Long-term follow-up of the SKI knee prosthesis
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Chapter 1

History and Design of the Total Knee Prosthesis
1.1 RESECTION ARTHROPLASTY AND EARLY DESIGNS OF TOTAL KNEE PROSTHESIS

The development of arthroplasty of the knee is characterized by the search for acceptable interposition materials, the development of a method of secure fixation of prosthetic components in bone, and the provision of stability. Resection arthroplasty of the knee was first reported by Fergusson \(^1\) in 1861. In 1863, Verneuil \(^2\) inserted a flap of joint capsule between the two resected joint surfaces of the knee to prevent them from growing together. Later, other surgeons used different substances like fat (Lexer \(^3\) in 1917), muscle, chromatized pig’s bladder (Baer \(^4\) in 1918), a combination of fat and fascia lata (Murphy \(^5\) in 1913, Putti \(^6\) in 1921 and Albee \(^7\) in 1928), cellophane (Sampson \(^8\) in 1949), sheets of nylon (Kuhns and Potter \(^9\) in 1950) and skin (Brown \(^10\) in 1958). None of these efforts was significantly successful. During the 1920s and 1930s, Campbell popularized the use of free fascial transplants as an interposition material and with his method he achieved limited success in ankylosed knees but not in arthritic joints.

The concepts upon which total joint replacement is based can be traced to the lectures given by Gluck in 1890. He used ivory components fixed with a mixture of colophony, pumice and plaster \(^11\). Because of poor metallurgy, improper fixation and frequent infection, these early hinge replacements oftentimes failed. After the successful use of a Vitallium mold in arthroplasty of the hip by Smith-Petersen \(^12\), Boyd and Campbell \(^13\) designed a metallic mold to cover the femoral condyles for hemiarthroplasty of the knee in 1940. This device failed. Smith-Petersen’s efforts in 1942 with a metallic femoral mold hemiarthroplasty of the knee were unsuccessful too. After a medullary stem was added to the femoral mold for fixation, the Massachusetts General Hospital design \(^14\) achieved limited success. In 1947, Judet \(^15\) designed the first hinged prosthesis made of acrylic. Magnoni \(^16\) reported the first successful use of a hinged total knee in 1949. In the early 1950s Walldius \(^17\), Shiers \(^18\) and others developed hinged implants with medullary stems for fixation to replace both joint surfaces, to provide stability and restore limb alignment. The biomechanical incompatibility of these simple hinges with the complex motions of the knee in combination with the negative effects of their metal-on-metal surface contact resulted in unacceptably high failure rates for these implants, except in sedentary people. McKeever \(^19\) in 1960 and MacIntosh \(^20\) in 1966 developed designs with a metal tibial component. None of these designs provided significant long-term relief of pain in arthritic knees and they were all subject to painful loosening.
1.2 THE MODERN ERA OF KNEE ARTHROPLASTY

The 1970s marked a period of experimentation, evolution and consolidation. The modern era of total knee arthroplasty began with Gunston’s report in 1971\textsuperscript{21} of his experiences with minimally constrained total knee components. Gunston’s design incorporated the low-friction concept and materials proven in the development of total hip arthroplasty during the 1960s, pioneered by Charnley\textsuperscript{22} and McKee\textsuperscript{23}. The design of Gunston consisted of steel surfaces articulating with two high-density polyethylene surfaces. The components were fixed in bone by polymethylmethacrylate. Gunston attempted to duplicate in his design the polycentric motion of the normal knee. Although the first results were encouraging, the prosthesis failed at a later stage. It was designed with a minimal amount of prosthetic material to reduce operative complications and to permit arthrodesis should the arthroplasty fail. A narrow metallic implant replaced the femoral condyle’s weight-bearing portion and two plastic runners were cemented in the tibia, thereby allowing minimal rotation. The rotational constraint and the small contact area led to loosening and failure of the tibial components. The design of Gunston was modified by Bryan and Peterson at the Mayo Clinic. They have used it in a large series of patients with excellent results\textsuperscript{24}. Since then, several hinged and non-hinged prostheses have been developed.

