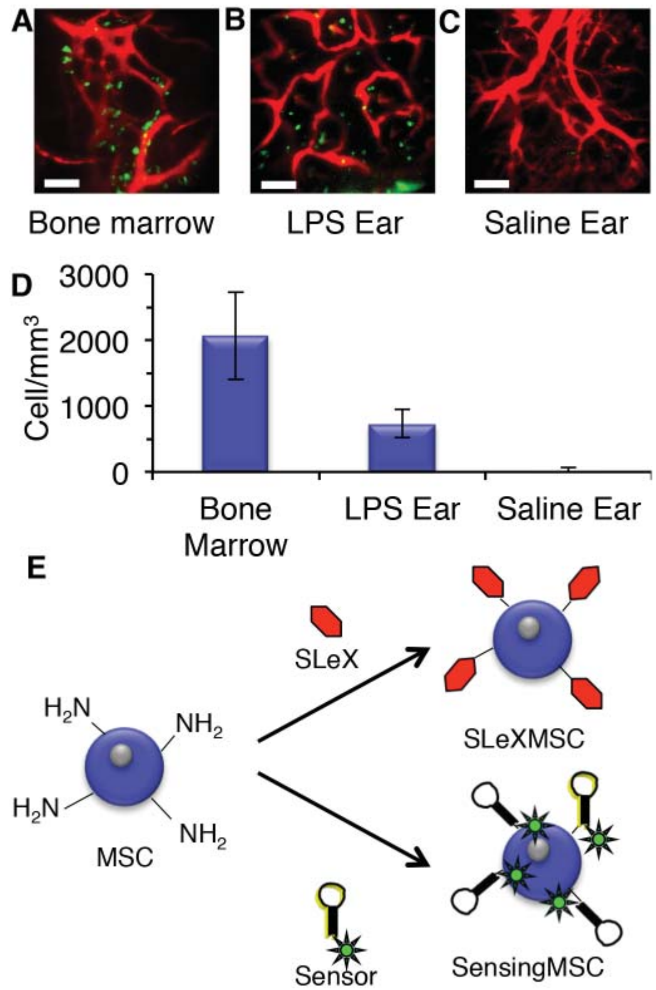

FIGURE 3. MSC homing to bone marrow and inflamed tissue twenty-four hours after systemic infusion. (A) MSC homing to calvarial bone marrow. (B) MSC homing to LPS treated ear tissue. (C) Lack of MSC in saline treated ear tissue. MSC (green); Blood vessels (red); Bar = 100 μm. (D) Cell density per cubic mm. (E) Chemical engineering of MSCs with homing ligands and molecular sensors.

We have also developed molecular sensors that can be placed on cell surfaces to sense the local microenvironment of MSCs that have homed to bone marrow (Figure 3E).[23] We believe that these chemical engineering methods will enhance the efficacy of MSC therapies and could lead to discoveries about the make-up of the microenvironment that MSCs encounter in vivo.

Perivascular Cell Proliferation and Migration After Osseous Injury

Little is known about the process of osseous regeneration at the single-cell level. In general, repair and regeneration of osseous injuries depends on the recruitment, activation, and differentiation of competent adult MSCs as well as angiogenesis and production of reparative bone matrix. Osseous regeneration requires the spatial and temporal regulation of multiple cell types at various stages of differentiation. MSCs may be recruited from the local milieu, or mobilized to the injury from distant sites. These cells gradually advance into the core of the defect leaving a trail of new tissue. Our long-term goal is to generate a clear understanding at the single-cell level of osseous regeneration.

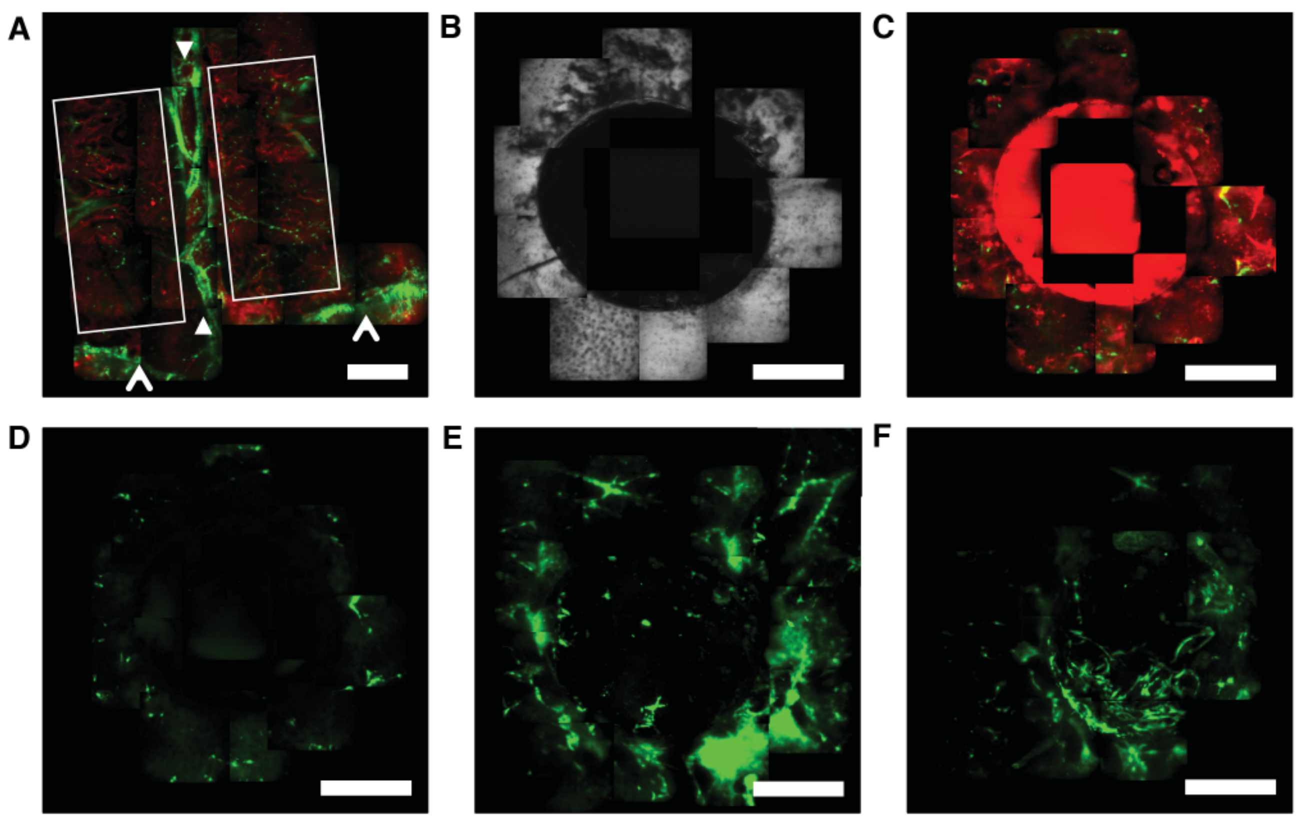

FIGURE 4. SMA-EGFP$^+$ cell dynamics during osseous regeneration. (A) Images of uninjured animal showing parasagittal regions outlined with white box, central vein and sagittal suture running top-to-bottom between closed arrowheads, and coronal vein and suture running left-to-right highlighted with open arrowheads. Vascular smooth muscle cells can be seen wrapped around arterioles associated with the central and sagittal sutures. Perivascular SMA-EGFP$^+$ cells can be visualized in the parasagittal regions. (B) Representative images of calvarial bone surface after creation of 1.2 mm osseous defect. (C) Representative images of blood and SMA-EGFP signals after creation of osseous defect. (D-F) Time-lapse imaging of SMA-EGFP signal immediately, three days, and five days after osseous injury. SMA-EGFP (green); blood (red); bone (white); Bar = 500 μm.

This knowledge can be used to develop the potency of therapies for regenerative medicine and tissue engineering. Although the in situ identity of MSCs has been controversial, recent evidence suggests that perivascular cells, namely pericytes and adventitial cells, are the in vivo origin of MSCs.[17,18,26] Therefore, we applied in vivo imaging techniques to visualize the response of perivascular cells during osseous regeneration.

Immediately after injury, a hematoma formed within the defect (Figure 4C). Time-lapse microscopy revealed a significant increase in EGFP signal and number of SMA-EGFP+ cells in bone marrow adjacent to the defect at two days post injury (Figure 4D & 4E). Three days post injury, the number of SMA-EGFP+ cells inside the defect increased. This data suggests that SMA-EGFP+ cells respond to osseous injury by proliferating and migrating into the defect.

Conclusion

We applied live-animal single-cell in vivo imaging techniques to characterize various aspects of MSC therapies and MSC-host inter actions during inflammation and osseous regeneration. These imaging techniques have allowed us to demonstrate the improved homing of engineered MSCs, the feasibility of sensing the MSC microenvironment, and the endogenous perivascular SMA-EGFP response to osseous injury. This imaging technology will be helpful to understand the molecular mechanisms that MSCs use to tether and adhere to inflamed endothelium and transmigrate across endothelium. By characterizing the activities of MSCs during osseous regeneration, the mechanisms or specific cues that mediate the migration and differentiation may potentially be identified. These techniques could also be used to determine how bone-engineering strategies regulate MSC migration and differentiation.

Acknowledgements

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Osteochondral Interpositional Allograft for Revision of a Malunited Olecranon Fracture, *Olecranon Malunion Revision*: A Case Report

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[1]*Investigation performed at aMassachusetts General Hospital, Boston, MA*

The anatomic relationship of the sigmoid notch of the olecranon to the humeral trochlea is fundamental to the stability and the motion of the elbow joint. Fixation of displaced olecranon fractures should take into account both the anatomic restoration of the articular surface as well as the restoration of the length between the coronoid to the olecranon. Inability to restore the length of the sigmoid notch has been cited as a factor leading to limitation of elbow function and increased joint contact pressures with early osteoarthritis.[1-4] Small articular step-offs at the base of the olecranon are well tolerated, but failure to restore the large depressions in the articular surface and shortening of the sigmoid notch results in malunited fractures with poor outcomes.

