Uncemented Fixation

Trabecular Metal Tibia
NexGen® Trabecular Metal™ Tibia

- High Porosity (80%)³ for optimal bone ingrowth
- 0.98 coefficient of friction² against bone to reduce micromotion and increase ingrowth
- 3D structure similar to that of bone

Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years—measured with radiostereometric analysis

David A J Wilson¹, Glen Richardson², Allan W Hennigar², and Michael J Dunbar¹,²

- 70 patients with severe osteoarthritis were randomised to receive either a Trabecular Metal Nexgen LPS monoblock tibial component or a cemented Nexgen Option stemmed tibial component
- The tibias were combined with cemented femoral components and cemented patellas
- RSA examination post-op and at 6 months, 1, 2, and 5 years
- 45 patients were available for analysis at 5 years (27 in Trabecular Metal and 18 in cemented groups)
- Trabecular Metal components showed a significantly larger subsidence than the cemented components (P=0.001)
- Total “at risk” components at 5 years, represented by Maximum Total Point Motion (MTPM), was 2 of 18 in the cemented group and zero of 27 in the Trabecular Metal group (P= 0.2)

Conclusion: The study suggests that Trabecular Metal components can achieve long-term stability despite high initial migration seen in some cases. Referring to the Trabecular Metal components, the authors “report stability of this implant up to 5 years in all cases”
Prospective Results of Uncemented Tantalum Monoblock Tibia in Total Knee Arthroplasty
Minimum 5-Year Follow-up in Patients Younger Than 55 Years

Atul F. Kamath, MD, * Gwo-Chin Lee, MD, *† Neil P. Sheth, MD, †
Charles L. Nelson, MD, § Jonathan P. Garino, MD, *† and Craig L. Israelite, MD*†

- 100 consecutive patients with Trabecular Metal monoblock uncemented tibial components (combined with uncemented NexGen LPS femurs and cemented all-polyethylene patellas) were compared to a group of 312 concurrent cemented controls.
- 97% survivorship at 5 years
- 3 revisions un-related to implant fixation
  (1*arthrofibrosis, 1*instability & 1*peri-prosthetic fracture)
- No progressive radiographic lucencies
- No osteolysis noted & no change in component position over time
- Significant decrease in operating time (tourniquet time) in uncemented group compared to the cemented group (12 minutes saved: $P < 0.01$)

“The use of a porous tantalum tibia at minimum 5 years has yielded promising clinical and radiographic results in a younger patient population.”
Total Knee Arthroplasty with an Uncemented Trabecular Metal Tibial Component: A Registry-Based Analysis

Mika Niemeläinen, MD, Eerik T. Skyttä, MD, PhD, Ville Remes, MD, PhD, Keijo Mäkelä, MD, PhD, Antti Eskelinen, MD, PhD

- Study of the NexGen uncemented Trabecular Metal monoblock tibial component based on the Finnish Arthroplasty Register
- 1,143 uncemented Trabecular Metal tibial components were implanted between January 1st 2003 and December 31st 2010

- The femoral components were either cemented (48%) or uncemented (52%) – The patellas were either left unresurfaced (85%) or resurfaced with a cemented button (15%)
- Mean age of the study population was 63.6 years

Conclusion: Survivorship at 1, 5, and 7 years post-op was 100% with revision for aseptic loosening as the end-point
A retrospective review was performed of patients undergoing primary cementless total knee replacement (TKR) using porous tantalum performed by a group of surgical trainees. Clinical and radiological follow-up involved 79 females and 26 males encompassing 115 knees. The mean age was 66.9 years (36 to 85). Mean follow-up was 7 years (2 to 11). Tibial and patellar components were porous tantalum monoblock implants, and femoral components were posterior stabilised (PS) in design with cobalt-chromium fibre mesh. Radiological assessments were made for implant positioning, alignment, radiolucencies, lysis, and loosening. There was 95.7% survival of implants. There was no radiological evidence of loosening and no osteolysis found. No revisions were performed for aseptic loosening. Average tibial component alignment was 1.4° of varus (4° of valgus to 9° varus), and 6.2° (3° anterior to 15° posterior) of posterior slope. Mean femoral component

- Retrospective review of 115 knees (105 patients) received porous monoblock implants by surgical trainees.
- Femoral implants was fibermesh PS.
- Mean age 66.9 years (36-85).
- Average BMI 32.5.
- Four patients were revised for infection (3.5%) and one for femoral mismatch.

