International Orthopaedics

The history of resection prosthesis

--Manuscript Draft--

Manuscript Number:	INOR-D-22-02161R3
Full Title:	The history of resection prosthesis
Article Type:	Orthopaedic Heritage
Funding Information:	
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Author Comments:	Editorial Proposal

December 30th, 2022

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Statements and Declarations

Funding

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

Competing Interests

Financial interests: Authors A.C., O.B., D.J. declare they have no financial interests. One author (P.R.) is a paid consultant for Stryker and Exactech, the same author receives royalties from Exactech; one author (D.L.) is a paid consultant for Stryker.

Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Alberto Crimì, G Douglas Letson, Odion Binitie, David Joyce and Pietro Ruggieri. The first draft of the manuscript was written by Alberto Crimì, and all authors commented on previous versions of the manuscript.

All authors read and approved the final manuscript.

Ethics approval

Not applicable

Consent to participate

Not applicable

Consent to publish

Not applicable

Acknowledgements

Not applicable

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Method

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After the first works of Gluck and Giordano, with ivory and metal and the pioneer shoulder prosthesis by Pean in the late 1890s, a great advancement was brought by reconstructions performed for injured soldiers of the Great War. By the 1940s replacement of all the main joints had been attempted, and documented.

Discussion

Walldius in the 1950s developed a fully constrained hinge knee, offering for the first time a consistent and replicable method of substituting the joint. In 1953 Shiers' prosthesis allowed for good flexion and extension. Stanmore and GUEPAR group prosthesis in the 1960s were the first to have a different right and left side model. The rotating hinge was developed in 1978 by Walker, with the innovative concept of 6 degrees of freedom. Between the 1979 and 1982 Kotz developed the modular segmental replacement that, added to a fixed hinge knee, permitted the revolutionary creation of the modern distal femur replacement.

Conclusion

The study of the materials and mechanical solutions that brought to the modern distal femur resection prosthesis are a good example of a virtuous multidisciplinary teamwork between orthopaedic surgeons, anatomists, and biomechanical engineers.

Keywords

Distal femur replacement, resection prosthesis, Limb salvage, Orthopaedics historical heritage

Introduction

In the ancient world there are numerous examples of limbs' external prosthetic replacements, the great toe prosthesis from a mummy, identified as Tabaketenmut (950–710 BC), the bronze prosthetic leg found in a roman grave in Capua (300 BC), and the prosthetic leg made of leather, goat horn and hoof of a horse excavated in Turfan, China (300 BC) [1]. But the first account of endoprosthetic replacement is in Mythology. The roman poet Ovid, in his Metamorphoses, tells the story of Tantalus who offered as a sacrifice his son, Pelops. Pelops was cut up, boiled, and served in a banquet for gods, to test their omniscience. Only Demeter ate the left shoulder of the kid, while immediately the other gods recognized the true nature of their meal and disgusted by it, decided to resuscitate the young Pelops. Tantalus was severely punished, and the resuscitated Pelops had an ivory shoulder replacement [2].

Historical articles are useful to understand the linkages between past and present [3-6], the purpose of this historical review is to highlight the progression and development of prosthetic reconstruction with a focus on the modular distal femur and hinged total knee arthroplasty.

Early resection prostheses

The first scientific accounts of prosthetic reconstruction of the extremities are of the late 1800s. A tibial resection prosthesis was documented in 1890, in the book by Delitala “Endoprotesi in sostituzione di parti interne del corpo umano” [7]: “The year was the 1936 and I was discussing with Davide Giordano my attempts to replace a resected tibia for tumour with an aluminium piece and Giordano said: “ What an invention.... in 1890 I took a metal stick with two ivory plugs at the extremities, I boiled it in a phenic solution and implanted it in the leg of a little lady”. The surgery is completely described in a Giordano's paper of 1890 [8]. The technique was enthusiastically described also by a surgeon from New York, Dennis, during the meeting of the Medical Society in Philadelphia of the same year, 1890 [9].

In the same period Gluck performed in Germany arthroplasty experiments with ivory [10], developing models for the replacement of shoulder, elbow, hand, and knee (Fig. 1a) joints [11].

Also in France the first endoprosthetic reconstructions were attempted, and the first known shoulder resection arthroplasty was ideated by Pean using biocompatible materials [12]: a platinum-iridium alloy and hard rubber, the first already used in dentistry, the latter used for drain tubes in general surgery. The arthroplasty was planned to substitute part of the humerus and part of the scapula (Fig. 1b). The patient had osseus tuberculosis destroying the proximal third of the humerus and glenoid. A wide resection of the humerus and glenoid was conducted, during the same surgery the arthroplasty was implanted with a big humeral component connected by metallic wires to the remaining scapula, permitting the suspension and movement of the upper limb. Few days after surgery the patient conditions improved.

Development of resection prostheses

König implanted an ivory endoprosthesis in a humerus [13], a rubber-metallic prosthetic replacement was produced by Contremoulin and implanted by Delbert and Giraud [14] in two patients with war wounds with a wide loss of radial diaphysis, with a good outcome documented. Almost at the same time, a distal humerus replacement was performed in a 20 years old male [15]. In the 1930s experiments were conducted on different metals to assess their bio-compatibility [16]. A particularly promising material (already used in dentistry) was the Vitallium, a Chromium-Cobalt-Molybdenum alloy. Some years later there was the first known use of a reconstruction prosthesis for proximal femur resection by Moore and Böhlman [17], performed for a giant cell tumour. The prosthesis was in Vitallium with a very particular "art-déco" taste (Fig. 1c). It was implanted in September 1940 and remained in place until the death of the patient from cardiac attack on June 1942.

Following the positive example other replacements in Vitallium were successfully implanted: Kellog [18] from Chicago was the first to use a prosthetic Vitallium replacement of the proximal radius. Looms implanted a Vitallium proximal femur in a male patient who had a gunshot wound and a blown-up upper femur, the outcome was very good [19].

Delitala reported seven cases of metallic replacement of the shafts of long bones following resection for malignant bone tumours [20]. In the late 40s an endoprosthetic reconstruction of the proximal femur with a polythene implant was performed in a 12 years old boy with a cartilaginous lesion [21].

In the 1950s there was a "prosthesis rush" with an increasing number of reports with scattered outcomes in different kind of bone resections and replacements: Venable used a Vitallium prosthesis to replace the distal humerus, after a resection in a violin player with regain of enough function to let the patient going back to music almost 2 years after surgery [22]. Boron used an acrylic proximal humerus in Great Britain [23]. MacAusland reported 4 cases of replacement of the lower humerus with an acrylic prosthesis [24]. Casuccio performed a distal humerus and proximal ulna resection with a metallic elbow prosthesis for a fibrous dysplasia [25]. Brav et al. published a report of 5 cases of shaft replacement or articular replacement with Vitallium prosthesis [26].

In the 1960s the possibility of metallic prosthetic replacement after tumour resection was a well-established procedure also if applied in relatively few patients with precise indications (mainly when patients refused amputation). Marcer used an elbow prosthesis with a wide humeral component after a metastasis resection in the distal humerus [27]. Simultaneously the normal arthroplasty technique, mainly the hip arthroplasty, had a sprint with the work of John Charnley [28] and the use of poly methyl methacrylate (PMMA) cement.

The etymology of the words used in scientific literature to describe the prosthetic replacements after tumour resections widely varies among authors. The term 'endoprosthesis' is the most used [7,14,20], generic term 'substitute' [21] is also used, 'internal prosthesis' or 'prosthesis' [19,21], and 'replacement' [24] are other synonyms. While 'megaprostheses' seems to be a more recent terminology, it has been first used in the 'International Workshop on Design and Application of Tumor Prosthesis', held in Mayo Clinic, in 1981 [29]. The use of the definition 'Modular prostheses' started from the 80s with the introduction of the Kotz modular system prosthesis [30-33].

The evolution of fixed and rotating hinge knee

The history of prosthetic reconstruction after tumour resection is deeply interconnected with the history of joint arthroplasty, and it is not possible to understand the advances of the first without following the glorious path of the latter. The key elements that characterize the good results of the modern limb salvage resection prosthesis are modularity and recreation of physiologic joint motion, obtained, in the knee, by rotating hinge and, in some prosthesis, condylar bearing. These factors give versatility/adaptability, reduced implant fractures/prosthetic loosening and reduced wear of the components of the implant.

The first attempts to substitute a knee joint are attributed to Gluck, as described earlier, in 1890 [10], he replaced a osseous tuberculotic knee joint in a 17 years-old girl with an ivory and metal prosthesis. The implant was successful in short term. Gluck did experiments on prosthesis fixation to the bone. He was also the first to use bone cement, somehow futuristically anticipating Charnley work [11].

