



## Case report

## Tapered modular fluted titanium stems for femoral fixation in revision total knee arthroplasty

Jeffrey B. Stambough, MD<sup>\*</sup>, J. Bohannon Mason, MD, Aldo M. Riesgo, MD, Thomas K. Fehring, MD

OrthoCarolina Hip & Knee Center, Charlotte, NC, USA

## ARTICLE INFO

## Article history:

Received 7 January 2017  
Received in revised form  
2 March 2017  
Accepted 10 March 2017  
Available online 21 April 2017

## Level of Evidence:

IV  
Case series

## Keywords:

Revision knee arthroplasty  
Femoral fixation  
Fluted modular stems  
Cementless

## ABSTRACT

Consensus regarding femoral stem fixation options in revision total knee arthroplasty remains controversial. Tapered, modular, fluted titanium (TMFT) stems have an excellent track record in total hip arthroplasty for their ability to provide axial and rotational stability in situations of compromised host bone. We present 3 successfully treated cases in which the Food & Drug Administration granted permission to use custom TMFT stems in situations of failed femoral fixation in multiple revised knees. These stems hold promise to achieve stable fixation in revision total knee arthroplasty where host metadiaphyseal bone is deficient. Implant manufacturers should consider dedicating future resources to create adapters that can link existing successful TMFT stems currently used in hip arthroplasty to revision total knee components when host bone is severely compromised.

© 2017 The Authors. Published by Elsevier Inc. on behalf of The American Association of Hip and Knee Surgeons. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## Introduction

As more patients undergo total knee arthroplasty (TKA), the demand for revision TKA has continued to rise [1]. The increasing incidence of aseptic failures brings about concerns with revision fixation strategies to preserve bone stock and maximize function [2]. Stems are an attractive adjunct due to their ability to provide a diaphyseal reference for length, bypass metaphyseal bone defects, and reduce interface stresses in damaged bone. Although stems have been used in revision TKA for decades, debates over fully cemented vs hybrid cementless fixation remain [3–5]. Long-term concerns of loosening with non-ingrowth surface designs exist in cases of substantial bone loss with highly constrained articulations.

Diaphyseal fixation in revision total hip arthroplasty has been improved by the introduction of tapered, modular, fluted titanium

(TMFT) stems. Tapered fluted stems are now preferentially chosen given their excellent long-term survivorship with low reported rates of stem failure and high rates of bone fixation compared to cylindrical fully porous designs, particularly in compromised bone [6–9]. The versatility of such a design affords the surgeon the chance to obtain diaphyseal fixation when the periarticular bone stock is poor. Evidence further suggests that regeneration of proximal trabecular bone may be possible due to the transmission of forces produced by the conical design of the stem combined with titanium's lower modulus of elasticity [10,11].

Given the success of TMFT stems in revision hip arthroplasty, we adopted a similar fixation strategy in a series of revision TKAs where femoral bone stock was severely compromised and conventional stem fixation strategies had failed. This report focuses on the technique, outcomes, and application of TMFT stems as the possible future of fixation in revision TKA.

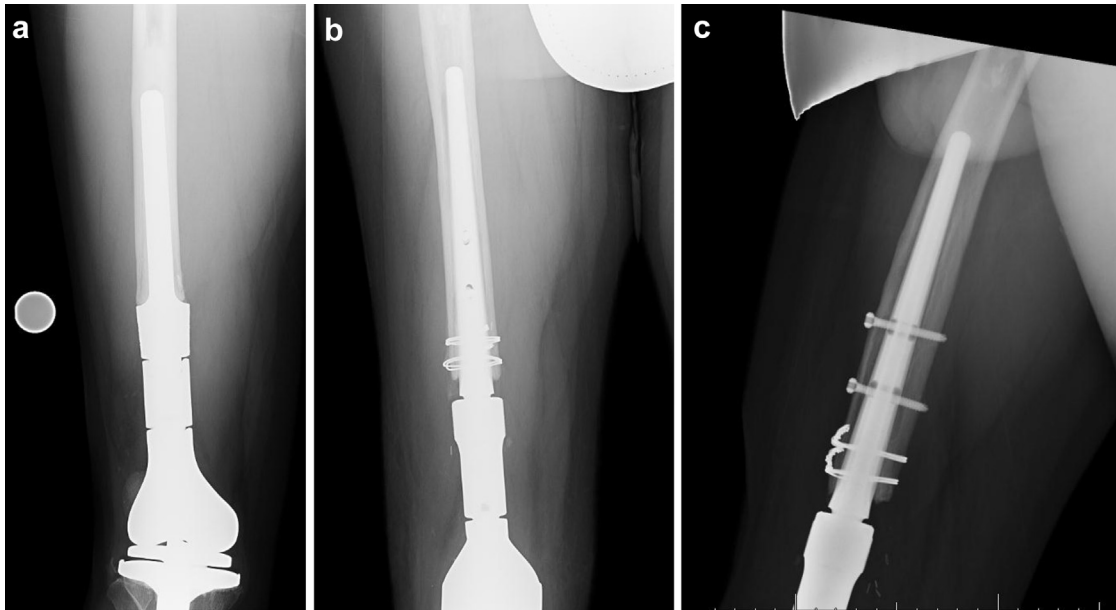
## Case histories

We retrospectively identified 3 cases in which a custom TMFT stem design was utilized in revision TKA by the senior author (T. K. F.) between 2012 and 2015. Each patient provided informed consent to be included in this case report. All 3 subjects are at least

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to <http://dx.doi.org/10.1016/j.artd.2017.03.006>.

