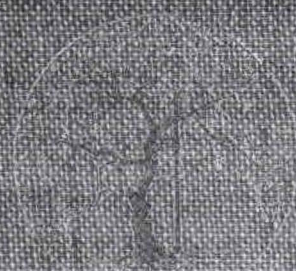


Copyright Clearance Center
222 Rosewood Drive, Danvers, MA 01923
www.copyright.com

81

Unicompartmental Knee Arthroplasty

edited by PH. CARTIER, MD
JA. EPINETTE, MD
G. DESCHAMPS, MD
Ph. HERNIGOU, MD



Copyright Clearance Center

S&N EXHIBIT 1035
S&N v. BSI
IPR2013-00629

Cahiers d'enseignement de la SOFCOT

Collection dirigée par J. DUPARC

61

UNICOMPARTMENTAL KNEE ARTHROPLASTY

edited by

Ph. CARTIER, M.D., J.A. EPINETTE, M.D., G. DESCHAMPS, M.D., Ph. HERNIGOU, M.D.

Contributors

Th. PANDRIACCHI, J.H. AUBRIOT, S.A. BANKS, R.M. BARDEN, Th. W. BAUER, J.L. BENSADOUN,
R.A. BERGER, G. BERGMANN, J.L. BESSE, L. BLANKEVOORT, P.M. BONUTTI, Ph. CARTIER, R.B. CASPARI,
J.P. CECCALDI, P. CHAMBAT, F. CHATAIN, R.L. COATES, D. DEJOUR, H. DEJOUR, F. DELTOUR,
G. DESCHAMPS, P. DJIAN, J. DUPARC, J. DUPUY-PHILLON, A.A. EDIDIN, J.A. EPINETTE, J. FEIKES,
A. FERREIRA, G. GACON, J.O. GALANTE, J.W. GOODFELLOW, Groupe GUEPAR, S. HABI, M.K. HARMAN,
Ph. HERNIGOU, Y. HIRASAWA, A.W. HODGE, R. HUISKES, A. IMRAN, M. JIANG, M. KESTER, A. KOBAYASHI,
T. KOSHINO, J.L. LERAT, S. LEWOLD, A. LINDSTRAND, T.W. LU, M.T. MANLEY, G.D. MARKOVICH, L. MARMOR,
Ph. MAS, B. MOYEN, D.W. MURRAY, Ph. NEYRET, K.G. NILSSON, R. NIZARD, J.J. O'CONNOR, T. OH,
T. OHDERA, I. ÖNSTEN, M.D. PEYRACHE, L. PIDHORZ, J. ROBERTS, M.H. ROSAS, A.G. ROSENBERG,
J.L. SANOUILLER, R.D. SCOTT, A. STENSTRÖM, F. SÜSSENBACH, S. TAKAI, F. TROTT, S. TSUTSUMI,
R. VANAS, F. VOSS, D.R. WILSON, J. WITVOET, N. YOSHINO

EXPANSION SCIENTIFIQUE FRANÇAISE
15, rue Saint-Benoît, PARIS VI^e

Catalogage Electre-Bibliographie

Unicompartmental knee arthroplasty/Ph. Cartier, J.A. Epinette,
G. Deschamps, Ph. Hernigou. – Paris : Expansion scientifique française, 1997.
– (Cahiers d'enseignement de la SOFCOT ; 61)
ISBN 2-7046-1532-2

RAMEAU : arthroplastie
 genoux artificiels
DEWEY : 617.2 : Chirurgie et sujets connexes, Orthopédie,
Public concerné : Universitaire. Professionnel, spécialiste

© 1997 by Expansion Scientifique Française. All rights reserved. This book is protected by copyright. No part of it may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or recording, or otherwise, without the prior written permission of the publisher.

Made in France

Tous droits de traduction, d'adaptation et de reproduction par tous procédés, réservés pour tous pays.

La loi du 11 mars 1957 n'autorisant, aux termes des alinéas 2 et 3 de l'article 41, d'une part, que les « copies ou reproductions strictement réservées à l'usage privé du copiste et non destinées à une utilisation collective », et, d'autre part, que les analyses et les courtes citations dans un but d'exemple et d'illustration, « toute représentation ou reproduction intégrale, ou partielle, faite sans le consentement de l'auteur ou de ses ayants droit ou ayants cause, est illicite » (alinéa 1^{er} de l'Article 40).

