

# Joint Implant Surgery & Research Foundation Chagrin Falls, Ohio, USA



## **Clinical Review of the Zweymuller Femoral Stem**

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### Abstract:

This review summarizes published literature from a range of reputable sources regarding hip prostheses (stems) utilized currently in cementless Total Hip Arthroplasty. The critical review of published clinical studies shows Zweymuller style (Alloclassic and SL-Plus) stems in all critical characteristics.

Since the introduction of cementless total hip arthroplasty in the 1970s, a range of design philosophies for femoral and acetabular components have demonstrated variable clinical success<sup>1,3</sup>.

The Zweymüller stem was introduced to the global market in 19738. Since its introduction the Zweymüller stem has been implanted in over 700,000 patients9 and has undergone minor design updates. The first generation Hochgezogen was a straight stem with a rectangular cross section tapering in the sagittal plane. The stem was forged from titanium alloy (Ti-6Al-4V) with a grit-blasted surface finish. In 1986 the second generation Alloclassic-SL (StepLess) was introduced10. The Alloclassic evolved from the Hochgezogen to taper in both the sagittal and frontal plane and to replace the Vanadium with Niobium in the Titanium alloy due to cytotoxicity concerns11. The SL alludes to the way the stem sizes increase steplessly and proportionally to allow downsizing without sacrificing stability9. The latest generation of the Zweymüller stem, the SL-PLUS has been selected as the predicate for the Signature Pegasus stem. The SL-PLUS differs slightly from the Alloclassic geometrically, with slight modifications to the neck, proximal surface and cross section3,12.

Recently cementless components have been yielding clinical results on par and in some cases even surpassing their cemented predecessors<sup>2,4,6</sup>. As a result, cementless THA is gaining in popularity<sup>1,7</sup>. The short-term results of four of the best cementless femoral components recorded in the Norwegian Arthroplasty Register as described by Havelin et al, included the Corail, IMT, Profile and **Zweymuller** stems with revision for loosening <1% at 4.5 years which was comparable to cemented counterparts.

The review presents the findings of a literature review conducted to evaluate the clinical performance and survivorship outcomes of the later generations of the **Zweymüller** stems.

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Gaining initial and secondary stability is important to the clinical success of a hip stem implant14. The Zweymüller stem gains initial stability both axially and rotationally. The Zweymüller stem is double tapered to gain axial stability [9]. Early subsidence of the stem is frequently reported15,16; however, it stops once the stem contacts cortical bone, and early subsidence of this stem has not been shown to negatively affect the clinical outcome15. For rotational stability the Zweymüller has a rectangular cross section9. Rotational stability is provided according to the 'square peg in a round hole' philosophy. The stem is press fit into the intramedullary canal until the corners of the stem contact cortical bone, thus locking it in place9. A combination of the above design features allow initial stability and hence full weight bearing immediately post-operatively4, even in patients with osteoporotic bone9.

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The initial stability ensures osseo-integration is possible leading to long-term secondary fixation and stability.

The Zweymüller stem's grit blasted surface promotes osseo-integration and rapid secondary stability8 without the risk of coating delamination17. Svehla et al 18 evaluated the pull out strength of small cylindrical implants made of Ti-6Al-4V with 5 different surface finishes (grit-blasted, grit-blasted with HA, Porocoat, Porocoat with HA and smooth) in an ovine model. It was found that the grit-blasted implants had improved pull out strength compared to the smooth implants. Porocoat and HA coating further increased the implant's pull out strength; however, the study covered a period of only 12 weeks. Longer term clinical follow-ups of the Zweymüller stem with a grit blasted surface show excellent secondary stability as proven by high rates of radiographic osseo-integration6,15,17,19,20 and often lower rates of revision for aseptic loosening than popular cemented stems4,5. Based on clinical and radiological follow-ups the Zweymüller stem is shown to have sufficient immediate and long term stability6.

The **Zweymüller** achieves stability due to a diaphyseal press fit<sup>16</sup>. As a result, the proximal femur is shielded from compressive stresses thus leading to bone remodeling in accordance with Wolff's law<sup>21</sup>. The bone remodeling observed is typically cortical atrophy in the proximal femur and diaphyseal cortical hypertrophy<sup>4,12,16,19,22,24</sup>. However, the stress shielding is not associated with instability<sup>12,19,25,26</sup> or poor clinical outcomes<sup>4</sup> and typically stabilizes after two years<sup>23</sup>.