Knee arthroplasty with fixed hinge

Although only after the Second World War there was a sprouting of attempts to substitute the knee joint with prosthetic replacement. Judet brothers work on acrylic hinged knee in 1947 [34] and Magnoni acrylic hinged knee in 1949 [35] are the first known examples. Walldius elaborated an arthroplasty of the knee (Fig. 2a) in stainless steel hinged by acrylic resin [36] A report 8 years after the first surgery showed good results [37].

Rovere [38] showed the results of a vitallium made Walldius prosthesis with anterior femoral and posterior tibial lip as stabilizer, preventing the prosthetic rotation. The femoral lip was also an articular surface for the patella. The stems worked as stabilizer, the complications highlighted were related to lack of axial rotation and patella related failures. The hinged prosthesis by Walldius was the most used until the early 1970s. Already in early prosthesis the main problems were addressed: stress on the structural components of the prosthesis (stabilizers to reduce rotational stress) and physiological joint motion (care to manage the patellar tracking).

Almost at the same time as Walldius, Shiers hinged knee [39] was developed, it was a prosthesis made of molybdenum and stainless steel, with a femoral female and tibial male surface designed to allow for limited extension, retaining lateral stability (Fig. 2b). The early design of the Shiers prosthesis was burdened by a high stem fractures rate. It was fully constrained, with metal-on-metal articulation. The original prosthesis proved to have a potential weakness at the points where the intramedullary stems were screwed into the hinge halves, after some modifications, prosthetic stem fatigue fractures were not as common [40].

Physiologic total knee arthroplasty

Only with the Stanmore [41] prosthesis, in 1968, the first physiologic prosthesis was introduced, with a separate right and left extremity model. Other physiologic characteristics of Stanmore prosthesis were the long stems and a large articular surface for the patella (Fig. 2c). It had some disadvantages, loosening and periprosthetic fractures. It was thought to be used for severe destructive arthropathy. On the work of the first 100 Stanmore prosthesis implanted there were good results [41]. During this early experience loosening of stem and risk of periprosthetic fractures were addressed with longer stems, to manage the patellar tracking and the risk of lateral patellar dislocations it was important to have for the first time a left and a right.

Almost contemporary to the Stanmore prosthesis, the GUEPAR group prosthesis was introduced in France [42]. Design was again a fully constrained, physiologic, prosthesis. It had some disadvantages: early axial loosening, patellar subluxation, femoral stem fracture. The GUEPAR group aim was to realize a knee prosthesis with the valuable characteristics of each type of the previous prosthesis (Fig. 3a). Tibial component had a frontal vertical blade, penetrating into the tibial epiphysis, locking the rotation. During extension a small silastic thruster absorbed the impact of the two parts one against each there. In the first report on 100 patients there were 14 failures.

Condylar bearing total knee arthroplasty

Another way to deal with the still high failure rate of the early knee arthroplasty was the development of the condylar bearing prosthesis, the first one was introduced by Blauth in 1972 (Fig. 3b), a constrained hinged knee. The novelty was related to the large contact area of the condylar surface, to increase the weight bearing area, reducing the stress on the hinge [43].

To reduce the rotational stress of the hinge system, Sheehan developed a multicentric semi-hinged prostheses. It combined the advantages of the hinged type of prosthesis with those of the unconstrained or hinge-less prosthesis, it had good stability associated with a multicentric axis of movement. For the first time rotational stress was addressed acting on the hinge itself [44].

Rotating hinge

The solution of the rotational stress-related failure of the hinge knee prosthesis was gained by the Melbourne prosthesis (Fig. 4a), it was the first true rotating hinge knee prosthesis, developed in 1974. It decreased the load at the bone-prosthesis interface, that was the major cause of loosening and stem breakage [45].

Four years later Walker introduced the Kinematic rotating hinge. It was a constrained hinge that allowed controlled axial rotations and distraction (Fig. 4b). The innovative concept was the 6 degrees of freedom of the axle of the hinge: controlled flexion, extension, varus, valgus, internal and external rotation of the axle was possible, greatly reducing the stress on the components of the prosthesis, these relevant concepts were based on his works on physiology of the knee. In the first report on the use of this prosthesis, it was achieved excellent short-term result on pain relief [46].

On the same path, Porter et al designed the Endo-Model rotating hinge [47], this prosthesis combined the rotating hinge and the condylar bearing for the first time (Fig. 4c), using an intercondylar rotating hinge.

By the early 80s it was clear that a fixed hinge prosthesis transmitted higher stress to the interface between the implant and bone or cement, causing loosening and early failure [48-50]. The rotational degree of freedom allowed the reduction of axial shock loads acting at the prosthetic stem [47,51].

The last way to deal with the rotational stress was developed by Lacey [52], it was a tibial knee component with a mobile bearing, the prosthesis used the combination of a rotating hinge and a mobile bearing, creating a mobile bearing hinge knee. This idea came from the observation that the lack of rotation in the axial plane led to aseptic loosening [53]. Loosening was the result of excessively high shear stresses at the bone-cement interface, because the planes of rotation are over constrained by the single hinge plane [52].

Modern resection prosthesis

Until the 1970s, prosthetic replacement of the knee and distal femur was mainly limited to patient with: tuberculosis or disruptive infection of the knee, rheumatoid arthritis and osteoarthritis. In tumour surgery it was used only in those 10% of patients that were not treated with an amputation, and in limb salvage case it was still favoured the use of allografts [54].

The 1970s were also the years of the development and affirmation of chemotherapy for treatment of osteosarcoma [55], permitted the use of limb sparing techniques with the amputation rate that went from 90% of OS to 10% in a decade, and limb salvage became the first choice for patient with primary bone sarcoma. Scientific literature started to show that with the introduction of chemotherapy amputation was no more necessary in great part of cases of osteosarcoma and limb salvage had similar disease-free survival rate [56].

At the start of the 1980s the first elements, that made possible the equation of distal femur limb salvage, were already in place: the mechanical solutions for a long-lasting hinged knee were addressed in different or combined ways with the rotating hinge and the condylar bearing. These two factors were essential to have a low rate of prosthetic failure and a more physiologic function of the prosthetic knee. The third element, probably the pivotal one, was the introduction of the modularity, that permitted to overcome the long process of creating a custom prosthesis for every patient and granted a faster in-surgery customization and technical adaptability.

Modular Prostheses

Kotz developed in 1979 and introduced in 1982 a fixed hinge knee with modular segmental replacements (Fig. 5a), he was the first to create and use modular elements connected by morse tapers directly during surgery [30]. The implant material was a Co-Cr-Mo alloy (Vitallium), the modular system could be implanted with or without cement. For the knee joint it was favoured a hinged knee, used to achieve stability in case of extensive tumour resection and ligaments not reliability. The hinge allowed an amuscular stance and a good ROM. The distal femoral part was designed with 6° of valgus between the tibial and femoral component. The patella bearing surface was anatomically shaped. The diaphyseal fixation was provided by two flanges added to an intramedullary stem. The two flanges had three holes each for a total of 6 screws fixing the stem to the cortex. The main issues of the first implants were the wear of the polyethylene bushings and stem breakage at the level of the first cross screw fixation [57].

Few years later, in 1984, Kotz started a collaboration with Campanacci, Capanna and Ruggieri [58], from Istituto Ortopedico Rizzoli - Italy, to improve the KMFTR (Kotz modular femur tibia reconstruction) system. After more than 400 prostheses implanted [59], the system was modified adding a porous coating of the prosthetic surface, introduced to give extra cortical bone bridging (Fig. 5b). The stem was also modified to be with one plate and three screws, minimizing the stress shielding. The results with the new system in 198 cases showed a survival of 98 patients (51.9%), with 37.5 % of prostheses requiring changes and 16.4 % bushing changes, compared to a 41% rate of the previous model [60].

The late 80s and 90s are the blooming years of the resection modular prosthesis, in 1988 the collaboration between the European surgeons (Kotz, Campanacci) and American surgeons (Malawer, Eckardt) [61,62] created the Howmedica Modular Reconstruction System (HMRS), a distal femur replacement system compatible with KMFTR. Initially it was designed with a new model of fixed hinge knee with inserts in new generation polyethylene placed centrally in the metallic hinge [63,64], the stem was anatomically designed, and it had only one lateral flange (Fig. 6a). In the American model a rotating hinge was used since the first model, as it was in the original MRS (Modular Resection System) created by Malawer (Fig. 6b). The MRS, used since 1982, was a custom distal femur prosthesis combined with the kinematic rotating hinge by Walker. In 1984 it was modified adding modular components, available only on a custom base.

