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Original article

Biomechanical Evaluation of Intraosseous Distal Radioulnar Joint Prosthesis: A Prosthesis Designed Based on Sauvé-Kapandji Procedure

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ABSTRACT

Introduction: To avoid the DRUJ surgical procedures disadvantages, a new intraosseous distal radioulnar prosthesis designed on Sauvé-Kapandji procedure has been introduced. Stability of the prosthesis and biomechanics are to be evaluated in this article.

Materials and Methods: On a cadaveric study, during placement of the prosthesis, biometry of the bones, prosthesis stability (in axial and lateral tractions, wrist pronation and supination, and squeeze test), wrist range of motion before and after implantation, and radiographic evaluation were done on 16 cadavers.

Results: Range of motion of the wrist joint before and after the insertion of the prosthesis, had no significant difference in all six directions. Stability of the prosthesis, when rotational pronation force was exerted, was greater than when rotational supination force was exerted. The prosthesis showed significant stability against longitudinal traction forces in a way that no prosthesis dislocation was observed up to 150 N forces. Stability of the prosthesis was investigated when lateral force was applied to different wrist positions. The most stable position of the prosthesis was in the case of lateral traction forces in supination where no case of dislocation was observed.

Conclusions: The intraosseous distal radioulnar prosthesis demonstrated stable structure with no effect on wrist range of motion.

Level of evidence: IV

Keywords: distal radioulnar prosthesis, cadaver study, Kapandji procedure

INTRODUCTION

In 1912, Darrach introduced distal ulna resection as a salvage procedure for the treatment of distal radioulnar joint (DRUJ) arthritis and instability [1]. However, this resulted in ulnar stump instability and impingement on the radius leading to unsatisfactory results in the long term[2-4]. Bowers introduced hemiresection interposition arthroplasty of distal ulna in 1985 [5] after which DRUJ arthrodesis in addition to distal ulna pseudoarthrosis was introduced by Kapandji in 1986 [6]. These procedures also failed to relieve symptoms due to destabilization of the ulnar stump, impingement on the radius with Sauvé-Kapandji, and convergence of ulna and radius with Bowers [7, 8] [9].

In the past decade, implant arthroplasty has been introduced as an alternative method. Implementation of this method has technically resolved some complications including articular instabilities and radioulnar impingement due to partial or total resection arthroplasty [10, 11]. In addition, implants provide a more normal transfer of forces in the wrist [10, 12]. Various prostheses have been used for DRUJ arthroplasty. These prostheses are divided into two general categories based on their design: ulnar component only ("UHP, Martin GMBH, Germany" and "U-Head, Stryker Corporation (NYSE:SYK), USA" prostheses), and prostheses that radial sigmoid notch is also replaced in addition to the ulnar component ("Aptis DRUJ Prostheses, Aptis Medical, USA" as well as the prosthesis designed by Schuurman AH) [13].

To address the drawbacks of different surgical techniques and various prostheses, we designed an "intraosseous" DRUJ prosthesis that is inserted in between the ulnar osteotomy where the pseudoarthrosis is carried out in the Sauvé-Kapandji procedure. This theoretically stabilizes the ulnar stump avoiding convergence and impingement while the motion is preserved through the prosthesis instead of the DRUJ. In this study, we evaluated forearm stability and the effect of prosthesis on the biomechanics and motion of the wrist.

METHOD

The present study is conducted to evaluate the function of a newly-designed "intraosseous" prosthesis of the distal radioulnar joint (DRUJ) and its effect on the biomechanics of the wrist (IRB approval number of IR.MUMS.fm.REC.1396.334). We used 16 fresh frozen cadavers to examine the biometric specifications, changes in range of motion, stability of the prosthesis, and its radiographic changes after inserting the prosthesis.