When patients present with malunited fractures, surgical options include revision surgery, olecranon excision with triceps advancement, massive allograft reconstruction or a total elbow replacement. In a young patient, revision surgery is the only suitable initial option. Revision surgery with autologous and allografts are commonly advocated but literature on such methods is limited.[5] Use of massive osteochondral allografts in the elbow has been used only as salvage procedures for reconstruction of the elbow published in limited cases.[6-8] However, specific use of small osteochondral allograft contoured to restore the articular congruity and the length between the olecranon tip to the coronoid process has not been previously published.

We report a case of comminuted olecranon fracture that was initially treated with tension band wires. This fixation construct failed, and the patient developed a malunion with both shortening of the coronoid-olecranon interval and a large depressed central articular surface that led to a painful and stiff elbow. Revision surgery involved osteotomy of the olecranon and interposition of small fragment of fresh osteochondral allograft. Although use of osteochondral allografts have been previously reported for many different fracture types including the talus, tibial plateau, femoral head and humeral head and its use in elbow is not unique, use of small osteochondral allograft contoured specifically to restore articular congruity and length of the coronoid-olecranon interval has not been previously addressed in literature.

Case

A 30 year-old right-hand-dominant male truck driver fell off a trailer and sustained a comminuted right olecranon fracture. It was initially treated at an outside hospital with a tension band technique. The patient presented to our institu

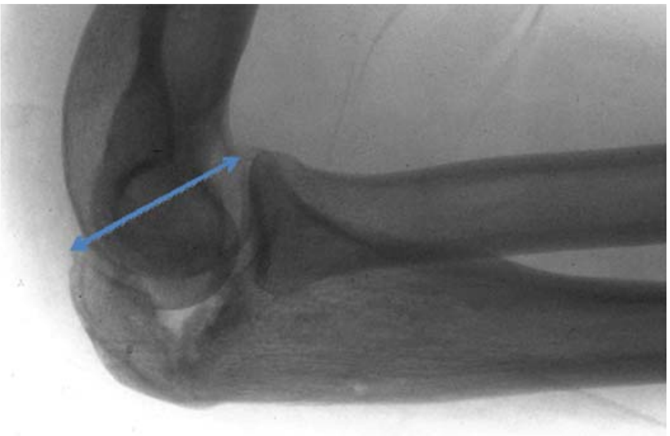

FIGURE 1. Lateral xray of the patient showing the olecranon malunion with a large osteochondral defect and shortened coronoid-to-olecranon interval (blue arrow).

tion 8 months later with a complaint of motion block with inability to fully flex or extend the elbow. Examination of his left elbow revealed limited active and passive elbow motion with less than 100 degrees of functional arc of motion. He had painless full supination and pronation of his forearm. Radiographs of the elbow revealed a malunited olecranon with a large defect in the articular surface of the olecranon with a narrowed coronoid-to-olecranon interval (Figure 1). Examination under anesthesia revealed that the elbow was stable to varus and valgus stress but the elbow was catching prior to full flexion and extension at the humeroulnar articular contacts of the coronoid and the olecranon. Diagnostic elbow arthroscopy revealed grade II chondromalacia of the radial head and grade I to II chondromalacia of the capitellum. The trochlea showed grade I chondromalacia while the olecranon had a significant defect in the articular surface with interposed fibrous tissue.

Given the significant osteochondral defect and proximal ulna shortening, the patient underwent a transolecranon osteotomy. Using the posterior incision from the previous surgery, a chevron osteotomy was created distal to the previous fracture site to reflect the proximal ulna along with the articular step off. Fresh medial tibial osteochondral allograft was carefully selected and contoured to the shape of the articular defect of the greater sigmoid notch to restore the articular congruity. The appropriate length of the graft was determined by comparing the coronoid-to-olecranon distance of the unaffected elbow. Allograft trials were provisionally fixed with K-wires and the sigmoid notch was reduced to determine restoration of smooth arc of motion in flexion and extension. Once the appropriate osteochondral allograft was appropriately contoured, it was inserted and internally fixed with 3 Herbert screws to the proximal ulna applied from inside the joint to outside (Figure 2). The proximal ulna osteotomy was reduced and internally fixed using tension band technique. Intraoperatively, full smooth arc of elbow motion was achieved.

The fixation of osteochondral allograft 6 months later went into fibrous-type nonunion, so the tension band wires were replaced with a compression plate which provided a more stable construct with

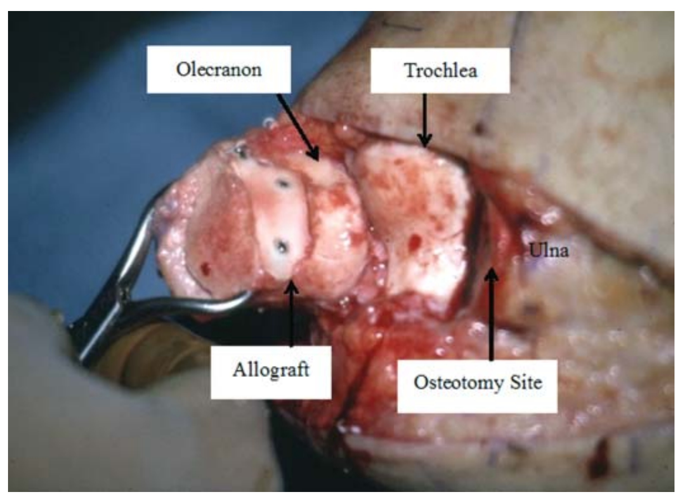

FIGURE 2. Intraoperative photograph: Proximal part of the sigmoid notch at the osteotomy site flipped 180-degrees showing the articular surface with tibial osteochondral allograft fixed with herbert screws.

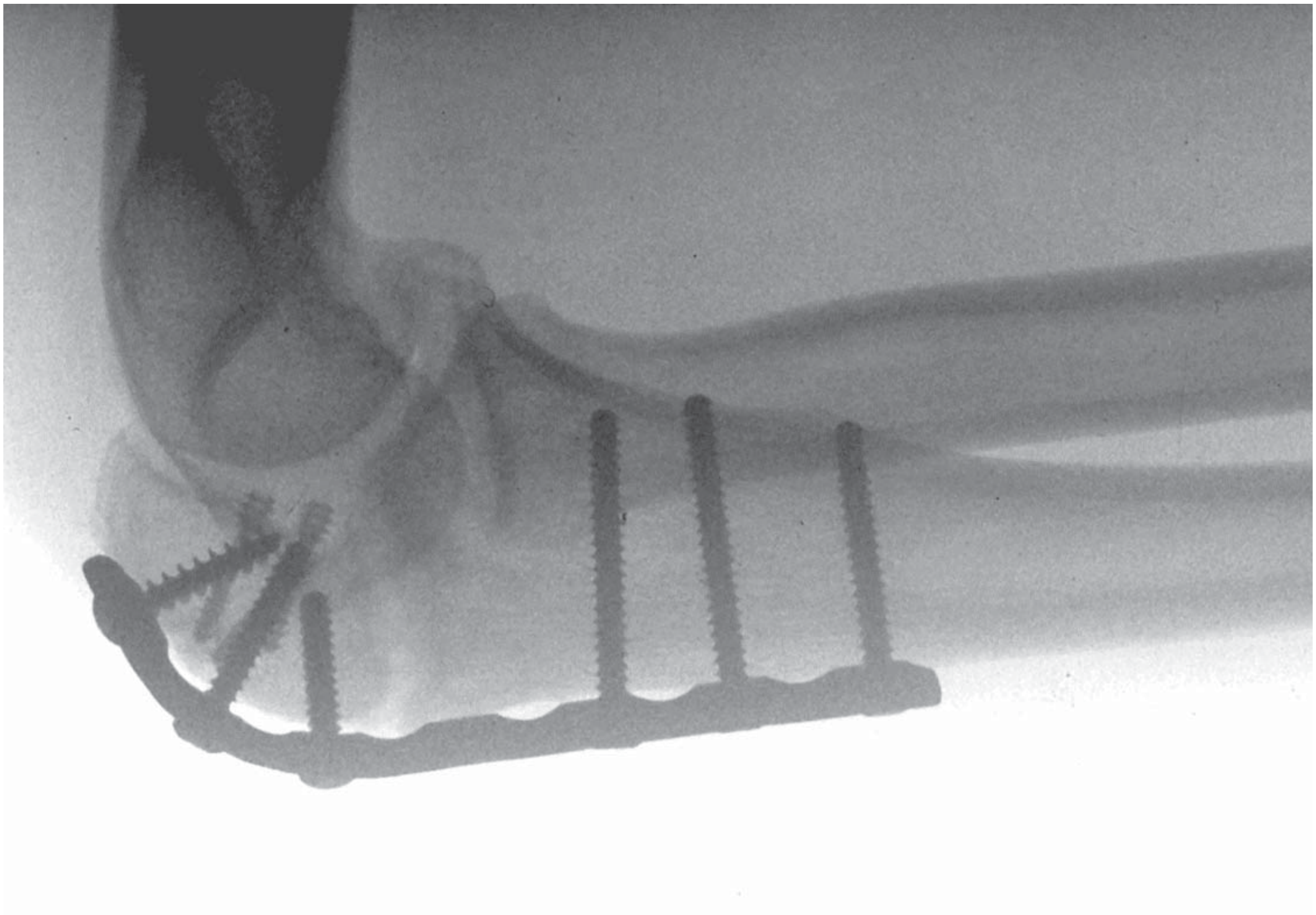

FIGURE 3. Postoperative lateral xray of the elbow revealing reconstruction construct with the osteochondral allograft.

union noted in 1 year follow-up (Figure 3). Patient also regained 105° arc of motion from 10-115°.

