

Compliant Wrist Endoprosthesis for Extensive Pan-carpal and DRUJ Damage

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INTRODUCTION: Total wrist fusion (arthrodesis) is the sole option for many patients suffering from advanced pan-carpal pathologies (e.g. giant cell tumors, post-traumatic osteoarthritis) and high-energy fractures. Conventional total wrist replacements lack durability and stability, and therefore are not typically appropriate for many patients, especially those who are young and active; in fact, complete wrist fusion (WF) is about five times as common as total wrist arthroplasty (TWA) in the US over the past decade. Unconstrained wrist implants, such as those most commonly used for TWA, are not inherently stable, and are thus prone to subluxation under load-bearing conditions. This results in injuries, rapid implant deterioration, and a non-biological stress distribution on the radius and carpal/metacarpal bones that hold the prosthesis in place. Bone resorption and aseptic loosening also contribute to reduced durability as synthetic particles from implants are released by friction between articulating surfaces. Conversely, patients who undergo WF retain full hand function, but limitations in wrist function lead to compensatory motions that may result in other disabilities and joint pathologies such as shoulder arthritis.

As an alternative to conventional TWA, we present a novel compliant wrist endoprosthesis that represents a fundamental reimagining of joint architecture to guide motion via *deformation* rather than *articulation*; this architecture has the unique potential to overcome limitations of both arthroplasty and arthrodesis. The implant is built around compliant mechanisms, which consist of flexible elements that deform under load to produce desired motion, rather than rubbing or sliding of bearing surfaces. This architecture allows the device to achieve biological joint compliance without particulate wear. The central mechanism, called a cross-axis flexural pivot (x-pivot) is also inherently stable, which eliminates subluxation as a failure mode. The absence of rigid connections enables the distribution of axial shock and off-axis loads across the compliant structure, rather than concentrating these loads at the bone-implant interface.

METHODS: Our objective was to demonstrate feasibility of replacing wrist function with a compliant mechanism. We first evaluated potential mechanisms, and selected the x-pivot for its ability to accommodate a large range of motion about a single axis, while resisting high axial forces orthogonal to that axis. We then designed the compliant endoprosthesis as a series arrangement of two x-pivot mechanisms, creating two orthogonal rotational degrees of freedom (DOFs). This architecture creates an inherently stable flexion/extension mechanism that encases the radio/ulnar deviation x-pivot (Fig. 1). Alignment of the axes of rotation of the two stages, which cross in the same transverse plane, permit fluid combinations of the two DOFs (e.g. circumduction and dart-throwing motions).

We next sought to tune the flexible elements of the implant design to withstand the motions and loads necessary for wrist function. Our efforts began with a published musculoskeletal model of the wrist joint [1], which we used to quantify the internal joint loads seen during flexion/extension and deviation, with a 100 N force applied to the fingertips. We assumed 1,400 cycles/day when assessing the implant's durability, based on published cycle counts for upper-extremity activities [2]. Grade 5 Titanium (Ti64) was selected for the implant due to its biocompatibility and exceptional fatigue life. The flexural elements, which can be described as “blades” of variable thickness, were assigned parameters related to the properties that can influence their mechanical performance, such as length, width, minimum thickness, base thickness and variable thickness length. We generated an extensive set of finite element analysis (FEA) simulation results, linking peak stress in a x-pivot to geometric parameters and applied load/deformation. These results were used to train a neural network, which then allowed us to rapidly iterate across flexure geometries until we found geometries for which the peak expected stresses remained below Ti64's fatigue limit at 5×10^7 cycles (488 MPa). The resultant design was verified in FEA (Abaqus, Dassault Systems) under peak expected loads condition and ADL-relevant loading path, and key blade parameters were manually tuned to minimize implant and maximize range of motion.