Zweymüller et al 27 investigated the progress of radiolucent lines that tend to be seen around the Zweymüller stem. Based on the radiographic outcomes of 95 patients, he concluded that consistency in radiolucent lines between 6 and 10 years is an indicator for long-term implant survival. Vervest et al [28] used DEXA (Dual Energy X-ray Absorptiometry) technology to examine the bone mineral density in the femur after implantation of a Zweymüller stem. The study of 32 patients that underwent an unilateral hip replacement allowed the contralateral hip to be used as reference. The study found that at 10 years the most notable reductions in bone mineral density were in zones 6 and 7 (calcar region) and zone 2; however, this was not associated with any clinical consequences or radiographic abnormalities.

Karachalios et al 22 documented a 10-year prospective, random study in which 80 female patients diagnosed with osteoarthritis were assigned to four groups. Each group had a Zweymüller, Corail, Optifix, or Autophor 900S hip stem implanted. Each group showed the highest bone loss in Gruen Zone 7 (proximal femur) at two years follow-up. After two years the bone loss stabilized and the bone density steadily recovered. The same phenomenon was observed in stems that depend on a proximal HA coating for fixation, however to a lesser extent. In no cases did the stress shielding result in unsatisfactory clinical outcomes. The cause of periprosthetic bone loss is multifactorial, and based on the results of the study the author suggests the clinical and theoretical relevance of stress shielding is overestimated in literature.

It has been hypothesized that adding a proximal HA coating to the *Zweymüller* stem would reduce proximal bone atrophy by promoting osseo-integration. Christ et al <sup>29</sup> and Steens et al<sup>21</sup> have evaluated the effectiveness over the medium term of adding a proximal HA coating to the SL-plus stem. Both studies found that the HA coating improved osseo-integration, increased the bone mineral density and reduced the occurrence of radiolucent lines in the proximal femur. Neither study linked the HA coating to improved clinical outcomes; however, the authors agree that a longer term follow-up is necessary to determine if the superior radiographic findings lead to improved clinical outcomes.

Periprosthetic osteolysis results in bone loss around an implant and can lead to a loss of stability and eventual revision<sup>22</sup>. In clinical studies following patients with **Zweymüller** stem implants, cases of osteolysis were rare, mild, and did not have a clinical relevance<sup>6,11,15,20,23</sup>. A leading cause of periprosthetic osteolysis is wear debris generated from polyethylene acetabular cup liners. Hip stems with high levels of osseo-integration inhibit the distribution of wear particles distally along the stem; therefore, femoral osteolysis is less prevalent around well osseo-integrated stems<sup>30</sup>.

Stem migration is frequently observed with the *Zweymüller* stem<sup>15,16</sup> as is typical for tapered stems. The stem is secured in the femoral canal by pressing against the cortical wall, thus creating compressive stresses at the bone prosthesis interface. Due to the viscoelastic nature of bone, the compressive stress is relieved and the stem subsides further down the femoral canal. The tapered design allows the stem to regain stability after initial subsidence<sup>14</sup>. As a result, stem subsidence is not an unusual finding with the *Zweymüller* stem; however, it is typically non-progressive<sup>15</sup> and ongoing subsidence is not observed after the 2<sup>nd</sup> post-operative year<sup>16</sup>.

The surgical approach for accessing the hip joint is largely based on the surgeon's preference. The direct lateral<sup>5,31,32</sup>, anterolateral <sup>4,6,15,31,33,34</sup> and posterolateral<sup>34,35</sup> approaches to implanting the **Zweymüller** stem have been reported in clinical literature. Many surgeons have developed less invasive mini-incision approaches to implant the *Zweymüller* stem<sup>25,36,39</sup>; however, with the large lateral trochanter flair insertion in a single direct anterior approach can be very difficult requiring more posterior soft tissue releases. The surgeon must be aware of the consequences of their chosen surgical approach. The muscular trauma endured during the procedure may lead to redistribution of muscle forces and subsequent bone remodeling. Perka et al <sup>40</sup> showed that the transgluteal approach leads to significantly lower bone mineral density in the proximal femur when compared to the anterolateral approach.