1.2.1 Hinged prostheses

A great many hinged prostheses were developed, like the Sheehan prosthesis in 1971\textsuperscript{25}, the Attenborough prosthesis in 1973\textsuperscript{26}, the St. Georg prosthesis in 1976\textsuperscript{27,28}, the Guepar total knee prosthesis in 1976\textsuperscript{29,30} and the Stanmore knee prosthesis in 1984\textsuperscript{31}. These designs had a high rate of patellofemoral complications, occasional breakage of the implant, early wear and loss of fixation. Modern rotating hinge prostheses that are still used include the Endo model, developed by Bucholz, the Blauth hinge prosthesis\textsuperscript{32}, the rotating SROM hinged prosthesis\textsuperscript{33}, the Finn knee\textsuperscript{34} and the Kinematic Rotating Hinge prosthesis\textsuperscript{35}. Loss of stabilizing structures around the knee such as in tumor resection and in revision surgery is a specific indication for the rotating hinge prosthesis\textsuperscript{34}.

1.2.2 Meniscal bearing and rotating platform knees

In 1975, Pappas and Buechel designed a low-contact-stress (LCS) knee to replace the tibial, femoral and patellofemoral articulation\textsuperscript{36}. Goodfellow and O’Connor developed the Oxford Meniscal Knee arthroplasty\textsuperscript{37}. Mobile bearing and rotating platform knee replacements were designed to minimize wear and loosening problems. It is unclear
if possible reduced wear and loosening will compensate for complications and failures due to subluxation, dislocation and polyethylene breakage 38-40. Further redesigning of this prosthesis may be necessary before superior long-term results are noted over conventional designs 41.

1.2.3 Total condylar type prostheses
In 1971, Freeman and Swanson began using the Imperial College London Hospital (ICLH) knee 42. Both cruciates were sacrificed and the implant relied completely on component geometry and soft-tissue balance to provide stability. Certain aspects of the technique of this implant are still used today, like geometrically patterned resection of condylar bone, maintenance of a large contact area to minimize polyethylene wear and reliance on medial and lateral soft tissue for stability. However, this implant failed because the tibial fixation peg was too short and there was no provision to prevent medial-lateral translation 43.

Between 1970 and 1973, three condylar design implants were developed independently. All three designs emphasized preserving the cruciates to ensure knee stability. Averil, Coventry, Riley, Finerman, Upshaw and Turner generated a geometric prosthesis, made of chromium and cobalt. The feature of the design was conforming geometry of the femoral and tibial components to reduce stresses in the polyethylene. The femoral components were joined together with a narrow metal bar and the patellofemoral joint was not replaced. The tibial component was made of polyethylene and had three small pegs to enhance fixation. Both cruciates were preserved 44. The first geometric knee was implanted in 1971. Several modifications were introduced, but due to increasing incidence of fixation failure these knees were discontinued by the late 1970s. Yamamoto 45, Seedhom 46, Townley 47, Waugh 35 and Éwald 48 designed an anatomic knee. Different designs were made, but due to a high incidence of failure caused by poor fixation of the tibial component and lack of medial-lateral stability, these knees were eventually discontinued 11. In New York, Walker, Ranawat and Insall developed the total condylar knee 11. In 1971, the first duocondylar knee was implanted by Ranawat and Insall 49. In 1974, Ranawat, Insall and Walker introduced the first total condylar knee. The features of this design are multiple radii of curvature, following more closely the anatomical shape of the human condyles, and replacement of the trochlear groove and patella. The load-bearing surface of the tibial and femoral components had round-round geometry in both coronal and
sagittal planes, with partial conformity and a central eminence to provide mediolateral stability. Today total condylar has become a generic term to describe a surface knee replacement that provides patellofemoral resurfacing and has a single piece tibial component with a central stem or keel. 50

Efthekar and Gand 51 designed and implanted a total knee with modularity of both components. Efthekar was the first to note the importance of metal backing, particularly for polyethylene modularity.

In 1975, the first uncemented resurfacing knee arthroplasty was performed 52. Many uncemented designs were developed since then 53-56. That same year Cloutier introduced metal augmentation for the tibial baseplate to compensate for tibial bone loss 57.

