Radial Head Implant Fit varies with Radial Shaft Morphology

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INTRODUCTION: Proximal radial head (RH) implants are used to treat severe fractures of the radial head. These implants consist of a conical stem placed within the intramedullary canal (IC) with variable types of fixations. RH implants have a high revision rate of 7.3%-13.6%. The most frequent reason for revision (30%) is aseptic loosening, likely due to insufficient mechanical fit of the stem within the IC. The IC has a complex morphology, narrowing after the RH and significantly increasing in width at the bicipital tuberosity, presenting challenges for placing a stem. This study explores how morphological variation in an average population group impacts the mechanical fit of implant stems.

METHODS: 52 three-dimensional (3D) models of the proximal radius (PR) and the corresponding IC were created from high resolution CT-scan from the New Mexico Decedent Image Database. The study was regarded as exempt by the institutional review board. 26 average sized females (160-165 cm) and males (173-178 cm) divided in two equally sized age groups (25-30 and 40-45 years) were used (4 groups total). The radii and canals were algorithmically aligned with the z-axis, and 0.1 mm thick axial slices were created for a length of 60 mm starting from the end of the RH. Axial slices were then fitted using an ellipse. From each fit, minor axis, major axis, midpoint coordinates, and the root mean squared (RMS) error of both the RC and IC were extracted. Standard cylindrical implant stems (SCS), optimally sized cylindrical implant stems (OCS) and tapered circular stems (TCS) were chosen. Implants were given a standard length of 40 mm. The diameter of the OCS was designed to leave at least 1.5 mm of bone remaining at the narrowest part of the PR. The SCS diameter was picked in 1 mm increments so that at least 1.5 bone are left remaining. The TCS had a slope of 1/20, or 2.9 degree and a base diameter measured to leave at least 2 mm of bone remaining. Due to the elliptical nature of the IC, two different types of contact were defined, full circumference contact (FCC), meaning the whole circumference of the implant is in contact with cortical bone, and two-point contact (TPC), meaning at least two opposing points of the implant are in contact with cortical bone (see Figure 1). The length of each contact with the bone was calculated. FCC and TPC differences between groups were compared via a Mann-Whitney U test, with p-values less than 0.01 regarded as significant, accounting for multiple hypotheses testing.

RESULTS SECTION: FFC length for OCS implants ranged from 0 to 22.5 mm (female: 10.2±6.3 mm male: 8.4±5.5 mm), for SCS from 0 to 19.2 mm (female: 7.3±5.9 mm male: 6.2 ±5.5 mm), and for TCS from 0 to 16.9 mm (female: 5.2±3.9 mm male: 7.3 ±5.0 mm). TPC length ranged for OCS from 1.1 to 30.5 mm (female: 23.4±7.8 mm male: 24.7±4.8 mm), for SCS from 0 to 19.2 mm (female: 17.5±7.5 male: 14.3±6.6 mm) and for TCS from 0 to 28.1 mm (female: 11.8±5.6 mm male: 16.9±5.8 mm). No FCC was present for 9.6% (5/52) radii with OCS, 21.1% (11/52) radii with SCS, and 19.2% (10/52) radii with TCS. No TPC was present for no radius with OCS, for 1.9% (1/52) radii with SCS, and for 3.8% (2/52) radii with TCS (See table 1 for an overview of the results). OCS had significantly more TPC than TCS and SCS. TCS had the lowest TPC of all implant types. TCS had significantly more TPC for males than for females within the study population.

DISCUSSION: Due to radial shaft morphology, current cylindrical and conical implant designs are not able to achieve full circumference contact (FCC) for the full length of the stem. This is due to the BT and the eccentricity of the shaft. For a smaller proportion of the population, FCC becomes minimal to zero. Further research is necessary to determine how much length is needed for a successful fit and to avoid long-term failure of the implant. This study provides an explanation why current implants fail. Limited options in stem sizes provided by manufacturers further magnify these issues. Choosing tapered over cylindrical stems to facilitate insertion among other reasons has significant impacts on the mechanical fit, primarily for female patients. In this study we only simulated tapered implants with a moderate slope of 1/20 or 3.8% with a diameter that was optimally sized for their respective IC. Further research is needed to evaluate the impact of different slopes and using the limited diameters provided by manufacturers.

SIGNIFICANCE/CLINICAL RELEVANCE: (1-2 sentences): This study shows that the mechanical fit of radial head implants, an implant type with a high complication rate, varies greatly with radial shaft morphology with some patients having no full circumference cortical bone contact at all. These findings could explain why current implants fail and have therefore important implications for future implant design.

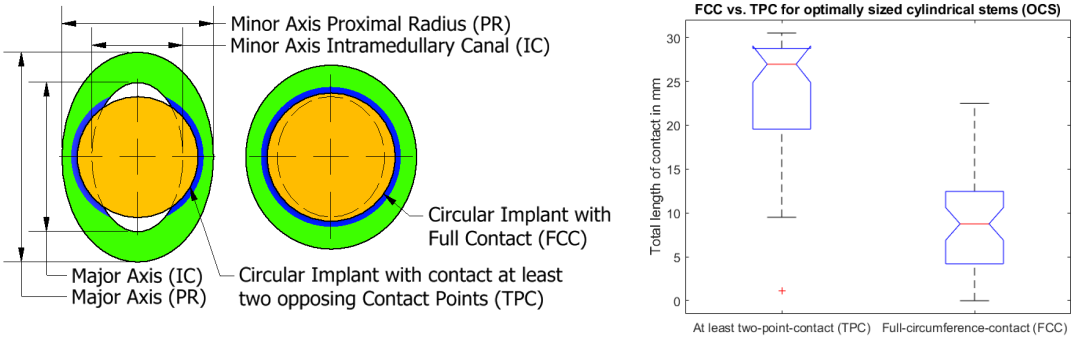

Figure 1: Implant stems (orange) can have full contact (right, blue outline) within the IC if the major axis of the intramedullary canal is shorter than the diameter of the implant. At the same time the minor axis of the PR (green) must be larger than the implant diameter, to make sure there is no hole in the bone. Since the radial shaft is eccentric (minor axis < major axis) for some patient's full-circumference-contact (FCC) cannot be achieved at any point within the IC. At least two-point-contact (TPC, left, blue outline) is achieved, when the minor axis of the intramedullary canal is less than the diameter of the implant.

Table 1: Summary of calculated contact length for the different implant types. *Significantly different to OCS ($p < 0.01$) [A, B] not significantly different to OCS ($p = 0.012$ and $p = 0.027$ respectively)

	Full-Circumference-Contact (FCC) in mm				Two-Point-Contact (TPC) in mm			
Implant Stem Type	Min to Max	Mean±Std	No FCC	FCC <5 mm	Min to Max	Mean±Std	No TPC	TPC <5 mm
Cylindrical Stem (OCS)	0 to 22.5	9.3±5.9	9.6% (5/52)	25.0% (13/52)	1.1 to 30.5	24.0±6.5	0% (0/52)	1.9% (1/52)
Standard Stem (SCS)	0 to 19.2	6.8±5.7[A]	21.1% (11/52)	42.3% (22/52)	0 to 29.9	20.4±7.3*	1.9% (1/52)	1.9% (1/52)
Tapered Stem (TCS)	0 to 15.3	6.2±4.5[B]	19.2% (10/52)	34.7% (18/52)	0 to 28.1	14.2±6.2*	3.8% (2/52)	7.7% (4/52)