Short-term results of the PROSNAP linked elbow prosthesis with a snap-in structure and modular flange for the reconstruction of severely damaged rheumatoid elbows

Keiichiro Nishida, MD, PhD\textsuperscript{a,b,\ast}, Kenzo Hashizume, MD, PhD\textsuperscript{b}, Ryuichi Nakahara, MD\textsuperscript{b}, Masatsugu Ozawa, MD\textsuperscript{b}, Ryozo Harada, MD\textsuperscript{b}, Takahiro Machida, MD\textsuperscript{b}, Yoshihisa Nasu, MD, PhD\textsuperscript{c}, Toshihumi Ozaki, MD, PhD\textsuperscript{b}, Hajime Inoue, MD, PhD\textsuperscript{b}

\textsuperscript{a}Department of Human Morphology, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama City, Japan
\textsuperscript{b}Department of Orthopaedic Surgery, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama City, Japan
\textsuperscript{c}Department of Orthopaedic Surgery, Kurashiki Sweet Hospital, Kurashiki City, Japan

Background: We aimed to evaluate the early clinical results of the reconstruction of problematic elbow joints due to rheumatoid arthritis (RA) using a PROSNAP linked elbow prosthesis (Kyocera Medical, Osaka, Japan) for total elbow arthroplasty.

Methods: Seventeen elbows in 14 RA patients were replaced with a PROSNAP elbow with cement fixation. The patients comprised 1 man and 13 women, with a mean age of 63.9 years (range, 52-83 years) at the time of surgery. The preoperative conditions of the elbows were arthritis mutilans (n = 10), an ankylosed or stiff elbow with a preoperative range of motion of 45° or less (n = 4), and loosening of a primary total elbow arthroplasty (n = 3). The mean follow-up period was 47.7 months (range, 32-69 months), with a 100% follow-up rate. The clinical outcome of the elbows was evaluated by the Mayo Elbow Performance Index (maximum, 100 points).

Results: The mean postoperative Mayo Elbow Performance Index score improved from 57.6 points to 97.1 points. Preoperatively, 3 of the 17 elbows were judged as good, 7 as fair, and 7 as poor; at final follow-up, 16 elbows were judged as excellent and 1 as good. Complications were noted in 1 elbow (6%), which had undergone a postoperative fracture.

Conclusions: The PROSNAP elbow prosthesis can be safely implanted through a relatively easy procedure and provides satisfactory short-term clinical outcomes for the reconstruction of severely damaged RA elbows.

Level of evidence: Level IV, Case Series, Treatment Study.
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As a result of 3 decades of modifications and improvements to elbow prostheses, the total elbow arthroplasty (TEA) has become a reliable procedure for the reconstruction of damaged rheumatoid arthritis (RA) elbows. Modern elbow prostheses have either unlinked (non-constrained, resurfacing) or linked (semiconstrained) designs. Unlinked designs rely on the presence of sufficient bone stock to seat the prosthesis, as well as ligaments and capsular structures to provide stability to the elbow. In contrast, linked devices do not require osseous or ligamentous integrity and therefore can be used in a broad variety of indications, including reconstruction of severely damaged and unstable RA elbows due to arthritis mutilans or revision surgery for failed TEA. Presently, the most frequently used linked prostheses include the GSB III prosthesis (Zimmer, Warsaw, IN), the Coonrad-Morrey prosthesis (Zimmer), and more recently, the Discovery prosthesis (Biomet, UK). However, previous reports have described numerous issues related to these prostheses, including prosthesis disassembly with the GSB III prosthesis and polyethylene wear and late failure of the locking mechanism with the Coonrad-Morrey prosthesis. Furthermore, intraoperative complications may occur because of the learning curve for surgeons who are not familiar with the surgical procedure for the implantation of the elbow devices.

The development of a new linked elbow prosthesis (PROSNAP; Kyocera Medical, Osaka, Japan), which possesses a unique assembly system, began in 2003; this prosthesis was initially to be used for the relatively small bony structure of Japanese patients. PROSNAP has been in clinical use since November 2007, and as of July 2013, a total of 30 RA elbows have been replaced by this implant. In this study, we aimed to evaluate the clinical results of TEA for the reconstruction of problematic RA elbow joints using the PROSNAP elbow prosthesis, with a minimum follow-up period of 2 years.