The Zweymüller stem uses a "fit without fill" surgical technique. The intramedullary canal is prepared by impacting the cancellous bone using a broach by this technique. In contrast, many competing cementless stems use a "fit with fill" surgical technique in which the intramedullary canal is prepared by clearing its contents. The "fit without fill" technique boasts many advantages over the latter technique, including preserving endosteal blood supply, improving initial stability and fitting a variety of bone shapes9. The endosteal blood supply is preserved because the contents of the intramedullary canal are less disrupted by the Zweymüller surgical technique. Hence the Zweymüller stem can gain initial stability in a wide variety of femoral bone shapes because the canal is broached to the size of the stem, as opposed to the "fit with fill" technique where the stem depends on fitting the irregularly shaped femoral canal for stability.

In 1998, Bourne et al<sup>41</sup> established an algorithm for deciding whether a cementless or cemented stem should be used, based on experience and a review of the current clinical literature. They suggest that cementless stems should be used in patients younger than 75 years with Dorr type A or B bone shapes and good quality bone stock. Bourne et al suggest that patients older than 75 years with cylindrical type C bone and poor bone stock are better suited to cemented hip replacement. Many surgeons employ this philosophy. Delaunay et al <sup>34</sup> avoided using the *Zweymüller* stem in patients with poor bone stock in favor of a cemented alternative and Garcia-Cimbrelo et al<sup>15</sup> do not use cementless stems in older patients or those with cylindrical femoral canal. However, Zweymüller<sup>27</sup> and Suckel et al<sup>4</sup> reported success using the *Zweymüller* stem regardless of patient specific conditions including anatomy, age, bone quality, comorbidity or mobility. After a short term follow-up, Huo et al<sup>26</sup> also showed that the *Zweymüller* stem yielded 95% stability and no thigh pain even in a patient demographic consisting of largely bone type B or C (70% and 24% respectively).

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The **Zweymüller** stem only requires contact with the cortical wall at the corners of the stem's rectangular cross section. The stem does not have to fit the shape of the intramedullary canal therefore it is suited to a wide variety of bone shapes<sup>9</sup>. Wick et al <sup>10</sup> and Swanson <sup>37</sup> reported using the **Zweymüller** stem in patients with type C bone without complications particular to the bone shape.

Cementless stems are commonly chosen for younger more active patients<sup>14</sup>. Revision surgery can often be accomplished without complications associated with a cemented implant like excessive bone loss or need to perform a fenestration of the femur to remove the distal cement plug. Widmer et al <sup>42</sup> found that with use of the *Zweymüller* stem, sportsmen achieve better outcomes than non-active patients, including significantly reduced prevalence of osteolysis. The *Zweymüller* stem demonstrates its applicability across a range of ages where it has been reportedly used in patients as young as 15 years<sup>35</sup> and as old as 99 years <sup>4</sup>.

Turchetto <sup>24</sup> has reported her experience with the *Zweymüller* stem used under special conditions including malunion, coxa vara, osteoporosis and dysplasia. After osteotomy if required, each of the 16 cases of malunion observed by Turchetto were corrected using the *Zweymüller* stem. Coxa vara correction is made easier by the lateralized offset version of the stem, which allows the surgeon to reconstruct the offset while avoiding impingement between the greater trochanter and ilium. Turchetto states that osteoporosis is not a contraindication for the *Zweymüller* stem, which is confirmed by Swanson who has allowed immediate weight bearing in patients with osteoporotic bone<sup>9</sup>. Turchetto suggests that the Zweymuller stem is appropriate for patients with dysplasia after an adjunctive osteotomy is performed to position the stem correctly. Perka et al <sup>31</sup> performed a prospective study of 139 dysplastic hips over 9 years. They found an improvement of Harris Hip Score from 34.0 to 84.1 postoperatively, and a Kaplan-Meier survivorship of 100% with revision for aseptic loosening as the endpoint.

Based on an FEA model, Hu et al <sup>43</sup> have found a high stress concentration along the edge of the stem where it contacts the cortical wall which may result in a higher rate of periprosthetic fracture. Delaunay et al<sup>8,16</sup> have reported a high incidence of femoral fracture during **Zweymüller** stem implantation; however, this is uncommon across surgeons and the author suggests it may be due to the surgeon's learning curve. Other surgeons have reported no problem with regard to femoral fracture<sup>19</sup>.