- 18 minute reduction in OR time.
- Overall survival 97.5% at mean followup of 7 years (2 to 11).
- No revision was performed for aseptic loosening.
Midterm Results of a Porous Tantalum Monoblock Tibia Component

Clinical and Radiographic Results of 108 Knees

Anthony S. Unger, MD, and John P. Duggan, MD

- 108 consecutive *NexGen* CR-Flex fiber metal femurs with CR *Trabecular Metal* Monoblock tibias
- The patella was resurfaced in all cases (TM monoblock: n=90; all polyethylene: n=18)
- No patients were lost to follow-up
- Mean follow-up: 4.5 years (range: 2.9 – 6.7 years)
- Mean post-op knee flexion was 138° (range: 133° – 147°)
- No tibial revisions and no progressive radiographic lucencies

- Mean post-op Knee Society Knee score: 88
- Mean post-op Knee Society Function score: 85
- 105 knees/more than 97% of patients had good or excellent Knee Society scores

“Midterm clinical and radiographic results of 108 consecutive *Trabecular Metal tibia components have a high rate of success”
22,691 PATIENTS

National Joint Registry for England and Wales

Patients implanted with the NexGen System* show the largest improvements in both OKS and EQ-5D when compared to all other knee implants (p < 0.001) listed.
PATIENT SATISFACTION: Study of 22,691 NJR-PROMs records

Summary

- Patient-reported outcome measures (PROMs) assess the effectiveness of care from the patients’ perspective using the Oxford Knee Score (OKS), and the EuroQol-5D (EQ-5D), which is a validated measure of general health outcomes.
- This study analysed 22,691 NJR-PROMS records.
- The authors concluded that the large sample allowed the identification of significant between-implant differences in outcome that have not been recognised by smaller studies.
- The greatest improvement in OKS reported for a competitor knee was 15.4 (PFC). This was lower than the smallest improvement in OKS (15.9) reported for the NexGen knee.
- *NexGen* showed the largest improvements in both OKS and EQ-5D when compared with all other implant types (*p* < 0.001).
- This paper refers to *NexGen* as the “reference” knee for PROMs.
- Of the variables examined, the choice of implant brand was the only surgical factor within a given hospital’s control, that could positively influence their PROMs improvements.

Effects of each variable on the predicted improvement in PROMs are additive, meaning that the effects of implant brand are the same irrespective of changes in the other variables.
The NexGen CR/NexGen has the lowest 10 year cumulative percent revision of all combinations with 10 year follow up regardless of fixation (3.2%, 2.9% and 2.7% respectively)"

Overlevelse efter 7 år på 97,2%

Antal patienter: 6.586

https://aoanjrr.dmac.adelaide.edu.au/annual-reports-2014
NexGen TM (Ucementeret) har den laveste revisions risiko med en (relative risiko ratio på 0,53) 95% CI (0,29-0,97)

Antal patienter: 751
Each product submitted is given a rating:
- Number to represent the time period (FUP)
- Letter to represent the evidence level
  - e.g. 10A: strong evidence @ 10 years (90% survival)
  - Newly 10A* (95% survival)
NEXGEN & ODEP RATING

ODEP Actual Status – Zimmer KNEE

10A*:
- NexGen LPS cemented fixed bearing standard Poly with patella
- NexGen LPS cemented fixed bearing standard Poly w/o patella

7A*:
- NexGen LPS Flex cemented fixed bearing standard Poly w/o patella
- NexGen LPS uncemented TM monoblock fixed bearing standard Poly w/o patella
- NexGen CR cemented fixed bearing standard Poly with patella
- NexGen CR cemented fixed bearing standard Poly w/o patella
- NexGen CR Flex cemented fixed bearing standard Poly w/o patella
- NexGen CR uncemented TM fixed bearing standard Poly w/o patella
In summary

• Revision rate at 7 Years 100% endpoint aseptic loosening. 95,7% Revision all causes.

• 5 years RSA with non “RISK” patients in the TM group vs. 2 in the cemented “Golden std. Group.

• ODEP rating 7A.

• Significant improvement in patient satisfaction.

• Significant decrease in operating time uncemented vs. Cemented.

Elimination of:

• PMMA
  – An interface for potential failure.
  – Monomer induced hypotension.
  – Thermal necrosis of bone.
  – Third body wear from retained cement debris.
  – Cement preparation.
  – Pulse lavage.
Preliminary Results of an Uncemented Trabecular Metal Tibial Component in Total Knee Arthroplasty

Anthony T. Helm, FRCS (Tr+ Orth), Cronan Kerin, MRCS, Simon R.A. Ghalayini, MRCS, and George J. McLauchlan, FRCS (Tr+Orth)

- Reports the results of a prospective cohort of 105 consecutive primary total knee arthroplasties using an uncemented Trabecular Metal monoblock tibial component. A cruciate retaining approach was used and the patella was not resurfaced routinely.
- At minimum 3-year follow-up (range, 36-56 months), 89 knees were left for analysis.
- There was a significant improvement in Oxford Knee scores and Short Form-12 scores postoperatively.
- No radiolucencies at the implant-bone interface on any postoperative radiograph were observed.
- There was one (1%) revision of the tibial component for trauma.