A dummy version of the refined implant was 3D printed in carbon-fiber-diffused nylon, and evaluated in a cadaveric wrist for attachment and range of motion. Our goal in this dissection was to evaluate tendon routing, potential for impingement and tightness of the wrist capsule. We then implemented a simplified version of the implant in Ti64 in a shim-based configuration that separates the envelope from the flexural elements. This facilitated benchtop testing of the endoprosthesis on a robotic manipulator (KUKA), to assess range of motion and response to acute overloading.

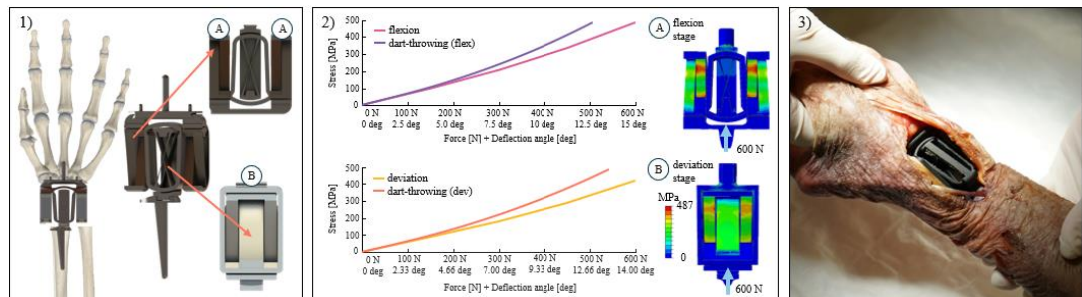
RESULTS: The machine learning search and subsequent manual tuning produced a blade length of 31 mm, width of 5.25 mm, minimum thickness of 0.3 mm, base thickness of 1.35 mm, and variable thickness length of 12.01 mm. Those parameters resulted in a stress, for the maximum loading condition, of 487 MPa in flexion/extension and 417 MPa in radio/ulnar deviation (Fig. 2). Simultaneous loading of the two DOFs produced asymmetric stresses that would limit the amount of the load the implant can sustain in those circumstances (Fig 2). The implant's total range of motion is 30 deg in flexion/extension and 28 deg in deviation. The implant (47 x 44 x 24.5 mm) fit well within the cadaveric wrist envelope, with no impingement (Fig. 3). Benchtop testing results of the simplified x-pivot mechanism were consistent with model predictions.

DISCUSSION: The compliant wrist endoprosthesis has the potential to address both the instability of TWA and functional limitations of WF, without the risk of wear-related loosening. Based on our simulation results, the implant is designed to withstand 100 years of loading within the body, with no friction wear. This would enable young active patients to maintain a healthy lifestyle with reduced levels of compensation, without high risk of revision procedures. Asymmetric stresses during combined articulation of the two DOFs (e.g. dart throwing motion) are a potential concern, but can be addressed with the addition of load-dependent and angle-dependent hardstops that engage selectively to prevent overloading of the central mechanism during low-cycle-count activities. Our first target for compliant wrist endoprosthesis is patients affected by advanced pan-carpal pathologies; however, successful implementation of this device would lay the foundation for application of compliant mechanisms to general joint arthroplasty.

SIGNIFICANCE/CLINICAL RELEVANCE: The proposed implant introduces a long-lasting solution that addresses the instability of TWA and the functional limitations of WF. With this implant, post-operative quality of life and functional outcomes may significantly improve, effectively closing the gap between conventional arthroplasty and the unmet needs of young, active patients undergoing extensive wrist reconstruction procedures.

IMAGES:

Fig. 1. Compliant wrist endoprosthesis. A depicts the flexion/extension mechanism and B depicts the deviation mechanism. Fig. 2. Von Mises stress as a function of load and angle for each stage. Fig. 3. Cadaveric testing of 3D printed implant prototype.



REFERENCES: [1] J. Eschweiler et al, “Musculoskeletal Modeling of the Wrist via a Multi Body Simulation,” Life. Apr. 2022

[2] B. L. Kincaid and K.N. An “Elbow joint biomechanics for preclinical evaluation of total elbow prostheses” J Biomech. Sept. 2013