To evaluate the likely failure modes of the *Zweymüller* stem, the FDA's MAUDE database was reviewed to collate the adverse events occurring between 1992 and 2011. The findings are compared to the *Zweymüller's* competitors.

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Incident Tupo	Stem Type				
incluent Type	Zweymuller	Taperloc	Corail	Synergy	Secur-Fit
Breakage - Stem	4.2%	6.5%	14.8%	0%	3.7%
Breakage - Neck	0%	0%	33.2%	3.6%	1.2%
Breakage - Device, non-spec.	4.2%	3.2%	1.1%	14.3%	0%
Bone Fracture	4.2%	9.7%	13.4%	17.9%	18.3%
Dislocation	2.1%	0%	2.2%	14.3%	0%
Loosening	54.2%	9.7%	10.1%	10.7%	13.4%
Disassociation	0%	0%	0.7%	0%	1.2%
Pain	10.4%	25.8%	1.4%	0%	18.3%
Revision, non spec.	2.1%	0%	4.0%	3.6%	0%
Other	12.5%	32.3%	10.8%	7.1%	36.6%
Instrument - Broach	0%	6.5%	2.5%	10.7%	4.9%
Instrument - Other	6.3%	6.5%	1.8%	17.9%	2.4%

# Table 1: Zweymüller stem and competitor's adverse event profiles from MAUDE

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The findings tabulated from the MAUDE database are given as a percentage of the total number of incidents reported, not as a percentage of the total number of stems implanted. Therefore, the data can be used to determine to which failure modes each stem is susceptible, but not conclusions regarding the frequency of failures. The competitors were chosen to represent the varied design philosophies within the cementless stem market. The *Corail* and *Taperloc* are similar to the *Zweymüller* by design, however they are coated in HA and Titanium beads respectively. The *Synergy* and *Secur-Fit* stems were selected to represent the "fit with fill" design philosophy.

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Example of a fractured Zweymüller

The most common adverse event for the *Zweymüller* stem is revision due to loosening, which accounts for over half of the adverse events reported to the FDA between 1992 and 2011. However, the *Zweymüller* stem has clinical performance history of superior Kaplan-Meier survivorship out past 10 years<sup>5,12,23,44</sup>. Hence femoral loosening as a percentage incident per total implants is relatively low and aseptic loosening remains a known adverse event for every femoral stem design. The prediction by Hu et al<sup>43</sup> that the *Zweymüller* stem would be prone to failure by periprosthetic fracture is not supported by the surgical experience in the US and adverse event records to date (See Table 1).

Patients who receive a **Zweymüller** hip stem are highly satisfied with the outcome of the surgery. The number of patients who report on-going postoperative pain is very low<sup>15,17,19</sup> and the occurrence of disabling thigh pain is rare<sup>17</sup>. A high degree of function is returned to the patient as demonstrated by post-operative Harris Hip Scores ranging from 84 to 90 in the function domain<sup>4,5,19,20,23,31,44</sup>.

While the collection of clinical data in various regional and national joint registries has been valuable in establishing survivorship benchmarks for orthopaedic implants and detecting early poor performing designs, one should be cautious in drawing strong conclusions from the data in isolation of details available from published controlled clinical studies as many confounding factors may not be considered. We reviewed the English, Australian and Norwegian joint registries for relevance to the Pegasus style femoral implant. Survivorship data published in 2010 in the English National Joint Registry 7th annual report45 covering implant survivorship from 2003 to 2009 from the UK describes the overall survivorship for a hip replacement as 97.1% at 5 years, but decreases to 96.6% at 5 years if only cementless hip replacements are considered.

The SL-PLUS generation of the Zweymüller stem was the 4th most commonly used cementless stem. The survivorship for the SL-PLUS stem is slightly below the average for cementless stems at 95.6% after 5 years. Australian data was collected from the 2010 AOA joint registry report46 covering implant survivorship from September 1999 to December 2009. The average survivorship for a hip replacement was 96.5% at 5 years, 95.6% at 7 years and 94.6% at 9 years. In 2009 the Alloclassic and SL-PLUS were the 5th and 6th most commonly used cementless stems in Australia. The Australian registry reports survivorship by stem and cup pairing. Using the Australian data as a guide, one could expect a survivorship between 93.8 - 98.3% at 5 years depending on which design of cup paired in the THA. Hallan et al [3] presented the data for all cementless stems used in Norway between 1987 and 2005. Survivorship of 95.2% at 7 years, 94.0% at 10 years and 91.7% at 15 years were reported for the Zweymüller stem.