Cette représentation ou reproduction, par quelque procédé que ce soit, constituerait donc une contrefaçon sanctionnée par les Articles 425 et suivants du Code pénal.

© Expansion Scientifique Française, 1997

Adresse postale : 31, boulevard de Latour-Maubourg, 75343 PARIS CEDEX 07 (France).

ISBN : 2-7046-1532-2
ISSN : 0338-3849

Unicompartmental Knee Arthroplasty: a US Experience

P.M. BONUTTI, M.D., M.A. KESTER, Ph.D.

Treatment of unicompartmental arthritis of the knee is a difficult challenge. There are a number of treatment alternatives which must be individualized for each patient. Conservative treatment options include anti-inflammatories, bracing, weight reduction and activity modifications. Surgical options include arthroscopy and debridement, abrasion arthroplasty, biologic resurfacing, osteotomy, Unicompartmental Knee Arthroplasty (UKA) or Total Knee Arthroplasty (TKA).

In the United States in 1995, approximately 250,000 knee arthroplasties were performed of which less than 5% were UKA [102]. This contrasts with Sweden studies which look at a large series of knee arthroplasties. Multiple Swedish authors have identified the utilization of UKA ranging from 40% to 90% of all patients with osteoarthritis undergoing knee arthroplasty [64, 202, 270]. This utilization of UKA differs markedly from the US experience. There are many factors which relate to the US experience in utilizations.

Current indications and contradictions for UKA in the United States have evolved (Figs 1 and 2). Indications include 1) patients greater than 60 years of age with a sedentary life style, 2) osteoarthritis in a single compartment, 3) range of motion must be greater than 15° to 90°, 4) deformity of less than 10° of varus or 15° of valgus. One cannot correct severe contracture angular malalignment with UKA implant for fear of damaging critical ligamentous structures during the balancing process [123]. Contra-indications to UKA include: 1) significant bicompartamental disease, 2) symptomatic patellofemoral compartment, 3) obesity – greater than 200 pounds, 4) deformity greater than 20°, 5) ruptured ligaments – ACL, PCL or MCL, and 6) inflammatory arthritis. In the US, Stern and Insall, et al. using most rigid criteria identified that only 6% of patients in the United States meet their strict criteria for UKA [293].

Evaluation of UKA suggests variable long term results. Some studies suggest long term UKA results are inferior to TKA results. However, these studies often evaluate first generation UKA designs and compare them to second or third generation TKA designs with difference in instrumentation, surgeon technique, cement technique, patient criteria and implant design.

For example, Marmor notes in his first generation implant design, a 70% survivorship at 10 to 13 year follow-up [221]. Contrast this with Scott's, et al. more recent study describing a second generation design with a 90% survivorship at 9 year follow-up [274]. There is no question that the UKA is a very surgeon and technique dependent procedure. There are marked variation in the implants and instrumentation. Instrumentation is very similar to TKA instrumentation, however, UKA is markedly different with preservation of the ACL, PCL, contralateral compartment, as well as the patellofemoral joint. Clearly it is difficult to achieve the ACL and PCL isometry while maintaining the balance in the contralateral compartment and the patellofemoral joint with traditional implant instrumentation.

The US experience in knee arthroplasty differs markedly from the European experience. Christensen's study with 575 UKA at 9 year follow-up identified a 96% survivorship [64]. A more extensive study by Lindstrand, et al. evaluating 3,777 UKA at 8 year follow-up showed a 15% revision rate for PCA and 7% revision rate for St. Georg and a 5% revision rate for Marmor implants [202]. He notes survivorship for UKA appears very implant and design specific. Likewise studios identified, for example that PCA TKA has a much lower survivorship than other contemporary TKA [306]. The following table compares the long term US survivorship of contemporary UKA (Table I).

TABLE I

	<i>Author</i>	<i>Patients</i>	<i>Follow-up</i>	<i>Survivorship</i>
1	Heck	294	10 YRS	91%
2	Swank	82	8,5 YRS	81%
3	Capra	52	10 YRS	93%
4	Rougraff	120	10 YRS	93%
5	Scott	100	9 YRS	90%

The poorest long term UKA results, that of Swank and Stulberg, et al. should be evaluated critically [301]. These implants were PCA and Microloc UKA. If one looks at comparable series of PCA, TKA and Microloc

