All surgeons who are planning a Total Wrist Arthroplasty with the Maestro™ implants should be aware

Ingo Schmidt
Med. Versorgungszentrum Bad Salzungen GmbH (Betriebsstätte Wutha-Farnroda), Lindigallee 3, 36433 Bad Salzungen, Germany.

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Abbreviations: PCWJOA: Pancarpal Wrist Joint Osteoarthritis; TWA: Total Wrist Arthroplasty; WRS: Wrist Reconstructive System; CoCr: Cobalt-Chromium; TWF: Total Wrist Fusion; THA: Total Hip Arthroplasty; PE: Polyethylene; FDA: US Food and Drug Administration; PPO: Periprosthetic Osteolysis.

Case Presentation with its first clinical consequences resulting from the withdrawal of both Maestro™ implants from the marketplace

A 49-year-old male with low-demand claims in his activities of daily living, initially presented with a long-standing history of right post-traumatic pancarpal wrist joint osteoarthritis (PCWJOA), sustained primarily a total wrist arthroplasty (TWA) utilizing the non-cemented resurfacing Re-Motion™ total wrist (Stryker Corporation, Kalamazoo, Michigan/USA) in 2012. Due to loosening of the carpal plate, an exchange TWA utilizing the non-cemented locking Maestro™ Wrist Reconstructive System (WRS, Zimmer Biomet Holdings Inc., Warsaw, Indiana/USA) with an intercalated cobalt-chromium (CoCr) head size +4 became necessary secondarily in December 2017. Both procedures were done by a colleague from another institution. The further course was eventful, the patient reported about atraumatic dislocations of implant several times a day (starting in January 2018) that were always closed reducted by himself. At first presentation in our hospital, static and dynamic (i.e. pulling the wrist longitudinally by the examiner) radiographs revealed instability of implant, and a broken radial variable locking screw of carpal plate with migration of the head of screw into the articular space (Figure 1A-B). It had to be recommended on our part to perform a total wrist fusion (TWF), and that was done again by the colleague from the another institution who has made the 2 previously performed procedures.

TWA is the motion-preserving alternative to TWF for treatment of rheumatoid or non-rheumatoid PCWJOA in patients with low-demand claims in their activities of daily living. Recent evidence of the National Inpatient Sample database (USA) suggests that the complication rate utilizing the new anatomic-biaxial 3rd generation TWAs with 7% in patients undergoing a TWF [1], and Herzberg and Adams [2] noted in 2012: “The future appears positive for greater adoption of total wrist arthroplasty for patients who are willing to accept somewhat greater risks for the benefit of improved function”. Recently, implant survival with the new 3rd generation TWAs is reported to be 90-100% at 5 years in most series, but it declines from 5 to 8 years [3]. Recent evidence suggests as well that the complication rate of all 3rd generation TWAs is significantly lower (p=0.002) than older generation types (range 0.1-2.9% vs.0.2-8.1%) [4]. However, it must be exclusively noted that all surgeons who are performing a TWA need a learning curve for realization of correct insertion of an implant [5, 6].

The non-locking Maestro™ Total Wrist (Zimmer Biomet Holdings Inc., Warsaw, Indiana/USA), developed in 2002 by Strickland / Palmer / Graham, available in Europe since 2005 and first published with encouraging results by Dellacqua in 2009 [7], is one of the new 3rd generation TWA that is currently in use worldwide [3, 4, 8-10]. The design of the implant has 3 essential differences as compared to the other 3rd generation types (Re-Motion™, Universal 2): (1) the design resembles a total hiarthropathy (THA) in which a metal head articulates in an ultra-high molecular weight polyethylene(PE) cup; (2) the titanium alloy radial stem is to be inserted pressfit into the radial diaphysis primarily without the need of cementation; and (3) the concave to distal shaped carpal plates are available without or with various scaphoid augments that provides a sufficient support of the carpal plate with it titanium alloy capitae peg onto the base of the trapez/trapezoid bones even in cases when the scaphoid bone is removed that is associated with the advantage that bone grafting between the surrounding carpal bones is exclusively not required (Figure 2A-B). The Maestro™ WRS is the further development of the implant. It has 2 changes as compared to the Maestro™ Total Wrist: (1) the carpal plate is inserted with fixed or variable locking screws that should reduce the shear forces at the implant-bone interface (Figure 2B), and in order to avoid backing out of a non-locking screw (if it would be loosened) into the articulating components’ space potentially leading to PE wear or fracture; and (2) the intercalated CoCr carpal heads are set up externally onto the cone of the previously inserted carpal plate where as the carpal heads of the Maestro™ Total Wrist are screwed onto the carpal plate over the capitae peg before its insertion. This new feature allows an exchange of the carpal heads such as required in case of instability without the need for revision of the entire carpal plate (Figure 2C) [11, 12]. Noted that the US Food and Drug Administration (FDA) in 2009 reported 1
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Figure 1 (Case Presentation): (A) Posterior-anterior and lateral radiographs of the right wrist with the non-cemented Maestro™ WRS under static conditions showing in contrast to Figure 3B abnormal angulation (i.e. breakthrough) of the radial variable locking screw inside the scaphoid augment of carpal plate (red lines) whereas the ulnar variable locking screw (crossing the 4th carpometacarpal joint) that suggests too large carpal resection as well, in contrast to Figure 3B showing correct placement without its breakthrough (black lines), and the head of the broken screw migrates into the articular space. Note that the articular space is not widened (light blue lines). For alignment of implant, the longest available intercalated CoCr head size +4 was inserted. There are marked arthritic changes at the distal radioulnar joint, but in the absence of any clinical symptoms. (B) Posterior-anterior and lateral radio-graphs of the right wrist under dynamic conditions (same patient) showing pronounced widening of the articular space (i.e. instability, light blue pointed lines and yellow arrows, the distal light blue pointed line in the lateral plane demonstrating exclusively the supernatant of the intercalated CoCr head over the volar and dorsal edges of the radial component as advice for possible dislocation when moving the wrist) in comparison to the static conditions presented in Figure 1A.