Most of the knee designs used today are similar to the early total condylar prosthesis. By the 1980s and 1990s, surgeons became aware of the importance of attaining correct limb alignment and anatomically balanced knee ligaments. Correct limb alignment and balanced knee ligaments are important to properly distribute weight-bearing and other forces on the surfaces of the implants, reduce wear, enhance kinematics and increase range of motion. Improved instrumentation was developed to meet these goals in a consistent manner.

The SKI prosthesis was developed in the early 1980s. The only result described in the literature is a short-term follow-up study by Miehlke and Keller 58. This prosthesis was used in eight different hospitals in the Netherlands and seven hospitals in Germany. The SKI prosthesis is no longer used.

1.3 GENERAL DESIGN CRITERIA FOR KNEE PROSTHESES

The primary indication for total knee arthroplasty is a painful joint, secondary to rheumatoid arthritis, degenerative arthritis, traumatic arthritis, and certain other forms of nonseptic arthropathy. Relative contraindications are poor general health, global soft tissue deficiency around the knee, severe osteoporosis, neuroarthropathy and vascular insufficiency. Absolute contra-indications are recent or current joint sepsis and uncorrectable extensor mechanism deficiency 59.

Anatomically, the knee is classified as a diarthrodial or freely mobile joint of the ginglymus or hinge type. Several kinematic studies have confirmed that motion in the knee is not that of a simple hinge, but is an extremely complex series of movements about variable axes and in three separate planes. Flexion and extension are accomplished by both rolling
and gliding motion between the femoral and tibial condyles. In addition to flexion and extension, concomitant abduction and adduction and internal and external rotation occur.

The stability of the knee is provided by various anatomic structures. The shape of the articular surfaces and the dynamic action of muscles crossing the joint are important stabilizing factors; the ligaments and other soft tissues around the knee are the primary stabilizing factors. Medial stability is provided by the joint capsule, the medial collateral ligament, the medial meniscus, the cruciate ligaments and the pes anserinus. Lateral stability is provided by the joint capsule, the iliotibial band, the lateral collateral ligament, the lateral meniscus, the cruciate ligaments and the popliteus. Anterior stability is provided by the anterior cruciate ligament and the joint capsule, posterior stability is provided by the posterior cruciate ligament and joint capsule. Rotatory stability is provided by appropriate combinations of these structures to resist the direction of the rotatory force applied.

The goals of total knee replacement are to obtain pain relief, restore function and mobility and correct deformity. Knee replacement is expected to be a durable procedure lasting at least 10 to 15 years. To conform to these requirements, a knee prosthesis should meet the following criteria:

1. It should allow a normal or near-normal range of motion in all three planes of knee motion (flexion and extension, abduction and adduction, and rotation). A normal range of motion in a knee prosthesis should be provided by a constantly changing center of rotation, as does the normal knee. This is best met by constructing a femoral component that is convex in two planes and which articulates with a tibial surface that is concave in two planes.

2. It should provide enough stability. To this end, the design should allow preservation of the normal ligaments whenever possible and it should provide for balancing soft tissue tension by appropriate surgical releases.

3. It should be able to resist the loads that are applied upon the prosthesis and its fixation. Morrison calculated that the joint surfaces of the knee are subjected to a loading force equal to three times the body weight in level-walking and four times the body weight in climbing stairs.

4. It should restore normal limb alignment. Long-term success of arthroplasty is greatly dependent on restoration of the normal alignment of the lower limb.
1.3.1 Design of the femoral component
Femoral components replace the condylar surfaces. They are designed to allow resurfacing of the patellar groove of the femur. The patellar sulcus may be anatomically shaped with an asymmetric right and left femoral component. In femoral components with a symmetrical sulcus there is no difference between the right and the left component.

The present consensus is that femoral components should be made of one of the modern high-strength metal alloys such as cobalt-chromium. Cobalt-chromium materials appear to be better suited for articulating surfaces than titanium alloy in its native state. Cobalt-based alloys are quite resistant to fatigue and to cracking caused by corrosion and they are not brittle. The advantage of cobalt-chromium on the femoral side is the superior wear properties when articulating with polyethylene. This arrangement of metal on plastic produces optimal low-friction weight-bearing surfaces 60.