<sup>\*</sup> Corresponding author. 2001 Vail Ave, Suite 200a, Charlotte, NC 28207, USA. Tel.: +1 704 323 3834.

E-mail address: [jeffrey.stambough@gmail.com](mailto:jeffrey.stambough@gmail.com)



**Figure 1.** (a) Distal femur replacement with pre-existing cemented modular femoral endoprosthesis before explantation for infection. (b) Anteroposterior radiograph of custom Zimmer Biomet OSS fluted modular stem with 2 proximal locking screws. (c) Lateral radiograph of custom Zimmer Biomet OSS implant with fluted modular stem and 2 anterior-to-posterior femoral interlocking screws to backup axial support.

1 year out from surgery and none have required a return to the operating room or surgical complication.

#### Case 1

A 37-year-old male who underwent a right distal femoral replacement for osteosarcoma over 10 years ago was referred to the senior author (T. K. F.) for management of an acute hematogenous infection (Fig. 1a). He initially underwent irrigation and debridement with modular component exchange but subsequently required explantation with placement of a static antibiotic spacer. After appropriate antibiotic treatment, he underwent reimplantation. For the revision, given the patient's age, functional status, and sclerotic femoral diaphysis, the decision was made to proceed with a custom TMFT stem (Zimmer Biomet Inc., Warsaw, IN) linked to hinge components from their Orthopaedic Salvage System line. A preoperative computed tomography scan of the femur was obtained to accurately size the stem diameter and length ahead of time and sent to the manufacturer for assembly. For the surgery itself, a standard extensive revision knee exposure was utilized and pre-existing implants were meticulously removed and the remaining bone stock surveyed. Prophylactic wires were placed at the distal 3 cm of intact diaphysis of the distal femur prior to reaming to prevent propagation of nondisplaced cracks (Fig. 1b and c).

As in the revision hip setting, reaming the canal by hand or power until solid engagement of the reamer inside the bone is achieved is absolutely necessary to ensure proper sizing and to prevent subsidence of the final implant. We also advise inspecting the reamer to gain feedback on how much bone is being removed. For this custom design, interlocking screws were utilized for additional axial and rotational stability. As with any distal femoral replacement, we took great care to provide adequate external rotation of the stem to ensure proper patellar tracking. This was done at the onset of stem implantation as the flutes engage the endosteal cortical bone preventing late adjustments. On the tibial side, there was sufficient cancellous bone available to allow the use of a cemented stem along with metaphyseal cone fixation. At a

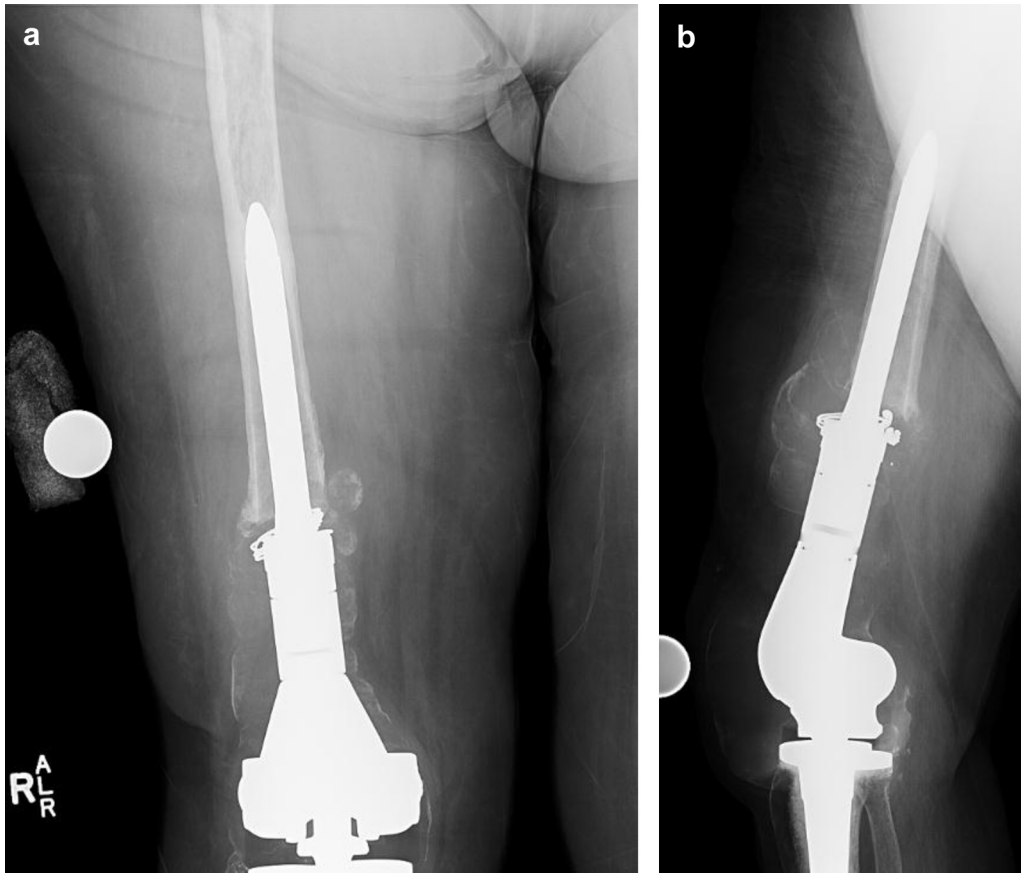
follow-up of 27 months, the patient remains active with radiographic evidence of osseointegration of his custom implant.

