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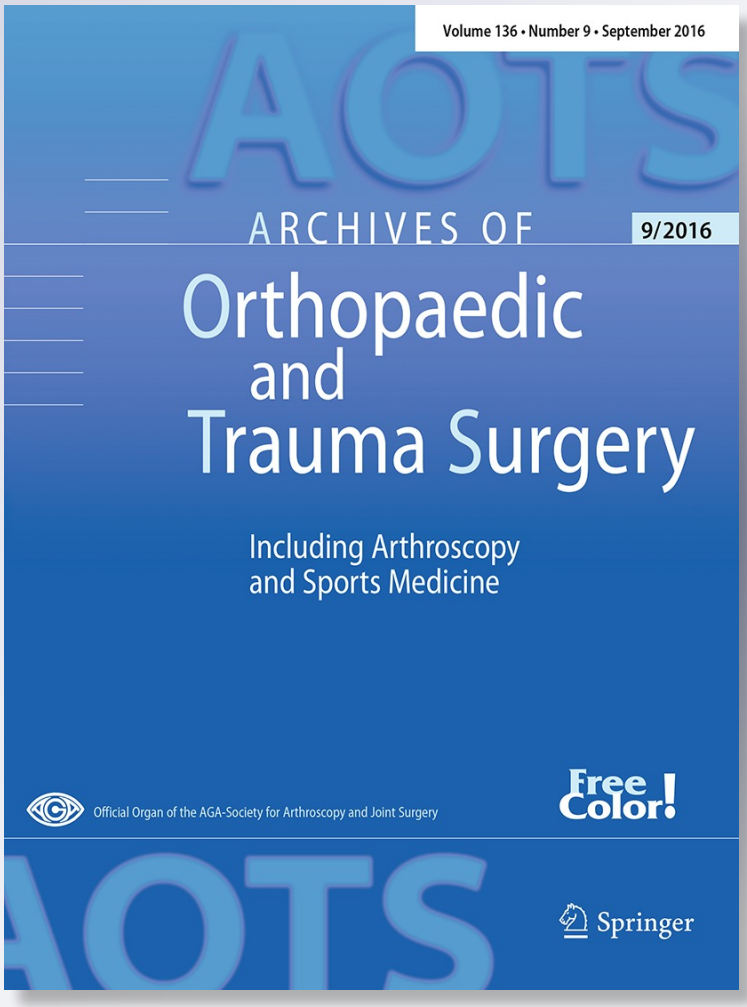

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HANDSURGERY

Osteointegration of a modular metal-polyethylene surface gliding finger implant: a case report

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Abstract
Introduction Primary press fit and secondary osteointegration is a precondition for component anchoring in articular surface replacements, also in the case of proximal interphalangeal (PIP) joint. Nevertheless, many existing prostheses for the PIP joint have failed to show sufficient osteointegration. CapFlex-PIP© implant is a modular metal-polyethylene surface replacement for the PIP joint consisting of a proximal and distal component each having a titanium pore backside, which allows secondary osteointegration at the bone-implant interface. To evaluate osseous integration of this implant, we report a histological analysis of an explantation of a CapFlex-PIP© finger implant.
Case presentation We present a case of a removed CapFlex-PIP© implant due to a soft tissue complication in an 84-year-old woman. The patient received bisphosphonate medication as treatment for osteoporosis. For the histological analysis, the bone-implant contact (BIC) was measured on all stained sections using a Zeiss Axioplan microscope. The summated BIC was 40.7 % for the proximal component and 46.5 % for the distal component of the implant. Histology showed that the implant was in direct contact with the bone at various locations, with no signs of wear or degradation.
Conclusions This case demonstrates successful osteointegration of the CapFlex-PIP© implant. Both components of the investigated implant show osseous integration to an extent which is comparable to that of other load-bearing and articulating implants at different locations in the human body.

Keywords Osteointegration · Proximal interphalangeal joint · Arthroplasty · Surface replacement · CapFlex

Introduction

Primary press fit and secondary osteointegration is a precondition for component anchoring in articular surface replacements, as it is associated with primary and secondary stability and also in the case of a proximal interphalangeal (PIP) joint subsequently preserves the function. To date, many existing ceramic and pyrocarbon prosthesis designs have failed to show sufficient osteointegration. A significant number of migrations and insufficient stability at the bone-implant interface present as clinical evidence for the lack of osteointegration [4, 8–10, 18]. To improve osseous integration of the implant, the modular prosthesis CapFlex-PIP© (KLS Martin Group, Tuttlingen, Germany), a metal-polyethylene surface replacement consisting of a proximal and distal component, was developed to offer primary solid bone anchorage. Long-term cementless fixation of the CapFlex-PIP© should be achieved with initial press-fit technique allowing secondary osteointegration at the bone-implant interface. With press-fit fixation, the rough titanium pore backside of the components ensures a maximum surface for osteointegration [12]. Titanium pore

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backsides have already been used in large joints such as the hip, knee, and shoulder, and show good osteointegration in the long term [3, 14, 17]. However, it is difficult to obtain evidence of such osteointegration using clinical standard radiographs. The most detailed and accurate statements can be made by histological analysis, but this requires retrieval of the bone-implant interface and thus rarely occurs.