Intraosseous prosthesis of the DRUJ

The intraosseous prosthesis of the DRUJ is made of stainless steel 316 LV and is composed of four components: Distal and proximal stems, locking system, and an interconnecting ball (rotating bead) (Figure-1 and 2)

Stems: Proximal non-porous coated stem is inserted in the proximal stump of the ulna, and is designed with one length of 7.5 cm and two diameter sizes of 4.5, and 6 mm (Figure-2). This component has a cylindrical hole at its distal end that stays outside of the medullary canal and is meant to be connected to the locking system. This connection is done by using 4 radial screws (Figure-2).

The distal component is composed of two parts including an intramedullary stem and a cup at its proximal end which holds the ball and is connected to the locking segment (Figure-2). The proximal and distal cups are designed in the way that their inner radius is equal to the outer radius of the ball which helps the ball fit inside the embracing cups while it can also freely rotate. There is a longitudinal slip in the distal intramedullary stem that creates a pathway for screws used in the arthrodesis of the DRUJ (Figure-2).

Locking System: The locking system consists of two concave units acting as two hemispheres embracing the ball proximally and distally. By placing the two units of the locking system together, these two hollow hemispheres form a complete hollow sphere which is the place for the rotating ball. Each concavity has a notch in the peripheral border allowing the ball to be press fit inside the cancavities only when both notches are in line with each other. After inserting the ball, the locking segment is rotated 180 degrees to lock the ball inside while it can rotate freely (Figure-3).

The stem of the locking segment matches with the internal canal of the proximal component. After inserting the proximal component and fitting its stem in the medullary canal, the locking segment is fitted inside the proximal stem (Figure-2). The height of the locking segment can be adjusted by fixing its stem at different levels inside the proximal component. Proximal and distal components of the prosthesis can bend about 10 degree in all planes in relation to each other and can translate less than the radius of the rotating ball in transvers and vertical planes without dislocation.

Rotatiting ball: the ball locates in between the concavities created by the proximal and distal cups in the locking system. It allows rotations as well as vertical motion of the segments along the ulnar axis (Figure-1).

How to place the DRUJ prosthesis

Before starting the procedure, the cadavers were placed at ambient temperature for at least 12 hours [14]. At first, the lengths of ulna and radius bones were measured based on the distance between the tip of the olecranon in proximal and the tip of ulnar styloid in distal region, and the distance between the head of radius in proximal and the tip of the radius styloid in distal region, respectively; they were recorded by a ruler in millimeters by an experienced orthopedic hand surgeon (AM). Also, wrist passive range of motion was measured and recorded in six directions including flexion, extension, ulnar deviation, radial deviation, supination, and pronation.

A longitudinal incision was made over the ulna starting in the mid forearm toward the ulnar styloid. Ulna was exposed through the interval between extensor and flexor carpi ulnaris (ECU and FCU). In this cadaver study, we were not able to assess bone ingrowth and union. In order to insert the prosthesis, we fixed the DRUJ by two horizontal screws while the ECU and FCU tendons were not released. Then the following steps were taken in sequence.

Using a designed guide and an intra-osseous DRUJ prosthesis insertion set, we determined the level of bone cut in the distal stump as well as the location of the two screws for fixing the DRUJ.

1- DRUJ screw holes were drilled through the guide using a 2.7 mm drill bit, and then a fully-threaded 4.0 mm cancellous screws was inserted distally and a partially-threaded 4.0 mm cancellous screw was inserted in the proximal hole.

2- By referencing from the ulnar styloid using the guide, we marked the cutting level at approximately 18 mm from the distal ulnar head. From this level, a 20 mm cylindrical bone was cut and excised proximally using an oscillating saw. This space allows for insertion of the components. However, the height could be adjusted by fitting the depth of the locking segment inside the proximal component.

At this stage, indices of the removed segment were measured and recorded as bellow:

1. Segment length (Figure-4, C)
2. The internal and external cross-sectional diameters of the removed bone segment on both distal and proximal sides (Figure-4, A and B).

Before insertion of the prosthesis, the length of the gap was measured and recorded in various positions of the forearm, including full-pronation, full-supination and in neutral position using a caliper (figure-4, D). In a normal forearm, ulnar variance changes during axial rotation. Knowing this, we aimed to test if the gap length varies significantly. If this was proved significant, the design of the prosthesis had to be revaluated.

