Apparatus and methods for total elbow replacement which allows a surgeon to intraoperatively select a linked or unlinked constraint by utilizing a modular connection located on the body of the humeral and ulnar stem. In addition, the device has different stem designs to accommodate cemented or cementless fixation.

**Problem / Unmet need:** The two leading clinical indications for total elbow arthroplasty are rheumatoid arthritis and posttraumatic arthritis. The two primary elbow replacement types used to treat these arthritic events are constrained and unconstrained designs, also referred to as linked and unlinked, respectively.

**Linked elbow replacements** have intrinsic stability as the humeral and ulnar components are mechanically connected to one another, usually by a hinge. Some laxity exists to permit a small degree of varus-valgus and internal-external rotational movements.

**Unlinked elbow replacements,** the humeral and ulnar components are not mechanically connected. For these implants, the degree of varus-valgus and internal-external rotational movements are dependent primarily on the quality of ligamentous and muscular integrity.

Some drawbacks of these systems include:

The Coonrad-Morrey total elbow arthroplasty (TEA) system employs linked components, including polyethylene bushings on the humeral and ulnar components through which a metal axle passes, and an anterior flange on the humeral component used in conjunction with bone graft to increase torsional and anteroposterior stability in vivo. The humeral and ulnar components are cemented into place. The hinge permits ±3.5° of varus-valgus motion, with the intent that the load will be transferred to the soft tissues before max angulation is achieved.

- Shi et al (JBJS 2007) recently reported on 67 Coonrad-Morrey TEAs. Of these, 37 were primary arthroplasties with a five-year survival rate of 72%. The remaining 30 were revision arthroplasties, which had a five-year survivorship of 64%. Aldridge et al (JBJS br 2006) reported ten-year survival of 51% and fifteen-year survival of 24%. Clinical results have only rivaled hip and knee replacement in less active patients, such as those with rheumatoid arthritis. For this group, implant survivorship is about 90% at five to ten years (Little JBJS 2005, Gill JBJS 1998).

- An implant-related failure mode with the Coonrad-Morrey TEA is wear and deformation of the polyethylene bushings, causing both decreased function of the joint as the bushing-axle constraint decreases and osteolysis secondary to the release of large volumes of polyethylene wear particles. Mighell et al. (JBJS-BR 2005) reported radiographic evidence of bushing wear in three of six patients after less than five years, requiring two patients to undergo revision surgery. Similarly, Wright et al. (Jses 2005) reported bushing wear as the cause of failure in ten patients, all of whom required revision surgery an average of five years postoperatively. Lee et al. reported that 1% of their patients required revision surgery for an isolated bushing exchange at an average of eight years after their TEA (JBJS 2005). Goldberg et al. (JBJS 2008) examined components retrieved from sixteen elbows in fourteen patients and found that damage to the humeral and ulnar polyethylene bushings was nearly universal with asymmetrical thinning and elliptical plastic deformation. Metallic wear on the fixation stem of the ulnar component, consistent with loosening at the implant-cement interface, was observed in most of the cases, underscoring the additional problem of aseptic loosening in TEAs.
The Discovery Elbow System from Biomet, Inc. is another linked, cemented total elbow replacement. The hinge has an hourglass shape to maximize articular surface contact between the humeral and ulnar components. Minimal bone resection maintains the integrity of the humeral epicondyles. The device preserves the ulnar collateral ligament. The condyles are made of Cobalt chrome.

The Latitude Total Elbow Prosthesis from Tornier is a modular, cemented total elbow replacement. This device is designed to restore the normal kinematics of the elbow joint creating a modular spool that allows the surgeon to adjust the central, posterior, and anterior offset of the joint axis. A second articular component can be attached to the ulnar component to convert from unlined to linked. The device also has an optional radial component. Limitations of using the Latitude include the complete dissection of the distal humerus, the use of multiple jigs to locate the natural joint axis that may not be present in a patient with rheumatoid arthritis, limited triceps split to gain access to the ulnar canal, and cementing of the components.

- Hinged systems require that one match the hinge axis of the fixator to the hinge axis of the elbow joint, using either fluoroscopy or a pin directly through the axis of the joint. But it’s difficult to precisely place the axis, and if the alignment is off, the device may bind and lead to more limited motion or even subluxation.
- In an emergency setting, the requisite skilled personnel and equipment may not be available.

**Details of the Invention:** It would be desirable to provide apparatus and methods for total elbow replacement that allow a surgeon to intraoperatively select a linked or unlinked constraint, as well as accommodate cemented or cementless fixation. We have developed an external fixation device for the elbow with benefits that include:
  - Simplified device application with the ability to maintain joint motion
  - Easy removal for rehabilitation; device can be removed then reapplied (e.g., re-linked) for protection of the joint.
  - Requires less training and less OR time
  - Lower profile and therefore easier for the patient to manage during activities of daily living
  - "Simple-release" locking mechanism allows for easy to remove the rigid elbow constraint, actively move the joint through a safe range of motion, and return the elbow to a rigid state
  - Use of the device may protect the elbow from subluxation

**Advantages:**
  - Simple application that does not require the identification of kinematic axis
  - Device provides for pin sites in "safe zones," as well as flexible pin placement
  - Device can be adaptable to existing bone fixation systems
  - Simple operation and use: once in place, the frame can be unlinked for motion, and re-linked for joint protection
  - Device allows a therapist or family member to disengage the frame for protected, limited motion during rehab
  - Unilateral or combined (medial and lateral) stabilization
  - Allows pin exchange due to, for example, infection
  - May be constructed at least in part of radiolucent material
  - May be reusable in whole or in part or may be constructed for one-time use
  - Could be made available as a "kit" for emergency room application

**Patent status:** provisional

**Further information:** Please contact the Office of Technology & Intellectual Property Development

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