Since 2010, 129 CapFlex-PIP© implants were implanted in 125 patients at our clinic. Only one of these prostheses had to be removed due to a soft tissue complication, allowing us to examine it histologically and analyse the osteointegration at the bone-implant interface of a human patient.

Case presentation

An 84-year-old woman had suffered from severe osteoarthritis in the finger joints for many years and from osteoporosis as comorbidity, which was treated with a bisphosphonate medication. Over the years, degeneration of the PIP joints and the resultant loss of mobility became worse. In the PIP joint of the right index finger, the radial ray showed deviation in the ulnar direction concomitant with clinical insufficiency of the radial collateral ligament. Increased functional restriction with pain, loss of mobility, and axis deviation provided the indication for surgery with the CapFlex-PIP© surface replacement [12]. The preoperative ulnar angulation was corrected by relevant bone resection from the radial side at the base of the middle phalanx. At postoperative follow-up, the patient was free from pain and the treated PIP joint had an active range of motion of 35°, with flexion of 75°. In view of the good results, treatment was concluded 3 months after surgery. After 11 months, however, the patient reported a traumatic shear event involving the treated finger when she had been gardening some weeks earlier. This trauma resulted in a spontaneous deviation of the axis, which increased significantly with time. When we first saw her, 3 months after the injury, there was no possibility of passive redress for the stiff joint with axis deviation (Fig. 1a). Radiographs showed correctly positioned proximal and distal components without any signs of migration, osteolysis or loosening (Fig. 1b–d). Functional limitations with the severe angulation provided the indication for revision surgery. As patients choice of a definite solution within one procedure, we decided not to reconstruct the radial collateral ligament and performed removal of the CapFlex-PIP© prosthesis and joint arthrodesis. At operation we found a complete rupture of the radial collateral ligament. The proximal and distal components of the prosthesis showed mechanically stable integration and the ultra-high-molecular-weight polyethylene inlay (UHMWPe) was intact (Fig. 1e–g). Arthrodesis using a mini-plate with spongy bone from the radius was straightforward, and stable bony consolidation was documented 8 weeks postoperatively.

The removed implants and attached tissues were immediately fixed in 70 % methanol and kept at 4 °C for 2 weeks, for descriptive and quantitative histological analysis of osteointegration. After dehydration, the two samples were embedded in methylmethacrylate (MMA). The blocks were cut in the transverse plane using a saw microtome (Saw Microtome Leica SP1600, Leica, Muttenz, Switzerland). Consecutive sections with a thickness of approximately 200 µm were glued on plastic slides, ground and polished with an EXAKT 400CS grinding system (EXAKT, Norderstedt, Germany), and finally stained with Giemsa–Eosin. The stained sections (remaining thickness approximately 80–120 µm) were examined with a Zeiss Axioplan microscope (Zeiss, Göttingen, Germany) equipped with a digital camera (Zeiss AxioCam HRc). Bone-implant contact (BIC) is assessed as the ratio between the actual length of bone-implant contact and the possible maximum length available for bone-implant contact [16]. BIC was measured on all stained sections along the bone-implant interface on images with a pixel size of 0.53 µm. Examples are shown in Fig. 2. The average BIC value was 40.7 % for the proximal component and 46.5 % for the distal component of the prosthesis. Histology showed that the implant was in direct contact with the bone at various locations, with no sign of wear or degradation. The soft tissue filling the marrow spaces next to the implant showed a few signs of mild focal inflammation. However, the peri-implant bone tissue appeared to be vital and exhibited cell nuclei filled lacunae.

Discussion

Osteointegration of metal implants with cementless fixation has been demonstrated in the resurfacing of large joints such as the knee, hip, and shoulder. Pure titanium coating of the cobalt-chrome alloy has shown excellent osteointegration in various studies [3, 14, 17]. In smaller joints, bone ongrowth has also been confirmed for titanium implants in animal experiments [4]. Good osteointegration and the related stability of a primary cementless fixed surface replacement are indispensable for the long-term survival of all artificial joints. Histological and histomorphometric evidence of osteointegration at the bone-implant interface is, therefore, important in the evaluation of implant stability and present still a rarity in the field of finger arthroplasty.

