

The history of the development of the regular straight stem in hip arthroplasty

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- Since the middle of the 20th century, total hip arthroplasty has become a very successful treatment for all end-stage diseases of the hip joint. Charnley solved with his low frictional torque arthroplasty the problem of wear and friction with the introduction of a new bearing couple and the reduction of the head size, which set the prerequisite for the further development of stem design.
- This narrative review presents the major developments of regular straight stems in hip arthroplasty. It does not only provide an overview of the history but also assembles the generally scarce documentation available regarding the rationale of developments and illustrates often-unsuspected links.
- Charnley's success is based on successfully solving the issue of fixation of the prosthetic components to the bone, using bone cement made of polymethyl-methacrylate. In the field of cemented anchorage of the stem, two principles showing good long-term revision rates emerged over the years: the force-closed and the shape-closed principles.
- The non-cemented anchorage bases on prosthesis models ensure enough primary stability for osteointegration of the implant to occur. For bone to grow onto the surface, not only sufficient primary stability is required but also a suitable surface structure together with a biocompatible prosthetic material is also necessary.

Keywords

- ▶ development
- ▶ hip arthroplasty
- ▶ femoral stem

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Introduction

Total hip arthroplasty (THA) is a very successful operation, alleviating the symptoms of many different end-stage conditions of the hip joint (1, 2). THA is recognized as one of the most successful operations of the 20th century (3). This narrative review presents the major design modification of the straight stem. An overview in the form of a genealogical tree is provided in Fig. 1. The essential milestones are discussed more in detail. The review focuses on major developments of well-established designs, nearly all still being available nowadays. A citation from Santana, a Spanish philosopher, aptly captures the development of the hip prosthesis: ‘Those who cannot remember the past are condemned to repeat it’ (4).

Sir John Charnley is acknowledged as being the first one to have performed hip arthroplasty with reliability and success (5, 6, 7). His success started in 1959 using

bone cement made of polymethyl-methacrylate (PMMA) for anchoring of Austin Moore femoral head prosthesis, inspired by techniques used in dentistry (8). In 1960, he added a cup to replace the acetabulum (5). He used stainless steel as a material for the stem, and, to reduce wear and torque, he chose a head diameter of 22.25 mm (5). Starting from there, THA had widespread success (6, 7).

Evolution of cemented stems

Charnley used a lateral incision with a trochanteric osteotomy (5, 9, 10). Buchholz, a surgeon from Germany and pioneer of the addition of antibiotics into bone cement (11), modified the Charnley prosthesis. He used a cobalt-chromium (CoCr) alloy as material, a 32 mm head and the stem was significantly longer compared to the Charnley prosthesis, with the intention