In order to insert the prosthesis, the following steps were taken respectively:

1- Curettage and broaching of the medullary canal in both proximal and distal stumps.

2- Selection of an appropriate stem size with regard to internal diameter of ulnar medullary canal (4.5 or 6 mm)

3- Implantation of distal and proximal stems in the medullary canal on both sides using bone cement.

4. Connecting the locking segment to the proximal stem and fixing it using screws.

5- Placing the ball in between the two concavities of the locking system using the pusher. A 180-degree rotation of these two pieces relative to each other for the final locking of the prosthesis locks the ball inside (Figure-3).

After inserting the prosthesis, antroposterior and lateral radiographs of the wrist and forearm were taken (Figure-5). After confirmation of accurate insertion of the prosthesis, wrist range of motion was measured using a goniometer (Figure-6, A and B). Prosthetic stability indices were tested including stability with longitudinal traction (Figure-7, C), full supination and pronation (Figure-7, A and B), lateral traction in supination, neutral and pronation (Figure-7, D), and while squeezing the distal forearm.

Tools and Variables:

Range of motion parameters:

To measure wrist flexion and extension angle, at first, the longitudinal axis of the third metacarpus and the radius bone were defined and used for further measurements; Then, the wrist was placed in maximum possible flexion and extension. Next, one arm of the goniometer was placed on the dorsal or volar surface of the forearm and hand for flexion and extension, respectively; the angle was measured as wrist flexion or extension angle. We measured flexion once before and once after insertion of the prosthesis (Figure-6, B).

Similar steps were done for measuring wrist extension (Figure-6, A). To measure ulnar and radial deviations, the line that was drawn along the longitudinal axis of the radius and another line that was drawn along the dorsal surface of the third metacarpal bone were used. To reduce interpersonal errors all the biomechanics tests including ROM have been performed by one experienced hand surgeon (AM) while identical force applied.

Prosthesis stability indices:

To test the prosthesis stability, we simulated carrying a bag by using a longitudinal traction, turning a steering wheel or tightening a cortical screw in cortical bone by applying torque on the wrist in pronation and supination, and stability in different side tractions by applying lateral force in different forearm rotation as well as the squeeze test. After insertion of the prosthesis and before starting the stability test, we fixed the humerus to the side table with three screws and the elbow was held in 90 degrees flexion. Since the prosthesis internal angulation before failure was limited to 5 degrees, which was difficult to accurately measure in a cadaver lab, we decided to categorize the force-angulation curvatures as "failed" and "not failed". Component dislodgement, ball dislocation, and prosthesis dislocation was considered a prosthesis failure. Prosthesis stability indices which were evaluated and recorded were as follows:

1. Longitudinal traction: This test was simulating carrying a shopping bag by patient. A 150*5 mm schanze pin was inserted in the capitate dorsally and longitudinal traction force was exerted toward distal with a dynamometer (SULMILE, FM-207-100K, Arcadia, CA) and the maximum amount of tolerable force before failure for the prosthesis was measured and recorded. To prevent damage to the prosthesis and bones,

we increased the longitudinal force incrementally up to 150 N which is equal to the force for carrying a bag weighing about 15 kg (Figure-7, C).

2. Applying torque on the wrist in pronation and supination: A 200*5 mm schanze pin was placed in the radial side of the distal radius perpendicular to the bone through radial styloid. The distance between the free end of the pin and ulna was about 200 mm. Then, supination and pronation torque was applied through the schanze pin until prosthesis dislocation occurs. To prevent damage to the prosthesis and bones, maximum force and torque were set on a maximum of 25 N and 5N/m, respectively which is more than the stripping torque of cortical and cancellous screw.) (Figure-7, A and B).[14]

3. Another biomechanical parameter that was evaluated was the resistance of the prosthesis against ulnar, dorsal and volar forces. One of our concerns was gap length variations during forearm axial rotations; Normal ulnar variance alters during forearm pronation and supination. In Sauvé-Kapandji procedure, this alteration may affect the gap length that may subsequently affect prosthesis stability. Having said that, we designed lateral force traction tests in different rotations. It is similar to the ulnar pull test for checking DRUJ stability.*[15]* We attached a dynamometer to the proximal section of the prosthesis, and we measured the tolerable traction force by the prosthesis at neutral position. Then, without changing the direction of the applied traction, forearm was placed in pronation and supination and the force was measured. To prevent damage to the prosthesis and bones, maximum force was set on 50 N (Figure-7, C).

