A Design of Experiments Approach to Identify Optimal Cementing Conditions in TKR

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Disclosures: **M. Miller:** None. **T. Damron:** 1; Journal AAOS, Up To Date, Wolters Kluwar Health, Clin Orth Rel Res. 3B; Cerament. 5; Cerament, Stryker, Wright Medical. 8; CORR, JOR, Medicina, Open J Orthop, PLOS One. **K. Mann:** None.

INTRODUCTION: In total knee replacements (TKR), aseptic loosening is a leading cause of clinical failure, with the majority of aseptic failures attributed to mechanical loosening of the tibial tray component [1]. Recently, there have been several reports of complete debonding of the tibial tray-cement interface at the time of revision, indicating that this interface contributes to the failure of the construct. The specific surgical or implant design factors contributing to this lack of implant cement adhesion [2] are unknown. Further, because cementing technique can vary widely by surgeon and is not fully documented for each clinical case [3], it is possible that certain combinations of the cementing process result in a sub-optimal tibial tray-cement bond. To address this issue, we used a design of experiments (DOE) approach to determine the effect of four factors (and interactions of the 4 factors) on implant-cement interface strength. The Aims of this study were to: 1) develop a test platform that recapitulates the primary features of the cementing process of the TKR tibial tray to the tibial bone surface and 2) perform tensile strength tests of implant-cement specimens created using this system while altering 4 factors in the DOE framework: timing of cement application, degree of pressurization during implant placement, implant surface roughness, and motion of the implant prior to cement cure. The overall goal was to determine clinically relevant factors that may lead to weak cement-implant interfaces, such that these could be avoided in practice.

METHODS: A cemented tibial tray 'test platform' was developed consisting of a flat TiAl6V bar as a mock tibial tray 'implant', a custom-created acrylic bone analog with trabecular spaces to allow for cement interdigitation, and a mold that controlled flow of PMMA cement (**Fig 1a**). The bone analog was placed in the mold, with a recess for the mixed PMMA cement, and the implant was pressed into the mold using a mechanical test frame (Fig 1b). Implant *surface roughness* was either satin (Ra= 1.2µm) or grit blasted (3.8µm). The *time to implant* (2 or 6 min) was from the start of cement mixing to the time to press the implant into the cement. An implant *plunge depth* (2.0 or 2.8mm) was the distance the implant traveled into the cement recess. A plunge depth of 2mm created a low-pressure environment because the displaced cement volume did not completely fill the trabecular spaces. The 2.8mm plunge depth generated a high-pressure environment since cement overfilled the trabecular spaces. The final factor, *liftoff,* simulated implant motion after the initial placement (plunge) of the implant and was achieved by reversing the direction of motion (up) from the plunge direction (down). Liftoff was either 0 mm (no motion) or 0.75 mm (up). Following cement cure, the test specimens were removed from the mold and stored in 0.9% saline solution for 7 days at 37 deg C. Mechanical testing consistent of a tensile test to failure at 1.0 mm/min in displacement control (Fig 1c). A full factorial DOE approach was used to determine the influence of the four test conditions on the tensile interface strength. A total of 48 samples were tested with 2 replicates for each test combination.

RESULTS: Implant-cement tensile strength ranged from 0 to 10MPa (**Fig 2**), with samples mainly failing at the implant-cement interface. Of the 48 samples, 28 samples had cement adhered to the implant after failure. The median strength of these samples was 4.2MPa, while the other 20 samples with no cement adhesion on the implant had a median strength of 0.6MPa. ANOVA with first-order interactions of the 4 test parameters resulted in a high overall explanation of the variation in tensile strength (r^2=0.90 p<0.0001). The top 4 significant contributing variables were *time to implant* (LogWorth=15.03 p<0.0001), *surface roughness* (logWorth=8.00, p<0.0001), implant *liftoff* (LogWorth=7.62, p<0.0001), and time to implant*surface roughness (logWorth=6.96, p<0.0001). The combination of test conditions that produced the greatest tensile strength was a time to implant at 2 min, a grit blasted surface, no liftoff, and a plunge depth of 2mm ((9.8 MPa strength) or 2.8mm (9.4 MPa strength). While a time to implant of 2 minutes generally resulted in stronger interfaces, use of a satin surface in combination with liftoff motion resulted in a mean tensile strength of less than 2 MPa. All but one test condition with a time to implant of 6 minutes had a tensile strength of less than 3 MPa; a grit blasted implant with a 2.8mm plunge depth and no liftoff had a tensile strength of 3.5 MPa.

DISCUSSION: The cementing test platform allowed us to create a large combination of relevant cementing and implant variables in a consistent and time-efficient manner. The DOE approach with full factorial design allowed us to test all combinations of these variables and identify combinations that were strong. Perhaps more importantly, we identified the combination of factors that resulted in negligible interface strength. As the goal is to create an enduring bond at the tibial tray-cement interface, efforts to identify the surgical/implant conditions that result in weak interfaces are important. It is important to note that single-factor investigation, such as evaluating implant surface roughness, without exploring this in combination with other cementing factors can lead to very different outcomes (eg a satin component cemented at 2 minutes may be much stronger than a grit component cemented at six minutes). This work could be extended to test other conditions including early application of cement to the implant surface, sensitivity of timing of implantation, and a variety of implant motion protocols.

SIGNIFICANCE/CLINICAL RELEVANCE: Implant loosening in TKR can be caused by several factors including surgical technique used while cementing and placing the implant components, features of the implant design, and patient-related factors. Using a novel test platform to test combinations of 4 different factors that may affect the strength of the implant-cement interface, we demonstrated that cementing late during the working phase of the cement, use of a satin implant surface, with low pressurization, resulted in the weakest interface.

REFERENCES; [1] Sharkey, J Arthroplasty, 2014 [2] Torrino, Clin Orthop Relat Res, 2022, [3] Martin, J Arthroplasty, 2022

ACKNOWLEDGEMENTS: Funded by NIH AR42017.

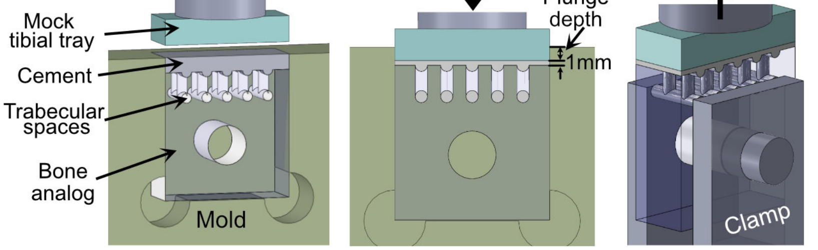

Fig 1a. Cementing **b**. Implanting **c**. Tension testing

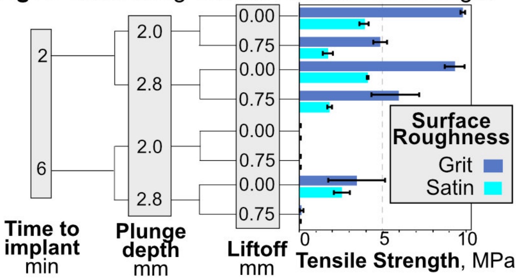

Fig 2. Cementing conditions effect on strength

ORS 2024 Annual Meeting Paper No. 392