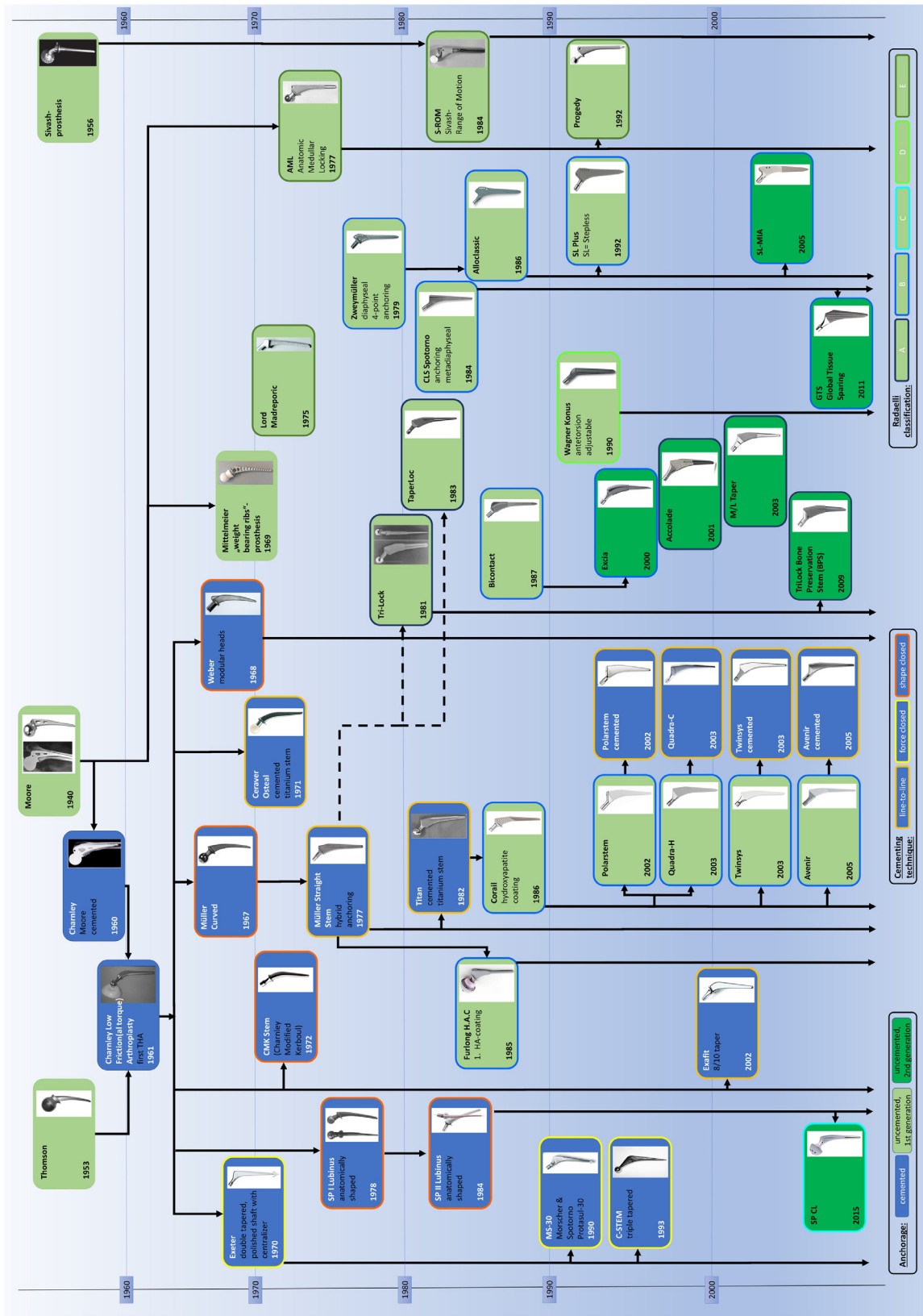


Figure 1

Overview of the development over time of the straight stem in hip arthroplasty. Grouping is performed following design derivations. Uncemented fixation is marked in green, whereas cemented fixation is marked in blue. The cemented stems were marked according to the cementing technique: line-to-line, force closed, and shape closed. The uncemented stems were classified according to Radaelli's classification: (A) flat tapers; (B) rectangular and quadrangular tapers; (C) (anatomic) fit-and-fill; (D) conical; (E) cylindrical (135).

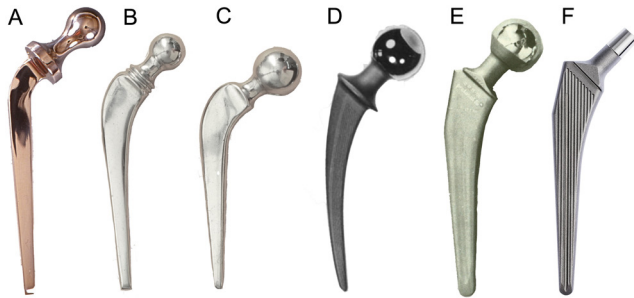


Figure 2
Evolution of the Müller stem. In (A), the first model called ‘Setzholz’ (engl.: dibble) implanted in 1962; in (B) and (C), the ‘Setzholz’ prostheses from 1964 and 1965; in (D), the curved Müller stem from 1967; and in (E) and (F), the straight stems available from 1977 onwards. The modular head was introduced for curved and straight stems in 1975 (stems were provided by the medical collection of the Inselspital Bern, Bern, Switzerland).

of optimizing load transmission (12). The Swiss surgeon Müller recognized the potential of Charnley’s prosthesis and further developed the stem. Müller started with a straight stem (1962), then turned to curved stems (1967) in order to be able to implant the stem through an anterolateral approach, without requiring an osteotomy of the greater trochanter (13, 14). From 1964 on, he again experimented with straight stems, which ultimately led to the introduction of the Müller Straight Stem in 1977 still in use nowadays (Fig. 2) (15).

The next major innovation came in 1968 by Weber, another Swiss surgeon, who designed a stem with a cylindrical connection for modular heads (Fig. 3) (16, 17). Adaptation of heads with different neck lengths provided more options for reconstruction of leg length and femoral offset as well as adjustment of the soft tissue tension, while reducing inventory (16, 18). Initially, the heads, designed to rotate around the neck, were made from Delrin, a polyacetal, which was replaced in 1971 by stainless steel due to wear issues and finally in 1974 by aluminium oxide ceramic heads (17, 19). Nevertheless, no long-term advantages could be shown regarding the rotating neck (20). However, as the head sizes of 32 mm were innovative at that time, dislocation rates associated with the Weber stem were low (20). Like the curved Müller stem, the Weber stem had a matt surface and a collar. Such a fixation corresponds to the later denominated concept of shape-closed or composite-beam cementation (16, 21, 22, 23). A similar prosthesis was developed independently and introduced in 1965 by Christiansen in Denmark, who used a stainless steel stem and a head made of polytetrafluoroethylene, later from high-density polyethylene, connected by a trunnion-bearing (24, 25, 26, 27). Since 1968, the head was reinforced with an additional metal cap (27). However, the results of this