1.3.2 Design of the tibial component
In the past, all-polyethylene tibial components were used. It has been demonstrated that metal-backed tibial components minimize deflection and deformation of the polyethylene and transmit the load better to the underlying bone 64. A short medullary stem greatly improves fixation of the tibial components by resisting shear forces generated during the stance phase of gait 60,64. Central tibial stems have varied from solid rectangular shapes to cruciate keels or tapered stems with fins. These shapes should provide better resistance to varus/valgus, compression/distraction forces and anterior/posterior rocking forces, thereby improving fixation. Proper sizing of the tibial component is important. A small tibial component will not reduce the load over the entire surface of the cancellous bone and is at greater risk of subsiding.

Ultra-high molecular weight polyethylene (UHMWPE) is the current material of choice for use as a bearing surface in total joint replacement. UHMWPE is a viscoelastic material that has limited flexibility under loading conditions. There are three methods used to produce the polyethylene in orthopedic devices. The first method is direct molding, in which polyethylene powder is placed into the final shape of the device. It is then heated under pressure. The surface finish of molded components is glassy smooth. The second method is ram extrusion of the powder into a cylindrical bar stock. The implant is then machined from this bar stock. The third method is molding large sheets of polyethylene. The implant can be machined from the molded sheet. The surface finish of machined components is dull and slightly rough. The
manufacturing techniques have not been shown to produce a significant difference in wear characteristics. Devices made of UHMWPE can function for more than fifteen years, but there is evidence that debris from UHMWPE may limit its longer-term use. The recommended minimum height of the polyethylene in knee prostheses is 8 mm.

Modularity of the tibial component was developed to have the ability to change the polyethylene at the time of revision surgery when polyethylene failure has occurred. Isolated tibial insert exchange is a quick, simple, safe and bone stock-preserving procedure. Modularity allows the surgeon to construct, within limitations, customized implants at the time of surgery and allows hospitals to reduce their inventory of implants.

1.3.3 Design of the patellar component

In the past, metal-backed patellar components were thought to be advantageous over all polyethylene patellar components for reducing stresses at the prosthesis-bone interface. However, significant complications resulting from wear and delamination were observed, leading to early failure and subsequent knee revision. Most current total knee designs have an all-polyethylene dome-shaped patella when resurfacing is performed.

1.3.4 Fixation

The excellent results of cemented total knee arthroplasties in the 1970s and 1980s using the condylar design have set the gold standard for other types of fixation. Hybrid total knee replacement using a porous-coated femoral component is preferred by some surgeons in young patients with good bone stock. Disadvantages include increased cost of the femoral component and necessity for precise fit of the component. Porous-coated tibial components with additional screw fixation have been problematic due to micromotion of the tibial component. Reports of fretting of the screws against the tray with subsequent debris and osteolysis has caused concern and have led to a trend back toward cemented total knee replacement.

1.4 DESIGN OF THE SKI PROSTHESIS

For the Schalen-Kniegelenkprothesen system modell Interplanta (SKI, Waldemar Link, GmbH & Co, Hamburg), three different models of the tibial component have been in use:
1. A tibial component with two separate all-polyethylene tibial plateaus (Figure 1.1a)
2. An U-shaped tibial plateau with an inlet to spare the cruciate ligaments (Figure 1.1b)
3. The stemmed stabilizing “Totalplateau”. (Figure 1.1c)

Figure 1.1a-c. The SKI prosthesis consists of three different designs for the tibial component:
- Two separate all-polyethylene tibial plateaus (Figure 1.1a)
- An U-shaped tibial plateau with an inlet to spare the cruciate ligaments (Figure 1.1b)
- The Stabilizing “Totalplateau” (Figure 1.1c). This type was used at Groningen University Hospital in all cases.

The femoral component is anatomically shaped. The back side of the femoral component is roughened to enhance fixation of the cement. The all-polyethylene patella is dome-shaped.
Depending on the stability of the knee, these three different models could be used. The stemmed model was originally indicated for unstable knee joints with absent cruciate ligaments. At Groningen University Hospital, the stemmed model was the implant of choice in all cases, regardless of the stability of the knee.