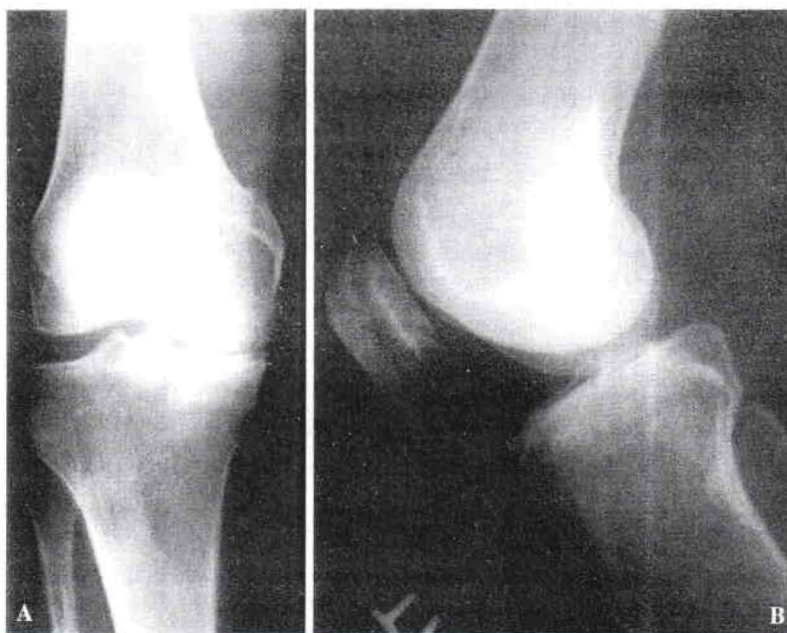


Fig. 1.

- A) Pre-operative AP X-ray. Isolated medial compartment OA.
B) Pre-operative lateral X-ray.

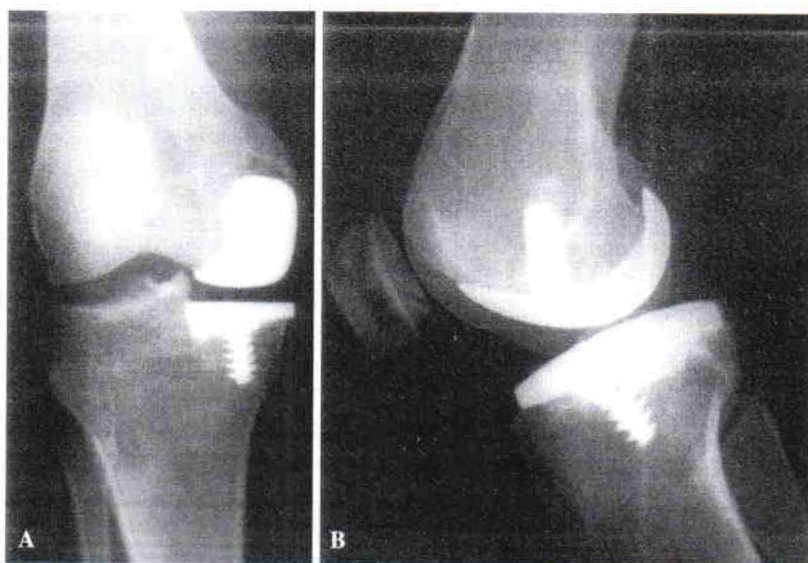


Fig. 2.

- A) Post-operative UKA. AP view.
B) Post-operative lateral X-ray.
C) Post-operative UKA. Merchant view.



TKA, one will find similar poor results. Therefore, one must compare comparable implants, comparable designs and patient criteria. Therefore, just like TKA designs which have variable success rate, UKA implants also have a variable success rate and poor results of UKA may be attributable to implant designs or techniques.

If one contrasts UKA long term studies with those of long term studies of TKA, there is also a marked variation. Evaluate the following table of contemporary TKA designs (Table II).

TABLE II

	Author	Patients	Follow-up	Survivorship	Implant
1	Insall	139	9 YRS	94%	I.B.
2	Rorabeck	344	3 YRS	91%	M.B.
3	Rand	7200	10 YRS	79%	Multiple
4	TSAO	80	6 YRS	80%	PCA

If one contrasts UKA long term survivorship with those long terms studies of TKA, obviously the best studies quoted are those of Insall's, et al. classic paper which notes a 94% survivorship in 9 to 12 year follow-up [291]. However, as Lindstrand, et al. identifies UKA survivorship is very implant dependent. TKA survivorship is also very implant dependent [202]. If one looks critically at comparable series, one finds for example, Tsao, et al. using a PCA TKA implant reports a 6 year follow-up with only an 80% survivorship and 20% re-operation rate [306]. Contrast this with Swank's, et al. study at 8.5 year follow-up of PCA UKA's with an 81% survivorship [301]. One can see comparable survivorship and again this is implant related. Clearly with similar implant designs, one sees comparable results.