The Alloclassic stem is the second generation of the Zweymüller series of stems and has the most clinical follow-up data. The survivorship of the Alloclassic has been described as amongst the very best when compared to published results in recent literature44 and is as good or better than modern cemented techniques<sup>5,21</sup>. Kaplan-Meier survivorship of 100% have been reported at 9.3 years<sup>31</sup>, 11.2 years<sup>11</sup>, 13.1 years44, and 15 years23 with aseptic loosening of the stem as the endpoint. Survivorship at intermediate follow up (5-10 years) is also very high, ranging from 91.5% to 100%13.14.16.25.27 where survivorship's at the low end of the range have revision for any reason as the endpoint19,34. Using revision for any reason as the endpoint underestimates the femoral survivorship because revisions are more often for the cup or liner as opposed to the stem<sup>5,23,31,44</sup>.

Reigstad et al <sup>5</sup>, provide long term follow-up clinical data from a 75 patient study (average age of 52). With an active patient demographic (age < 60 y.o.) the *Alloclassic* stem has a demonstrated KM survivorship of 95% at 18 years for femoral revision for any reason. Reigstad et al, conclude that the *Zweymüller* performs comparably to the best cemented stems. Below is a listing of the survivorship data compiled from recent published literature for the *Alloclassic* stem

The latest version of the *Zweymüller* series of stems is the *SL-PLUS*, which was first introduced in 1992 hence this stem has far less clinical data available than its predecessors. Korovessis et al<sup>47</sup> reported 91.6% survivorship at 6.4 years with revision for any reason as the survivorship endpoint. The author

Author	Year	Kaplan-Meier Survivorship	Follow-up (years)	Survivorship Endpoint	
Delaunay et al [8]	1998	99.3%	8	Revision due to stem aseptic loosening	
Delaunay et al [17]	2001	100%	10	Revision due to stem aseptic loosening	
	2001	91.5%	9-10	Revision for any reason	
Delaunay& Kapandji [34]		99.3%	9-10	Revision due to stem aseptic loosening	
Grubl et al [20]	2006	98%	15	Revision of stem for any reason	
Garci-Cimbrelo [15]	2003	94.1%	12	Revision for any reason	
Perka et al [31]	2004	100%	9.3	Radiographic loosening of the stem	
Karachalios et al [22]	2004	100%	10	Revision for any reason	
Pospischill et al [23]	2005	100%	15	Revision due to stem aseptic loosening	
Vervest et al [11]	2005	100%	11.2	Revision due to stem aseptic loosening	
Pieringer et al [44]	2006	95.6%	13.1	Revision for any reason	
		100%	13.1	Revision due to stem aseptic loosening	
Reigstad et al [5]	2008	95%	18	Revision of stem for any reason	
Suckel et al [4]	2009	98%	17	Revision for any reason	
Floren et al [25]	2006	100%	10	10 Revision due to stem aseptic loosening	
Girard et al [35]	2010	100%	9 Revision due to stem aseptic loosening		

proposed that the inflated revision rate of the stem was due to a systemic immune reaction to the wear debris generated by the metal on metal articulation, which has been confirmed by other findings48. In contrast, Steens et al21, found that no SL-PLUS stems required revision after 6 years when the majority of the patients received a conventional ceramic on polyethylene articulation. Few longer term studies of the SL-PLUS stem have been completed. Zwartele et al [33] found that after 10 years only one stem required revision, resulting in a survivorship of 99.8%.

Table 2: Alloclassic Hip Stem KM-Survivorship

Korovessis et al<sup>12</sup>, provides retrospective data at 11 years from 172 hip replacements using the *SL-PLUS* stem and conventional ceramic on polyethylene articulation. The *SL-PLUS* showed durability and was reported to be effective in reducing the incidence of cortical hypertrophy in Greun zones 3 and 5 when compared to the *Alloclassic* stem. The reported KM survivorship was 98% at 11 years with an endpoint of revision for aseptic loosening. The following table lists further survivorship data for the *SL-PLUS* stem.