The polyethylene (PE) insert of the SKI prosthesis is replaceable. The insert is fixed underneath a raised border of the metal tibial baseplate. To prevent rotation, the PE insert is fixed to the tibial tray with a screw on the anterior side (see Figure 1.2).

![Figure 1.2. The polyethylene insert of the SKI prosthesis is fixed with a screw.](image)

The manufacturing technique of the UHMWPE was machined from extruded bar stock. The polyethylene was sterilized in ethylene oxide (ETO). The PE insert was available with a thickness of 7, 9, 11 and 13 mm. The SKI prosthesis has an anatomically shaped right and left femoral component. The femoral component is made of cobalt-chromium, with a roughened backside to enhance fixation of the cement (see Figure 1.1a). The tibial and femoral components were available in four different sizes (see Table 1.1). The patella of the SKI prosthesis is all-polyethylene and dome-shaped (see Figure 1.1b).

The femoral and tibial components of the SKI prosthesis were placed with the use of an external guidance instrument (see Figure 1.3a-b). The femoral component was mainly prepared with chisels.
Table 1.1. Sizes of the femoral and tibial component available for the SKI prosthesis.

<table>
<thead>
<tr>
<th>Size</th>
<th>Anteroposterior size (mm)</th>
<th>Mediolateral size (mm)</th>
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<tbody>
<tr>
<td><strong>Femoral component</strong></td>
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<tr>
<td>I</td>
<td>54</td>
<td>55</td>
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<td>II</td>
<td>60</td>
<td>62</td>
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<td>III</td>
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<td>69</td>
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<tr>
<td>IV</td>
<td>74</td>
<td>76</td>
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<tr>
<td><strong>Tibial component</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>35</td>
<td>56</td>
</tr>
<tr>
<td>II</td>
<td>40</td>
<td>62</td>
</tr>
<tr>
<td>III</td>
<td>45</td>
<td>68</td>
</tr>
<tr>
<td>IV</td>
<td>50</td>
<td>74</td>
</tr>
</tbody>
</table>

Figure 1.3a-b. The femoral component (Figure 1.3a) and the tibial component (Figure 1.3b) of the SKI prosthesis were placed with the use of an external guidance instrument.
1.5 THE OPERATION PROCEDURE AT GRONINGEN UNIVERSITY HOSPITAL

The stemmed model of the SKI prosthesis was used in all cases. A tourniquet was used in all cases. Antibiotic prophylaxis was given to all patients in the form of Velosef for 48 hours perioperatively. A lateral approach with a medial parapatellar arthrotomy according to Payr was used. If possible, the posterior cruciate ligament was retained, as recommended by Insall in 1986. It has been suggested that retention of the PCL improves the kinematics of the joint, imposing a femoral rollback and increasing the patella moment arm. This subsequently provides improved function with stair-walking and arising from a seated position.

All components, i.e. the femoral, tibial and patellar components were fixed with cement. The patella was replaced in all cases. At the end of the operation, two deep and one superficial drain were left. Postoperatively a bandage was given for 48 hours. Patients were mobilized with walking aids from the fifth postoperative day. They were discharged from the hospital when they could flex the operated knee more than 90 degrees. No continuous passive motion (CPM) was used at that time. Patients under the age of 80 received oral anticoagulants for three months postoperatively to prevent thromboembolic complications. Sodium heparin was given subcutaneously from the day of operation until the level of anticoagulation by oral medication was sufficient.

1.6 LOCKING OF THE SCREW

Because of loosening of the locking screw of the SKI prosthesis in the original design, a method to lock the screw was developed. A pin was inserted through the head of the screw through a drill hole in the anterior side of the PE insert (Figure 1.4 b). This pin was buckled through a drill hole at the top of the PE insert (Figure 1.4c-d).
Figure 1.4a-d. Locking procedure of the screw. The screw of the SKI prosthesis is inserted in the screwhole of the tibial insert and fixed to the tibial baseplate (Figure 1.4a). A pin is inserted through the screw by a drill hole in the anterior side of the PE insert (Figure 1.4b). This pin is buckled by a punch through a drill hole at the top of the PE insert (Figure 1.4c-d).