#### Case 2

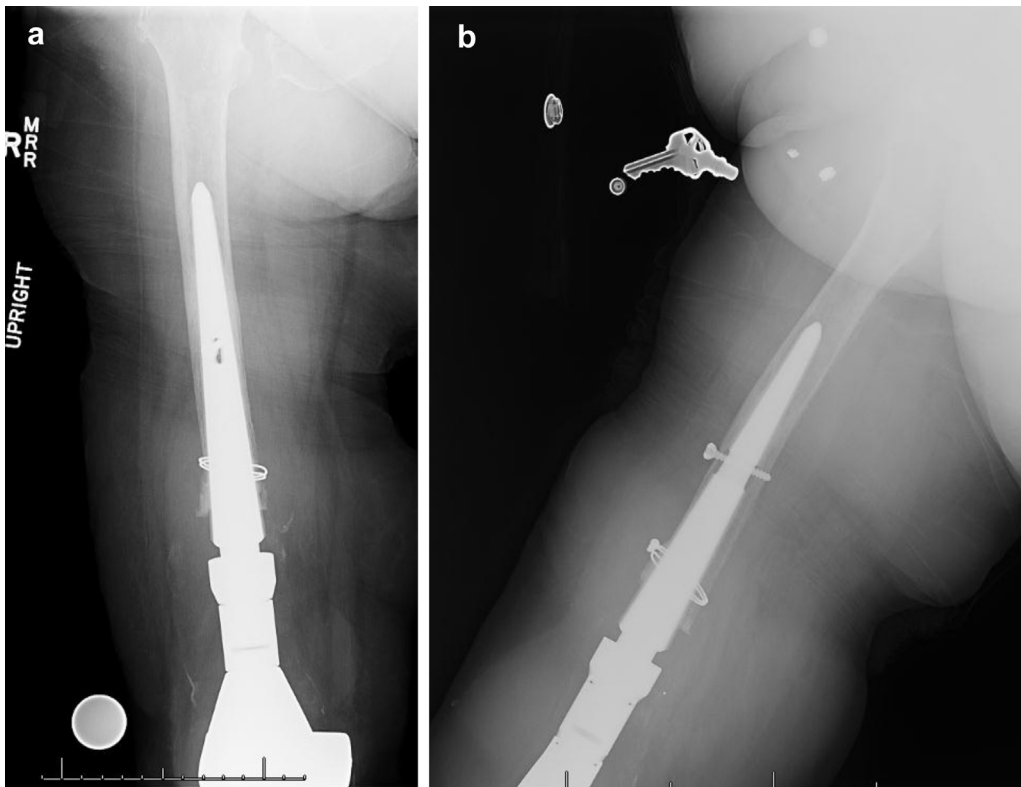
A 65-year-old female presented to the senior surgeon (T. K. F.) with a supracondylar femoral periprosthetic nonunion after attempted intramedullary fixation. Initially, she underwent distal femoral replacement with a cylindrical porous stem, which subsequently loosened over the course of 2 years (Fig. 2a and b). Because the remaining diaphyseal bone was sclerotic without an apparent cancellous bed to accept a cemented stem and a cementless porous stem had previously failed, the decision was made to utilize a custom TMFT stem (DePuy Synthes, Warsaw, IN) with an accompanying set of custom reamers. The stem diameter and length had to be templated and accurately sized ahead of time for fabrication with a preoperative CT scan. At the time of revision surgery, a cerclage wire was placed prophylactically during canal preparation to prevent fracture propagation of her already thin cortex. Once inserted, the female taper of the distal femoral component (Limb Preservation System [LPS]; DePuy Synthes) was impacted onto the custom male Morse taper fabricated specifically to mate with that LPS component. Final fixation of this implant called for one proximal interlocking screw to confer additional axial support. The postoperative protocol included touchdown weight bearing for approximately 6 weeks to allow for osseointegration and decrease the chance of stem subsidence. At a follow-up of 30 months, the patient walks without pain, and has stable fixation on serial radiographs (Fig. 3a and b).