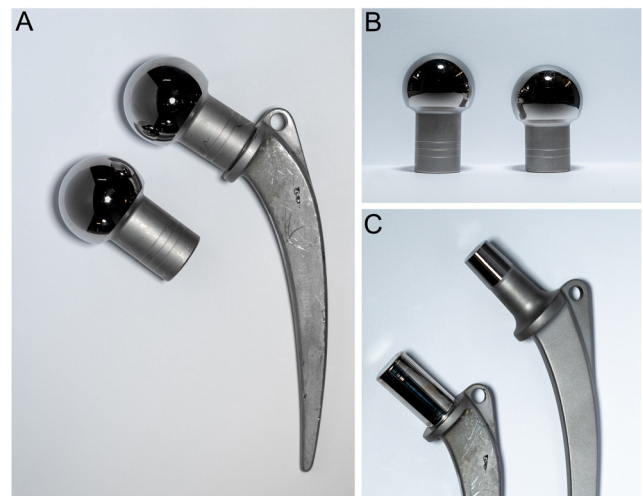


Figure 3
The Weber rotatory hip joint endoprosthesis (second generation with metal heads, Allopro, Baar, Switzerland). In (A), the stem can be equipped after the implantation with heads with different neck lengths. In (B), two of the three available neck lengths are illustrated. The variation is in steps of 5 mm. In (C), a comparison of the modular cylindrical connection of the original stem and the 12/14-taper from the current model, which is still available nowadays (implants from the private collection of the authors).

prosthesis were sobering compared to the Charnley prosthesis (26).

The next evolution in this family came with the Lubinus SP stem, marketed in 1978 and nowadays still one of the stems with very low revision rates. It was the first stem with an anatomic shape in the sagittal plane,

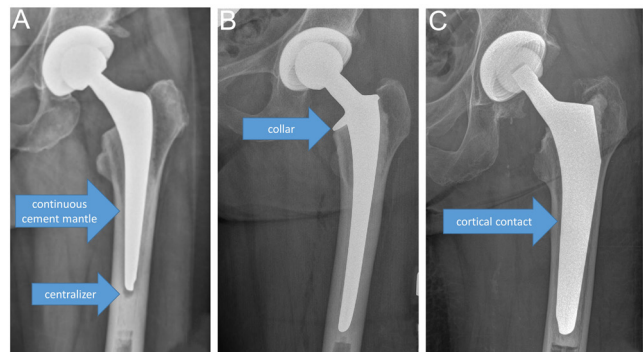


Figure 4
Zone of interest of anteroposterior radiographs of the pelvis, showing only the hip to illustrate different stem designs and fixation concepts of cemented stems. In (A), an MS-30 stem (Zimmer Biomet, Winterthur, Switzerland), a force-closed concept. In (B), a Lubinus SP II stem (Waldemar Link, Hamburg, Germany), a shape-closed concept and in (C), a Müller straight stem (Zimmer Biomet, Winterthur, Switzerland), a line-to-line cementation, a variation of the shape-closed concept often referred to as the French paradox cementation.

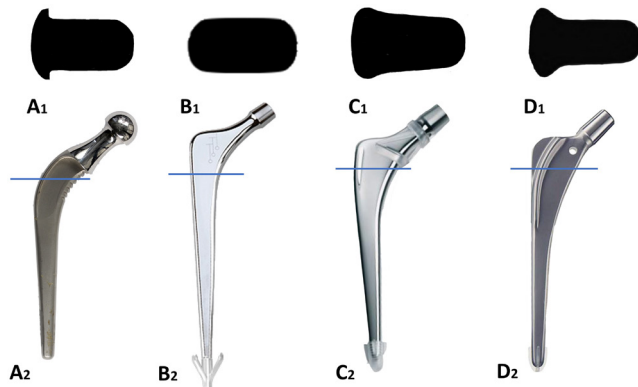


Figure 5

Comparison of the cross-section (blue line) of various cemented stem designs. The flanged Charnley stem (A) (Thackray, London, UK) was recognized as being less successful than the roundback original design. Based on identified failure modes from previous designs, the Exeter stem (B) (Stryker, Newbury, UK) was designed with a rectangular cross-section and rounded edges, in order to avoid stress risers. Flanges may however be found on other very successful stem designs with different origins and very low revision rates. The MS-30 stem (C) (Zimmer Biomet, Winterthur, Switzerland), a derivate of the Exeter-stem (B) and the Bicontact cemented (D) (B. Braun Esculap, Tuttlingen, Germany), a derivate from the uncemented Bicontact stem. This underscores that observations made regarding one specific feature may not necessarily be generalized.

adapted to the anatomy of the proximal femur (Fig. 4) (28, 29, 30, 31).