In the parallel development of the European HMRS model, a fixed hinge was generally preferred, also if a rotating hinge was available, both of them were based on the original Kotz knee.

In works comparing KMFTR and HMRS prosthesis KMFTR showed higher breakage rate (10.5% vs a 3.5%) [59], higher aseptic loosening rate (9.6% vs 4.9%) [59], higher bushing change rate 41% vs 16.4% [64], there was a statistically higher survival in HMRS prostheses [59]. The ten-year results showed a survival of 51.9%, with non-prosthesis related complication rate of 41.8%. Only 1.6 % of patients required an amputation.

In Europe a fixed hinge was still the main choice, because thought to be more reliable in wide resections with great loss of soft tissues around the knee, but in early 2000s (2003) the joint efforts of Kotz, Mercuri, Malawer and Eckardt created a new prosthesis, the Global Modular Reconstruction System (GMRS), with the best elements of the HMRS and of the newly modified Walker’s rotating hinge, Modular Rotating Hinge (MRH) system. It was confirmed the use of a rotating hinge knee, based on the Walker model, while the flanges were definitively removed from the design. The rotating hinge reduced consistently the mechanical stress and complications at the bone implant interface

[59,65]. In a study conducted on 295 GMRS implanted between 2003 and 2010 [66] there were no cases of breakage of prosthetic components or peri-prosthetic fractures. Aseptic loosening remained a cause of failure of the prostheses also if lower than in a previous fixed hinge HMRS series knee series [65].

During the 80s, modular prosthesis for tumour resections started to be applied not only for the reconstruction of the distal femur and proximal tibia, but also for other sites [58,67,68]. The success of Kotz's modular prosthesis, originally conceived for femur and proximal tibia replacement, led to the development of modular prosthesis for humeral resections [31-33], and the first attempts of total femur resection and reconstruction [69].

From this growing and wide experience, different companies developed their own modular prosthesis for tumour resection surgery. The Stanmore Modular Individualised Lower Extremity System (SMILES), created in 1991, introduced a rotating hinge knee design [70,71] for Stanmore prosthesis. In the paper reviewing the first 168 patients treated there was a failure rate for aseptic loosening of 9.9% in the distal femur prosthesis [71]. Stanmore developed also an effective modular endoprosthetic tumour system (METS) [72], design featured the axial bearings on the outside of the prosthesis. The five years postoperatively prosthesis survival rate was 79%. Among the different solutions to manage the stress shielding and the stem aseptic loosening, one of the original once, was represented by the Compress Pre-Stress Implant (Biomet), this kind of implant utilized a spring tension generated with short traction bars to generate high compressive forces at bone-prosthesis interface, promoting in this way the hypertrophy of the bone at the interface with the prosthesis. The idea was to obtain good stabilization without the need of longer stems and decrease the risk of stress shielding. Another advantage was the improved osteointegration of the bone in the interface with the implant [73].

Finn Biomet prosthesis, developed by Finn [74], had a rotating hinge, it was a condylar bearing prosthesis. The characteristics were an improved distribution of weight bearing forces and improved physiologic patellofemoral tracking. The main issue was that with internal and external rotation there was wear of the metallic ramp.

The Modular Universal Tumour And Revision System (MUTARS) was characterized by a curved anatomical stem with a hexagonal cross section, made in two versions, a cementless type in titanium alloy (TiAl6V4) and a cemented one in CoCrMo alloy [75]. The hexagonal stem was supposed to reduce the aseptic loosening, reduce the stem breakage and give an improved rotational stability [76]. Aseptic loosening rate was 8% and the stem fracture rate was 1.6%; in another work [75] aseptic loosening was as high as 22%. The deep infection rate was 12% in both papers [75,76].

In all the modern designs of distal femur replacement there are modules that can be added with morse tapers, and to decrease contact stresses, most systems incorporate cobalt chrome on polyethylene bearings [77]. Other than a transverse hinge axis, that allows for flexion and extension, there is a vertically oriented post-in-channel axis, that allows internal and external rotation [78]. As it was described in some models there is a condylar bearing added to the rotating hinge. In most cases there is a polyethylene bumper that provide a stop to hyperextension [79].

The existing systems available for distal femur reconstruction with modularity (Fig. 7), directly derived from the models of the 90s, are Zimmer-Biomet OSS® (Orthopedic Salvage System) (Fig. 7a), ZSS® (Zimmer Segmental System) and Compress® (Fig. 7b), Stryker GMRS® (Global Modular Replacement System) (Fig. 7c), Implantcast MUTARS® (Modular Universal Tumour and Revision System) (Fig. 7d), Stanmore METS® (Modular Endoprosthetic Tumour System) (Fig. 7e), also used with some variation in the hinge in the custom version for paediatric distal femur limb salvage with expandable prosthesis.

In recent studies the distal femur replacements showed a survival at 5 years of the implant in a range between 77 and 93%, with a mean MSTS of 85% [66]. Comparable with the functional results of other resection prosthesis, the proximal tibia resection prosthesis had a mean MSTS of 77% [80]; the proximal femur reconstructions had a mean MSTS score of 65% [81]; the proximal humerus reconstruction had a mean MSTS score of 67% [82].

From the largest series of megaprosthesis and analysis of complications, the failure rate was 27.4% for distal femur prosthesis, 33.9% for proximal tibia, 15.9% for proximal femur, and 17% for proximal humerus replacement [83].

Cement and cementless implants had similar MSTS score, 79.7% and 78.6% [84], in a work cement and cementless stems had comparable overall survival [85]. In another work cementless implants showed a slightly better survival, 86.1% vs 81.6% of the cemented stem [86].

MSTS score was better in rotating hinged knee compared to fixed hinged knee (90.6% vs 57.1%) [84], the rotating hinged knee showed a better 10 years survival compared to the fixed hinge, 77.7% vs 61.7% [86]. Patients who undergo surgery for tumour megaprosthesis of the lower extremity can nowadays expect an efficient gait and active lifestyles [87].

Conclusion

The history of the development of the limb salvage of the distal femur is the history of a success. A reliable and efficient endoprosthetic system was developed combining the study of the materials and of the mechanical solutions for a physiologic knee replacement, in a virtuous multidisciplinary teamwork between orthopaedic surgeons, anatomists, and biomechanical engineers. The modern distal femur modular systems allow the patient to have an overall good function, with low complications rate and long-lasting reconstruction. A better understanding of the processes and thoughts that create the prostheses in use today can lead to further improvements of the function and durability with better outcomes and higher satisfaction of patients.

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Legends to Figures

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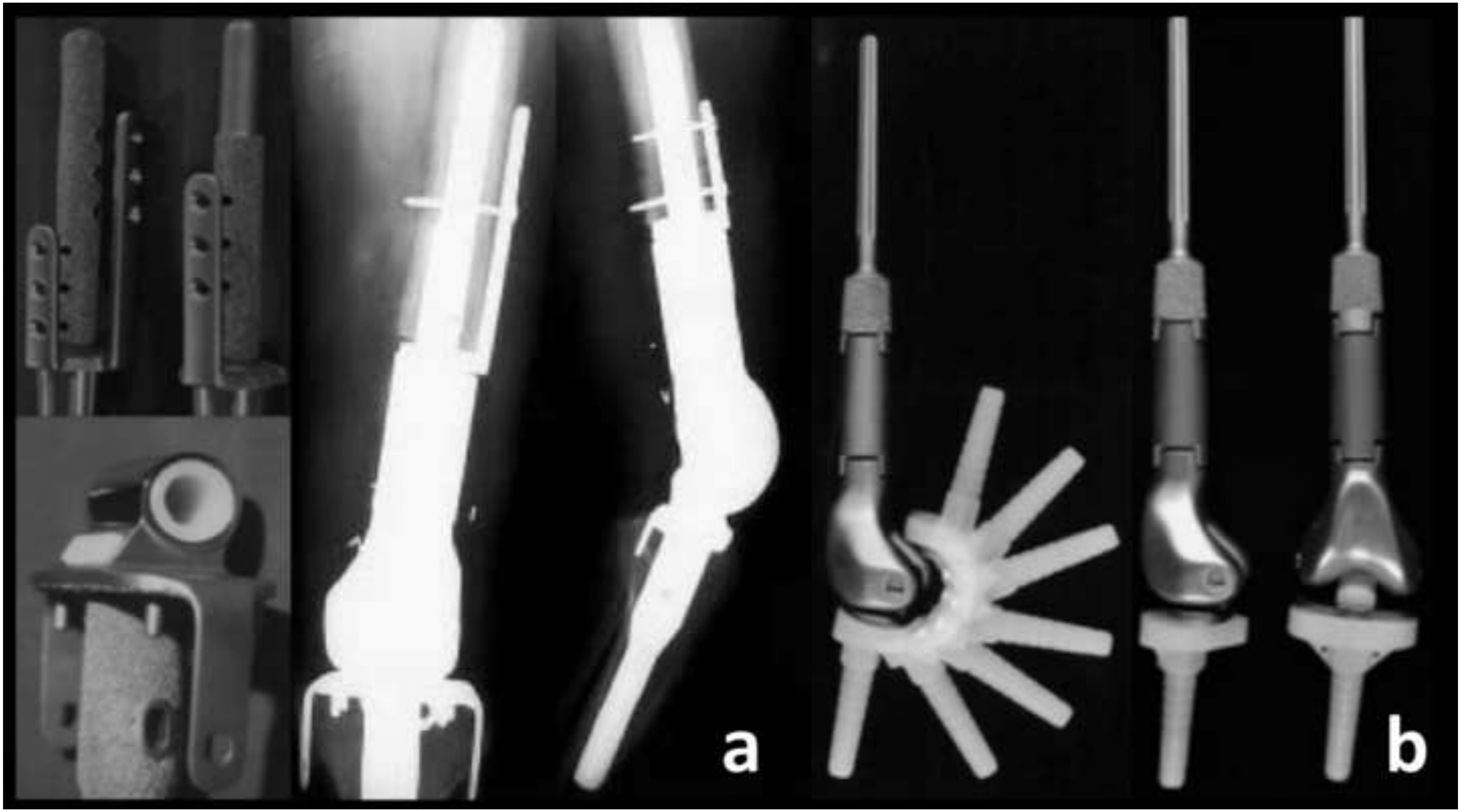
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Figure 7