In the past, it could only be assumed that implanted CapFlex-PIP© prostheses show sufficient osteointegration. The assumption was based on radiographic evidence

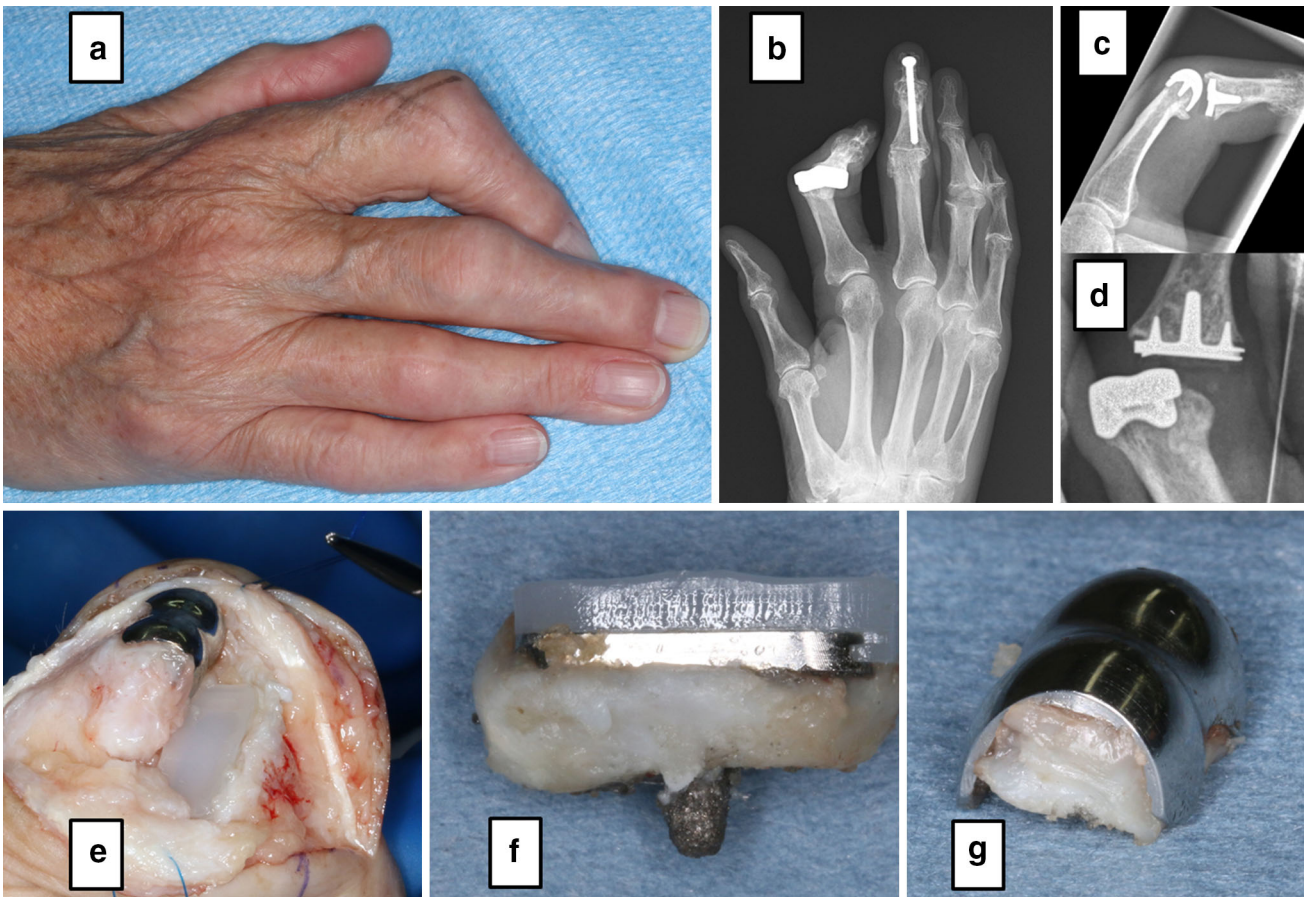

Fig. 1 **a** Preoperative status with fixed ulnar deviation of the index finger. **b** Preoperative anterior–posterior radiograph of the affected hand. **c** Preoperative lateral radiograph of the affected index finger. **d** Preoperative anterior–posterior radiograph of the affected index finger. **e** Intraoperative status documenting the correct position of the CapFlex-PIP© at the host bones. Note that there is no sign of migration of the distal and proximal components. **f** Volar view of the distal component with attached tissue still adhering to the structure after removal. **g** Lateral view of the proximal component after removal with firmly attached tissue

showing the implants remaining in the correct position. In addition, there have been no signs of insufficient osteointegration in finger joints, requiring secondary treatment such as tenolysis. These clinical assumptions have now been confirmed with the histological analysis of the proximal and distal components of a CapFlex-PIP© implant. Several studies that measured the bone-implant interface in other artificial joints using the parameter of bone-implant contact have demonstrated a high correlation with secondary implant stability. The BIC values for the explanted CapFlex-PIP© implant were within the range published for particular dental implants in mini pigs with an average value of 58.5 % [6] and were higher than those reported for the humeral parts of resurfacing shoulder prostheses with an average value of 20.5 % [13]. In our case report, the bone tissue was vital, as shown in Fig. 2. Vital bone tissue is a further important prerequisite for osteointegration, because vital bones are more qualified for bone ongrowth and for sufficient bonding with surgical implants [1, 11].