Ling, an orthopedic surgeon, and Lee, an engineer, both from the University of Exeter (England) made further developments of the Charnley stem to reduce the risk of loosening and failure. This incorporated a continuously tapered shape, a polished surface, and a centralizer (32, 33). This created the force-closed or taper-slip concept (Fig. 4) (21, 23, 34). The MS-30 stem, developed by Morscher, a Swiss surgeon, and Spotorno, an Italian surgeon, is based on the same anchoring principle (35). The MS-30 stem is a very successful design, despite having lateral flanges, a design feature recognized as less successful on the Charnley stem (Fig. 5) (30, 34, 36). These flanges decrease the tensile stresses of the PMMA in the proximal area (37). The Exeter stem was further developed by Wroblewski, the successor of Charnley, creating the C-Stem, characterized by an additional mediolateral taper (38). Theoretically, this third taper should provide better fixation and stability as well as greater compressive loading of the proximal medial femur, but this could not be confirmed in clinical applications (39). Certain registers show slightly higher long-term revision rates compared to Exeter stem (30)

The Charnley stem was further modified in France by Kerboull (40, 41). It was given a new, polished surface (40). Also, titanium alloy was used in France as a material

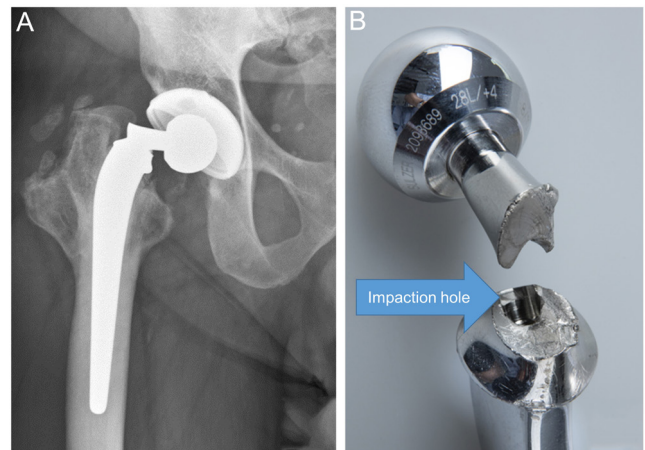


Figure 6

In (A), zone of interest of an anteroposterior radiograph of the pelvis, showing the right hip, illustrating a fractured Exafit stem (Zimmer Biomet, Winterthur, Switzerland). The stem was offered with an 8/10 taper, in order to increase range of motion with small head diameters. Due to the position of the impaction hole, stem fractures occurred more frequently until the design was adapted. Fracture surface features clearly indicate the impaction hole as the origin of the fatigue fracture, the small dimensions of the neck being a contributing factor.

for the first time in the development of the Ceraver Osteal stem, with a similar shape to the Charnley–Kerboull stem (42). In contrast to the previous stem types, a different cementation technique was used. Cancellous bone was removed extensively from the medullary cavity and the largest possible size was implanted (43). This resulted in an incomplete and thin cement mantle (44). Nevertheless, this proceeding also showed good long-term results (45, 46). This anchorage technique became known as the French paradox or as the line-to-line technique (47, 48). However, this corresponds in fact to a variant of the shape-closed concept (23, 49). A further French evolution of these stems, the Exafit, is worth mentioning, as it was offered with an 8/10 taper, in order to increase the range of motion with small head diameters (50). However, due to the narrow neck and the position of the impaction hole, stem fractures occurred more frequently until the design was altered in 2003 (Fig. 6) (51, 52).

Müller was also convinced by the line-to-line cementation concept and adopted it in the further development of his stem (13, 53). He designed in 1977 a straight stem, which had contact along the medial and lateral inner cortex of the femur, providing some self-locking longitudinal stability (15, 54). The straight stem is a further development of his original ‘Setzholz’ stem, which was created in 1962 (Fig. 2) (15), the cement then serving only to secure the primary press fit within the proximal femur (15, 53). A particular feature of the Müller straight stem is a thin anteroposterior diameter



Figure 7
The Müller straight stem changes its dimensions with increasing stem size only in its mediolateral dimension (A). The anteroposterior dimension (B) does not change with increasing stem size, having the same conicity throughout the length in this plane. The stem in blue is the smallest model, size 7.5, while the stem in orange is the largest model available, size 20 (stems were provided by the medical collection of the Inselspital Bern, Bern, Switzerland).