Looking closer at Rand's study at a long term follow-up of a large series of implants, he reported a 79% survivorship at 10 year follow-up [257]. Although, many physicians quote Insall's, et al. paper, it is unlikely that most orthopedic surgeons in the US can compare their results and technique to Insall's [291]. Perhaps we should use Rand's long term series as a true barometer of long term survivorship because his series included multiple surgeons, a large series and more objective analysis as a surgeon designer who was not evaluating patients. It is clearly comparable to literature published on UKA survivorship.

Furthermore, to compare UKA to TKA, one must evaluate implant's surgical technique and instrumentation. UKA in the United States has been suggested to have inferior results to TKA. However, failure appears to be related to implant design, polyethylene wear, subsidence and progressive disease in the contralateral compartment. In TKA, the ACL is sacrificed and with increasing frequency the PCL is sacrificed, the opposite compartment is removed, and the patellofemoral joint is usually replaced. In UKA, instrumentation is similar or derived from TKA instrumentation. However, UKA requires more precise soft tissue balancing, joint balancing and alignment is

more critical. The ACL and PCL are maintained and ligament balancing with isometry should be considered. As in the sports medicine literature, clearly if the ACL and PCL are not in isometric position, an increase in the rate of failure can occur. If the ACL is sacrificed, one clearly identifies a greater rate of failure in UKA. Also, the patellofemoral joint, as well as the contralateral tibia femoral compartment are spared. Instrumentation should take this into account, however, existing implants and instrumentation rely significantly on surgeon's technical ability to balance the compartments, and instrumentation has not been developed to adequately measure tension and isometry for the ACL and PCL ligaments as well as the contralateral compartment.

UKA has been documented to have a greater rate of failure than TKA. This may be related to implant design, polyethylene wear, subsidence and progressive disease in the contralateral compartment. The classic paper on UKA design, that of Hodge and Chandler, identify that with a constrained implant, there was a 70% 5 year survivorship with a 27% reoperation rate [142]. However, using an unconstrained UKA implant relying on ligaments and contralateral compartment for stabilization, there was a 92%, 5 year survivorship and only 8% incidence of re-operation. This article clearly identifies that in UKA, the implant should not constrain or stabilize the joint. The stability should be imparted by ligaments – ACL and PCL, as well as the opposite compartment and patellofemoral joint.

Comparing TKA to UKA, Callahan, et al. identifies, "Patient outcome appears to be worse for TKA than UKA." He concludes that UKA may afford better patient outcomes than TKA [54]. There are very few papers in the US literature comparing UKA to TKA. Rougraff, et al. performed a retrospective study comparing UKA versus TKA in similar patient populations [270] (Figs 3A, 3B, 3C and Table III).

TABLE III

	UKA	vs	TKA
Number	120		81
Revision	4% (5)		11% (9)
Reop	4% (5)		20% (11)
ROM	113°		98°
Knee Score	90		85
TransFusion	1%		67%

The authors identified statistically significant findings in the UKA versus TKA population were UKA had: 1) lower revision rate, 2) lower re-operation rate, 3) improved range of motion, 4) higher knee score, 5) lower transfusion rate.

In another comparable study by Laurencin, et al. a majority of the patients preferred UKA over TKA. The UKA had better range of motion and more normal gait pattern [194].

Chassin, et al. identified that 70% of patients with UKA have a normal biphasic gait pattern. This contrasts with only 23% of TKA. Furthermore, he found a low