**Methods**

**Design of PROSNAP elbow prosthesis**

The PROSNAP linked elbow prosthesis is manufactured from a cobalt-chromium alloy, with humeral and ulnar stems designed for cement fixation and an ultrahigh-molecular weight polyethylene (UHMWPE) articulation, incorporated by a metal backing of the ulnar component (Fig. 1). The cross-sectional shapes of the humeral and ulnar stems are designed for cement fixation. The modular anterior flange (small, regular, or large) is selected during surgery and press fit to the humeral stem through the square slit of the flange before implantation (Fig. 1). The details regarding the size of each component are provided in Supplementary Figure 1 (available on the journal’s website at www.jshoulderelbow.org). The ulnar component possesses a sleeve of UHMWPE, opening at approximately 45° of flexion to the axis of the ulnar stem, the width of which is smaller than the diameter of the humeral shaft (Fig. 2). The humeral and ulnar components are assembled by a snap-in fitting of the shaft of the humeral component through the sleeve into the articular surface of the ulnar component. After assembly, the theoretical flexion arc and extension arc of the prosthesis are 186.5° and −11.1°, respectively (Supplementary Fig. 2, available on the journal’s website at www.jshoulderelbow.org). The prosthesis cannot be assembled manually because it requires a special device, and it must be disassembled by inserting another device between the components from the posterior aspect with the joint held at 90° of flexion. The inner diameter of the ulnar sleeve is slightly larger than the outer diameter of the humeral shaft, creating a small clearance between the ulnar and humeral articular surfaces. On the anterior-posterior plane, the maximum curvature difference is 0.7 mm (range, 0.49-0.61 mm), thus providing 6° to 8° of inherent laxity incorporated into the ulnar-humeral coupling (Fig. 2).

**Patients**

This is a retrospective case series of 17 patients (21 elbows) with RA who underwent a primary or revision TEA with a PROSNAP prosthesis implanted between November 2007 and March 2011. Two patients (3 elbow replacements) died for reasons unrelated to the surgery. One patient reported a good condition of the operated elbow but could not attend the final follow-up visit because of severe functional disabilities of the other joints. In this study, we enrolled 14 patients (17 elbows) with a minimum follow-up period of 2 years. All patients met the American College of Rheumatology criteria for RA. The patients comprised 1 man and 13 women, with a mean age of 63.9 years (range, 52-83 years) at the time of the operation. The mean follow-up period was 47.7 months (range, 32-69 months). One surgeon (K.N.) implanted all the prostheses. The preoperative conditions of the elbows were arthritis mutilans with poor bone stock (n = 10), ankylosed (n = 1) or stiff elbow with a pre-operative range of motion (ROM) of 45° or less (n = 3), and loosening of a primary TEA (n = 3).

The clinical outcomes were evaluated with the Mayo Elbow Performance Index (maximum, 100 points), including ROM...
and postoperative complications. On the basis of this system, the results were defined as excellent (≥90 points), good (75-89 points), fair (60-74 points), or poor (<60 points). Anteroposterior and lateral radiographs were reviewed carefully and evaluated for the position of the implant and the cement mantle, radiolucent lines, bone resorption, and osteolysis.

Surgical procedure

The patient was placed in the full lateral position with the upper arm horizontal and the forearm hanging vertically. A posterior surgical approach was used in all elbows. The ulnar nerve was identified, and meticulous dissection was carried out proximal and distal to the first motor branch of the flexor carpi ulnaris. The superficial aponeurosis of the triceps brachii was elevated as an olecranon-based flap. The lateral side of the flap was extended distally along the lateral side of the ulna by elevating the anconeus muscle. The triceps tendon was detached from the olecranon, and the triceps muscle was longitudinally divided medially and laterally, exposing the posterior aspect of the humerus. After radial head excision, the elbow joint was further flexed and a synovectomy was performed. The joint was then dislocated, and the medial collateral ligament was sacrificed if present. The humeral end was trimmed, and intramedullary reaming was performed along the central guide pin. The guide instrument was set and a square bone cut was made to remove the damaged trochlea. After the ulnar surface was cut away with a bone saw, the thickness of the remaining olecranon was reduced to approximately 10 mm, the medullary cavity was enlarged with a reamer, and a circular rasp was used to create a circular bed for the ulnar component. The humeral and ulnar trial prostheses were then positioned to check the correct implantation, stability, and mobility of the joint. After irrigation, the humeral and ulnar components were fixed separately with bone cement. A specific device was then used to connect the 2 articulating components in a snap-in manner. Anterior translocation of the ulnar nerve was routinely performed. Before closure of the wound, the triceps tendon edges were firmly sutured to the olecranon by use of 2 drill holes at the olecranon, and the flap of the superficial aponeurosis was closed over the repair to reinforce the suture. In the case of triceps contracture, the surgeon performed a V-Y advancement, suturing the triceps tendon medially and the remaining aponeurosis and triceps muscle laterally with the edges of the flap of the superficial aponeurosis.

Postoperative care

The suction drain was removed 48 hours after surgery. Splint fixation, with the elbow at 90° of flexion, was used until postoperative day 2, followed by active ROM exercises. By postoperative day 21 to 28, the active ROM should have improved from 30° to 125° in extension and flexion. After 8 weeks, patients were encouraged to continue exercise to achieve functional ROM and strength of the elbow. Restrictions included no repetitive movements or activities that could cause additional stress on the joint. The patient was instructed to avoid heavy lifting, overhead activities, and any movements that could cause pain or discomfort. This period of modified activity lasted for a total of 3 months postoperatively.
motions using more than 2 kg and no single lifts of more than 5 kg when using the upper extremity.