(‘Flacheisen’), ensuring torsional stability within the cement mantle (Fig. 7) (15, 54).

Derived uncemented fixation and hydroxyapatite coatings

In 1982, the newly founded Arthro-Group from Lyon in France developed the TITAN stem, inspired from the Müller straight stem (55, 56). It had a similar shape in the frontal plane but also had a tulip-shaped thickening of the proximal stem in the sagittal plane, added with the intention of providing additional stability in the

metaphysis (55). Only a thin cement mantle was intended, acting as a secondary stabilizer. Over the years, some TITAN stems were implanted without cement (55). Short-term results were promising, but later loosening occurred (56, 57). Nevertheless, the development of uncemented anchorage was pursued.

Inspired by Osborn, a maxillofacial surgeon from Hamburg, hydroxyapatite, a non-resorbable calcium phosphate, was applied as a coating (58). Histological studies showed bone ongrowth onto hydroxyapatite coatings within a few weeks, provided the implant had sufficient primary stability (59, 60). In 1985, the first hydroxyapatite-coated prosthesis was implanted in England by Furlong (60). It had a tapered shape in the proximal part while the distal part was cylindrical. In the meantime, the Arthro-group modified the surface of the TITAN stem for uncemented use. The surface was sandblasted and coated with hydroxyapatite by plasma spraying, creating the Corail stem (61). The stem was slightly tapered in the middle and distal segments to prevent self-locking at the inner surface of the cortical bone, contrary to the Müller straight stem. In order to increase the primary stability without increasing stiffness, the macrostructure of the metaphysis was adapted, adding grooves and horizontal metaphyseal steps (55, 61). The Corail stem was marketed in 1986 (55, 62). Several studies showed excellent long-term results (62,

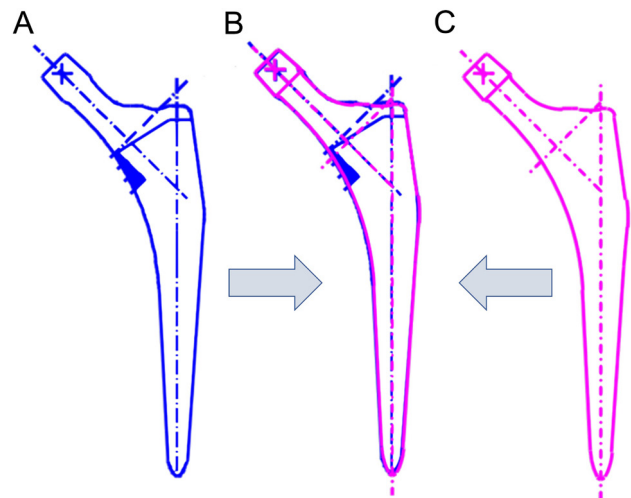


Figure 8
Comparing the shape of two uncemented, hydroxyapatite-coated stems, the Polarstem (A, blue) and the Quadra stem (C, magenta), show that both have the same shape (B). However, both stems differ with regard to surface finishing. Particularly, the Polarstem has rounded edges and a double coating of plasma-sprayed titanium with additional hydroxyapatite, whereas the Quadra is offered in sandblasted and hydroxyapatite-coated versions. The planning templates originate from the mediCAD program (version 6.5, Hectec, Altdorf, Germany).

63). However, compared to identically shaped models without hydroxyapatite, there is no advantage of hydroxyapatite coating regarding longtime revision rates (64, 65)). The hydroxyapatite layer may even delaminate, providing an additional mechanism for stem failure (66).

Over the following decades, the Corail stem was copied and modified several times. In 2002, the Polarstem was introduced on the market. Compared to the Corail stem, it has an increased offset and rounded edges (67, 68). Other derived models include the Quadra (69), the Twinsys (70), the Avenir (71), and the Metafix stems (72). These types of stems are used frequently nowadays, being used in over 48% of uncemented THA in Australia (36). However, these uncemented straight stems showed higher long-term revision rates compared to stems cemented following the force-closed principle (73). Despite similarities, the performance of the different stems differs. Particularly the Quadra stem is associated with higher revision rates, both in its sandblasted as well as in the hydroxyapatite-coated variants (74, 75). Interestingly, both the Polarstem and the Quadra have the same shape (Fig. 8) but differ in surface finishing. The Polarstem as well as the Avenir stem have a double coating, a layer of plasma-sprayed titanium being coated with hydroxyapatite (67, 71). Whether this results in an increased surface roughness compared to a pure hydroxyapatite coating and whether this is a reason for the different performance of the stems merit further investigation. The presence of a collar allows to transform vertical force to the calcar and increases primary stability toward vertical and horizontal forces (76) and reportedly improves the 30-year long-term outcome (77). In addition, register data from England and Germany show that the collar can reduce the risk of periprosthetic fracture in the first 90 days (78, 79). However, the collar may add technical difficulties whenever collared stems have to be removed.