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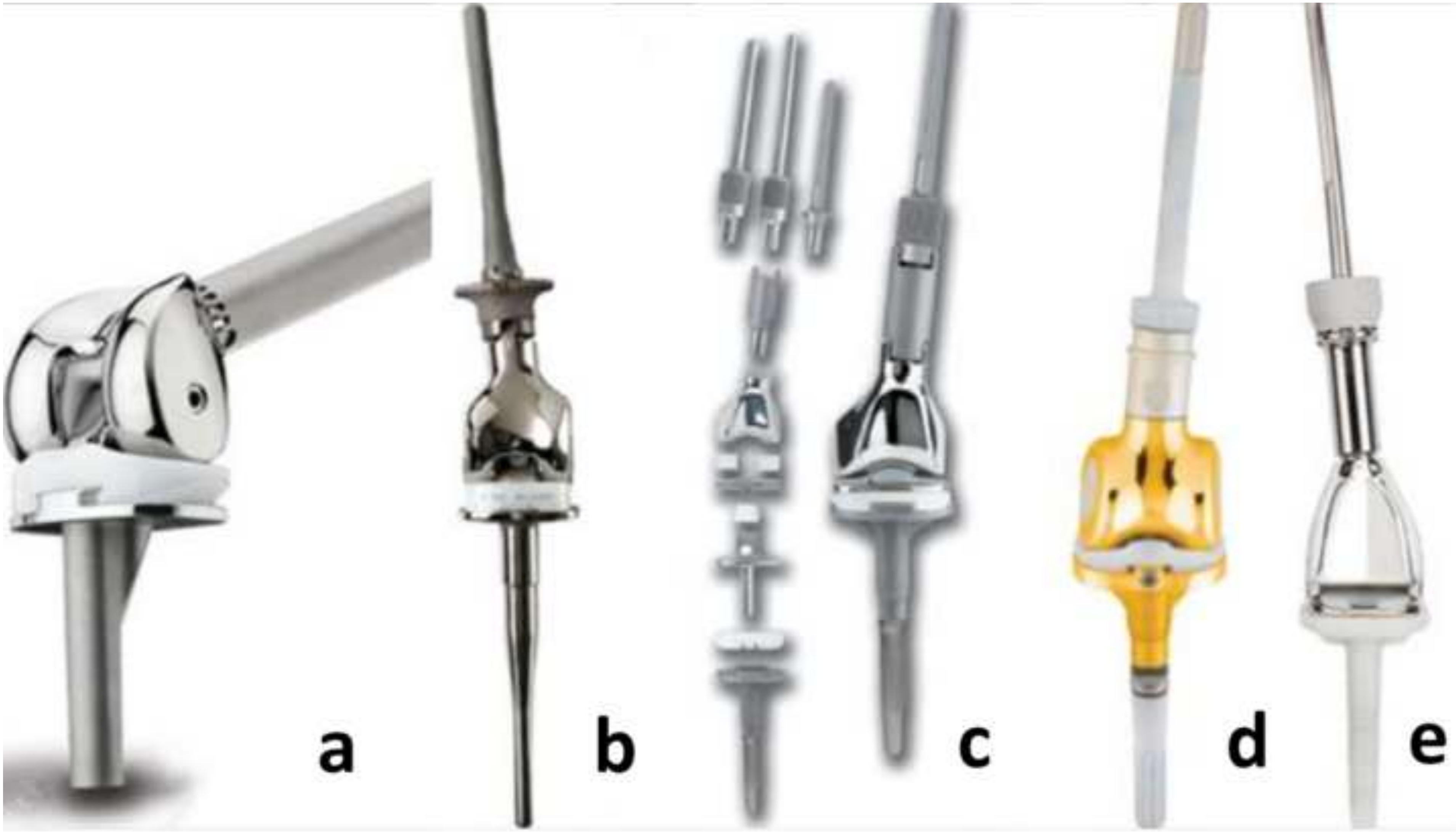

Figure 7 MtoM R1.pdf

Figure 1

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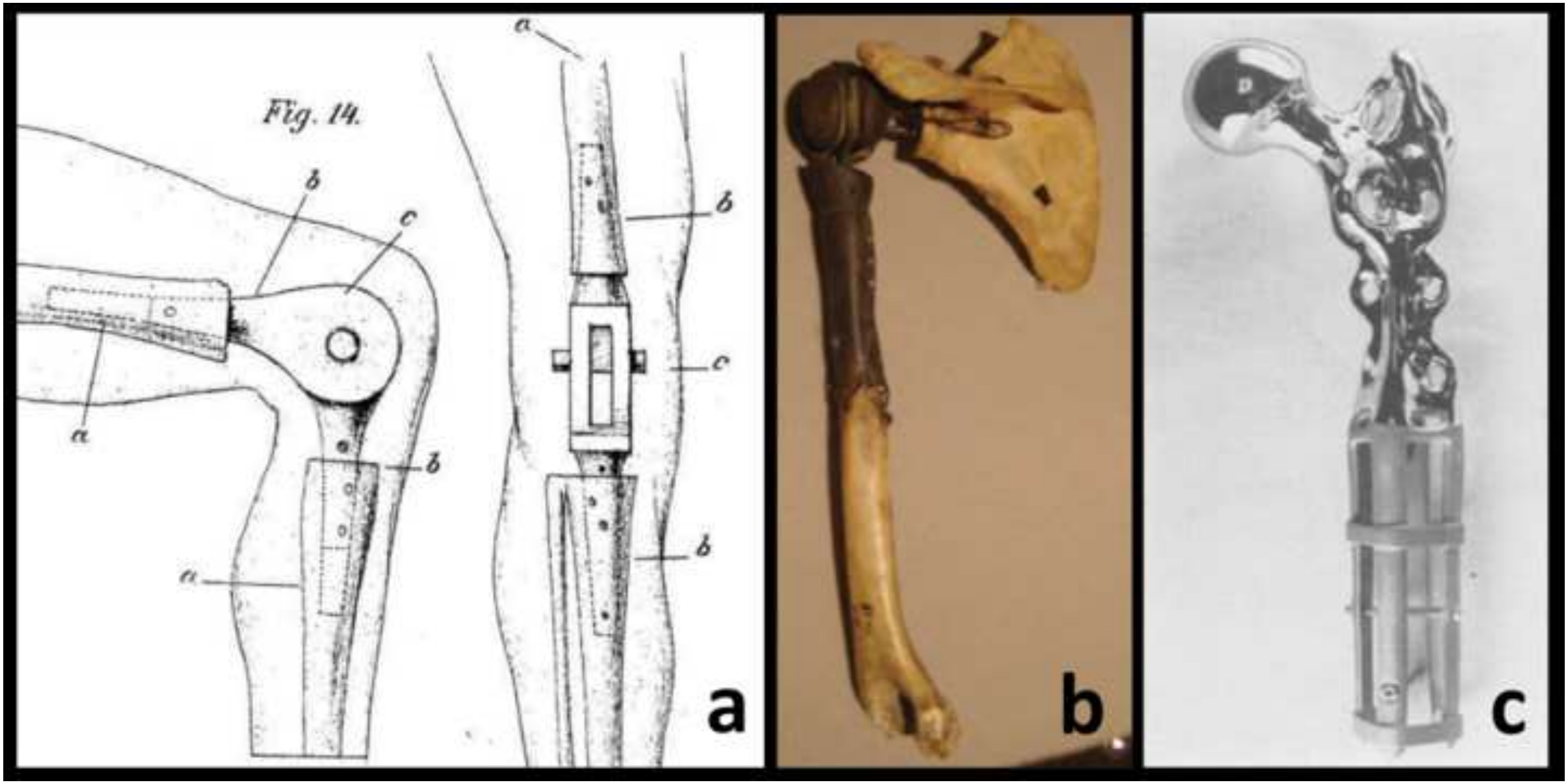