Results

Patient characteristics and precise results of the clinical evaluation are summarized in Supplementary Table I (available on the journal’s website at www.jshoulderelbow.org). The mean preoperative pain, stability, and function scores were 27.4 points (range, 0-45 points), 4.4 points (range, 0-10 points), and 12.4 points (range, 5-25 points), respectively; these improved to 45 (in all patients), 10 points (range, 0-10 points), and 12.4 points (range, 5-25 points), respectively, postoperatively. The mean ROM of extension/supination improved from 99° (range, 0°-145°) before surgery and 113° (range, 85°-145°) at the final follow-up. The mean ROM of pronation/supination improved from 99° (range, 0°-180°) to 160° (range, 75°-180°). The mean score for ROM improved from 13.5 points (range, 5-20 points) to 18.8 points (range, 15-20 points). The total postoperative Mayo Elbow Performance Index score improved from 57.6 points (range, 30-80 points) to 97.1 points (range, 85-100 points). Preoperatively, 3 elbows were judged as good, 7 elbows as fair, and 7 elbows as poor. At the final follow-up, all elbows were judged as excellent (n = 16) or good (n = 1) (Table I).

Intraoperative and postoperative complications were recorded in 1 elbow (6%). A postoperative fracture of the medial humeral condyle was noted after a direct hit to the elbow (elbow 15), causing moderate pain. The patient was treated conservatively, and bone union was observed at 3 months after the incident. No other complications, such as ulnar nerve neuropathy, infection, prosthesis loosening, or dislocation, were recorded.

Discussion

Linked elbow implants have been used to treat a wide spectrum of elbow disorders. The major concern with the use of fully constrained prostheses has been loosening as a result of the transfer of all stress to the prosthesis-cement-bone interface. The design of the Mayo-modified Coonrad prosthesis, which possesses a loose hinge and an anterior flange that resists posterior forces and rotational movements to the elbow joint, contributed to a decrease in the loosening rate, with promising long-term clinical results. These systems have been adopted in many of the modern linked elbow devices. Previous studies on the use of Coonrad-Morrey prostheses for TEA reported favorable results for the reconstruction of elbows with gross instability, ankylosed or very stiff elbows, or the replacement of a failed TEA. The basic configuration of the PROSNAP elbow prosthesis, followed that of the Coonrad-Morrey prosthesis, is shown in Figure 1. In this study, we investigated the early clinical and radiographic outcome of the PROSNAP prosthesis for severe dysfunction due to RA, obtaining satisfactory results (Figs. 3 and 4).

In the PROSNAP system, bone grafting between the anterior flange and the humerus is deemed unnecessary by selecting the proper size of the modular flange. The shaft at the joint portion of the humeral component is fitted, with a snap-in system, into the UHMWPE sleeve of the ulnar component, allowing the assembly of each component after cement fixation. In this series of patients, these modifications contributed to safe implantation with a relatively easy surgical procedure. The PROSNAP prosthesis was also designed with a loose hinge, as used in the other modern linked devices. The humeral shaft is shaped like a hand drum, not a cylinder, and articulates with the UHMWPE of the ulnar component with a small clearance. This small clearance permits lateral displacement and creates a self-centering effect of the ulnar component to the humeral shaft, thus reducing stress on the shaft and minimizing polyethylene wear.

Before the cement fixation of each component, correct alignment and positioning should be conscientiously confirmed by use of a trial prosthesis. If the prosthesis has not been implanted correctly, it may cause wedge loading and polyethylene wear, leading to implant loosening. A thickness of only 3 to 3.5 mm of UHMWPE at the
articulation of the PROSNAP prosthesis may be considered for longer-term survival of the prosthesis. In addition, it has been recognized that the clinical results of TEA using a linked elbow prosthesis for post-traumatic arthrosis are inferior to those for inflammatory diseases.\textsuperscript{12,14,16} Thus, we do not recommend the use of a PROSNAP prosthesis for the reconstruction of post-traumatic arthrosis at this time, especially in young active patients. In the case of revision surgery because of single polyethylene wear or breakage, the merit of the PROSNAP prosthesis is that the surgeon can disassemble the prosthetic joint and exchange the polyethylene articulation without destroying any of the bony structure.

**Conclusion**

Although additional follow-up is necessary, the results of our study suggest that the PROSNAP linked elbow prosthesis can be used to treat a wide array of rheumatoid elbow conditions and can be implanted through a relatively easy procedure.

**Disclaimer**

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Supplementary data

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References