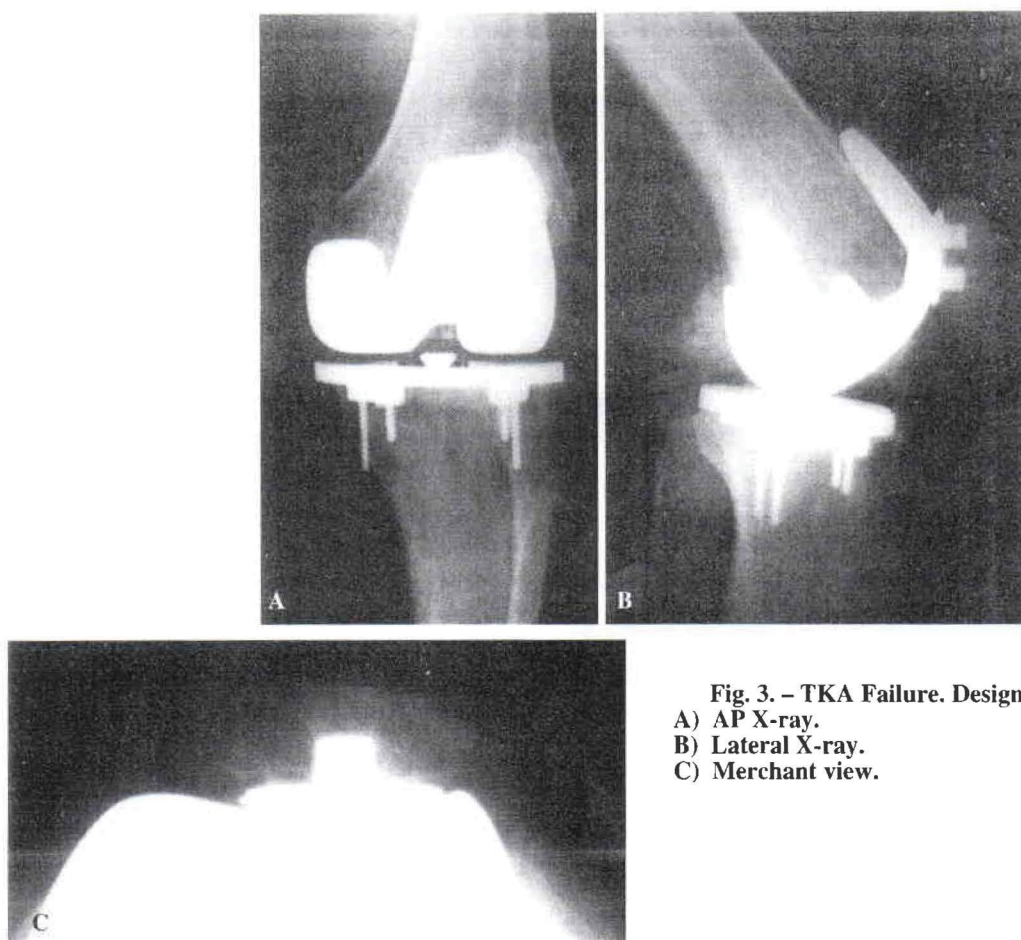


Fig. 3. – TKA Failure. Design and implant related.
A) AP X-ray.
B) Lateral X-ray.
C) Merchant view.

prevalence of quadriceps avoidance gait in UKA which appears to be associated with the retention of the ACL. This study further suggests that UKA patients have better gait patterns and function better than comparable TKA patients [62]. It appears that UKA patients function better than TKA patients, and if a patient is a candidate for UKA, UKA would provide better functional results.

In one of the best studies – the only *prospective study* comparing UKA versus TKA versus High Tibial Osteotomy (HTO), 50 patients were evaluated by Jefferson and Whittle [158]. They found that UKA have: 1) better ROM, 2) better function, 3) superior gait pattern in terms of cadence, velocity, stride length, 4) more predictable results than HTO. When compared to TKA, UKA had: 1) better correction of deformity and 2) better functional and gait pattern. This was a prospective study and objectively looked at the functional results and identified that UKA functionally out performed both HTO and TKA.

HTO may buy time for the younger more active obese patient or the cruciate deficient patient. However, there is significant evidence for disease progression over time. Results of HTO are highly variable with long term success ranging from 28% to 77% success rate [69, 226, 295]. In a comparative study of UKA vs. HTO, Kozinn and Scott identified that the UKA has better quadriceps

strength, increased single leg stance, increased maximum gait, and increased function over HTO [181]. Therefore, if one critically analyzes functional improvement, UKA appears to provide better clinical, functional results than HTO.

Weale et al. identified that with a long term follow-up of 12 to 17 years only 20% UKA had pain where as 57% of HTO had significant pain [22]. Therefore, at long term, greater than 12 year follow-up UKA has better pain relief than HTO.