4. Squeeze test (DRUJ compression test): To perform this test, distal forearm was compressed by the surgeon (AM) manually to squeeze radius and ulna together [16]. Stability of the prosthesis was assessed and recorded during this test. This is subjective

test and to decrease personal errors, all squeeze tests have been performed by a single orthopedic hand surgeon (AM).

After completion of the biomechanical tests, radiographs of the wrist and forearm were done in anteroposterior and lateral views (Figure-5).

RESULTS

Biometric results:

The mean lengths of radius and ulna bones were 24.7 and 26.6 cm, respectively (Table-1). The mean length of the created gap in the ulna was 20.1, 20.2, and 28.3 mm in pronation, neutral, and supination, respectively (P=0.977). The maximum and minimum values of the internal and external diameter of the removed segment in the proximal and distal cross sections, as well as the other recorded data are shown in Table-1.

Range of motions:

There was no significant difference in range of motion of the wrist joint before and after insertion of the prosthesis in any of the six directions (Table-2).

Stability:

The prosthesis stability was greater with rotational pronation force than supination (Table-3). No dislocation occurred with the maximum amount of 50N rotational force in pronation. However, in rotational supination force, 3 dislocations were observed with forces of 43, 42 and 28 N.

The prosthesis showed significant stability against longitudinal traction forces in a way that no prosthetic dislocation was observed when the maximum traction force of 150 N was applied.

Regarding the lateral pull test, the most stable position was when the lateral traction force was directed volarly. Four dislocations occurred in dorsal direction while in ulnar position; only 2 cases of dislocation were observed (Table-3).

Radiographic results:

In all cases, the prosthesis showed appropriate alignment inside the medullary canal and relative to other components. Radioulnar screws for the arthrodesis were placed in a proper direction traversing inside the bone and purchasing 4 cortices. The ball was symmetric relative to the proximal and distal concavities in all cases.

DISCUSSION

Resection arthroplasty was a preferred technique when an arthritic DRUJ was painful. However, this technique has failed to address wrist and forearm instability resulting in persistent pain and functional impairment[3, 8, 17]. Modifications to the technique and various prosthesis designs were developed. Biomechanical studies on cadavers have shown the superiority of using prosthesis in prevention of ulna and radius convergence and preservation of the wrist joint kinematics [10, 18, 19].

In the majority of DRUJ prostheses, TFCC has to be sacrificed and the prosthesis joints directly with the sigmoid notch. Since the anatomy of the sigmoid notch is highly variant, sigmoid notch erosion and instability of DRUJ presumably occurs in those prostheses [20].

There were some limitations in the present study. This was a cadaveric study and the prosthesis behavior in the human body has to be tested in future studies. We only tested static conditions while dynamic tests with the function of the muscles require further studies. We limited the forces only to simulate some activities of daily living and also to prevent bone and prosthesis break. Due to some equipment limitation in the cadaver lab, we had to use the prosthesis failure variable instead of the force angulation curves. Moreover, we did not create a real arthrodesis in the DRUJ but only fixed the joint with two screws.

The intraosseous DRUJ prosthesis had a very little effect on wrist range of motion which was one of our concerns because the forearm rotational axis and direction changes to a more proximal part. The other concern was stability of the prosthesis because of the change in normal ulnar variance with pronation and supination. To assess stability, we designed two tests: removed segment variation test and applying the lateral force to the prosthesis in different forearm rotations. Our results showed prosthesis stability in pronation as well as in volar-directed force to the proximal stump.