#### Case 3

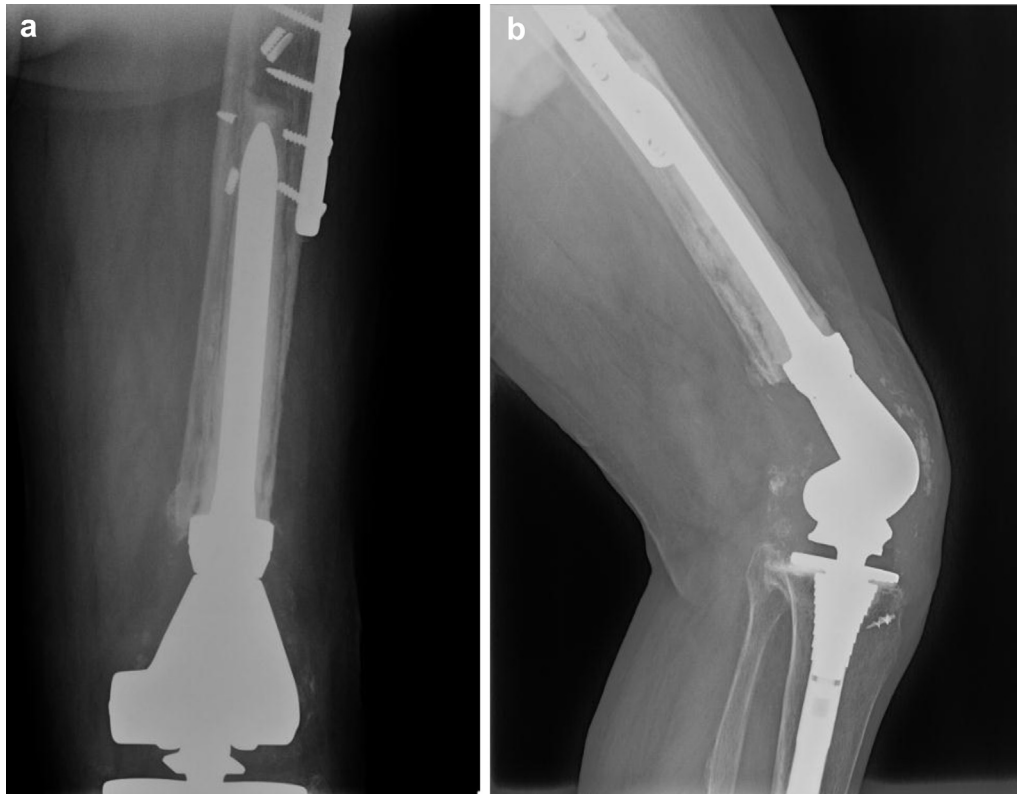
A 72-year-old patient was referred to the senior author (T. K. F.) with a failed distal, femoral, allograft prosthetic composite stem. This patient had a total of 32 previous surgeries in his left lower extremity, including at least 4 TKA revisions for recurrent aseptic femoral loosening. Initially, the failed allograft prosthetic composite was revised to a cemented hinge prosthesis, which subsequently



**Figure 2.** Anteroposterior (a) and lateral (b) radiographs demonstrating femoral loosening of a cementless distal femur replacement with osteolysis at the bone-prosthesis interface.



**Figure 3.** Anteroposterior (a) and lateral (b) radiograph of a custom DePuy fluted modular stem linked to Limb Preservation System femoral hinge at >2-year follow-up.



**Figure 4.** Anteroposterior (a) and lateral (b) radiograph of a revision distal femoral hinge prosthesis with lucencies surrounding the bone-cement interface of the femoral stem with a dynamic hip screw construct proximally.

failed within 18 months (Fig. 4). Other prior surgeries included patellectomy, a dynamic hip compression screw for an ipsilateral intertrochanteric fracture, and multiple periprosthetic fracture fixation plate constructs. The patient's operative extremity was 1.5 inches short secondary to bone loss from the multiple revision arthroplasty procedures (Fig. 5). Because of the compromised nature of the remaining femoral bone after meticulous cement removal, salvage options included a total femur replacement vs a TMFT stem reconstruction. After checking with the designing engineers, the patient was contraindicated from using the Compress spindle hinge prosthesis (Biomet Inc.) due to having <2.5 mm of cortical bone in the femoral diaphysis supportive for the minimum 400 pounds of compressive force required to stabilize the implant.

Rather than utilizing a single custom implant with the inherent risk of fracture if too big or lack of stable fixation if too small, a custom modular coupler was suggested by the other author (J. B. M.). This would afford the use of conventional reamers for canal preparation and implantation of a TMFT revision hip stem (Reclaim; DePuy Synthes) for femoral fixation. The custom coupler utilizing the Morse taper on the Reclaim TMFT stem could then link to an articulating hinge knee component (LPS; DePuy Synthes) (Fig. 6). Utilization of the custom adapter provided intraoperative versatility to choose from a greater number of stem diameters than one could necessarily plan for given the uncertainty of bone quality and the final site of conical wedge fixation after cement removal and canal preparation. Interestingly at the time of surgery, the final Reclaim stem chosen was 3 mm larger than the proposed custom stem that would have been fabricated from the CT data had a custom coupler not been used.