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Figure 2

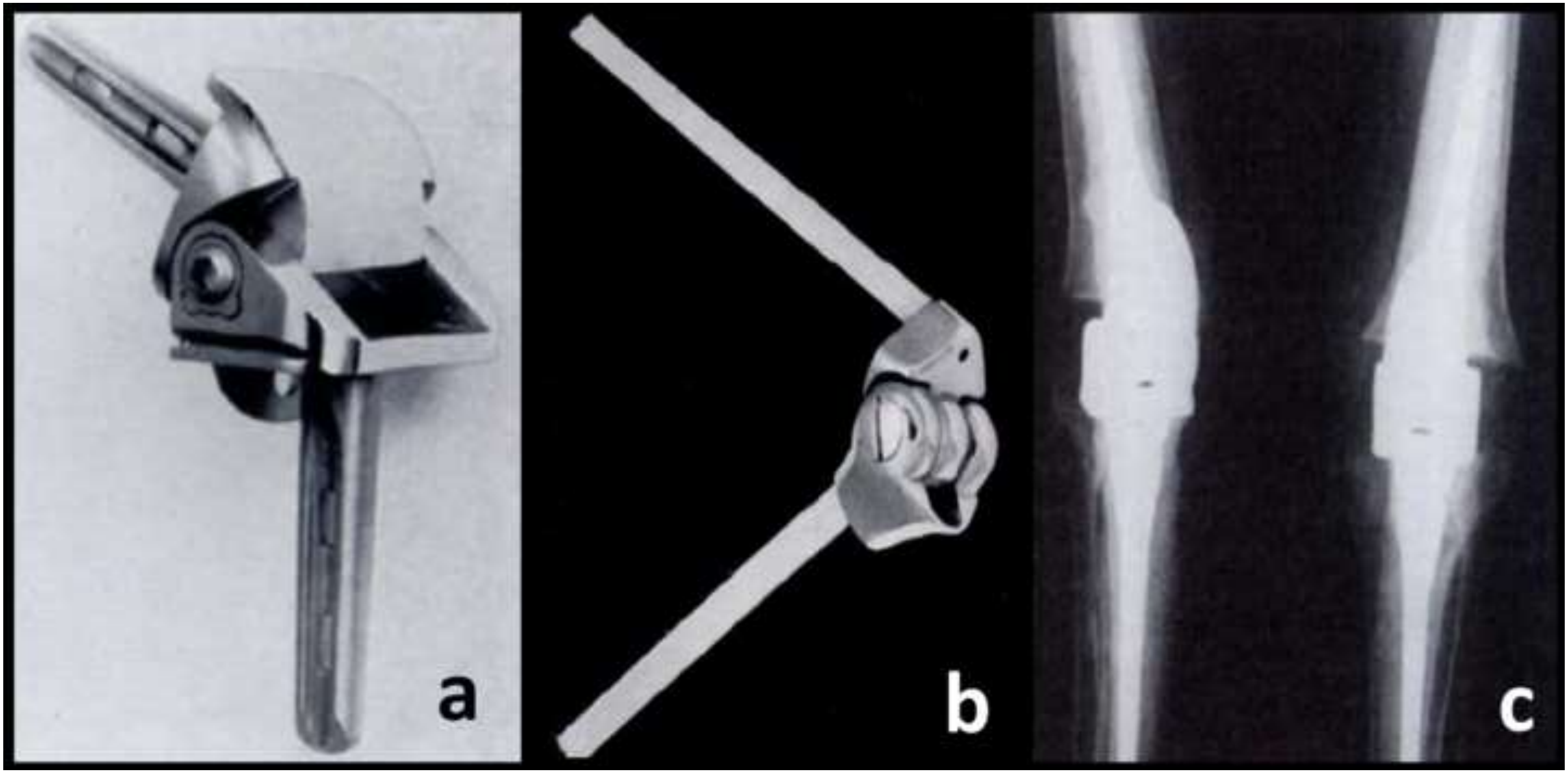
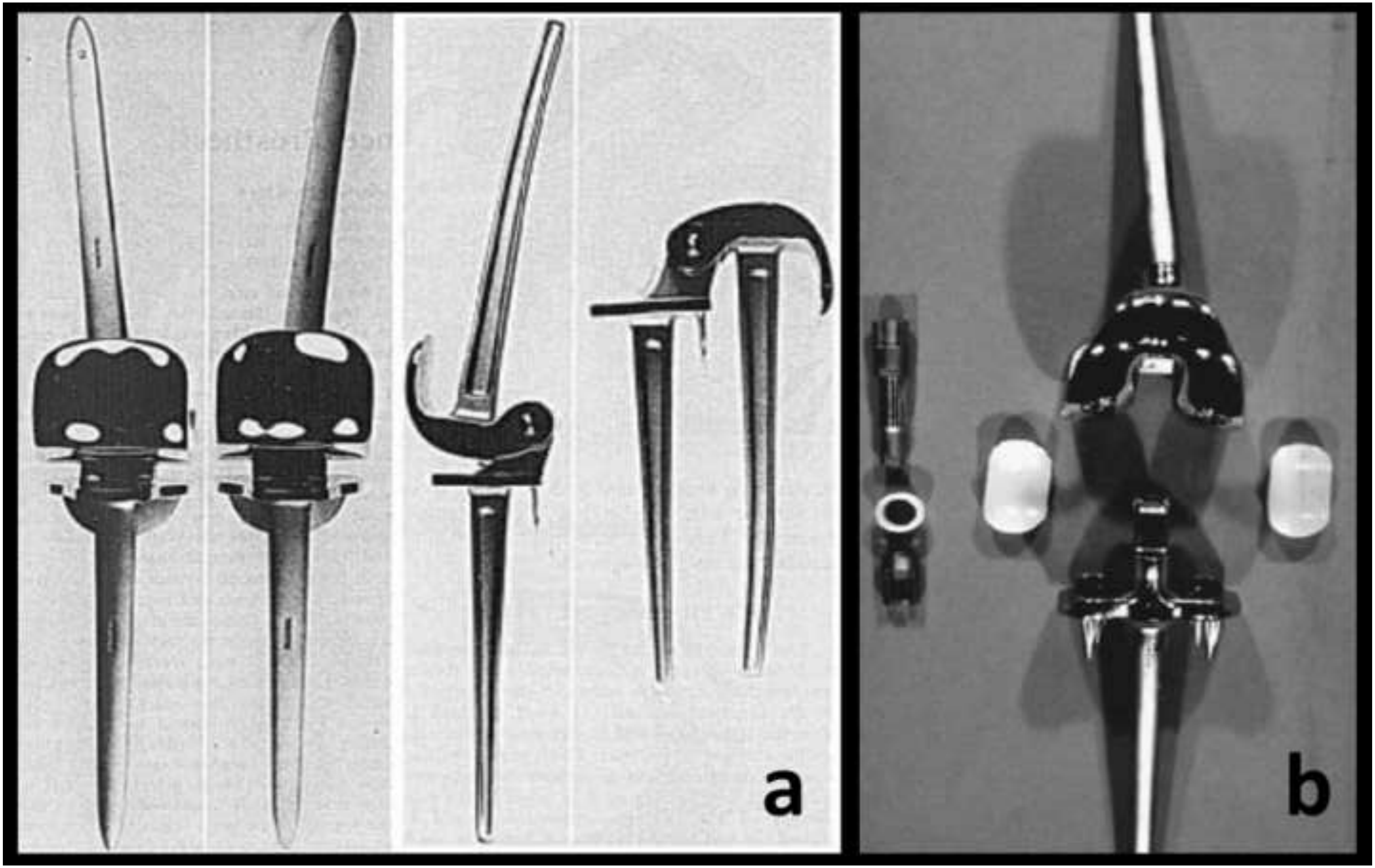