“The 3-year results using this prosthesis are as good as those published for the commonly used cemented prostheses.”
Minimum 6 year results of an uncemented trabecular metal tibial component in total knee arthroplasty

S.R.A. Ghalayini, A.T. Helm, G.J. McLauchlan *

Lancashire Teaching Hospitals, UK

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- Reports on a series of 109 consecutive unselected primary NexGen CR TKR followed for minimum of 6 years (mean 6.7 years)
- The same prospective cohort was reported on at 3 years in the JOA by Helm et al (2009)
- 76 of the 109 knees were available for analysis at 6 years
- No revisions (one knee, which was revised at 27 months for unexplained pain following a fall, was reported in the 3 year results)
- No radiographic signs of prosthetic loosening were observed in any of the 66 knees that were x-rayed at the 6 year review
- A small but non-significant decline in physical function, indicated by a decrease in SF-12 and KSS Clinical & Function scores, was observed between the 3 and 6 year follow-up
- As there were no changes in the pain scores for this population, whose average age at follow-up was nearly 78, these changes were attributed to be age-related rather than specifically related to the prosthesis
Simultaneous cemented and cementless total knee replacement in the same patients

A PROSPECTIVE COMPARISON OF LONG-TERM OUTCOMES USING AN IDENTICAL DESIGN OF NEXGEN PROSTHESIS

- Sequential simultaneous bilateral knee replacements. 50 patients/100 knees
- Cemented NexGen CR prosthesis in one knee and a cementless NexGen CR prosthesis in the other
- Mean follow-up 13.6 years (13 to 14 years)
- Post-op patient satisfaction with the cemented knee was 8.1/10 VAS (SD 1.9), compared to 8.3/10 VAS (SD 1.7) with the cementless knee
- Post-op range of movement in the cemented group was 124° (100 to 140°) compared to 128° (110 to 140°) in the cementless group
- Kaplan-Meier survivorship analysis revealed that the rate of survival of the femoral components in both groups was 100% at 14 years
- The survivorship of the cemented tibia was also 100% at 14 years, while following the revision of one cementless tibial component due to aseptic loosening post-op year one, survivorship of the cementless tibia was 98%
- No osteolysis was identified in either group
Minimum 6 year results of an un cemented trabecular metal tibial component in total knee arthroplasty

Reports on a series of 109 consecutive unselected primary NexGen CR TKR followed for minimum of 6 years (mean 6.7 years)

Result:

No revisions (one knee, which was revised at 27 months for unexplained pain following a fall, was reported in the 3 year results) No radiographic signs of prosthetic loosening were observed in any of the 66 knees that were x-rayed at the 6 year review
Total Knee Arthroplasty with an Uncemented Trabecular Metal Tibial Component 
A Registry-Based Analysis

Result:

Previous poor results have kept the appeal of uncemented total knee arthroplasties (TKAs) minimal. We analyzed the mid-term survivorship and reasons for failures of a contemporary uncemented porous tantalum monoblock tibial component nation-wide. During the study period (2003–2010), such tibial components were used in 1143 primary TKAs recorded in the Finnish Arthroplasty Registry.

Seven-year survivorship of these TKAs was 100% (95% CI 99–100) with revision for aseptic loosening of the tibial component, and 97% (95% CI 96–98) with revision for any reason as the respective end points.
Trabecular metal tibia still stable at 5 years
An RSA study of 36 patients aged less than 60 years

22 patients (26 knees) received an uncemented TM cruciate-retaining tibial component and 19 patients (21 knees) a cemented NexGen Option cruciate-retaining tibial component.

Results:

Both groups had most migration within the first 3 months, the TM implants to a greater extent than the cemented implants. After 3 months, both groups stabilized and remained stable up to the 5-year follow-up.
Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years—measured with radiostereometric analysis.

70 patienter med osteoarthritis blev randomiseret til at få enten TM implantat eller den cementerede komponent. RSA undersøgelse blev gjort postoperativt ved 6 måneder, 1 år, 2 år og 5 år.

Resultat:

Andelen af "risiko"-komponenter efter 5 år var 2 af 18 i den cementerede gruppen og 0 af 27 i TM-gruppen (p = 0,2).
Superior fixation of pegged trabecular metal over screw-fixed pegged porous titanium fiber mesh

A randomized clinical RSA study on cementless tibial components

Patienter yngre en 70 år.
Patienter var randomiceret til, 25 TM tibia komponenter og 25 Ti tibial komponenter.
RSA evaluering blev lavet efter uge: 1, 6, 6 mdr, 1 år og 2 år.