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Author	Year	Kaplan- Meier Survivor ship	Follow- up (years)	Survivorship Endpoint
Korovessis et al [47]	2007	91.6%	6.4	Revision for any reason
		92.5%	6.4	Revision due to stem aseptic loosening
Korovessis e al [12]	<sup>t</sup> 2009	98%	11	Revision due to stem aseptic loosening
Zwartele et a [33]	2008	99.8%	10	Revision of stem for any reason
Steens et a [21]	2010	100%	6	Revision of stem for any reason

Table 3: SL-PLUS stem survivorship

In a thorough review of 27 clinical papers and data from the Danish, English, Norwegian, Swedish and Australian joint registries, Janda et al48, collated and compared the survivorship for the various generations of the Zweymüller stem. They found that for the range of Zweymüller stems the average survivorship was 96% at 10 years, and that the Alloclassic had the highest survivorship (96.6% survivorship at 10 years). The author proposed that the revision rate for the SL-PLUS is inflated in recent literature because it is commonly used with the Sikomet low carbide metal on metal articulation which provoked wear reactions, so much so that manufacturer modifications were required. If only studies involving the SL-PLUS without metal on metal articulation are considered the difference

between the *Alloclassic* and *SL-PLUS* in terms of survivorship are not statistically significant.

The SL-PLUS differs from the Alloclassic only in minor aspects of its geometry [10]. Changes from the Alloclassic to the SL-PLUS include increasing the proximal surface and cross sectional area [3], and rounding the corners in an attempt to address the bone remodeling commonly associated with the use of the Zweymüller stem [12]. However, in a study comparing the radiographic outcomes of the Alloclassic and SL-PLUS stem, Wick et al10, found that the SL-PLUS stem has greater bone atrophy and radiolucencies in Gruen zones 2 and 6. The author proposes that increasing the cross sectional area of the stem increased its stiffness and resulted in greater stress shielding. The author noted that the increased bone atrophy could increase the likelihood of aseptic loosening and hence, discontinued use of the SL-PLUS stem in favor of the proven Alloclassic. Conversely, Zweymüller et al27, found that the occurrence of radiolucent lines with use of the SL-PLUS stem was almost identical to that of the Alloclassic.



Typical example of post-operative x-ray appearance

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I was very enthusiastic about the device (Alloclassic). It was the first non cemented hip without any significant thigh pain. It may have had some settling (minimal), was easy to insert, worked well without loosening, etc..

The problem I have with the SL-Plus is the configuration of its proximal portion which can caused some of the implants to get "hung up" in the intertrochanteric area and on the calcar preventing seating/settling/solid fixation in the diaphyseal region. That to me has been the cause of early failure, loosening, etc.. Having recognized this, I tend to leave the prosthesis a little "proud," get solid seating down in the shaft and leave room for some settling should our impaction not have been totally complete. I would assume most the surgeons using the SL-Plus or its SNR equivalent have learned that lesson and if their data were to analyzed, say from 2008 to 2011, it would probably show a lesser failure rate than in earlier years. You definitely must include the use of the Z-hip for total hip revisions. That was one of the things that also impressed me during my visits to Vienna. Zwymueller showed me some really amazing reconstructions with his stem and as a result I still use it in some of my revisions. In the late 90"s I was also presenting my first thirty consecutive revisions with the Zwymueller stem at Yale

Meetings, the Society for Arthritic Joint Surgery and the 30th Annual Mtg. of the Eastern Orthopaedic Society in 1999 (Vienna, Austria).

It was my experience with the Zwymueller that lead to the development of the Apex K2 proximal modular stem.



Eliminating the lateral profile reduced the amount of bone and damage to the abductor soft tissue and the addition of the proximal "Dual Press" modular shoulder facilitated insertion for the anterior approach and allowed fine tuning of joint mechanics. In fact, the basic stability of the Zweymuller (Trapezoidal shape) has been carried over into the short curved ARC<sup>™</sup> stem (curved trapezoidal shape with a proximal conical flair)that provides the same three point lateral fixation in a more tissue conservative stem style.



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