Discussion

Principles of intra-articular fracture fixation rely on restoration of the articular surface and stable fixation for early range of motion. Unique to the proximal ulna, the articular surface is a semilunar notch. The facets of the coronoid and proximal olecranon not only provide anterior and posterior elbow stability but they also serve as mechanical blocks at extremes of elbow flexion and extension.[9] Hence, for comminuted olecranon fractures, the contour of the articular surface as well as the length of the greater sigmoid notch must be restored to provide smooth arc of motion and to prevent early osteoarthritis.[2,3,10] Contemporary interests lie with attempts at restoration of the articular surface of the sigmoid notch with a variety of internal fixation techniques.[11-15] Tension band fixation converts the distraction force of the triceps on the cortical surface of the olecranon to generate compression forces on the articular surface of the trochlear notch. If the articular surface opposite tension band fixation is comminuted, it will not resist the compression forces generated by this technique and collapse, resulting in shortened coronoid to olecranon interval as was the case with this patient.[16] More stable fixation of comminuted olecranon fractures can be achieved with compression plate and screws supporting the cortical surface of the olecranon to maintain the sulcus distance of the greater sigmoid notch at the expense of small gaps in the articular surface. If the fractures are very comminuted, however, bone graft is necessary. The use of bone grafts to restore the articular surface of the greater sigmoid notch has been reported for olecranon fractures and nonunions.[11-14,17,18] Schatzker advocated elevation of the joint depression much like tibial plateau fractures and bone-grafting the resultant defect.[19] Bone grafts made of corticocancellous "bone plates" or bone plugs has also been used but these grafts are used to supplement as biology for healing and are not necessarily used as a structural graft for the purpose of interposition.

When malunion develops from inadequate initial fixation, reconstruction presents a major surgical challenge and literature on restoring these malunions are limited.[5,7,8] Some papers support that a large portion of the greater sigmoid notch can be removed without sacrificing elbow motion and stability.[20,21] Due to elevated joint pressures and humeroulnar joint constraints, current indications for olecranon excision have been limited to low-demand patients of 60 years or older with osteopenia and stable fractures requiring less than 50% olecranon excision.[3,9,12] Excision of the comminuted portion of the olecranon and re-approximating a shortened trochlear notch have also been described.[10,16] This method, however, causes further narrowing of the greater sigmoid notch and loss of motion.[2] Alternatively, if the malunion results in enlargement of the coronoid-to-olecranon distance, computer-assisted CT modeling has been described to preoperatively determine the amount of bone excision required to restore normal anatomy of the sigmoid notch.[22]

Doornberg and Marti presented a case report utilizing iliac crest autograft as interpositional graft for an olecranon malunion.[5] Because the base of the sigmoid notch is void of any articular cartilage this is a good option if the articular defect is small. If the initial fracture was severely comminuted, use of an osteochondral allograft may be a more suitable option with the possibility of fibrocartilage ingrowth and potential to avoid donor site morbidity with autograft harvesting.

In summary, we provide a technique for revising an olecranon malunion with large articular defect and shortening of the coronoid-to-olecranon interval. Use of an osteochondral allograft contoured to restore the articular step-off and re-establish appropriate length between the coronoid and the olecranon is a viable option for osteochondral defects that span beyond the bare area of the sigmoid notch and avoids the donor site morbidity associated with harvesting autografts. Careful preoperative planning is needed to identify the precise location of the osteotomy as well as the size and shape of the interposition bone graft.

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The "Almost Open" Calcaneus Fracture: Tips for Soft Tissue Management

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Open calcaneus fractures are relatively uncommon injuries with a reported incidence of 0.8% to 10% of calcaneus fractures. Most of these open lacerations, excluding injuries sustained from blast or gunshot wounds, are found on the medial hind foot. Given the high energy mechanism from which intra-articular calcaneus fractures are sustained and a relatively thin soft tissue envelope, open calcaneus fractures have significantly worse outcomes as compared to closed calcaneus fractures. The incidence of superficial and deep infection is increased and series in the literature have uniformly demonstrated poor outcomes. Case series have been published detailing management protocols for open calcaneus fractures which include urgent irrigation and debridement and various staged protocols involving temporary external/internal fixation with delayed definitive treatment.

The typical deformity in intra-articular calcaneus fractures is a depressed posterior facet with a shortened, widened tuberosity in varus angulation with comminution and expansion of the lateral wall. With increased severity, fracture lines propagate to the anterior calcaneus and can involve the calcaneal cuboid joint. There is little in the literature describing medial sided bony injury. The sustentaculum has long been believed to maintain anatomic position in these injuries, thus being termed the "constant" fragment. However, there is no evidence to support the notion that heel widening is solely due to lateral wall expansion and that the medial calcaneus, whether it be the sustentaculum or medial wall, maintains an anatomic position. Berberian, et al., in unpublished data, challenged the notion of the constancy of the sustentaculum fragment. They found a high percentage of displacement, angulation and fractures involving the sustentaculum in intra-articular calcaneus fractures. Given their findings and the lack of literature describing medial calcaneal bony injury, it is likely an important aspect of intra-articular calcaneus fractures especially given the observation that most open calcaneus fractures occur medially.

Soft tissue injuries fall along a spectrum and the simplified categorization of closed versus open fractures fails to take into account patients with significant medial soft tissue contusion without a clear open communication. As it regards to calcaneus fractures, studies have looked selectively at either open or closed injuries. Furthermore, much has been described about lateral wall expansion and subsequent issues with nonoperative treatment such as peroneal entrapment, subfibular impingement and shoe wear difficulties but little has been described about the effects of medial calcaneal wall bony expansion. There is no previous examination of the closed

FIGURE 1. Medial Hindfoot

calcaneus fracture with significant medial soft tissue injury which we call the "almost open" calcaneus fracture. (Figure 1)

We report an illustrative case and tips for management of these injuries.

Patient RM is a 17 yo female who sustained bilateral closed calcaneus fractures after a fall from height. The right side was amenable to percutaneous fixation with little soft tissue injury and was fixed acutely. The left side demonstrated a Sanders 3/4 calcaneus fracture and given significant soft tissue injury was treated surgically in a delayed fashion. (Figure 2)

FIGURE 2.

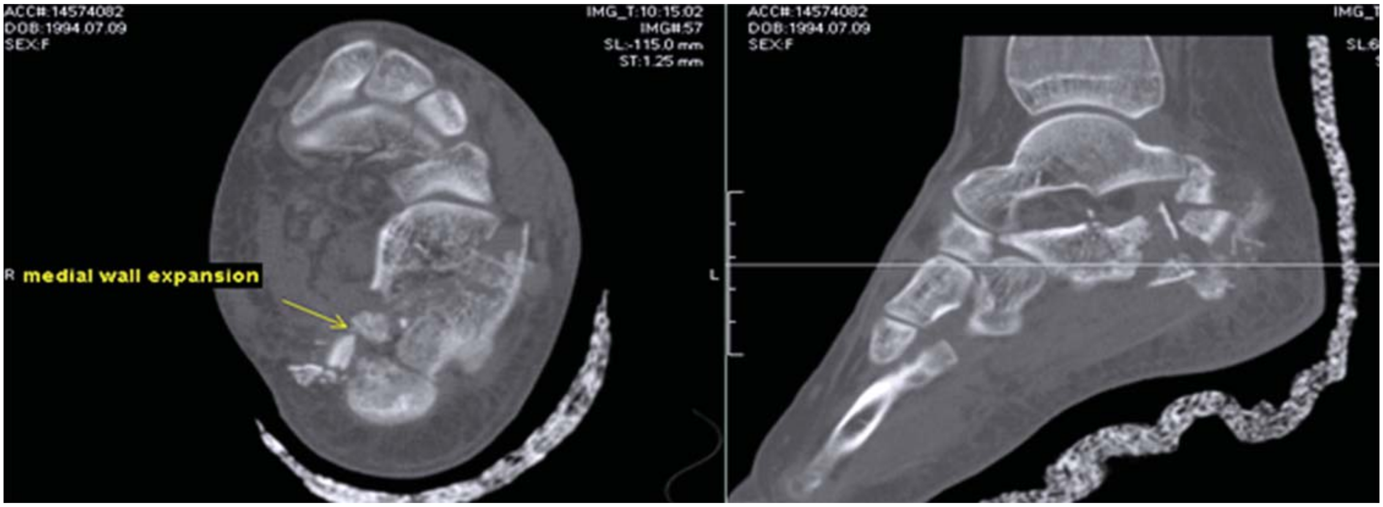

FIGURE 3. Preoperative CT

Preoperative CT demonstrated medial bony comminution. (Figure 3)

Physical examination at the time of surgery revealed a healed fracture blister on the medial hindfoot but not evidence of an open injury or full thickness contusion.

After successful open reduction internal fixation the patient was examined at her first postoperative visit 1 week later and was found to have full thickness ulceration medially. (Figure 4)

This was treated with urgent irrigation & debridement and removal of medial bony fragments and was successfully treated with prolonged negative pressure dressing therapy. (Figure 5)

FIGURE 4. (A)Full thickness ulceration (B) Medial bony fragments

FIGURE 5.

FIGURE 6A. (ii)

FIGURE 6A. (iii)

Examples of significant medial soft tissue injury in closed calcaneus fractures are presented with resolution with careful soft tissue monitoring and management. (Figure 6A and 6B)

FIGURE 6A. (i)

FIGURE 6B. (i)

FIGURE 6B. (ii)

FIGURE 6B. (iii)

Management

Several works in the published literature describe management protocols for open calcaneus fractures which include urgent irrigation and debridement and staged protocols with initial temporary stabilization and/or reduction of the tuber and delayed open reduction and internal fixation. Management of the "almost open" calcaneus fracture is similarly important to maximize outcomes and warrants special consideration.