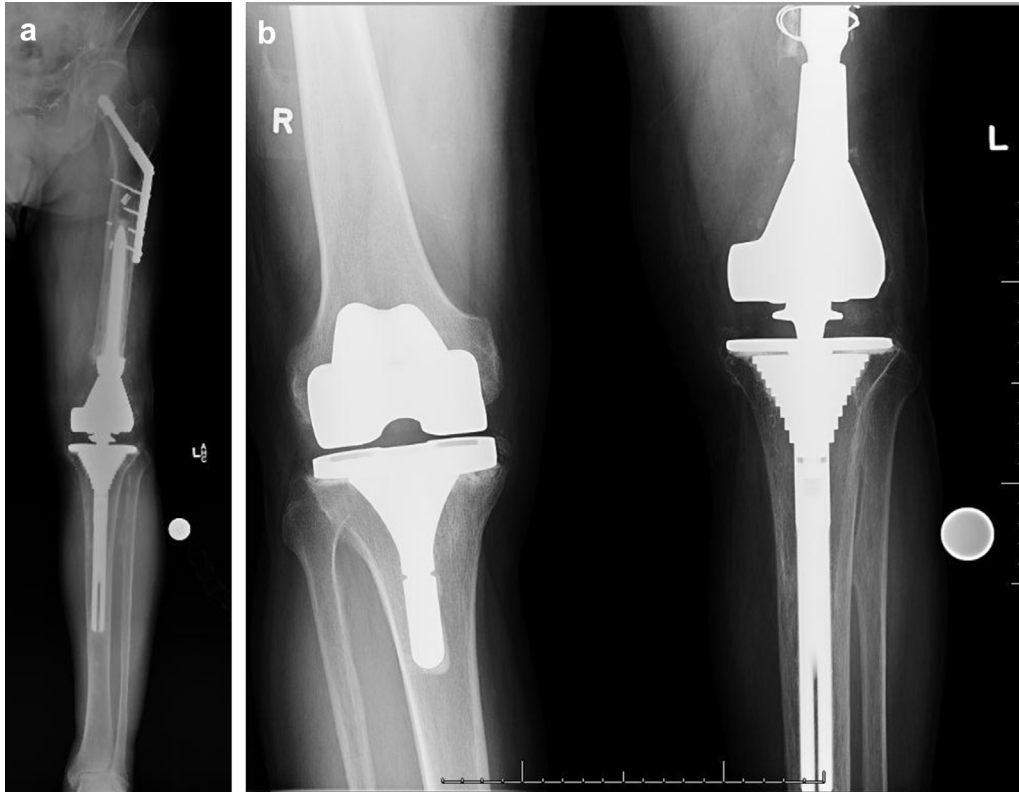
The patient is now 13 months out from surgery and is clinically doing well. He is walking without thigh pain and his radiographs

demonstrate spot welding proximally and laterally along the stem, indicating osseointegration (Fig. 7).

## Discussion

Absolute stem length is not the most important factor dictating component fixation; rather, it is the area of stem and bone engagement surface that dictates fixation stability [12]. Recently, the concept of “zonal fixation” was introduced by Haddad et al, where they divided the femur and tibia into 3 regions where surgeons can look to affix revision total knee constructs [13]. They classified the joint surface bone as zone 1, the metaphysis as zone 2, and the diaphysis as zone 3. Although the use of cones and sleeves has helped to address fixation in the setting of deficient metaphyseal bone (zone 2), a better solution to metadiaphyseal bone loss is needed. We believe that TMFT stems may be the tool required to address issues of stability that have plagued current cemented and cementless stem designs in revision TKA with compromised host bone.

Cement technique is significantly compromised without sufficient cancellous bone for interdigitation. When only a hollow, sclerotic tube is present, poor outcomes and rapid failure can be expected, even with the most meticulous cement technique. Although recent literature demonstrates superiority for cementless diaphyseal stems compared to cemented stems [14], current slotted cementless revision knee stems on the market lack the ability for bone ingrowth. Cylindrical porous revision stems are infrequently used because they lack sufficient rotational control when linked to constrained femoral components. A Compress (Biomet Inc.) rotating hinge prosthesis has reported 80% survivorship at 10-year average follow-up in patients with >2.5-mm cortical thickness at