Over the course of time, all these models were also provided as variants for cemented implantation. These were offered made from stainless steel with a polished surface but retaining the same shape, simplifying logistics using the same broaches. From a theoretical standpoint, however, this ends up mixing concepts, and consecutively, specific failures may be observed (80). Using identical broaches for uncemented and cemented variants may also influence the interdigitation of the cement with the surrounding bone, broaches for uncemented stems mostly being designed to impact cancellous bone, instead of removing it (81). The long-term results of these cemented versions of these models are not yet well investigated in the literature explaining the decreased Orthopaedic Data Evaluation Panel (ODEP) rating (82). In a study from 2019, a significantly increased rate of intraoperative femoral fractures was observed when using the cemented Corail stem (83).

Slightly higher revision rates compared to force-closed designs may be interfered from long-term revision rates available in the annual reports of well-established national arthroplasty registries, but no explicit analysis integrating particularly the quality of the polyethylene of the cup is available (36, 84).

Other evolutions of uncemented stems

As early as 1956, non-cemented implants were developed and used in the former USSR. In Western Europe, uncemented stem fixation was developed only once it was recognized that bone cement has a limited life span, whereas, in Eastern Europe, bone cement did not mark the initial developments of hip arthroplasty. The constrained prosthesis with a modular stem by Sivash, originally made of CoCr alloy, later of titanium alloy, was used more or less successfully (85, 86). For geopolitical reasons, this occurred independently from the above-mentioned developments in Western Europe. The Sivash stem, however, made it into the Western world, being marketed in 1984 as the S-ROM stem, following further developments (87, 88).

One reason for the failure of the Judet prosthesis, a model from the era prior to Charnley, was postulated to be due to pressure resorption of the bone on the contact surfaces (89). Mittelmeier, a surgeon from Germany, therefore tried to reduce the pressure on the surrounding bone by increasing the surface area and designed in 1969 the 'weight bearing ribs' prosthesis, which was used since 1974 (90). In clinical practice, the stem showed insufficient rotational stability, whereupon the shape was revised, and longitudinal ribs were added (90, 91) – a feature also present on the Corail stem and any derivate, still used successfully nowadays.

Lord, a French surgeon, chose another approach for uncemented anchorage. In animal studies, Lord found that a surface structure made of sintered small spheres 1 mm in diameter and 0.5 mm apart showed excellent osteointegration (92). Due to similarities with coral reefs, this surface treatment was named Madreporique (93). The fully coated cylindrical Lord stem was used clinically since 1973, confirming excellent osteointegration and satisfactory long-term results (91, 94, 95, 96, 97). However, due to the excellent osteointegration, stem exchanges were challenging and associated with massive bone loss (94, 95). The Anatomic Modular Locking (AML) stem was also made of CoCr alloy with a similar shape, just having smaller-sized spheres and pores on the surface, and was implanted from 1977 onwards (98). Despite a shape similar to Lords' stem, the AML stem is considered to be derived from the Moore prosthesis (98, 99). The pore size was later decreased to 250 µm for better bone ingrowth (98). Due to the pronounced ingrowth of bone

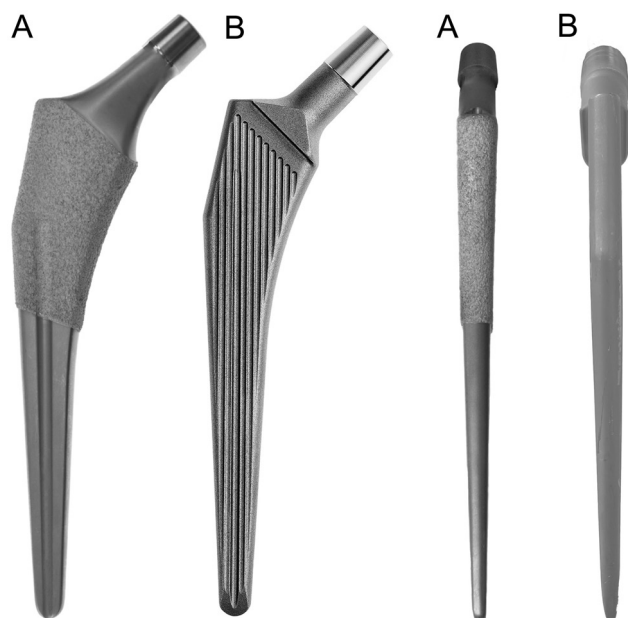


Figure 9

While the Trilock (A), an uncemented stem with a proximal porous surface, is recognized to have evolved from the cylindrical, fully-coated family of stems, it has a shape very similar to the Müller straight stem (B). Anteroposterior views are provided on the left and views from lateral on the right.

onto the surface of such implants with sintered beads, revision becomes excessively difficult after a few weeks and is associated with considerable bone loss. Proximal bone atrophy due to stress shielding, consecutive to distal, diaphyseal fixation, was also observed (100). This led to the development and marketing in 1983 of an AML stem with porous coating only on the proximal part (101, 102, 103). Both the Solution and the Prodigy stem were further developments from the AML. These stems also had an extensive coating and a blunt, polished tip (101, 102, 104).