Initial management entails careful examination of the hindfoot soft tissue envelope. While focus is often placed on the lateral soft-tissues, the medial hindfoot should be examined carefully as well for evidence of soft-tissue contusions, ecchymosis, skin threatening from displaced bony fragment and the presence of fracture blistering. These clinical signs may indicate a significant medial soft tissue injury. A careful neurovascular examination should be obtained. Given the intimacy of the tibial neurovascular bundle to the medial calcaneal wall, patients may present with plantar paresthesias or dysethesias. However this is not uncommon as the mechanism that produces calcaneus fractures can result in compression neuropraxias or contusion of the medial and lateral plantar nerves. In additional several works have demonstrated the association of tarsal tunnel syndrome in both acute calcaneus fractures as well as secondary to calcaneal malunion. Foot compartment syndrome should be assessed for. Foot compartment syndrome has previously been estimated to occur in 10% of calcaneus fractures although this has been challenged by recent literature which puts the estimate to be much lower.

Radiographic examination may give clues to the potential for evolving medial soft tissue injury not immediately apparent on initial clinical examination. The Harris axial heel view should be assessed for medial bony injury. As computed tomography scanning is often obtained when evaluating patients with intra-articular calcaneus fractures, careful attention should be paid to medial bony injury and displacement.

As operative calcaneus fractures (which are not amenable to percutaneous fixation or minimally invasive approaches) often require delayed definitive treatment, the injured extremity should be placed in a bulky Jones dressing with optional posterior plaster. Unless there is an associated ankle injury, a plaster "U" should not be placed as this may cause increased pressure along the medial and lateral soft tissues and offers no particular benefit. Patients may be similarly placed in a fracture boot which allows for more careful examination of the status of soft tissues but may not afford the compression and edema control that a Jones dressing does and may be poorly tolerated in the acute setting. While Thordarson and others demonstrated the effectiveness of foot pumps to reduce edema and resultant time to operative fixation for calcaneus fractures, this may not be the best management protocol for patients with significant medial soft tissue injury and a significantly contused soft tissue envelope.

Patients with the "almost open" calcaneus fracture should be followed more closely than patients without significant medial soft-tissue injury both preoperatively and postoperatively. If the patient is discharged from the emergency ward they should be seen within 1 week not only for potential surgical planning but to monitor the soft-tissue envelope. Patients admitted to the hospital should have daily examination of soft tissues to assess not only for timing of definitive fixation but also for evolving medial soft tissue injury. Patients with evolving medial soft tissue injury should be managed accordingly. Full thickness necrosis should be aggressively and urgently debrided. The size of the defect determines whether this can be managed by negative pressure/vacuum assisted closure management or if plastics consultation is warranted for potential flap coverage or other grafting procedures. Recently Romash, et al described a pedicle transfer of the abductor hallucis muscle to address medial sided hindfoot soft tissue defects after calcaneus fracture.

After calcaneus open reduction internal fixation patients are seen 1 week postoperatively to monitor not only the lateral incision but the medial soft tissues. This short term follow-up allows for early intervention should wound healing problems be noted. Patients are seen again 1 week later for suture removal.

Conclusion

Medial soft tissue contusions in closed intra-articular calcaneus fractures require special consideration and management. A careful physical and radiographic examination at time of injury and careful post-injury follow-up is required to optimize outcomes.

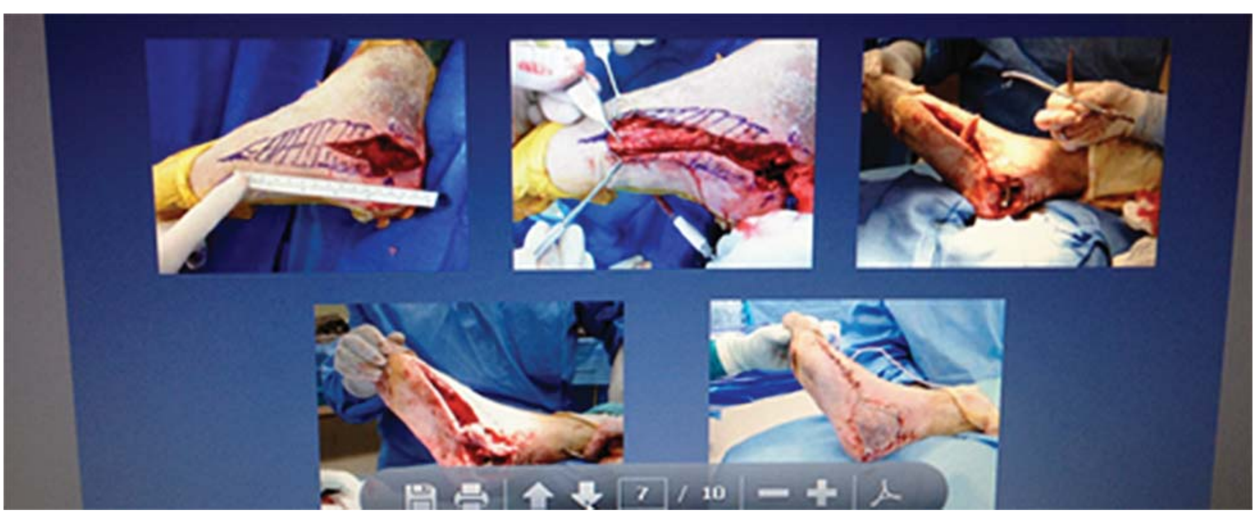

FIGURE 7.

An Update on Assessing the Validity of the Lauge Hansen Classification System for *In-vivo* Ankle Fractures Using YouTube videos of Accidentally Sustained Ankle Fractures as a Tool for the Dynamic Assessment of Injury

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The understanding of the deforming mechanisms which result in fractures has primarily relied on cadaveric fracture analysis. However, extrapolating from controlled cadaveric biomechanical studies an understanding of how fractures occur dynamically in "real life" injuries under physiologic loading, is itself subject to limitations. In the case of ankle fractures, Lauge-Hansen's[1] original work describing a mechanistic system to classify ankle fractures has been challenged at different levels.[2-5] Michelson, et al. attempted to duplicate Lauge-Hansen's findings using modern biomechanical techniques and showed the proposed mechanism of injury for the most common injury pattern, supination/external rotation was not reproducible according to Lauge-Hansen's described methodology .[2] Furthermore, the relationship between the described soft tissue injuries and fracture pattern could not be reproduced . Gardner, et al. evaluated ankle fractures using MRI and found poor reproducibility of the expected soft injury sequences as predicted by Lauge-Hansen.[3] Other studies have shown poor reproducibility as well poor intra and inter-observer reliability.[4-6] Despite these challenges and methodological shortcomings in his original paper, Lauge Hansen's work still stands as the basis for our understanding of the patho-mechanics of ankle fractures.

In 2010, we described a method for the dynamic assessment of injury in which we correlated radiographic images of ankle fractures sustained accidentally that were also recorded on live video clips. With the development of websites such as www.YouTube.com (YouTube.com), there is an ever-increasing number of videos publicly available through the internet that shows injuries of various types. Many of the videos contain events during which individuals sustain orthopedic trauma. The ability to correlate these in-vivo injury videos with the actual injury radiographs of the individuals sustaining these injuries allows for a valuable instrument to further the understanding of fracture mechanisms. We previously published the results of 12 ankle fractures using this technique in the Journal of Orthopaedic Trauma, August 2010. We now present our finalized case series consisting of 30 participants and their corresponding radiographs.

Participant Selection

Videos of potential study candidates sustaining ankle injuries were reviewed on YouTube.com. A video search was performed by including key words such as: "ankle, tibia, fibula, break, fracture, broken, snap, dislocation". The individuals posting these videos were then offered participation in the study. Potential participants were only contacted after it was determined that their YouTube posted videos were of sufficient quality to classify the injury mechanism and demonstrated sufficient trauma to likely have sustained an ankle fracture. Each potential study candidate was contacted via YouTube's email server regarding the purpose of the study. Candidates were sent our IRB-approved consent forms as well as a short demographics form. A mailing address or personal email was required as documents cannot be attached via YouTube.com's email server. After 2010, our IRB required notarized parental consent for participants who were less than 21 years of age, and limited participation to US residents. These restrictions hindered us from completing our initial goal of obtaining 50 participants.

Inclusion Criteria

1. Video demonstrating clear visualization of the mechanism of injury including foot position and deforming forces

2. Candidates who sustained a fracture or dislocation

3. X-rays of adequate quality revealing a fracture of the ankle

Candidates were asked to send their injury x-rays to the authors and upon receipt of the above materials were paid a stipend of $100-125 US dollars in gift card form for participation.

Video Analysis

Videos demonstrating the mechanism of injury for each study participant were reviewed by 4 reviewers: 2 fellowship-trained orthopedic traumatologists as well as 2 senior orthopedic surgery residents. Each mechanism of injury was classified independently into 4 categories by each reviewer: Supination/external rotation (SER); Supination/adduction (SAD); Pronation/external rotation (PER); Pronation/abduction (PAB)

Classification of the mechanism of injury was determined by consensus of at least 3 out of the 4 reviewers. If consensus could not be reached then the patient was excluded from our analysis. All videos were reviewed independently of the corresponding radiographs and free of any patient identifiers. Video enhancing with slow motion and magnification was used as needed.