In another comparative study of UKA versus HTO, Stewart, et al. reported that with HTO there was a 60% evidence of disease progression in the contralateral compartment at 5 year follow-up and 83% of progression of disease at 9 year follow-up in the contralateral compartment [295].

In UKA, however, there have been very different studies on disease progression with Hodge and Chandler identifying a 1.2% incidence of disease progression in the contralateral compartment at minimum 5 year follow-up [142]. The greatest evidence of disease progression (Surtani's, et al. study of lateral component UKA only) identified a 23% progression of disease in the contralateral compartment UKA at 8 year follow-up [299]. However, only 3.3% of patients were symptomatic enough at 8 year follow-up to require revision of UKA to TKA to progression of osteoarthritis.

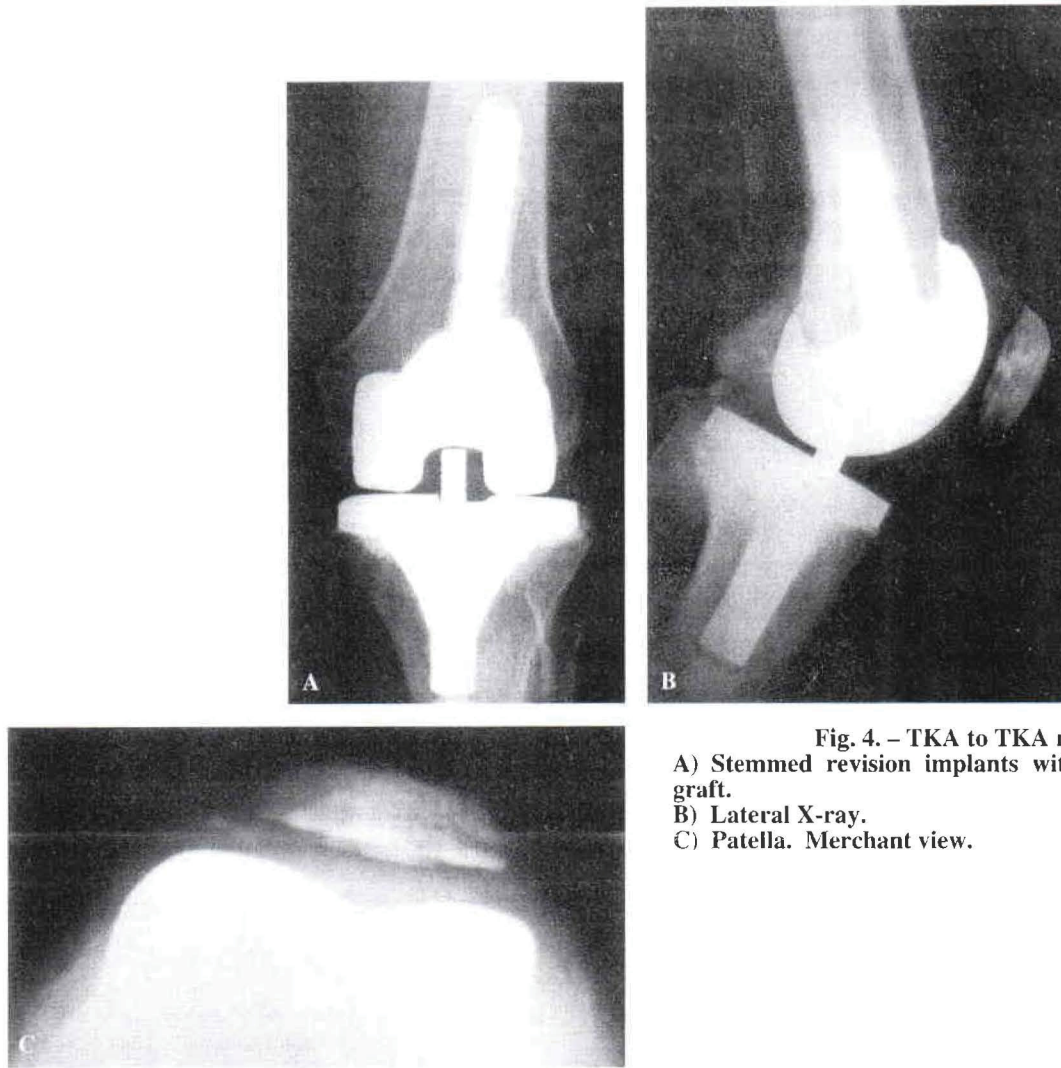


Fig. 4. – TKA to TKA revision.
 A) Stemmed revision implants with wedges and bone graft.
 B) Lateral X-ray.
 C) Patella. Merchant view.