The long-term results of the Lord and AML stems and the problems encountered at revision led to the creation of the TriLock stem, introduced in 1981 (105). The porous coating was limited to the proximal area, in order to ease revision and proximal femoral bone loss secondary to stress shielding (106). The shape of the TriLock appears to be very similar to the Müller straight stem (Fig. 9) (106, 107). From the point of view of the material, both CoCr and titanium alloys showed similar results (108, 109). The Taperlock was wider in the sagittal plane and filled more of the proximal femoral canal (110). Various other stems with similar shapes and fixation principles, including the Accolade and the M/L-Taper, were marketed over the course of time. In 2011, the TriLock was modified to Trilock Bone Preservation stem with a shorter length to facilitate implantation with minimal invasive approaches (111, 112).

While American designs rather focused on fully coated, cylindrical shapes, later developing into proximally coated stems taking over shapes similar to the Müller straight stem, European developments in uncemented fixation focused on rectangular cross-sections with diaphyseal fixation.

Spotorno developed a collarless, tapered, straight, grit-blasted stem made of titanium alloy, marketed in 1984 as the CLS Spotorno (113). It has a three-dimensional taper and a trapezoidal cross-section, as well as proximal longitudinal ribs to enhance the primary torsional stability, respectively, to provide a large surface area for osseous integration. Rounded edges should prevent stress concentration (106, 113, 114). The length was chosen in such a way that the stem centered itself within the diaphysis ((114), making the stem rather long and requiring sufficient exposure for introduction within the axis of the diaphysis. A modification of the CLS Spotorno was introduced in 2011, the Global Tissue Sparing (GTS) stem, designed for metaphyseal bone preservation and tissue-sparing implantation (115, 116). The GTS, however, performed poorly, with revision rates identified as outlier, showing again the relevance of modifications of successful designs (117).

Zweymüller, an orthopedic surgeon from Vienna, also was looking for a possibility of uncemented femoral anchorage. First attempts were made in 1977 with a Rizzoli stem (118). This stem had an elliptic proximal and round distal cross-section and was made of ceramic-coated titanium alloy. However, the proximal femur had to be reamed widely for implantation, leading to the weakening of the cortical bone (118). A new stem model was developed together with Semlitsch and Frey from the Sulzer company in Winterthur. Following tests on cadavers, a slightly conical shape was chosen to ensure primary longitudinal stability through press-fit, sharp edges of the rectangular cross-section cutting into the inner cortical bone to ensure torsional stability (119). The stem was further developed in 1986 into the SL (stepless) model. Zweymüller used also a sandblasted surface with a roughness of 3–5 μm , similar to the surface of the CLS Spotorno provided by the same manufacturer (120). In 1993, with further modifications of the proximal end, the SL Plus stem was marketed by Plus Orthopedics (121). Despite only minimal changes in the shape, there were statistically significant radiological changes in bone remodeling, unfavorable to the newer design (122). While an essential feature of the Zweymüller stem is sharp edges cutting into the inner cortical bone, the SL Plus stem has chamfered edges, despite having been developed by the original design team (Fig. 10). This could be an explanation for the inferior long-term outcome and shows that small differences in the design may be relevant. The Zweymüller stems have