X-Ray Review

Radiographs of each ankle fracture were independently reviewed and classified per the Lauge-Hansen as well as by the AO classification. All radiographs were reviewed independent of the corresponding videos and any patient identifiers were removed. In order to reduce any potential inter-observer differences between our reviewers they were given a half-hour instruction in the Lauge-Hansen classification prior to evaluating the radiographs and videos. This consisted of a review of fracture pattern, associated mechanism and radiographic findings as described by Lauge-Hansen.

Each ankle fracture was classified as either:

Supination/External rotation (SER);
Supination/Adduction stage (SAD);
Pronation (P);
Pronation/Abduction (PAB);
Pronation/External rotation (PER)
AO classification

After the videos and radiographs were independently classified according to the Lauge-Hansen fracture classification, each participant's video and radiograph was examined together for correlation between mechanism of injury and expected fracture pattern.

Results

Of over 2500 videos reviewed, only 625 were of sufficient quality to show an injury that could be described using the LH system. Of the 116 responders who were asked to submit ankle x-rays associated with their injury, only 30 completed enrollment by submitting the radiographs corresponding to the injury seen in the video.

The average age of participants was 18 years and the range was 13-38 years. While initially we preferred skeletally mature patients, after the first year, we increased enrollment to skeletally immature patients with adult fracture patterns in order to increase our enrollment objectives. Patients who sustained true Salter Harris fractures not classifiable per Lauge Hansen's classification system were excluded.

Injuries occurred as the result of skateboarding (n=20), bicycling (n=3), wrestling (n=2), martial arts (n=2), rollerblading (n=1), running (n=1) and trampoline jumping (n=1). There was 1 study participant with an SAD mechanism of injury who demonstrated a likely subtalar dislocation based on photographic evidence of his pre-reduction injury sent to us with his post-reduction x-rays showing no fracture. Despite demonstrating a significant mechanism 3 other study participants had radiographs which did not reveal a fracture, both with SAD mechanisms. There were 26 true ankle fractures (87%).

Of the 30 video clips reviewed, 16 had SAD deforming trauma and 14 had PER deforming trauma. No SER or PAB deforming trauma was appreciated in the videos. Injuries were secondary to skateboarding (20), bicycling (3), wrestling (2), martial arts (2), rollerblading (1), running (1) and jumping (1). There were 3 non-fractures despite videos suggestive of fracture. There was 1 subtalar dislocation after an SAD mechanism, and there were 26 actual ankle fractures. When correlating videos to x-rays, 12 fractures judged by video to be SAD injuries had corresponding SAD pattern radiographic fractures. However, only 5 of the 14 fractures judged by video to be PER injuries had PER radiographic findings. Eight PER video injuries resulted in SER ankle fracture patterns and another resulted in a SAD ankle fracture pattern.

When in-vivo video injury clips of actual ankle fractures are matched to their corresponding x-rays, the LH system is only 53% overall accurate in predicting fracture patterns from deforming injury mechanism. All SAD injuries correlated, but only 36% of PER injuries resulted in a PER fracture pattern. We have no video evidence that PAB and SER injuries occur in real life as described by the LH system with the resultant expected injury pattern.

When using the AO classification, all 12 SAD type injuries that resulted in a fracture actually resulted in 44A type fractures while the 14 PER injuries resulted in nine 44B fractures, two 44C fractures, and three 43A type fractures, suggesting the AO system is more consistently related to live injury mechanism than the LH system despite its development as a purely radiographic system. All 100% of the SAD mechanisms resulted in 44A fractures and 64% of PER injurires resulted in 44B fractures, an overall 81% rate of consistency.

Discussion

Our case series suggests that Lauge-Hansen's mechanistic classification may not consistently produce the radiographic fracture pattern predicted for a given injury mechanism in actual patients sustaining live injuries. Our series shows that when in-vivo injury videos are matched to their corresponding x-rays, the Lauge-Hansen system is only 53% overall accurate in predicting fracture patterns from deforming injury mechanism as pertaining to SAD and PER injury mechanisms. All SAD injuries correlated, but only 36% of PER injuries resulted in a PER fracture pattern. We found no video evidence that PAB and SER injuries occur in real life as described by the LH system with the resultant expected injury pattern. The AO classification, despite not being develeoped as a mechanistic classification system, may be more consistently related to mechanism of injury with 100% correlation of SAD mechansims to 44A type fractures and 64% correlation of PER mechanisms to 44B type fractures. The poor correlation of PER injury patterns with PER radiographic patterns is consistent with recent work by Haraguchi et al[7] who demonstrated that PER mechanism could cause both distal, short oblique and high fibular fractures.

Despite our shortcomings in final recruitment numbers (30 participants out of 50 initially intended) we feel that we have developed a flexible and valuable methodology for studying injury mechanisms; a methodology with a wide array of potential future applications. In our published methodology study[8] we initially reported findings from a case series with only 15 participants (12 ankle fractures) that challenged the understanding of the patho-mechanics of ankle fractures. We have now doubled that initial series and our results have remained consistent. We do recognize the numbers of participants required to address with clinical significance the validity of the Lauge Hansen as applied to live ankle fractures, will have to be higher in any future study. Yet we feel the present case series illustrates a method of significant research potential.

Acknowledgements

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Reengineering Operating Room Workflows: Surgeon to Central Processing Staff Interventions Improve the Mechanics of Safe Surgical Care Delivery and Decrease Infection Rates

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Post-surgical median total length of stay for open reduction and internal fixation from fractures nearly quadruples when infections are present (3.5 to 15 days) and the median total health care cost more than doubles from $2,481 to $6,104.[1] The safe delivery of orthopaedic surgical care is multifactorial yet critical to avoid complications such as infection. Safe care relies on hospital care-delivery systems, buy-in from all individuals into the institutional safety culture, and an active effort to identify shortcomings and improve upon them. In our hospital we had one example involving surgical site infections. By clearly defining the problem, identifying educational objectives and reengineering workflows, we were able to make a significant improvement in a specific safety problem impacting our patients.

Methods

We set out to clearly define the problem and then make a pointed intervention while monitoring infection rates and reoperation rates.

The Problem

Over a sixty day period, we had 3 infections out of 12 cases using a specific instrument designed for the management of periarticular tibia or femur fractures about the knee: the Synthes Less Invasive Stabilization System (LISS)[2] or analogous lateral locked plating systems. Each infection had a significant impact on our patients' post-operative health. All patients received a peripheral percutaneous indwelling central catheter to receive intravenous antibiotics for six weeks. Two of our patients returned to the operating room for management of their infections in addition to the IV antibiotics. During this time period we found ourselves opening extra kits during operating room set up because some equipment was visibly contaminated even though it had undergone our standard processing protocols. We were concerned that the spike in infections could potentially be related to deficiencies in the processing and cleaning of the surgical equipment.

The Intervention

Taking into account the increase in infections over such a short time interval using this type of instrumentation and the multiple episodes of contaminated materiel discovered during surgical set ups, we arranged for an educational session to address the problem. The first event was a training session where the surgical team informed the central processing unit about the severity of the problem, the indication for the use of these instruments in severely injured patients, and the technical aspects of the equipment and surgical procedures, emphasizing how contaminated material delayed care, introduced the risk in infection, and increased cost due to the need to open multiple system kits to have a complete set of properly cleaned instruments (Figure 1). In turn, the central processing team and operating room management set up an educational event for the surgeons and surgical team to learn about the central processing environment, the high instrument volume demand, their physical plant limitations, and other standard operating procedures (Figure 2).

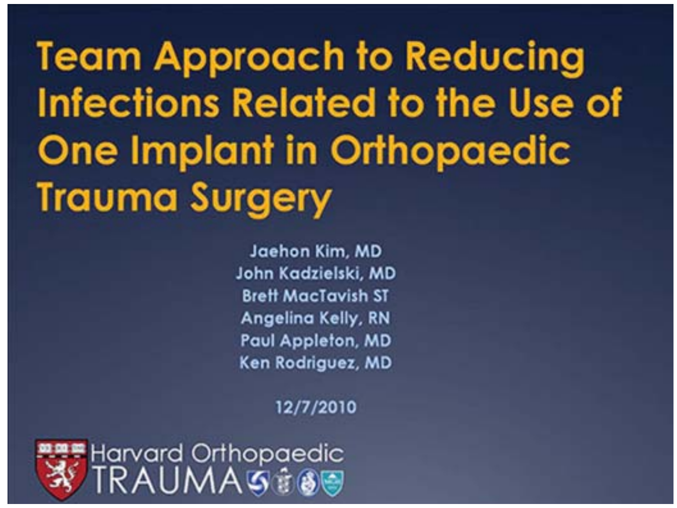

FIGURE 1. Title page of the presentation given to the entire operative team and the surgical equipment processing personnel.

FIGURE 2. The surgical team and the central processing team gathered together in central processing as each individual demonstrated how he carried out his tasks. We discussed how workflows could be optimized for efficiency and safety.

The surgical team then set up a mock surgery for which the entire group was invited into an operating room which was closed down during routine business hours for the purpose of training all staff about the intricacies of the application of the LISS on tibia fractures (Figure 3). The LISS over other lateral locked plating systems was selected for the educational intervention because it was the most complex system and offered several opportunities to show the staff how meticulous attention to detail impacted each step of the case and the eventual outcome of the patient. The large number of cannulated tools in the LISS tray increases the risk of contamination if not properly processed and cleaned. Several breaks in action were done to show each group of attendees how their own actions are critical links in the chain of safe patient care. Every member of the team was encouraged to speak up and tell the group how their actions affected everyone's workflows (Figure 4). Data was monitored for two months after the intervention to mirror the initial problem window and give staff feedback over a comparable time frame.

FIGURE 3. With the full support of the operating room administration, we shut down an operating room in the middle of the day and ran a mock surgery where the surgical team and the central processing team could see the results of the work and understand how everyone's role was critical in the safe delivery of patient care.

FIGURE 4. Everyone made a point of speaking up about how other people's performance affected the care of the patient. A point was made to establish a safe environment in which people felt comfortable sharing their thoughts.