This suggests that osteoarthritis may progress radiographically, however, the necessity to revise UKA patients to TKA for progressive osteoarthritis is small. Klemme, et al. used bone scans to analyze progressive disease in UKA and found that there was no radiographic evidence for progressive arthrosis in their unreplaced compartments.

He concluded disease progression in replaced compartments was unusual after contemporary UKA, and concluded that most failures and poor results are from mechanical inadequacies and were attributable to surgical technique and design considerations [173]. Disease progression in the contralateral compartment UKA is uncommon with appropriate implants and with appropriate surgical techniques. This confirms many other studies which suggest a low rate of progressive osteoarthritis in the contralateral compartment of UKA. In the US, several studies have suggested significant difficulty in revising UKA to TKA. Insall identified that the revision of UKA may be difficult. However, in all 19 of his patients which were early generation UKA designs, all were revised to primary TKA. None

required special revision implants, however, many required bone grafting to build up tibial bony defects. This again, is attributable to early implant designs and early cement techniques which removed significant tibial bone stock and has made revision more difficult. Yet, 89% of his UKA revisions were satisfied at follow-up [253].

In a comparative study, Insall, et al. compared revision of HTO to TKA and found that only 80% of patients were satisfied [154]. Jackson, et al. in another US series studied 43 patients: 23 revisions from UKA to TKA and 20 revisions from HTO to TKA [157]. The two groups were similar, however, 30% of the HTO'S which revised to TKA suffered serious post operative complications and were classified as poor results.

Munk, et al. studied revision of HTO to TKA in 67 patients and found that 37% of patients had fair to poor results. The range of motion post TKA was 108° with a 6% re-operation rate at 3 year follow-up. In a parallel study, he identified 94% success rate with primary TKA. This suggests revision from HTO to TKA may be more difficult than revision of UKA to TKA [242] (Figs 4A, 4B and 4C).

Therefore, after reviewing current literature in the US, UKA appears to have comparable long term survivorship to TKA. UKA appears to show better functional results than TKA, however, is still an underutilized procedure in the United States. The reasons for this underutilization may be multifactorial.

First, the US population appears to be different than the Swedish or European population. The biggest single difference appears to be the greater incidence of obesity in the US population which may limit the number of patients which are candidates for UKA. A study by the National Center for Health Statistics, a Division of the United States Department of Health and Human Services identified that 59% of American men and 49% of American Women are significantly overweight. This study also suggests that Americans over the last decade progressively are increasing in weight and this trend is worsening [196]. Therefore, on the basis of weight alone, over half the potential candidates in the US for UKA are eliminated.

Second, there also appears to be a surgeon's preference in the US for implantation of TKA over UKA. In residency training programs, there is the perception that the TKA obtains better results and have more reproducible results than UKA. As we have previously discussed, surgical technique for UKA is much more surgeon dependent because of balancing the ligaments, contralateral compartment and patellofemoral joint. UKA may be more difficult to teach in the US residency training systems, and therefore, more physicians leaving US training programs are unfamiliar with UKA instrumentation and implantation; and therefore, lean toward performing TKA.

An excellent study performed by Lavernia and Guzman, evaluated knee arthroplasties in Florida. Lavernia found that in Florida over 62% of all knee arthroplasties were implanted by surgeons who perform less than 10 joint replacements a year. For revision arthroplasties, 90% of revision arthroplasty were performed by surgeons who do 10 or less revisions per year [193]. If one extrapolates Insall's, et al. criteria that less than 6% of patients in the US qualify for UKA and if the average US surgeon performs 10 or less joint replacements per year, the average US surgeon would therefore find less than 1 patient who is a candidate for UKA per year [293]. Based on this relative unfamiliarity with UKA, many surgeons would lean toward performing TKA.

There are over 20,000 orthopaedic surgeons in the United States, and as evidenced by Lavernia's, et al. study, the majority of knee arthroplasties in the US appear to be performed by surgeons who have fairly limited experience with UKA [193]. This suggests a relative lack of familiarity and would make surgeons less likely to place an implant or perform techniques where they have limited indications and which requires greater technical skill.