case of backing out of a non-locking screw of the non-locking Maestro™ Total Wrist (inserted 2005 in this case) that required a conversion to a TWF [13]. Noted as well that for insertion of the radial component of both Maestro™ types a relatively deep bony resection into the distal radial metaphysis is required for placement its radial bodies (i.e. non-resurfacing type) (Figure 2A, Figure 3B).

Figure 2 (Design and features of both Maestro™ types [11, 12]): (A) Radiographs of a patient’s right wrist in both planes demonstrating correctly positioned Maestro™ WRS utilizing a carpal plate with a scaphoid augment after removal of the entire scaphoid bone (white arrow). The carpal plate is fixed with a variable locking titanium screw into the 2nd metacarpal bone and a fixed locking titanium screw into the hamate bone. The polished titanium alloy radial stem is press-fit inserted into the radial diaphysis (yellow arrows) that does not require cementation. Note the concave to distal shaped design of the carpal plate. Also note that for positioning of the radial body of radial component a relatively deep bony resection into the distal radial metaphysis is necessary (i.e. non-resurfacing type). (B) Clinical photographs demonstrating the Maestro™ WRS utilizing capal plates with (white arrow) and without (yellow arrow) scaphoid augments. Note the concave to distal shaped design of carpal plate. The undersurface is coated with a thick titanium spray (Macrobond). Note the green colored variable locking screw and the blue colored fixed locking screw that is the first change in comparison to the primary Maestro™ Total Wrist which had non-locking screws only. (C) Clinical photograph demonstrating the Maestro™ WRS after insertion of its carpal plate and radial component. Note that the intercalated CoCr carpal heads are set up externally onto the cone of the previously inserted carpal plate that is the second change in comparison to the primary Maestro™ Total Wrist (here the carpal heads are screwed onto the carpal plate over the capitate peg before its insertion that does not more allow its exchange in case of a dislocation without revision of the entire carpal plate).
Both Maestro™ implants have proven to be successful for treatment of rheumatoid or post-traumatic PCWJOA, gouty arthritis of the wrist, avascular osteonecrosis such as Kienböck’s disease, idiopathic wrist joint OA, failed previously performed wrist procedures such as four-corner-fusion, primary or early secondary wrist replacement in cases of highly comminuted distal radius fractures in selected older patients; it can also be combined with an ulnar head prosthesis, a total elbow arthroplasty, and a total carpometacarpal joint replacement of the thumb; and it can be successful as well for a conversion to a TWA if patients primarily received a TWF are unsatisfied [7, 8, 11, 12, 14-25]. Nydick et al. [26] reported in 2013 that patients who received primarily a TWA with the Maestro™ Total Wrist for treatment of post-traumatic PCWJOA rated their functional outcome in Patient-rated wrist evaluation statistically significant better than patients who received primarily a TWF (31 vs. 73, p=0.01). Furthermore, both Maestro™ types achieve the most favorable functional outcome as compared to the other 3rd generation types, and it may be justified by preserving the resection-related carpal height due to its 3 various intercalated CoCr carpal heads in combination with its design of ellipsoid surface articulation especially in order to avoid radial impingement that is mainly observed with the use of the Re-Motion™ Total Wrist with its in contrast to both Maestro™ types straight transverse design of carpal plate (Figure 3A) [27, 28]. Noted that the survivorship of the Maestro™ implants with 95% at 8 years is slightly superior compared to the other 3rd generation TWAs [4, 29]. Moreover, TWA utilizing the Maestro™ WRS in a non-cemented manner can also be an option for treatment of post-traumatic PCWJOA in single cases for younger patients with high-demand claims in their activities of daily living [30]. Both Maestro™ types are approved for carpal hemiarthroplasty by the FDA (creating a metal-on-cartilage/bone articulation”), but first published results are disappointing mainly presenting as ulnar-carpal translocation potentially leading to distal radioulnar joint disease, and probably based on a mismatch between the lunate facet and the CoCr head of carpal plate [31]. Both Maestro™ types are not approved for radial hemiarthroplasty by the FDA (off-label” use by creating a metal-on-PE articulation”) [32], but first published results are disappointing as well mainly presenting as PE wear or fracture subsequently leading to synovitis (“PE disease”) [33, 34].