Figure 3



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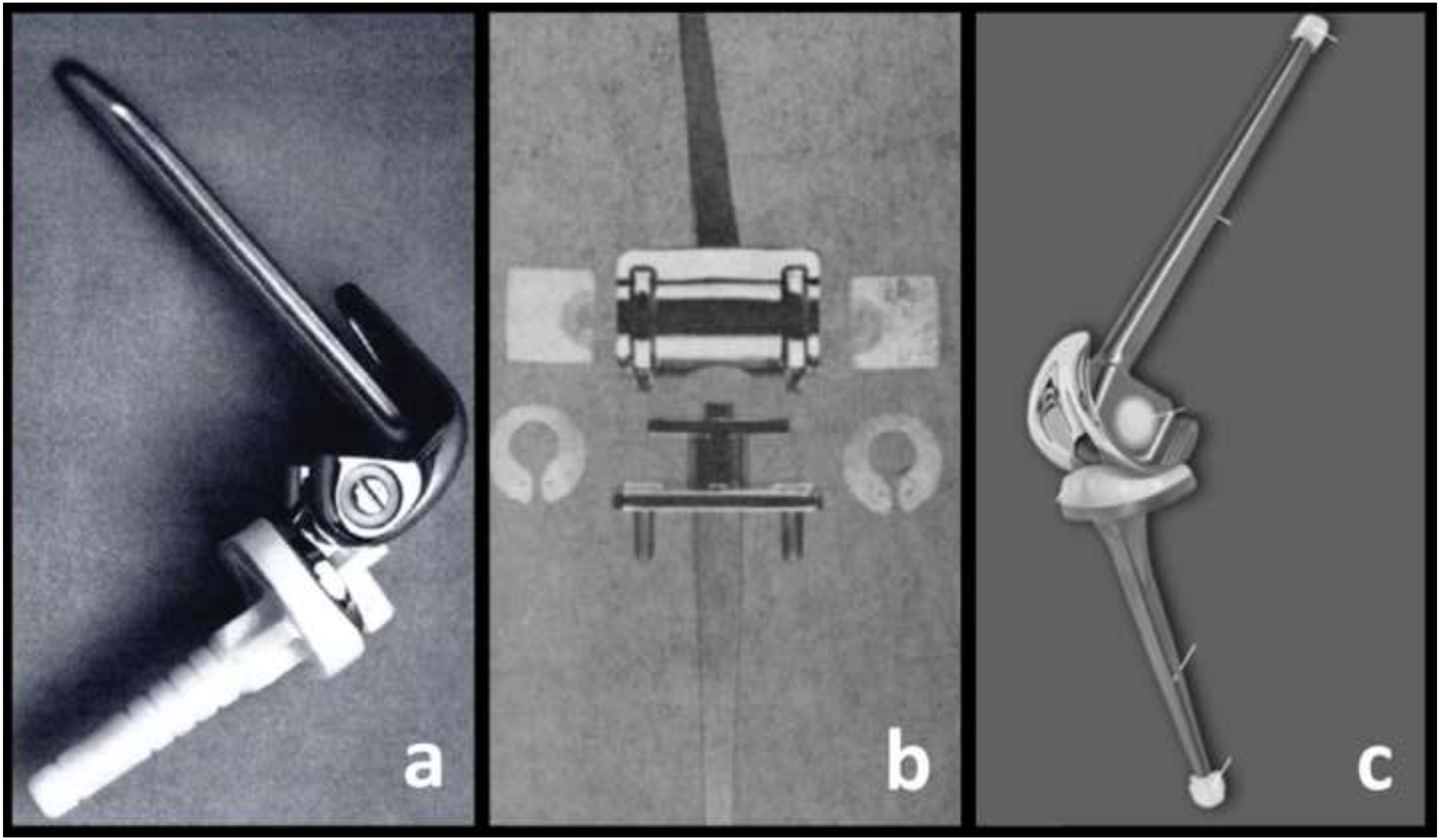

Figure 4 MtoM R1.pdf

Figure 5

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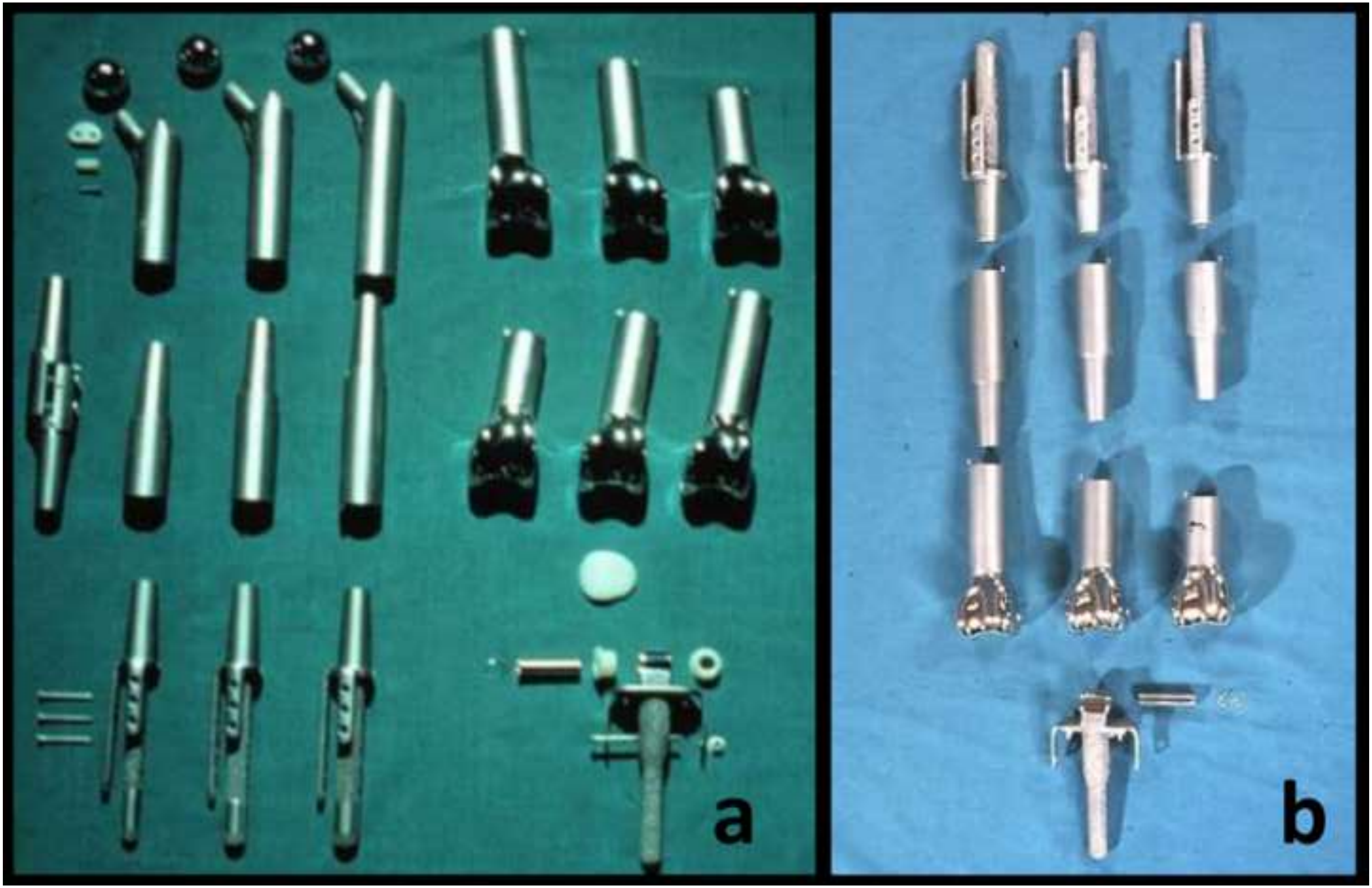