To the best of our knowledge, we did not find any study testing biomechanical properties of a DRUJ prosthesis. There are two mono-component DRUJ prostheses in the market including Herbert UHP® and uHead prosthesis. Van Schoonhoven et al. used an ulnar head prosthesis (Herbert UHP®) in their clinical study on 23 patients with DRUJ arthritis, which consisted of a titanium stem and a ceramic head. They reported acceptable stability in the short-term [11] and long-term [21] follow-ups. The prosthesis was stable in all patients with no need for further surgeries. In all patients, bone resorption in the distal ulnar stump occurred by collar stress shielding of the prosthesis. Moreover, sigmoid notch remodeling was evident because of the prosthesis head. In another clinical study, Willis et al. used another type of ulnar head prosthesis (uHead) for the treatment of DRUJ arthritis in 19 patients [22]. No significant improvement was achieved after arthroplasty. Two patients were found with stem loosening and one patient presented with prosthesis instability which were considered as complications.

The second generation of DRUJ prostheses includes multi-component prostheses in which, in addition to the ulnar head, the sigmoid notch of radius is also replaced. One of the most well-known designs is Aptis DRUJ prosthesis. The disadvantage of Aptis prosthesis is total resection of the distal ulna and extensive soft tissue dissection which might has an effect on stability [20].

In a systematic review [23], the most common complication of ulnar head replacement was radiographic instability and sigmoid notch erosion. Half of the cases with radiographic instability required further surgery. Secondary surgery was more common in the Aptis prostheses than others (21%), mostly because of the ECU tenosynovitis. The second common complication was irritation of the superficial radial nerve and synovitis of the first extensor compartment caused by prominent screws of the radial component.

Conclusion

We presented and tested a different design for the DRUJ prosthesis which we called an "intraosseous" DRUJ prosthesis. A distinctive feature of this new design is that the prosthesis is located in the ulnar shaft, and not in the true joint site meaning that we have a pseudoarticulation in the distal shaft of the ulna and moving the forearm rotational axis higher relative to the normal axis. The distal ulnar segment is not resected, and ulnar styloid attachments including ulnocarpal and TFCC ligaments are retained which help maintain wrist biomechanics and stability. This prosthesis did not have a significant effect on the wrist range of motions and showed efficacy in restoring function. Unlike significant prosthesis stability in longitudinal traction, there is some inherent instability in rotational force (especially supination). This is our concern and we plan to change the prosthesis design so as to resolve this issue in the future.

Conflict of interest

Ali Moradi, M.D. and Mohammad Hossein Ebrahimzadeh, M.D. are the designers of the prosthesis and involved in the prosthesis U.S. and Iran Patent.
The authors confirm that there is no known conflict of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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Authors' contribution:

Ali Moradi: study design, data collection, manuscript preparation, analysis and interpretation.

Reza Binava; data collection and analysis, manuscript preparation.

Arya Hedjazi: data analysis, manuscript preparation

Saeed Eslami Hassanabadi: study design, manuscript preparation

Negar Taher Chaharjouy: edition and manuscript preparation

Mohammad Hossein Ebrahimzadeh: overseeing the research, Manuscript preparation

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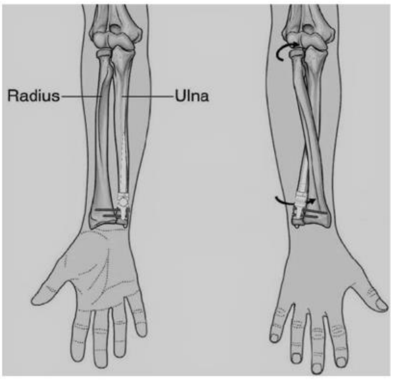

Figure 1. The “intraosseous” DRUJ prosthesis is designed and placed in ulna bone and DRUJ arthrodesis is carried out similar to Sauvé-Kapandji procedure. Forearm rotational movements in the pseudo-arthrosis of the ulna bone are performed through the prosthesis instead of DRUJ.