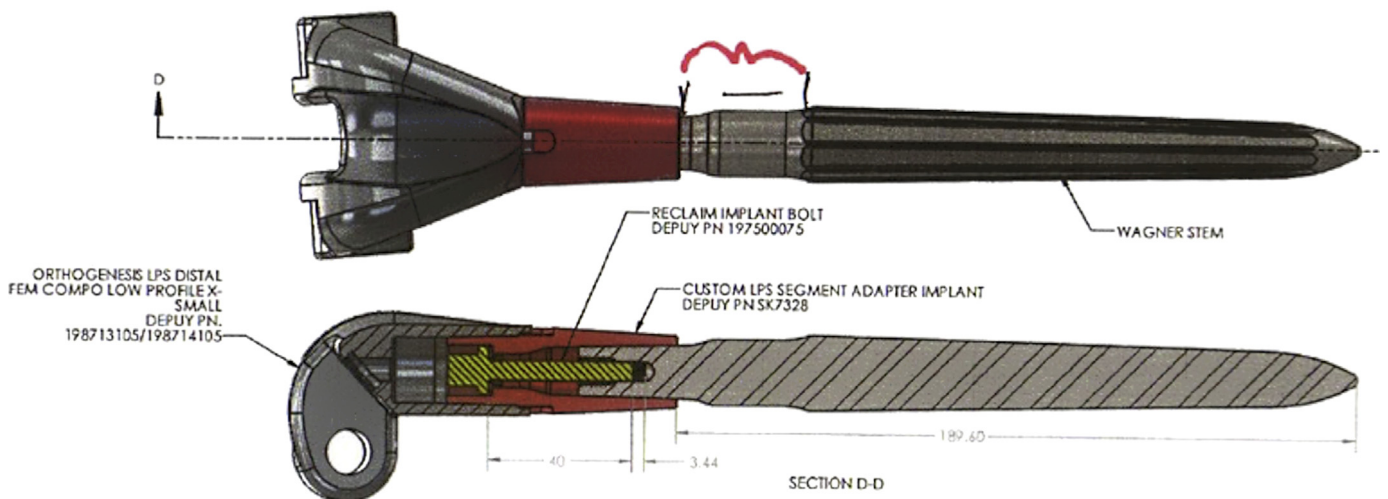
**Figure 5.** Standing hip-knee-ankle scanogram (a) and standing bilateral knee radiograph (b) demonstrating the 1.5-inch leg-leg length discrepancy after cemented revision hinge total knee arthroplasty with a healed intertrochanteric fracture and dynamic hip screw construct about the hip. The calibrated marker has a standard 25-mm diameter.

the proposed implant-femur shaft interface [15]. However, in the cases presented above, the diminished cortical thickness in these revised femurs precluded its use. A review of contemporary distal femoral implants, fixation strategies, and outcomes is summarized in Table 1.

Because TMFT stems are not currently available with current revision knee systems, custom stems must be manufactured. Before the actual surgery, legal and compassionate use clearances must be obtained from the patient, the hospital institutional review board, implant manufacturer, and ultimately the US Federal Drug

Administration (FDA). This process can take over a year to complete, as it did for the patient in Case 2.

Mihalko [21] recently examined the FDA custom device exemption (CDE) and compassionate use policies, with special emphasis on what adult reconstructive surgeons need to know to successfully navigate this daunting process. First, the surgeon must find a company with which to collaborate and agree on a surveillance and reporting schedule for at least 2 years and include this as part of the application. It is the device manufacturer who submits the proposal to the FDA as part of their annual report, and then the



**Figure 6.** Custom adapter design to mate a hinged knee femoral prosthesis to the TMFT stem using the normal locking bolt used to lock the proximal body of a revision hip arthroplasty implant to the TMFT stem.



**Figure 7.** One-year postoperative anteroposterior and lateral radiograph of proximal taper fixation demonstrating spot welding and stable osseointegration of the tapered modular fluted stem without a supplemental derotational screw.

FDA evaluates their recommendation if the surgeon's proposal actually meets CDE standards. To qualify as a CDE, the device must meet 5 criteria: (1) it must be requested by an individual physician; (2) not be otherwise commercially available; (3) devised to treat unique pathology that no other on-market device can do; (4) assembled on a case-by-case basis; and (5) intended to treat a

sufficiently rare condition that normal clinical regulatory and approval pathways would prove impractical. If all 5 of these requirements are not met, a surgeon can consider filing a compassionate use request through the implant manufacturer in which expedited and timely approvals can be achieved for patients with “unique and unusual” problems. As with CDEs, a monitoring plan and follow-up report must be provided to the FDA.

The design of custom tapered fluted stems requires great time and coordination. After partnering with a willing implant manufacturer, work on a prototype implant requires preoperative fine-cut CT scans and three-dimensional reconstructive models to map that patient's unique femoral morphology. Collaboration between the surgeon and engineer is vital to advance the stem specifications and improve upon iterative designs. Through a cooperative effort, the first iteration of our TMFT design came with a cross-lock screw, similar to an intramedullary nail, to provide backup rotational stability. A unique consideration when using a custom stem is that the manufacturer usually only provides one reamer based on a preoperative three-dimensional template. Therefore, an alternative option to address excessive femoral bone loss in a multiply revised total knee include utilizing a modular adapter to link a pre-existing tapered modular fluted hip stem to a hinge or distal femoral endoprosthesis. Our third TMFT stem construct design utilized pre-existing instruments to prepare the femoral host bone. This method affords an economic savings by cutting down on additional trays and intraoperative flexibility to change stem diameters (and length, depending on implant manufacturer options) if the fit of the splined reamers differs significantly from the templated size.