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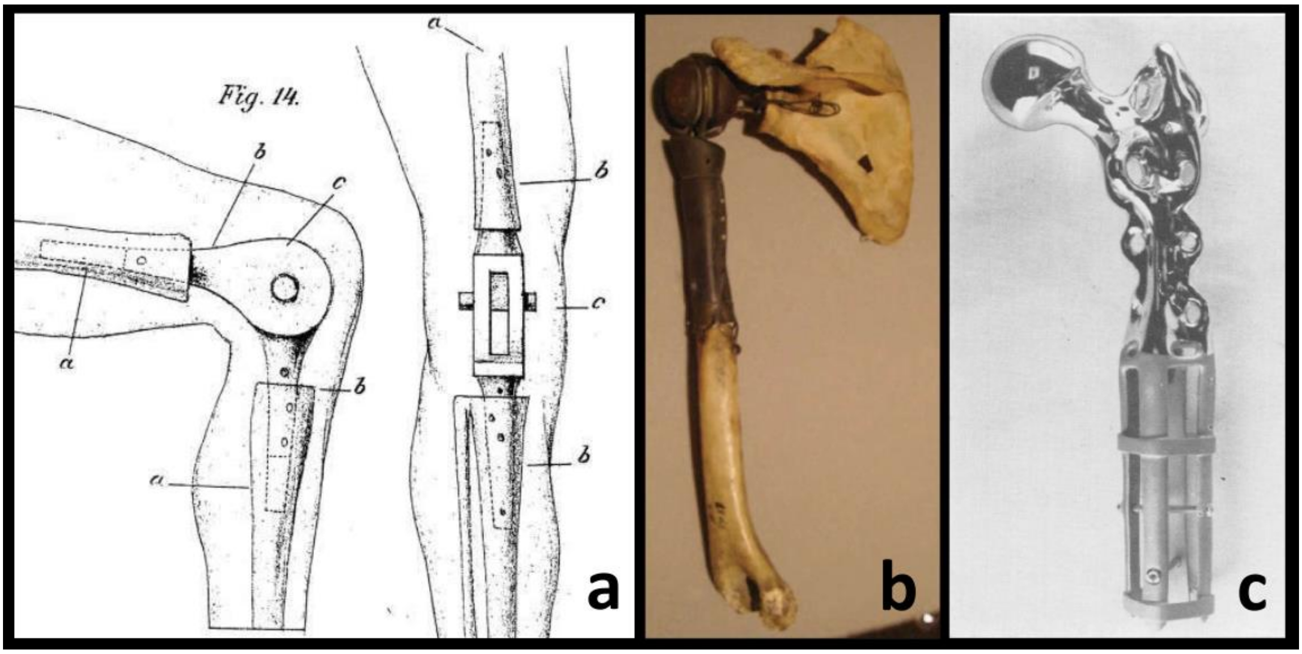

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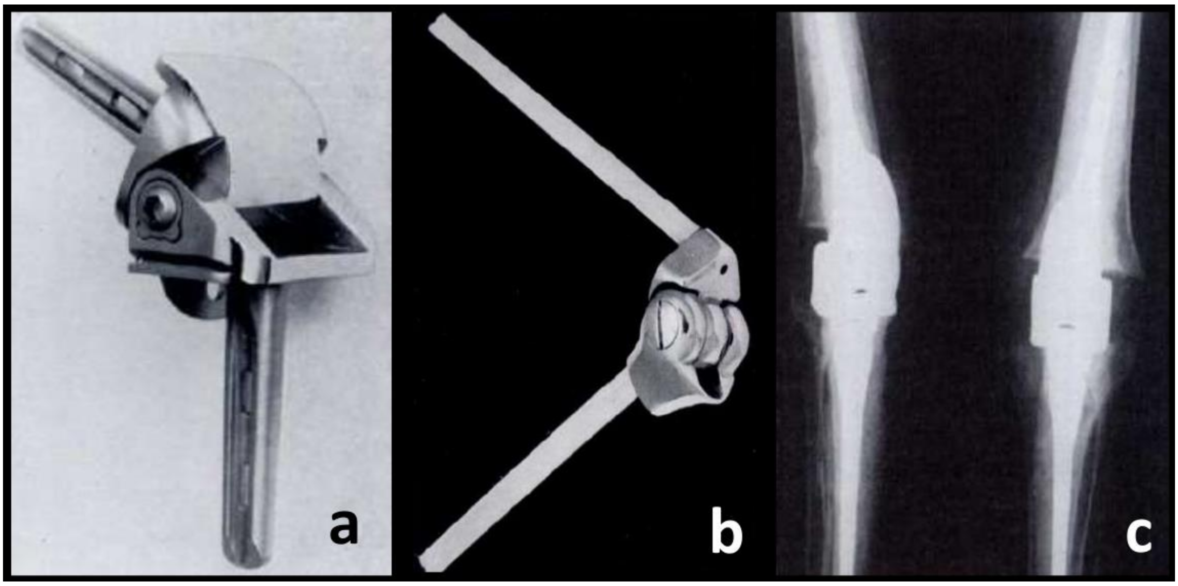

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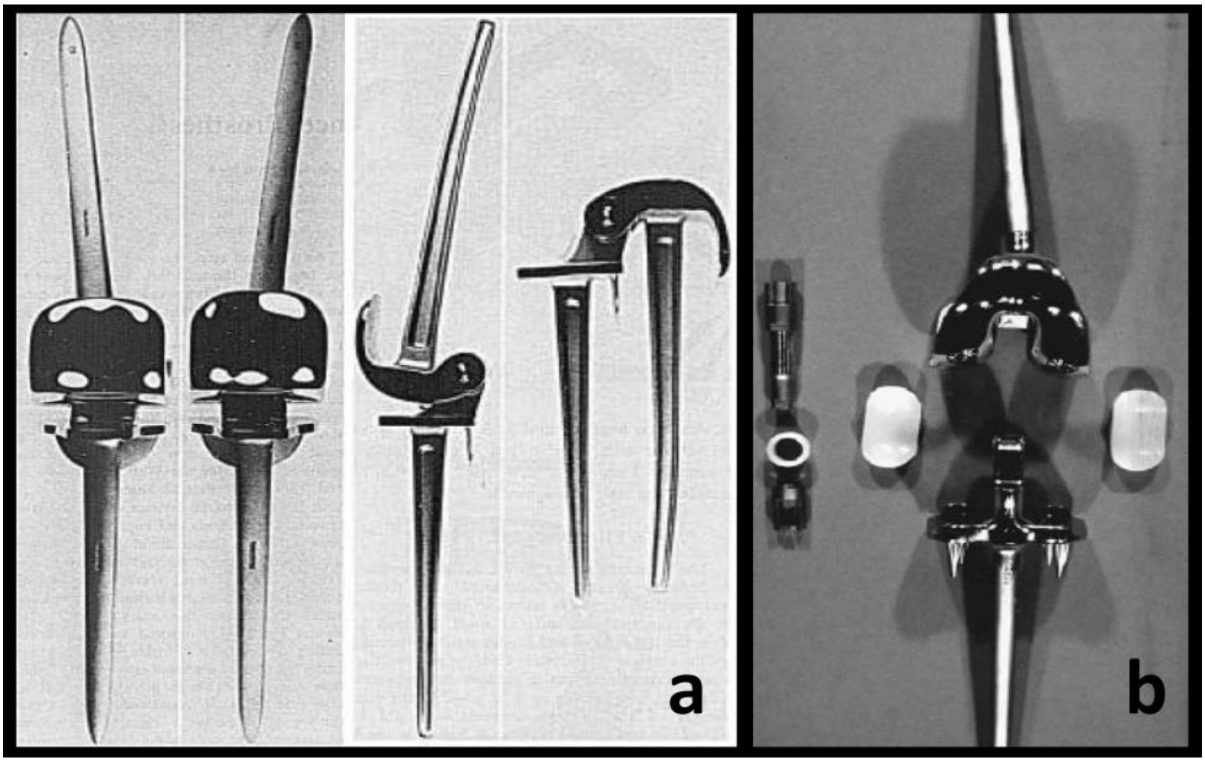

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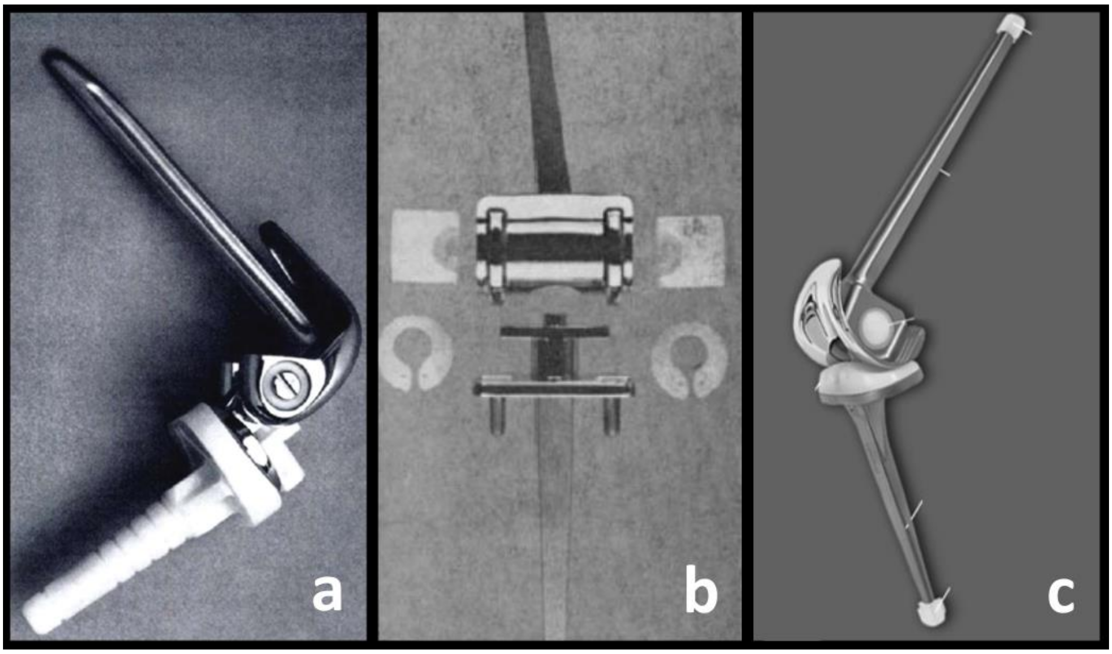