Results

Lessons Learned From Interventions

Much was learned about the working environment and the workflow:

1. All equipment from 18 operating rooms each doing several cases a day with several equipment trays was processed by only one person in the evenings.

2. Only one sink was available to wash all of the operating room equipment.

3. Soap dispensers at the operating room prewash station where instruments are first cleaned before being submitted to central processing were defective.

4. Too few ultrasonic sterilizers and autoclaves were present to process the equipment because they have fixed run times and predispose to bottle neck and delayed processing.

5. New Instrument tracking system were helping to keep track of different instruments at they were cleaned but the system implementation created extra initial work for the processing teams who were already short-staffed.

6. Instruments were sent down to processing in a way that makes it hard for them to stay organized, resulting in added sorting steps, increasing complexity, creating an opportunity for error, and creating a safety risk for processing staff who can get injured with the instruments.

7. No pipe cleaners were available to clean the LISS cannulas.

8. Three individuals were involved in completing each sterile kit but only one person's initials were on it for feedback and tracking, thus losing a level of accountability. The person who signed off on it was the first person involved in processing it, not the last.

9. Processing personnel were getting injured on instruments which were not put back in their proper sterilization position in the equipment box as operative surgical techs are rushing to clear their tables and clean the room between cases to hasten operating room turnover.

10. Specialized orange color trays have now been developed with a cleaning solution to pre-clean the insides of the cannulas before blood dries on their inner surfaces.

Safety Rules and Infection Rates

There were 12 patients in the 60 days leading up to this intervention who were treated with the LISS or an analogous locked lateral plating system. Three patients experienced post-operative infections. In the two months after the intervention, 12 patients were treated with similar instruments with no resultant infections. In the immediate 2 months after intervention, the infection rates dropped from 25% to 0%. A Pearson Chi-square test was used to determine if the patients treated after the team workflow intervention significantly different infection rates than those treated before the before the intervention. Despite its clinical impact, this early trend towards improvement was not statistically significant ($\chi^2 = 3.429$, $p = 0.064$). Results are depicted in Table 1. There was no significant difference in the ratios of LISS.

Work Flow Implications

The operating room teams and central processing teams have now begun actively setting each other up for success. The teams in the OR take extra time to pre-clean the instruments and arrange them such that they do not create extra work or injury risk for the people in central processing. The staff in central processing, despite limited resources, can now employ their time and their resources more effectively. A culture of mutual respect and safety has developed, which has decreased the infection rate in our patients during the study period from 25% to 0%, a clinically important while not statistically significant result.

TABLE 1. Number of infected cases before and after the intervention

	Infection		Total number of cases
	No Infection	Infection	
Time			
Pre Intervention	9	3	12
Post Intervention	12	0	12
Total	21	3	24

Discussion

Reported infection rates of closed and low-grade open proximal tibia fractures rage from 0% to 5% when treated with the LISS.[3-5] Orthopedic infections require aggressive debridement and often multiple operations followed by prolonged courses of intravenous antibiotics. They contribute to global antibiotic resistance, long-term disability, and high medical costs. Patients are unable to walk, drive, work, or otherwise engage in productive or recreational activities for months at a time. They are devastating to patient finances and result in significant social and family difficulties. In the most severe cases they may result in amputations and even mortality.

Using fracture specific technology like locked plating systems such as the LISS has revolutionized fracture care. It has allowed for control of difficult fractures with less hardware and smaller surgical exposure to reduce soft tissue trauma and improve union rates. However it has increased the technical complexity of surgery and reliance on complex instrumentation systems. Safe and successful treatment with locked plating systems such as the LISS requires a team approach to reengineer workflows and educate all team members so that the intricacies of the new instruments systems, their proper maintenance and cleaning, and their proper clinicaluse are addressed.

Limitations of this study are that there are no objective measures to monitor the direct person-to-person impact of the intervention. The time period monitored is a small window, but this was selected to give the staff rapid feedback on the intervention. Also, the total number of cases is low but this specific procedure has limited indications.

Conclusions

Our experience shows that even when dealing with today's most technologically advanced surgical equipment, effective human-to-human interaction is essential for the safe delivery of surgical care. Maintaining and cultivating these relationships facilitates ongoing education and safety innovation. We have shown the pitfalls of the application of frontline technologies but have also shown that staff working together with mutual respect and a rich safety culture can overcome and master the intricacies of each evolution in healthcare. Orthopaedic researchers have shown that safety climate, a snapshot of a group's safety culture, is one area in which our specialty is lacking when compared to other high-risk environments like naval aviation.[6] In an environment where safety reports are filed "against" people rather than for the improvement of a system, it is important to bring the focus back on interventions that improve relationships and culture. As leaders in healthcare struggle to innovate and obtain market share in their region, we hope that this case series serves as a reminder that in today's technically advanced environment, healthcare delivery is still about people caring for other people.

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Inside the Value Revolution at Children's Hospital Boston: Time-Driven Activity-Based Costing in Orthopaedic Surgery

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It is an exciting, and potentially turbulent time in the evolution of health care delivery in the United States. Despite decades of debate and piecemeal political reforms, the health care system remains inefficient in many ways and is becoming increasingly expensive. Increases in national health care expenditure continue to outpace inflation, exceeding 17% of the gross domestic product. Rising health care expenditures compromise both the economic stability of the United States and the treatment of the sick and injured. In addition, attempted regional and national health care reform has shouldered health care providers with further responsibility. The pressure is on providers to treat more patients, while offering better care at lower costs. "Better for less" is the demand. In this climate of change, physicians must educate themselves in the vocabulary of the epidemiological, political, ethical, and economic forces that influence the evolving health care economy, both to inform provider perspectives and to provide meaningful comment as reform progresses.

Based on the seminal work of Harvard Business School Professors Michael Porter and Robert Kaplan in value-based health care delivery,[2-5] the Department of Orthopaedic Surgery at Children's Hospital Boston has initiated a series of projects aimed at improving value in health care delivery - investigations specifically focused on reducing costs while maintaining or improving health outcomes.

Value in Healthcare Delivery

Value is a measurement of the relative quality and cost of a service or product. In health care, value should be measured in terms of patient health outcomes achieved per dollar spent to achieve those outcomes.[3,5]

Value = Health Outcomes / Cost

Health outcomes, as defined by Porter, do include patient satisfaction with health.[6] Through value improvement, patients, payers, providers, suppliers, and the government can all benefit while strengthening the economic stability and sustainability of the U.S. health care system. Cost reduction without regard to outcomes are "dangerous and self-defeating, leading to false 'savings' and potentially limiting effective care."[3] In contrast, by giving due consideration to health outcomes, value improvement respects the integrity of patient care while achieving lasting, meaningful reductions in cost.

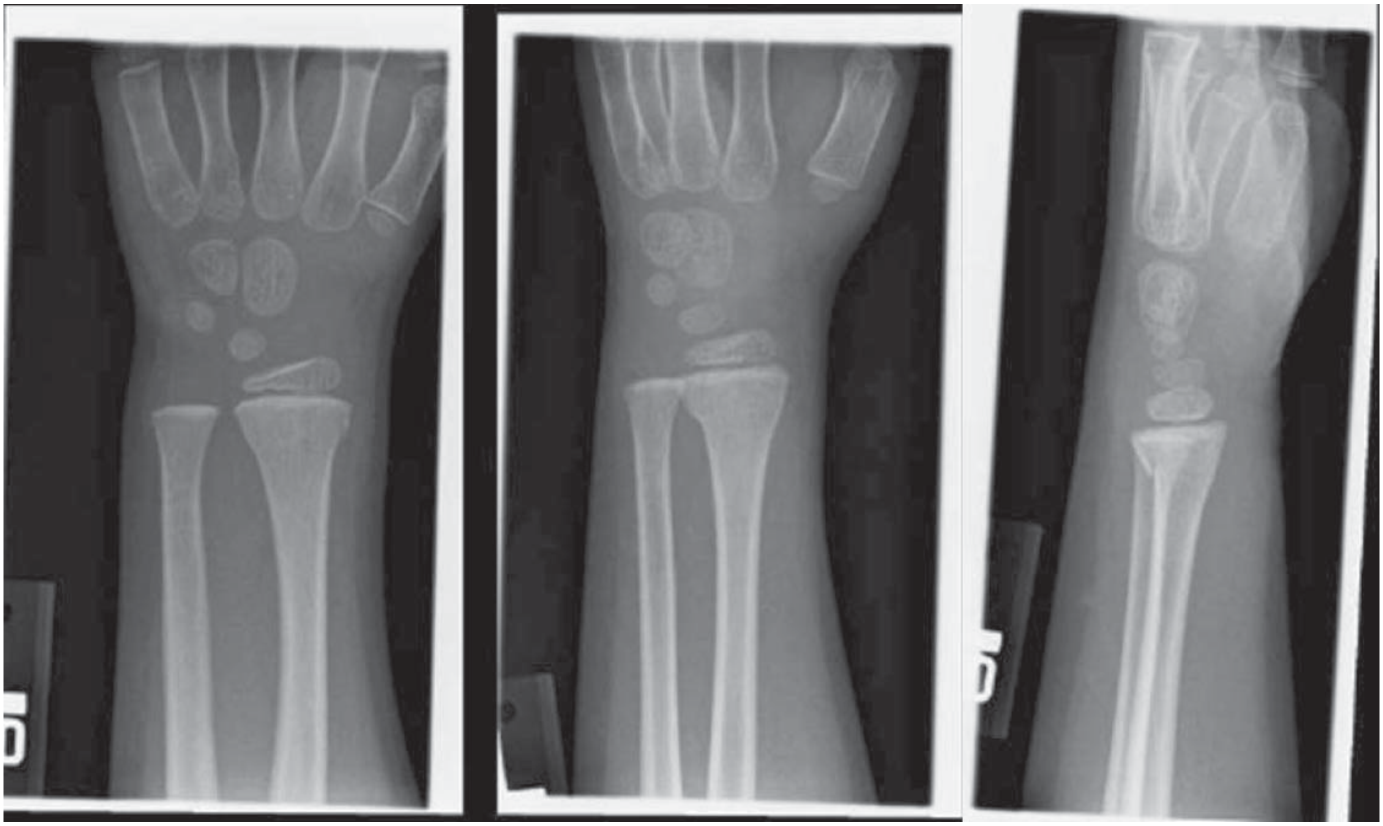

FIGURE 1. A torus (or "buckle") fracture of the pediatric distal radius resulting from a compressive load. There is costly variability in management practices for torus fractures in children despite the inherent stability of the fracture pattern.