Custom components are not unique to revision TKA. Gross and Liu [22] described their series of 28 revisions in which they utilized custom-made fully porous cylindrical cobalt-chrome stems mated to revision cemented femoral articular components, 12 of which were indicated for femoral loosening. These components employed a tapered Morse cone junction to affix the stem to the revision implant. They reported an overall 96% survivorship rate at 4-year follow-up with the lone failure occurring in a patient with a zone 2 deficiency and lack of endosteal fit with the custom porous stem. One obvious disadvantage with any customization strategy is that the stem has to be sized preoperatively. Therefore, if intraoperative sizing varies slightly, construct stability is sacrificed.

Typically, press-fit revision knee stems are composed of titanium alloy with slots and have a distal bullet tip to help offload endosteal stress concentrations and reduce end-of-stem pain. However, this type of cylindrical, slotted stem design lacks the ability to provide a wedge fit for rotational control that a TMFT stem would afford. Consensus is lacking regarding the optimal stem

**Table 1**

Literature review of modern results of distal femoral revisions.

Study	Method and type of reconstruction	Type of stem, zone of fixation	Number of stems	Follow-up in years, mean (range)	Aseptic loosening	Comments
Schwartz et al [16]	Cemented, megaprosthesis	Straight, diaphyseal	186	8 (0-28)	11.8%	Modular components (93.7%) improved survivorship vs custom implants (51.7%). High rate of aseptic stem loosening in young population
Pala et al [17]	Uncemented, megaprosthesis	Straight-fluted, HA-coated diaphyseal	187	4 (2-8)	5.6%	Mean patient age 32 y. All-cause failure was 29.1%
Capanna et al [18]	Mixed, megaprosthesis	Straight-fluted, diaphyseal	87	5.5 (2-12)	3.0%	8% prosthesis breakage
Hu et al [19]	Cemented, megaprosthesis	Straight, diaphyseal	43	7.4 (2-14)	11.6%	Equivalent reaming technique performed for both types of fixation. Six implant failures occurred in cemented group
	Uncemented, megaprosthesis	Straight, porous-coated diaphyseal	39		0.0%	
Healey et al [15]	Uncemented, compress megaprosthesis	Straight, compress, diaphyseal	82	4 (1-11)	15.8%	Contraindicated if remaining cortical bone at implant interface <2.5 mm
Cottino et al [20]	Mixed, megaprosthesis	Straight, diaphyseal	334	4 (2-12)	4.5% at 10 y	Patient <65 y with distal femoral hinge revision had 5.7 increased risk of aseptic failure

length and diameter to achieve press-fit femoral fixation, but a recent study by Gililland et al found that for a press-fit stem, the minimal stem length chosen should be one that achieves 4 cm of diaphyseal fit [23]. The conical taper of a TMFT stem allows for at least 4 cm of scratch fit for axial stability while providing superior rotational control with splines [24].

Currently, only one company (Waldemar LINK, Hamburg, Germany) has a cementless TMFT stem specifically for knee arthroplasty that was released in the United States in 2016. Their particular design utilizes femoral and tibial stems with a 2° conical taper, 12 derotational splines, and a porous ongrowth surface of ~160 microns similar to their cementless MP hip reconstruction prosthesis [25]. However, this construct's primary limitation is that it only offers one polyethylene bearing size to combine with its rotating hinge mechanism. One can easily imagine a scenario in which there is mismatch between the conical taper wedge in the femur and the distal femoral joint line, thus creating downstream problems with stability.

Current restrictions set forth in the FDA Safety & Innovation Act of 2012 limit CDEs to 5 instances per manufacturing company per year [21]. We believe revision knee manufacturers should consider adding TMFT stem options to their revision knee portfolios. This design allows surgeons to optimize diaphyseal stability and bone preservation, while also linking an existing technology used successfully in revision hip arthroplasty. By merely developing a modular coupler system to link TMFT stems to revision femoral articulating components, existing stems and reamers now available for hip revisions would be utilized for revision knee surgeries. This strategy minimizes implant equipment and inventory, thus decreasing cost and helping to streamline intraoperative workflow. Furthermore, this solution would eliminate the uncertainty of proper fit when singular custom stems are utilized. Intraoperative flexibility is critical in revision surgery where a range of diameters is necessary to cover the potential size variation during implant extraction and subsequent canal preparation. We strongly advocate the advancement of TMFT stem technology for revision TKAs given these conceptual reasons and the anecdotal success reported here.

## Summary

TMFT stems hold great promise to achieve stable fixation in revision knee arthroplasty where host metadiaphyseal bone is deficient. We urge implant manufacturers to dedicate future resources to create couplers that link existing successful modular fluted stems currently used in hip arthroplasty to revision total knee components when host bone is severely compromised.

## References

- [1] Kurtz SM, Lau E, Ong K, et al. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. *Clin Orthop Relat Res* 2009;467:2606.