It is well-known that metal wear (i.e. metallosis) was the main cause for failure of older TWA generation types utilizing a metal-on-metal articulation [35]. Since introducing the 3rd generation TWA types utilizing a metal-on-PE articulation, metal wear appears not to be responsible for its failure. It is reported with the Universal 2 (Integra LifeSciences Corporation, Cincinnati, Ohio/USA) in up to 16.7% of cases only, and common initially presented as carpal tunnel syndrome, pisiform impingement, or pseudotumor [36-39]. With the use of the Maestro™ Total Wrist, only 1 publication could be found in which metallosis led to capsular destruction with subsequent attenuation of the distal radioulnar joint leading to dislocation and destruction of the extensor mechanism, however, there was an impingement between the TWA and an additional ulnar head prosthesis with a metal head [40]; and the FDA reported in 2010 another case of metallosis with the Maestro™ Total Wrist due to fretting of a loosened non-locking titanium screw and the carpal plate, but a revision was required due to an infection and not due to implant issues [41]. However, the main cause of failure of all new 3rd generation TWAs (i.e. metal-on-PE articulation) is unchanged loosening of its carpal plates based on mechanical imbalances that is

![Figure 3](image-url)
followed by metal and/or PE wear, but noted that the amount of wear particles does not correlate with its loosening [36]. Periprosthetic osteolysis (PPO) can be concern in assessment of loosening (or not), it has been observed after TWA with the new 3rd generation types as well as after an ulnar head replacement. However, Boeckstyns and Herzberg [37] reported in 2014 on 44 patients received a TWA with the Re-Motion™ Total Wrist and evaluated at a mean follow-up of 3.7 years, significant periprosthetic radiolucency (more than 2 mm in width) were found juxta-articularly around the prosthesis components in 36.4% at the radial component and in 15.9% at the carpal component, where as clinical manifestation of loosening (defined as progressive angulation or subsidence) was present in 14% of all cases only. Moreover, PPOs seems to be stabilizing with in 3 to 8 years in the absence of clinical manifestation of loosening (Figure 3A-B) [37-39]. That phenomenon is probably not new. Julius Wolff, a german orthopaedic surgeon (†1902), first described in 1862 that cortical bones primarily became atrophic in lesser loaded regions whereas it became hyperthrophic in higher loaded regions, and resulted secondarily ina steady-state over time ("Wolff’s law") [40]. Hence, PPOs juxta-articularly around non-cemented prosthetic components of TWA (i.e. metaphyseal PPO’s) can also be probably discussed as result of sufficient osseointegration of its titanium alloys in the diaphyses distal to the metaphyseal PPOs (i.e. stress shielding) [9, 10, 37-39].