Another reported issue is reimbursement. In the US, a UKA requires comparable, if not a greater amount of time for a surgeon technically to implant. However, the reimbursement in the US for a UKA is significantly less

than that for TKA – approximately 40% less. TKA has the perception in the US as having better functional results and has a significant higher reimbursement ratio. Therefore, surgeons may subjectively lean to this treatment option.

Implant manufacturers in the US receive a greater reimbursement for the TKA implant over the UKA implant. UKA implants can range from \$800 to \$3,000 where TKA implants can range from \$1,500 to as much as \$6,000 or more. These marketing issues may have significant impact on implant manufactures and surgeons. In the US, company representatives routinely are in the operating theater advising surgeons during a surgery.

Finally, there appears to be less research and money invested for UKA implants. Companies are reluctant to invest millions of dollars to develop implants with new instrumentation for a perceived limited market with reduced reimbursements. All of these factors appear to place some overall perceived preference of the surgeons, of the US, for the utilization of TKA over UKA. Some studies such as Scott, et al. suggest that after 10 years there may be a progressive deterioration results for UKA. Survivorship in Scott's study shows that 95% survivorship at 9 years, 85% at 10 years, 82% at 11 years. To date, other studies have not identified this [181].

Meta-analysis performed by Callahan, et al. of 2,391 UKA in the US literature at 6 year mean follow-up identify an 18% complication rate and a revision rate of 9.2%. UKA implanted studies after 1987, however, showed significant better outcomes. However, for TKA patients at 3.6 year follow-up identified a complication rate of 30%, revision rate of 7.2% and a lower global rating score for TKA [54]. This may be due to the fact that TKA patients were worse pre-operatively. However, better outcomes were obtained in UKA patients and may be due to better patient selection. Yet patient outcomes were clearly worse for TKA than for UKA in this study. UKA currently uses a formal arthrotomy similar in scope to TKA. Future trends suggest that a possible limited incision or mini-arthrotomy approach without everting the patella may be of value in placing the UKA as intermediate treatment options. Litwin, et al. studied 24 patients who underwent UKA under arthroscopic guidance. He utilized a 3" to 4" L-shaped incision. Patients were discharged at 24 to 48 hours, and at 12 month follow-up, 3 of the 24 required revision. However, 21 of 24 were satisfied [204]. This short term study with a limited incision procedure suggests that UKA may have fast recovery and reduced pain. This is not a true arthroscopic procedure, however, as a 3" to 4" arthrotomy incision was performed. However, there was fairly rapid discharge from the hospital and fairly rapid return to function.

Caspari reported the first series of 6 patients implanted with a arthroscopic assistance. All 6 patients at greater than 1 year follow-up were doing well. The procedure was technically difficult and required fairly long operative times – greater than 3 hours. Caspari notes that all patients are doing well at follow-up and have not required further surgery [61].



Fig. 5. – Standing AP X-ray. Isolated medial compartment disease. Osteonecrosis.



Fig. 6. – Standing AP UKA. 2 yr post-operative.

The future holds promise for UKA in the United States. Improved instrumentation which would allow the surgeon to more precisely balance the ACL and PCL for isometry, as well as balance the patellofemoral joint and contralateral compartment may improve function and prevent progression of disease. Possibly a limited incision without everting the patella will allow for faster recovery time as less exposure is required for a single compartment. Implant fixation is an issue and improvements in implant stability, with implants that may have larger surface area for bone ingrowth, or for cement fixation need to be evaluated. Further studies on bearing surfaces with issues of wear appear to be critical for long term follow-up of these implants.

Recently, in the US literature, Grelsamer in a review article for US JBJS stated that in patients more than 70 years of age, UKA is a more cost-effective implant. He concluded that in terms of function and durability, a TKA will probably provide an excellent result, however, he

states, "UKA would be preferred in the appropriate matched patients over the age of 70" [123]. This appears to override current philosophy and practice in the US. However, based on his extensive study of literature he suggests that UKA is an under-utilized procedure in the US.

In conclusion, UKA is a highly successful procedure and with appropriate indications may be the preferred treatment option for patients with isolated unicompartmental knee arthritis. In the US, studies suggest that only a small percentage of patients may qualify for UKA, and this population may be limited due to weight, deformity, activity level, and severity of disease. However, in appropriate patients, UKA clearly outperforms TKA (Figs 5 & 6). Questions arise that in long term results greater than 10 years for UKA whether results will deteriorate. This issue still has to be answered, however, in the appropriate patient, UKA clearly has superior results and excellent long term results.