Osteoporosis is characterized by a progressive loss of bone mass and influences the quality of bone tissue such that it results in an increased susceptibility to fracture [15, 19]. The assumption that osteointegration is a risk factor and contraindication for bone ongrowth, is still controversial in the literature [5, 7]. In agreement with the finding of good osteointegration in our presented case, Shibli et al. described similar percentages of bone-implant contact of dental implants for osteoporosis and non-osteoporosis patients using histological analysis [15]. This is confirmed by the assumption that even in case of osteoporosis the formation of new bone is possible [2].

In conclusion, the present case demonstrates successful osteointegration of an implant used for articular surface replacement of human finger joints. Both components of the investigated CapFlex-PIP© implant show osseous integration to an extent which is comparable to that of other load-bearing and articulating implants at different locations in the human body.

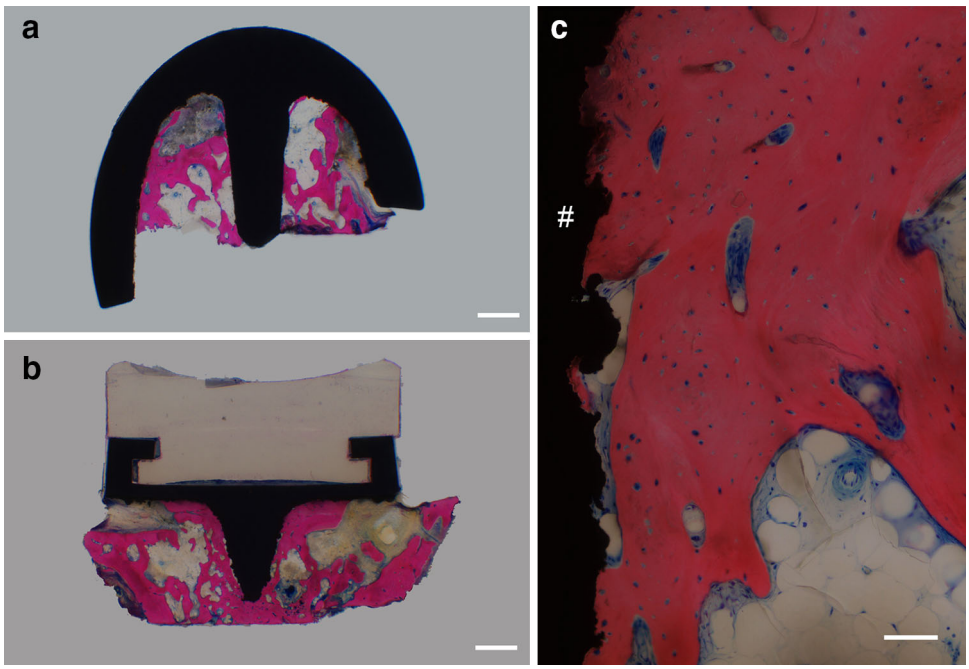

Fig. 2 Undecalcified, methacrylate embedded sections of implants and attached tissues stained with Giemsa–Eosin. The *red-stained* bone is in direct contact with the surface of the implant. The *blue-stained* cell nuclei in the osteocyte lacunae indicate vital bone. **a** Proximal implant cut parallel to the long axis of the finger. **b** Distal implant consisting of metallic and polyethylene parts. Bone tissue is in direct contact with the metallic implant surface and is concentrated around the intramedullary cone, which was inserted into the marrow cavity of the intermediate phalanx. **c** Higher magnification of the bone-implant interface showing intimate contact between the roughened implant surface (#) and the surrounding bone tissue (*scale bars* 1 mm in **a**, **b** 100 μm in **c**)

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Compliance with ethical standards

Conflict of interest The senior author (SFS) received royalties from the KLS Martin Group, Tuttlingen, Germany. KLS Martin Group, Tuttlingen, Germany payed the expenses of the histological investigation and received a bill from AO Research Institute, Davos, Switzerland. The senior author (SFS) and his family as well as this institution did not receive any further financial payments or benefits from any other commercial entity related to the subject of this article and preparation of the manuscript.

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