Resultat:

Ingen revisioner

Konklusion:

Vi konkluderer, at den mekaniske fastgørelse af TM tibia komponenter er overlegen i forhold til skrue-fikserede Ti tibiale komponenter. Vi forventer langsigtet implantat overlevelse til at være bedre med TM tibia.
Prospective Results of Uncemented Tantalum Monoblock Tibia in Total Knee Arthroplasty

We prospectively studied 100 consecutive tantalum monoblock uncemented tibial components and 312 concurrent cemented controls patients 55 years or younger (range, 37-55 years) control group 312 patients with a mean age of 63 years (range, 48-84 years)

Average follow-up was greater than 5 years for both cohorts (range, 60-83 months).

Result:

There were 3 uncemented group failures at 5 years, but none were due to failure of fixation.
Fixation of a Trabecular Metal Knee Arthroplasty Component
A Prospective Randomized RSA Study

70 patienter var randomizeret til at modtage enten trabecular metal tibia (cementeret) eller cementeret konventionel tibia. RSA analyser blev foretaget efter 6, 12 og 24 mdr.

Followup var komplet for 28 patienter i TMT gruppen og 21 i den cementeret.

Resultat:

Ingen trabecular metal tibia var i risiko for tidlig aseptisk løsning.
A trabecular metal tibial component in total knee replacement in patients younger than 60 years
A TWO-YEAR RADIOSTEREOPHOTOGRAMMETRIC ANALYSIS

26 trabecular metal CR tibia og 21 cementeret modular Tibia (Nexgen Zimmer)

Gennemsnits alder 53.

Resultat:

All the trabecular metal components migrated during the initial three months and then stabilised. The exception was external rotation, which did not stabilise until 12 months.

Unlike conventional metal-backed implants which displayed a tilting migration comprising subsidence and lift-off from the tibial tray, most of the trabecular metal components showed subsidence only, probably due to the elasticity of the implant. This pattern of subsidence is regarded as being beneficial for uncemented fixation.
Preliminary results of an uncemented trabecular metal tibial component in total knee arthroplasty.

Resultaterne af en prospektiv kohorte af 105 på hinanden følgende primære knæ alloplastikker ved hjælp af en ucementeret trabekulær metal (tantalum) tibialkomponent på et minimum 3-års follow-up (interval, 36-56 måneder)

Result:
There was no radiolucency at the implant-bone interface on any postoperative radiograph. There has been one (1%) revision of the tibial component for trauma.
Nexgen CR (Ucementeret) har den laveste revisions risiko på 0.32 (0.25, 0.40) pr. 100 observeret komponent år.

Antal patienter: 3266

Overlevelse efter 11 år 97,2 %.

NexGen CR-flex (Ucementeret) har en revisions risiko på 0.48 (0.36, 0.62) pr. 100 observeret komponent år.

Antal patienter: 3248

Overlevelse efter 5 år på 97,8 %
Cemented versus uncemented fixation of the femoral component of the NexGen CR total knee replacement in patients younger than 60 years: a prospective randomised controlled RSA study.

Resultat:

Omfanget og mønster af migration målt ved RSA var ikke signifikant forskelligt mellem den cementeret og ucementeret gruppe ved 2-års follow-up. Der var heller ingen forskelle mellem grupperne i kliniske parametre. Disse resultater antyder, at en ucementeret femoral komponent kan opføre sig lige så godt som en cementeret en på lang sigt.
Activation of human leukocytes on tantalum trabecular metal in comparison to commonly used orthopedic metal implant materials

Result:

In conclusion our *in vitro* study has shown that preferentially myeloid leukocytes (neutrophils and monocytes) are activated after contact to tantalum trabecular metal material. Their cellular response was characterized by a significantly increased cytokine release compared to the response to other conventionally used solid orthopaedic metal implant materials which are clearly different in structure. This effect is obviously related to the microtopography and microarchitecture of the TM material with a highly porous structure and rough trabecular strut surface. The leukocyte activation on TM material induced a microenvironment, which promotes local host-defence with an increased phagocytosis, chemotaxis and whole blood *S. aureus* killing rate.
Results:

Bacterial adherence of S. aureus varied significantly ($p=0.0035$) with the type of metallic implant. Pure tantalum presented with significantly ($p<0.05$) lower S. aureus adhesion compared to titanium alloy, polished stainless steel, and tantalum-coated stainless steel. Furthermore, pure tantalum had a lower, though not significantly, adhesion than commercially pure titanium and grit-blasted stainless steel.
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