- [2] Aggarwal VK, Goyal N, Deirmengian G, et al. Revision total knee arthroplasty in the young patient: is there trouble on the horizon? *J Bone Joint Surg Am* 2014;96:536.
- [3] Fehring TK, Odum S, Olekson C, et al. Stem fixation in revision total knee arthroplasty: a comparative analysis. *Clin Orthop Relat Res* 2003;217.
- [4] Kosse NM, van Hellemond GG, Wymenga AB, et al. Comparable stability of cemented vs press-fit placed stems in revision total knee arthroplasty with mild to moderate bone loss: 6.5-year results from a randomized controlled trial with radiostereometric analysis. *J Arthroplasty* 2017;32:197.
- [5] Heesterbeek PJC, Wymenga AB, van Hellemond GG. No difference in implant micromotion between hybrid fixation and fully cemented revision total knee arthroplasty: a randomized controlled trial with radiostereometric analysis of patients with mild-to-moderate bone loss. *J Bone Joint Surg Am* 2016;98:1359.
- [6] Revision Total Hip Arthroplasty Study Group. A comparison of modular tapered versus modular cylindrical stems for complex femoral revisions. *J Arthroplasty* 2013;28:71.
- [7] Munro JT, Garbus DS, Masri BA, et al. Role and results of tapered fluted modular titanium stems in revision total hip arthroplasty. *Bone Joint J* 2012;94-B:58.
- [8] Richards CJ, Duncan CP, Masri BA, et al. Femoral revision hip arthroplasty: a comparison of two stem designs. *Clin Orthop Relat Res* 2010;468:491.
- [9] Regis D, Sandri A, Bonetti I, et al. Femoral revision with the Wagner tapered stem: a ten- to 15-year follow-up study. *J Bone Joint Surg Br* 2011;93:1320.
- [10] Gutiérrez Del Alamo J, García-Cimbreló E, Castellanos V, et al. Radiographic bone regeneration and clinical outcome with the Wagner SL revision stem: a 5-year to 12-year follow-up study. *J Arthroplasty* 2007;22:515.
- [11] Böhm P, Bischel O. The use of tapered stems for femoral revision surgery. *Clin Orthop Relat Res* 2004;148.
- [12] Patel AR, Barlow B, Ranawat AS. Stem length in revision total knee arthroplasty. *Curr Rev Musculoskelet Med* 2015;8:407.
- [13] Morgan-Jones R, Oussedik SIS, Graichen H, et al. Zonal fixation in revision total knee arthroplasty. *Bone Joint J* 2015;97-B:147.
- [14] Edwards PK, Fehring TK, Hamilton WG, et al. Are cementless stems more durable than cemented stems in two-stage revisions of infected total knee arthroplasties? *Clin Orthop Relat Res* 2014;472:206.
- [15] Healey JH, Morris CD, Athanasian EA, et al. Compress knee arthroplasty has 80% 10-year survivorship and novel forms of bone failure. *Clin Orthop Relat Res* 2013;471:774.
- [16] Schwartz AJ, Kabo JM, Eilber FC, et al. Cemented distal femoral endoprostheses for musculoskeletal tumor: improved survival of modular versus custom implants. *Clin Orthop Relat Res* 2010;468:2198.
- [17] Pala E, Trovarelli G, Calabrò T, et al. Survival of modern knee tumor megaprotheses: failures, functional results, and a comparative statistical analysis. *Clin Orthop Relat Res* 2015;473:891.
- [18] Capanna R, Scocciati G, Frenos F, et al. What was the survival of megaprotheses in lower limb reconstructions after tumor resections? *Clin Orthop Relat Res* 2015;473:820.
- [19] Hu CC, Chen SY, Chen CC, et al. Superior survivorship of cementless vs cemented diaphyseal fixed modular rotating-hinged knee megaprosthesis at 7 years' follow-up. *J Arthroplasty* 2017 Jun;32(6):1940–5. <http://dx.doi.org/10.1016/j.arth.2016.12.026>. Epub 2016 Dec 22.
- [20] Cottino U, Abdel MP, Perry KI, et al. Long-term results after total knee arthroplasty with contemporary rotating-hinge prostheses. *J Bone Joint Surg Am* 2017;99:324.
- [21] Mihalko WM. How do I get what I need? Navigating the FDA's custom, compassionate use, and HDE pathways for medical devices and implants. *J Arthroplasty* 2015;30:919.
- [22] Gross TP, Liu F. Total knee arthroplasty with fully porous-coated stems for the treatment of large bone defects. *J Arthroplasty* 2013;28:598.
- [23] Gililland JM, Gaffney CJ, Odum SM, et al. Clinical & radiographic outcomes of cemented vs. diaphyseal engaging cementless stems in aseptic revision TKA. *J Arthroplasty* 2014;29:224.
- [24] Kirk KL, Potter BK, Lehman RA, et al. Effect of distal stem geometry on interface motion in uncemented revision total hip prostheses. *Am J Orthop (Belle Mead NJ)* 2007;36:545.
- [25] MP Reconstruction prosthesis - LINK <https://www.linkorthopaedics.com/us-for-the-physician/products/knie/revision/endo-model-m-modular-knee/?Modular=>.