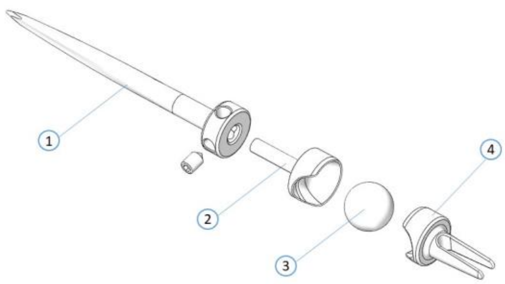

Figure 2. Intraosseous DRUJ prosthesis components are: 1- Proximal stem, 2-Locking segment including proximal concave unit, 3- Globe, and 4- Distal stem including distal concave unit.

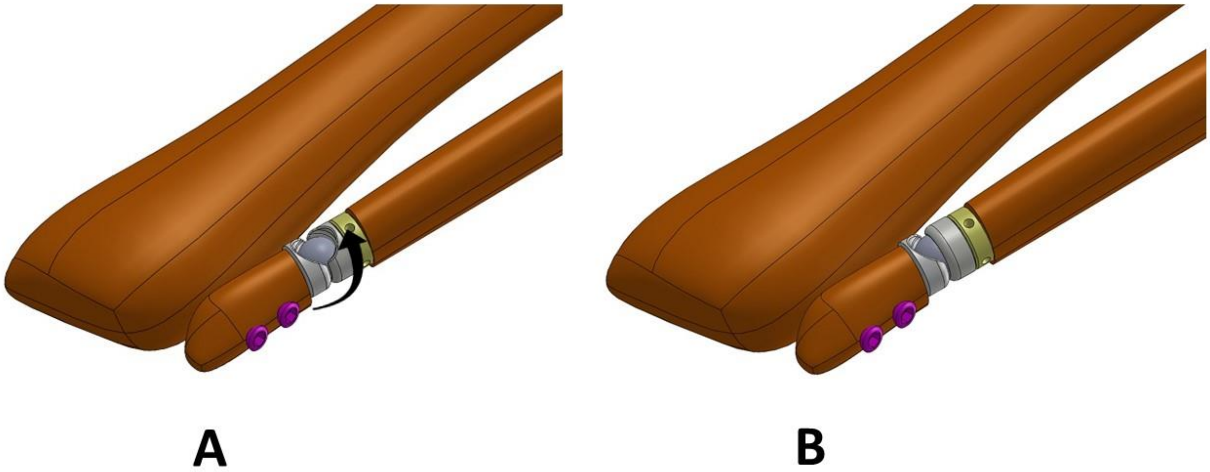

Figure 3: By turning locking segment 180 degrees around its longitudinal axis (A), the globe will be locked (B).

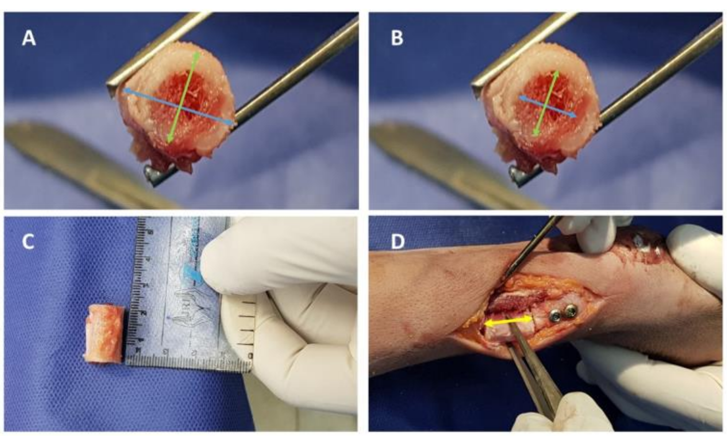

Figure 4A-D. Biometry of the resected segment is demonstrated. (A) Maximum and minimum of external diameters of the segment is calculated. (B) Maximum and minimum of internal diameters of the segment is calculated. (C) Length of segment is calculated. (D) Resected gap in forearm supination and pronation is shown.