Practice Pattern Variation

The first project in our "value improvement" series was an investigation of single hospital variation in practice patterns. Providers today are often criticized for providing "too much" care – amassing "unnecessary" costs without improving patient health outcomes. In some instances, it is clear that too many tests are ordered, too many appointments are scheduled, and too many dollars are spent. Physicians may argue that patient health and safety are sufficient motivation for providing more care, but health economists counter that fee-for-service payment systems foster a culture of "excessive" care by reimbursing providers for volume of care rather than the quality of care delivered.[7] Profligate malpractice litigation is also an acknowledged factor in incentivizing defensive medicine and care excesses.

Our investigation examined practice pattern variations in the treatment of torus (or "buckle") fractures of the pediatric distal radius (Figure 1). Multiple randomized, controlled trials have demonstrated that distal radius torus fractures can be safely and effectively managed with removable splinting or bandaging and home removal.[9-13] In order to evaluate compliance with established treatment standards for distal radius torus fractures, our investigation sought to characterize the variation in practice patterns at a single tertiary-care institution, and determine costs associated with this variation. The study retrospectively reviewed medical records from a single calendar year, and defined excess medical care based on published recommendations by van Bosse et al and Farbman et al.[14,15] The study found that there is great variability in management practices for torus fractures in children despite the inherent stability of the fracture pattern. These findings suggest there are opportunities to streamline care, thus reducing costs, saving patient and provider time, and reducing exposure to unnecessary radiation. The results of this investigation were presented at the 2012 Annual Meeting of the Pediatric Orthopaedic Society of North America.

Standardized Clinical Assessment and Management Plan(SCAMP)

To seize the opportunities for cost savings and value improvement due to practice pattern variations, the Department of Orthopaedic Surgery at Children's Hospital Boston has also developed a Standardized Clinical Assessment and Management Plan (SCAMP) for pediatric distal radius fractures. A SCAMP is an algorithm based on best practices, designed to guide decisions made by physicians in the treatment of a specifically defined medical condition. Furthermore, a SCAMP facilitates identification of provider deviations from the treatment algorithm, to allow for appropriate modification and improvement of the plan over time (Figure 2). By standardizing best practice patterns, SCAMPs can help providers maximize value and prepare for financial success as the system evolves towards bundled payments. This transition in payment models has been a great concern among providers, especially since 2009 when the Massachusetts Special Commission on the Health Care Payment System recommended that the fee-for-service payment model be replaced with a bundled payment model with pay for performance measures.[7] The SCAMP for pediatric distal radius fractures will be launched in 2012, and is expected to provide multiple opportunities for cost savings and value improvement.

Measuring Value

The supporters of value-based health care acknowledge the fact that there are challenges in measuring both outcomes and cost.[3,16] Historically, medical investigation has focused primarily on improving health outcomes, the numerator of the value equation. This research has resulted in tremendous advances in health care quality over the last 25 years. However, measurement of these advances is difficult, as health outcomes are defined by various standards according to the plethora of medical conditions and the multiple dimensions of each conditions. Outcomes must be risk-adjusted in order to be measured fairly, and the "full cycle of care" for many chronic illnesses may be indefinite. While important work on the numerator of the value equation should continue, physicians and researchers must take an equally rigorous approach to cost, the denominator, in order to improve value. The development of advanced medical treatments and assessments tends to progress more rapidly than our ability to understand fully which advances offer the highest value.

The measurement of costs is just as challenging. The system of health care delivery is complex, highly fragmented, and highly variable. Additionally, the involvement of third party payers (government and private health insurers) perverts incentives in ways that encourage ambiguity in cost data. Interestingly, however, recent designs to overhaul the health care payment system have brought to light an odd dichotomy between reimbursement and cost measurement – it seems their granularities are inversely proportional. It seems as payments become more broadly defined, costs must be measured more finely. Historically, payers have reimbursed providers for specific services rendered, but costs have been evaluated more generally at the level of the department, service, or support activity, rather than at the specific patient level. With recent efforts to bundle payments more broadly – either episodically (over a defined episode of care)

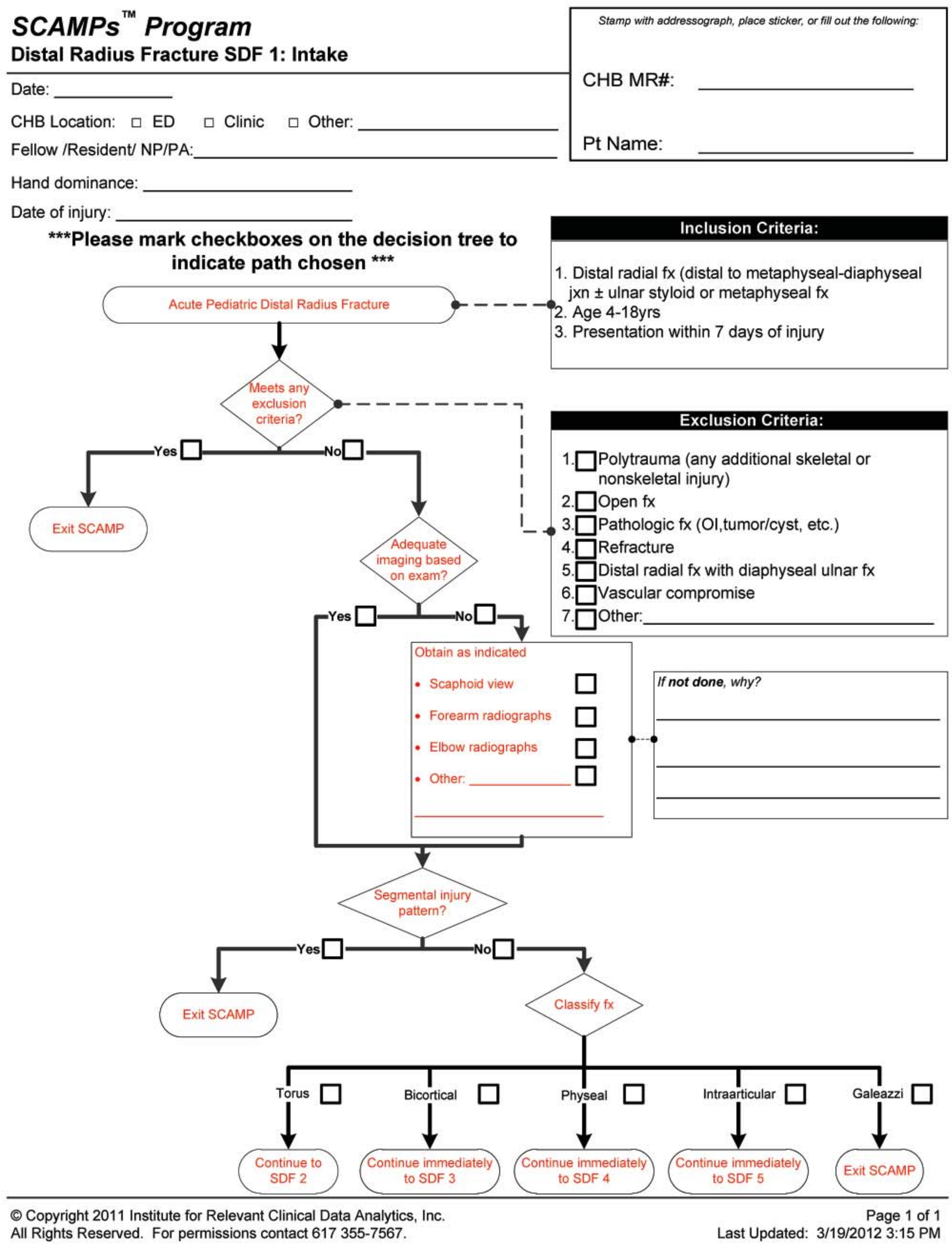

FIGURE 2. Example of an algorithm from a Standardized Clinical Assessment and Management Plan (SCAMP) developed for managing pediatric distal radius fractures at Children's Hospital Boston. This algorithm depicts the initial care for bicortical distal radial fractures. Rectangles indicate services provided. Diamonds indicate decision points.

or globally (over a defined time period of care) – providers are seeking more rigorous, patient level cost estimates. If patient outcomes and the costs of achieving those outcomes are not well-defined and measured, it will be impossible to evaluate the benefits or losses that result from system changes, or guide future decision making. This is not to say that resource costs are not currently measured specifically. For instance, the salary of a provider and the cost of supplies are readily available and indisputably accurate – but the cost of a provider or supplies per patient, per medical condition, or per outcome remains amorphous.