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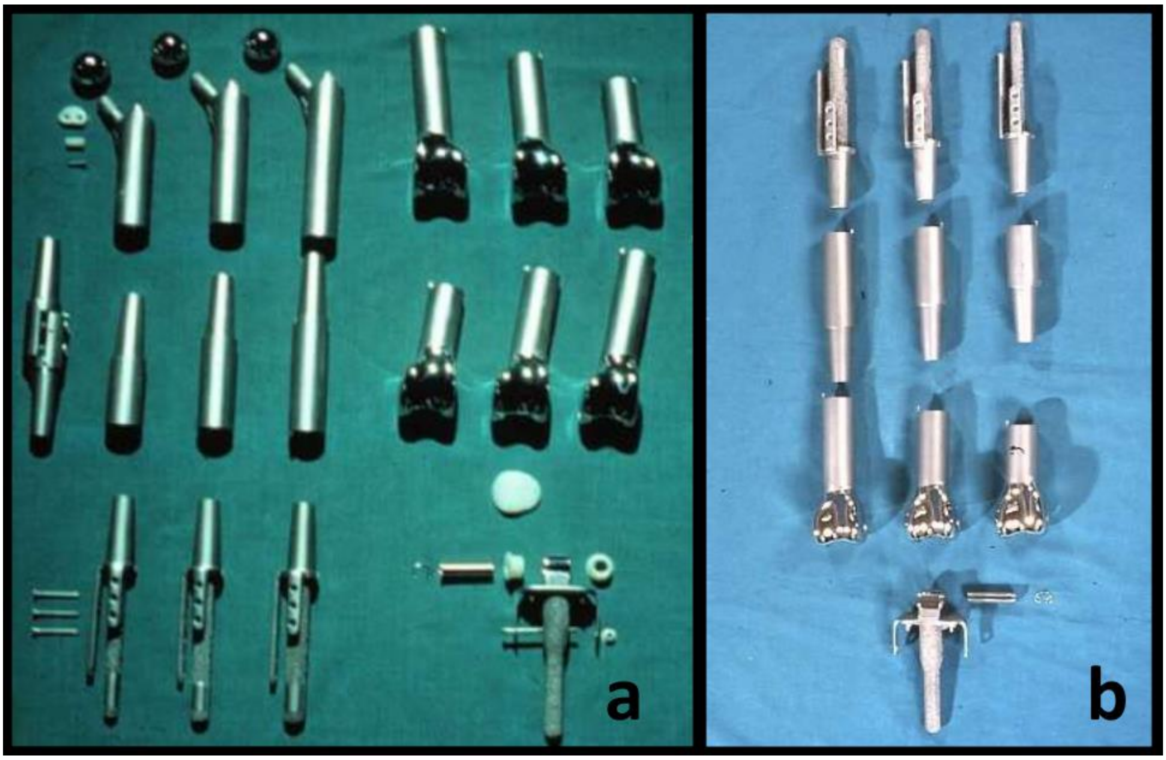

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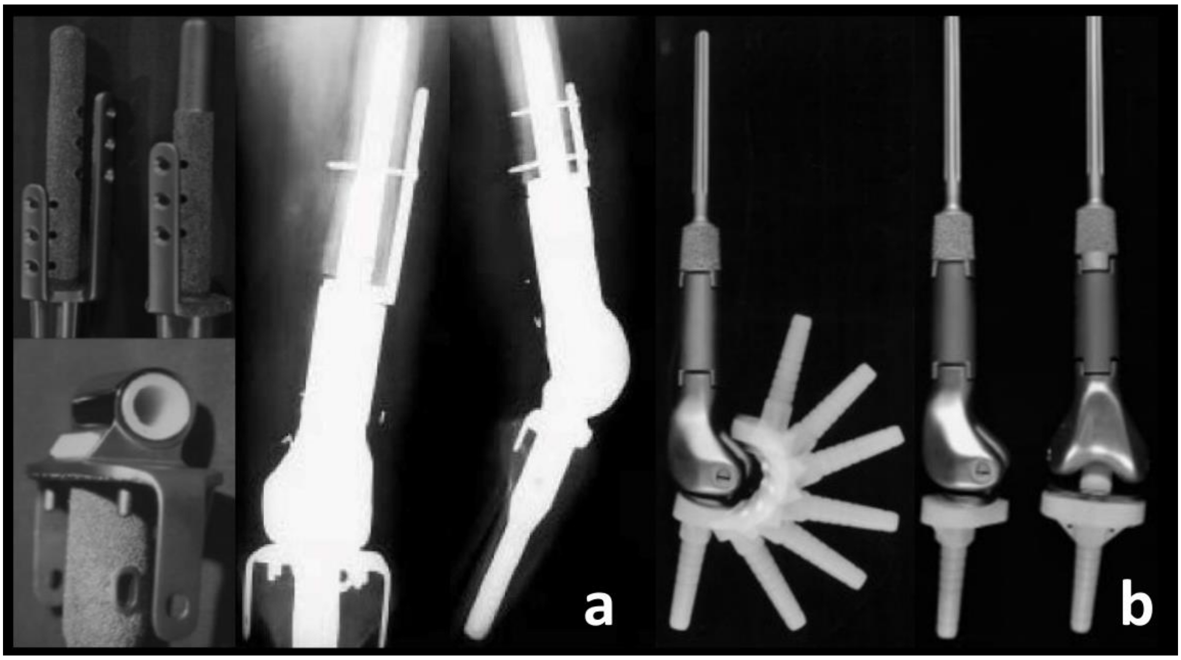

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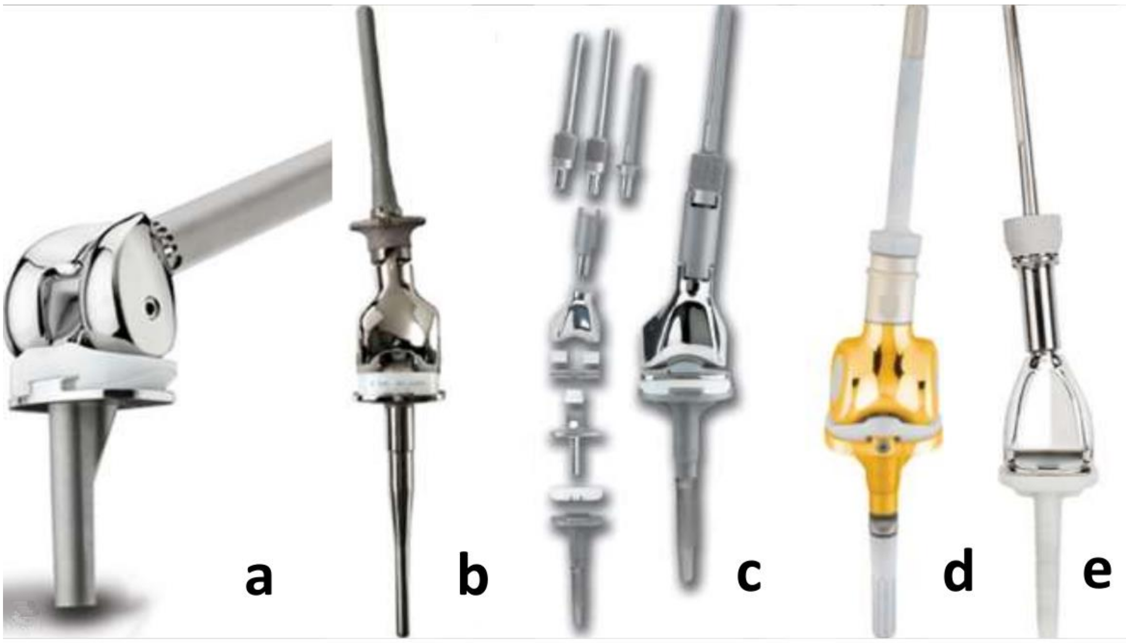

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