Figure 5. Anteroposterior and lateral radiographs of intraosseous DRUJ prosthesis are shown.

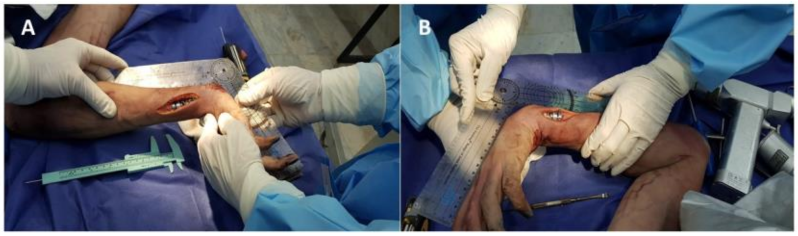

Figure 6. Wrist range of motion is measured. (A) Wrist extension is measured. (B) Wrist flexion is measured.

Figure 7A-D. Stability tests are performed. (A-B) Torque is applied on the wrist in pronation and supination. (C) Longitudinal traction is tested. (D) Resistance of the prosthetic to the lateral, dorsal and volar forces is tested.

Table 1: Forearm biometery for intraosseous DRUJ prosthesis are shown.

Forearm biometry	Minimum	Maximum	Mean	Std. Deviation
Ulna Length (cm)	23.80	30.50	26.6	2.18
Radius Length (cm)	22.00	28.00	24.7	1.97
Resected segment block length (mm)	16.50	19.50	17.95	0.90
Resected segment gap in (mm) :				
Pronation	18.00	23.80	20.14	1.59
Supination	18.50	22.00	20.29	1.19
Neutral	18.50	23.00	20.23	1.09
Proximal ulna segment (mm)				
Inner-Length	6.00	10.00	7.66	1.01
Inner-Width	5.40	9.00	6.48	0.90
Outer-Length	11.00	14.00	12.03	1.09
outer-Width	8.50	12.10	10.58	1.11
Distal ulna segment (mm)				
Inner-Length	7.00	15.30	8.88	2.11
Inner-Width	8.90	12.30	10.40	0.93
Outer-Length	11.00	17.40	12.83	1.69
outer-Width	8.90	12.30	10.40	0.93

DRUJ= Distal Radioulnar Joint

Table 2: Wrist range of motion before and after intraosseous DRUJ prosthesis implantation is calculated (measurements are in degrees).

wrist range of motion	**Mean**	**Std. Deviation**	**P-value**
Pronation			
Before Surgery	82.31	15.83	0.28
After Surgery	84.87	11.36	
Supination			
Before Surgery	83.68	11.20	0.56
After Surgery	84.62	8.68	
Wrist Flexion			
Before Surgery	73.62	10.68	0.27
After Surgery	75.37	14.10	
Wrist Extension			
Before Surgery	69.75	10.34	0.86
After Surgery	69.43	10.69	
Ulnar Deviation			
Before Surgery	34.31	9.56	0.23
After Surgery	36.12	11.37	
Radial Deviation			
Before Surgery	16.68	5.10	0.25
After Surgery	18.37	7.28	

DRUJ= Distal Radioulnar Joint

Table 3: Result of stability test after implantation of intraosseous DRUJ prosthesis implantation is shown.

Stability test	**Maximum force was applied**	**Result**
Longitudinal traction force for Dx	150 N	No failure
Rotational force on wrist	50 N (Turk=10 N/m)	
Pronation		No failure
Supination		3 Dx *
Squeeze force for Dx	Stable/Unstable	No failure
Lateral force for DX	50 N	
Volar		No failure
Ulnar		2 Dx**
Dorsal		4 Dx***

* Dislocation happened in 28N , 42N , 43N

** Dislocation happened in 9 N, 23 N

*** Dislocation happened in 11 N, 11N, 22 N, 35 N

DRUJ= Distal Radioulnar Joint, Dx=Dislocation, N=Newton