For example, many hospitals and physician organizations currently use a Ratio of Cost to Charge (RCC) approach to costing. The RCC is calculated by dividing the total costs for the year by the total annual charges for services rendered. The estimated cost of a service, such as a surgical procedure or an office visit, is then calculated by multiplying the charge for that service by the RCC. This methodology does allow hospitals or physician organizations to evaluate financial positions on the whole, but it does not allow evaluation of how much it costs to deliver care to a specific patient, or how those costs compare with health outcomes achieved for that patient. Another method in wide use is the Relative Value Unit (RVU) approach, which can theoretically generate refined cost estimates. RVUs are estimates of the relative time, complexity, and value of a service, used to more accurately allocate costs to individual procedures and activities. In theory, RVUs can accurately reflect real costs, but in practice allocation methodologies tend to be imprecise. This lack of granularity often leads to unintended cost distortions. It may be possible to improve cost estimates using RVUs with rigorous methodology.

With the purpose of determining the accuracy of current cost accounting techniques at Children's Hospital Boston, a pilot study was initiated to evaluate the orthopaedic cast room. The investigation compared an alternative costing technique, Time-Driven Activity-Based Costing (TDABC) with the existing cost accounting system, which relies on less granular cost accounting techniques such as the aforementioned RCCs and RVUs. In the investigation, three types of casts were evaluated: long leg casts, Petrie long leg casts, and club foot casts. At the outset of the study, cast technicians and physicians both expected that the cost of a long leg Petrie cast would amount to roughly twice the cost of a single long leg cast, reflecting the time and complexity of Petrie cast application. However, according to the RCC and RVU methodologies currently utilized at Children's Hospital Boston, a single long leg cast was estimated to have a higher cost than a Petrie cast. In contrast, the TDABC analysis produced cost estimates that made better intuitive sense: the estimated cost of a Petrie cast was roughly twice that of a single long leg cast (Figure 3). The findings of the cast room study provided evidence to support the hypothesis that cost estimates from current accounting methods often do not necessarily reflect the true costs of care (The application of TDABC in this investigation has been so successful that it is being adopted as a case study for use at the Harvard Business School and other business administration programs.)

Explanation of TDABC

TDABC is a complicated name for a simple concept:

Total Cost = Cost Rate x Time

To carry out a TDABC analysis, the hourly cost rate of each resource that contributes to a specific patient's care is multiplied by the amount of time each resource spends contributing to that patient's care. The total cost of all contributing resources can then be summed in

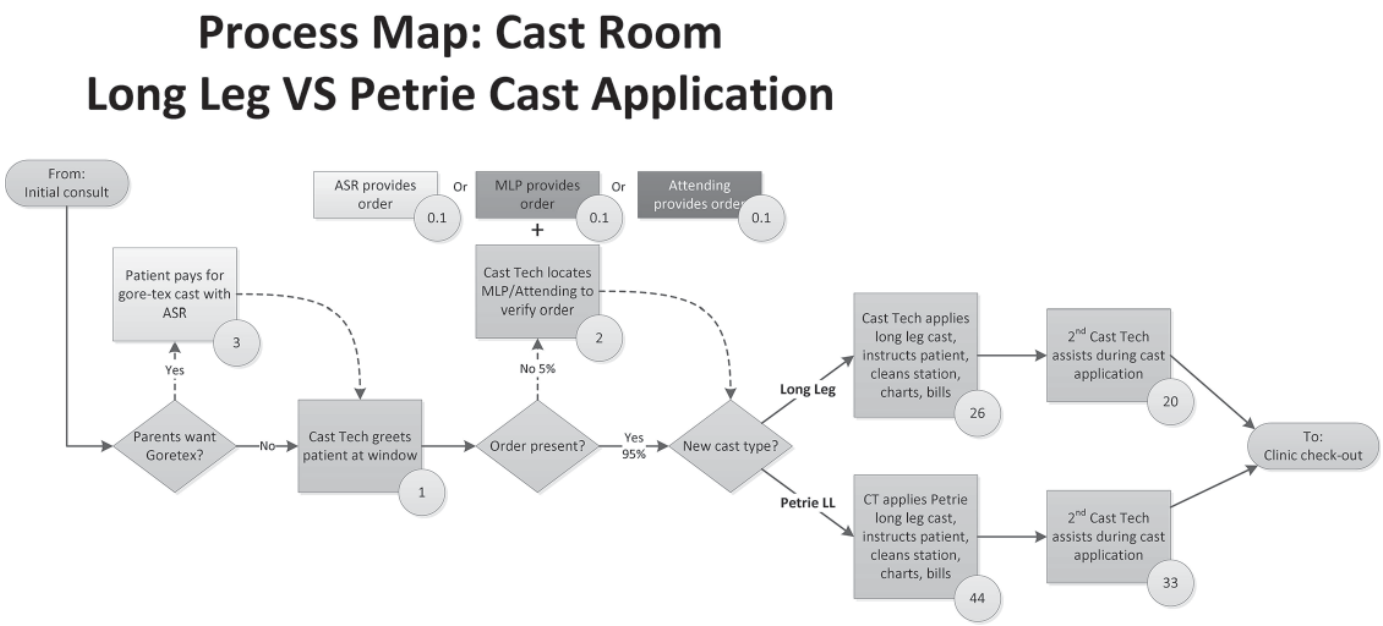

FIGURE 3. Example of a process map developed as part of the Time-Driven Activity-Based Costing project at Children's Hospital Boston examining the costs of services in the orthopaedic cast room. This process map follows patients through cast application. Rectangles indicate care provided by specific medical personnel (physicians, midlevel providers, cast technicians, ambulatory service representatives, etc.). Diamonds indicate decision points. Circles indicate average time (in minutes) required for specific services. This map shows that the cast technician's labor cost of a long leg cast is roughly half that of a Petrie long leg cast (46 minutes versus 77 minutes). In order to determine the full cost of this service, the time estimates illustrated in this process map must be multiplied by provider cost rates (inclusive of overhead and indirect costs), and added to direct costs such as casting supplies (see step 4 of TDABC). This map also illustrates the cost associated with a minor communication lapse (untimely completion of the cast order).

order to calculate the cost of treating a specific patient for a complete cycle of that patient's care:

$$\textit{Total Cost} = (\textit{Cost Rate}_{\textit{Resource A}} \times \textit{Time}_{\textit{Resource A}}) + (\textit{Cost Rate}_{\textit{Resource B}} \times \textit{Time}_{\textit{Resource B}}) + \ldots$$

In order to calculate medical costs using TDABC, several basic steps are required[2]:

1. Define the medical condition of interest. For acute conditions, investigate all costs related to that condition from the beginning to the end of an episode of care. For chronic conditions, define the cycle of care as a period of time, such as a year.

2. Chart the principal activities involved in a patient's care for the medical condition, along with the locations of those activities. Develop process maps of each activity in patient care delivery, documenting the various providers that directly interact with the patient.

3. Obtain time estimates for all interactions between health care providers and patients.

4. Estimate the cost of supplying patient care resources by estimating the direct costs of each resource involved in caring for patients. The direct costs include compensation for employees, depreciation or leasing of equipment, supplies, or other operating expenses. Also identify and attribute all the support (indirect) resources necessary to supply the primary resources providing patient care. These data are gathered from the general ledger, the budgeting system, and other IT systems.

5. Determine the practical capacity for each employee or resource (hours available for patient care).

6. Calculate the capacity cost rate for each employee or resource using data gathered in steps 4 & 5.

7. Calculate the total costs of providing care for a medical condition over the entire cycle of care. Begin by simply multiplying the capacity cost rates (including associated support costs) for each resource used in each patient process by the amounts of time the patient spent with the resource. Then, sum up all the costs across all the processes used during the patient's complete cycle of care to produce the total cost of care for the patient.

When all processes have been mapped and measured in this way, they can be evaluated retrospectively, currently, and prospectively for respective inefficiencies and advantages. Costs that are higher than expected can be identified, and detailed data can easily be examined to understand cost drivers.

Further Applications of TDABC

In addition to the cast room study, The Department of Orthopaedic Surgery at Children's Hospital Boston has initiated a detailed pilot study investigating the use of TDABC in pediatric distal radius fractures. With the assistance of the Harvard Business School, our department has served as one of the early pilot sites for investigative work in TDABC, along with the Department of Plastic Surgery at Children's Hospital Boston (Boston, MA), the University of Texas MD Anderson Cancer Center (Houston, TX), and the Schon Klinik (Munich, Germany).

Throughout the progress of our pilot study with TDABC, we have experienced the many advantages that detailed cost estimates offer, including the identification of avoidable inefficiencies and cost distortions, the ability to perform prospective margin analyses of possible changes in care pathways, and insight for operational and strategic planning.

In our experience, the greatest concern with implementation of a TDABC system in a hospital or medical facility is the tremendous initial effort required to launch such a system. The fluid nature of medical care necessitates ongoing investment of time in maintaining a TDABC system as well. From our vantage, TDABC would benefit from a technology solution that seamlessly collects data on process flow, time stamping, and cost rates - thereby permitting efficient real time cost analysis and focus on value improvement.

Directly, TDABC is not expected to reduce costs or improve value – it is simply a tool that permits the accurate measurement of costs. The tree-sized weed that is the "health care cost crisis" in the garden of the American economy cannot be uprooted simply by trimming the leaves in distal radial fracture care or in the orthopaedic cast room. In both of these settings, costs are relatively low and patient outcomes are typically excellent. However, the fact that tremendous opportunities for value improvement exist in these simple settings suggests that the opportunities for capturing value in more complex and expensive conditions are potentially enormous. The largest drivers of health care costs include the overuse of new and expensive technology, defensive medicine practices due to potential malpractice litigation, and beginning-of-life/end-of-life care. If TDABC is found to be an effective tool for pruning the branches of excess cost, perhaps in the future it can be applied to cut roots.

Ultimately, the collection of more accurate cost and outcomes data will permit our society to abandon the current inefficient fee-for-service payment system, and move towards value-based reimbursement system, in which providers are reimbursed for creating value and not for providing services. A value-based reimbursement system will realign financial incentives with patient outcomes, driving costs down and quality up.

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