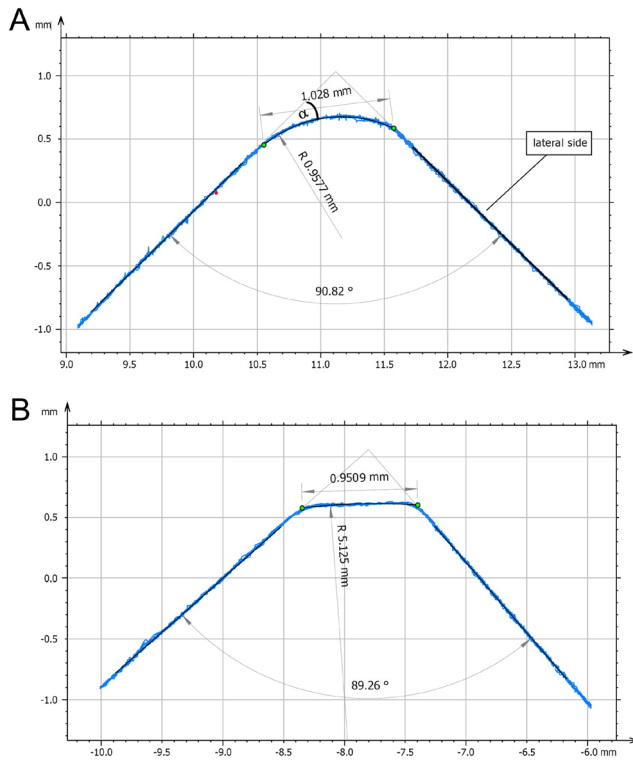


Figure 10

Profiles of the lateral edge of two different designs of the Zweymüller stem, in (A) the original Alloclassic from Allopro, nowadays Zimmer Biomet, and in (B) of the SL Plus from Plus Orthopedics, nowadays Smith&Nephew. Note the flattened edge of the SL Plus stem, despite having been designed by the same team, with a philosophy relying on sharp edges cutting into the inner cortical bone to ensure stability. The profiles were extracted from topographies, which were measured using confocal fusion, combining confocal microscopy and focus variation (S neox, Sensofar metrology, Barcelona, Spain). Contour analysis was performed with the MountainsMap software (version 8, Digital Surf, Besançon, France). Lines were fitted on the flat surfaces of the profiles and the angle between these linear fits was determined as a control. In addition, the radius of a circular arc and the length of the chord are defined by the endpoints of the circular arc. Based on these measures, the average angle between the circular arc and the prolonged linear fit was calculated (see angle α in Figure A). This angle was 12° for Allopro indicating a smooth transition from the circular to the flat part. In contrast, the average angle was 40° in the case of the SL-Plus stem. Together with the large radius, this demonstrates that in this case there was rather a chamfer on the edge than a rounded edge.

been copied several times (123). The SL Plus stem was even provided in a cemented variant, as were the stems from the Corail family, despite the strong belief of the designer that sufficient diaphyseal anchorage would always be available for uncemented fixation. The latest development of the Zweymüller stem was the SL-MIA. The shoulder was removed to allow implantation via minimally invasive approaches. As medium-term stability

issues were observed, a hydroxyapatite coating was later added (124, 125).

Another stem with similar features, the Bicontact, was launched in 1987. This one had a rectangular cross-section and the proximal part of the stem has a porous plasma-sprayed titanium coating. In addition, the stem cross-section was supplemented anteroposteriorly by two flanges, intended to provide additional stability (Fig. 5) (126, 127). Like the Weber stem, the Bicontact has a hole for removal with a bone hook, as well as a wing at the shoulder to increase bending stability. As for many other designs, the Bicontact was modified for minimally invasive approaches, providing the Excia stem, marketed in 2000 (128).

Due to the design of most non-cemented femoral stems, only limited adjustment of the antetorsion given by the native femur is possible. This may be particularly problematic in dysplastic hips. This led Wagner, a German surgeon, to introduce in 1987 a new concept of tapered, fluted, conical stems (129, 130). The aim of the design of the tapered stem was an anchorage at the proximal diaphysis, offering total freedom to adjust torsion, with high primary stability, especially in torsion, due to longitudinal flutes (131, 132). This design is widely used in revision arthroplasty when the proximal femur does not provide sufficient bone stock for the anchorage of a new stem (133, 134).

Summary

The well-recognized success of THA began in the 1960s, Charnley solving the issue of fixation of the components to the bone using bone cement. Various modifications emerged from this and the recognition of two principles of cement fixation of the stem: Over the years, attempts have been made to assign the individual stem design to a fixation concept. Stems that function according to the principle of force-closure usually have a polished surface and a conical shape, and they also rely on a complete cement mantle. On the other hand, the fixation of a stem can be based on the principle of shape-closure, in which case a rough surface or a collar usually provide more stability. With both concepts, a long-term fixation of the stem can be achieved. Derived from the Müller straight cement stem emerged a family of uncemented stems. Many of these stem designs were also offered as cemented versions so that surgeons still have the option of choosing a cemented fixation intraoperatively. This, however, led to hybrid fixation concepts. Uncemented stems rely on osteointegration for long-term stability. Sufficient primary stability and a rough surface are mandatory for the osteointegration of the implant. The primary stability depends on the design of the stem and can be ensured in various ways: sharp edges or flutes,

proximal support, a collar, or flanges. Many modifications of successful designs, however, appeared to be associated with less good outcomes, underscoring the importance of design details often not recognized.

ICMJE conflict of interest statement

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