Dislocation (i.e. instability) of a wrist implants is a concern, it has been observed in up to 8% with the older TWA generation types [3]. Sterling Bunnel (†1957) noted: “A painless stable wrist is the key to hand function”[41]. This problem seems to be solved with the use of the new 3rd generation types, and by increasing experience of the surgeons with their surgical techniques. The rates of instability or dislocation for the Re-Motion™ Total Wrist and both Maestro™ implants is reported to be 0.7% and 0.6% only [3, 7, 14, 27, 29, 34]. Atraumatic dislocation may occur either by iatrogenic injury of the volar extrinsic radioscaphocapitate ligament which the most important stabilizer of the wrist and potentially leading to a transverse instability, or by iatrogenic too large carpal resection potentially leading to a longitudinal instability. Schmidt [11] reported 1 case of an iatrogenic instability with the Maestro™ WRS (atraumatic dislocation to volar in the plaster splint 5 days postoperatively) which could be successfully treated by open surgical revision accompanied with an exchange of the formerly inserted CoCr head size +2 to size +4 in order to restore longitudinal alignment without the necessity of revision of the entire carpal plate (Figure 2C). The causes for the failed revision TWA with our presented case were: (1) too large carpal resection that could not be compensated by the already inserted longest size (+4) of the 3 available intercalated CoCr heads (standard +2, +4), and (2) failed angle positioning of the variable locking screw into the 2nd metacarpal bone (in contrast to Figure 3B) which obviously exceeded the normal range of the mobility between the head and shaft of the screw that led to its breakthrough (i.e mechanical imbalance) accompanied with migration of the head of this screw (external thread) into the articular space due to its insufficient locking mechanism with the carpal plate (internal thread). Noted that iatrogenic too large bony resection is also reported to be a main cause for dislocation of a thumb 1st carpometacarpal total joint replacement, and not due to implant issues as well [48].

Revision arthroplasty is the preferred first method of choice for loosened or unstable primary arthroplasties of the knee, hip, elbow, and shoulder in order to restore stability and providing joint motion before performing the other salvage procedures such as joint fusion or resection arthroplasty. This principle is also applicable for a failed TWA in selected cases [42]. Despite that the outcome is uncertain and in 16% to 25% of cases additional surgery is required, revision TWA is a valid option to TWF in the management of failed TWA [43, 44]. Independently of that a TWF would probably be the safest salvage option with our patient, a revision of the carpal plate utilizing the Maestro™ WRS again by preserving the radial component would have been technically possible when using a custom-made intercalated CoCr head longer than size +4, and a longer custom-made capitate peg for its placement into the 3rd metacarpal bone first described in 2009 by DellaVaca [7]. However, all german surgeons were personally informed on February 26, 2018 by the company Zimmer Biomet that both Maestro™ implants were definitively withdrawn from the market place in Germany, and this decision should also be extended worldwide in forseeable future. The company officially stated that the cause for the withdrawal is that as follows: „The Maestro™ implants are approved only for its cemented use by the FDA and there are no publications in the literature worldwide on favorable results with its cemented use, and so, it cannot be guaranteed a favorable surveillance of both implants by the company if inserted in a non-cemented manner (i.e. "off-label" use) ...hence, the Conformité Européenne (CE) mark for Europe is no longer requested when it expires in 2018” [12]. This reasoning must be extremely doubted because there is exclusively no evidence in the literature which supports a primarily cemented insertion of all 3rd generation TWA types with its titanium alloy radial stems (Figure 1A-B, Figure 2A, Figure 3A-B), and the primarily cemented insertion of all 3rd generation TWAs (including both Maestro™ types!) is recommended only in cases when poor bone stock is present, for revision TWA, or for the use of custom-made wrist implants in patients with bony tumors [1-11, 14-30, 33, 34, 39, 41-57], and these features are absolutely comparable with those of all modern total hip arthroplasties [12]. Noted as well that primary cemented insertion of a TWA does not decrease the risk of periprosthetic fracture both intra- and postoperatively, and it has been reported for the metacarpophalangeal joints that there is a higher risk of periprosthetic fracture intraoperatively when insertion of a prosthesis was done in a cemented manner [66, 67]. Moreover, the disadvantage of both Maestro™ types is that the PE insert is fixed to the radial body, hence,when PE wear or fracture occurs then a revision of the entire radial component becomes necessary. When the long radial stem of both Maestro™ types is primarily inserted into the radial diaphysis with cementation, then (in case of failure) an extended bony windowing along the entire radial component is needed for its removal that can be followed by another complications in the further course. In conclusion, this decision by the company contradicts any recent scientific knowledge. Furthermore, it does no more longer allow a revision for a failed Maestro™ TWA, and for such cases, the motion-restricting TWF is the salvage option only. Therefore, all colleagues who are planning a TWA with the Maestro™ implant in forseeable future should be aware. Noted that a (re-)revision TWA utilizing one of the other 3rd-generation types with its resurfacing radial components and short radial stems for placement into the metaphyses (Re-Motion™, Universal 2 or Freedom) appears not to be possible with our presented case due to the previously required deep bony resection into the distal radial metaphysis for placement of the radial body of the Maestro™ total wrist (Figure 1A-B, Figure 2A, Figure 3A-B). It is fact that patients often do not have any knowledge about such a proceeding (i.e. „think they got inserted a bad implant”) potentially leading to explantation miseries for the surgeons alone to their patients regarding the administrative decision by the company Zimmer Biomet.
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