The role of radiostereometric analysis in the evaluation of orthopaedic implants in the upper extremity

Bart ten Brinke

The Role of Radiostereometric Analysis in the Evaluation of Orthopaedic Implants in the Upper Extremity

Bart ten Brinke

Colofon

The role of radiostereometric analysis in the evaluation of orthopaedic implants in the upper extremity

ISBN: 978-94-6423-643-9

Cover design: Jeroen de Goffau

Lay-out: ProefschriftMaken | www.proefschriftmaken.nl

Printing: ProefschriftMaken | www.proefschriftmaken.nl

Printing of this thesis was financially supported by: Amphia Ziekenhuis, stichting Anna Fonds|NOREF, Centrum Orthopedie Rotterdam, Chipsoft, afdeling Orthopedie & Sportgeneeskunde Erasmus Medisch Centrum, Erasmus Universiteit Rotterdam, Link Lima, Nederlandse Orthopaedische Vereniging, Reinier de Graaf, Stichting Research Orthopedie Delft.

The Role of Radiostereometric Analysis in the Evaluation of Orthopaedic Implants in the Upper Extremity

De rol van radiostereometrische analyse in de beoordeling van orthopaedische implantaten in de bovenste extremiteit

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof.dr. A.L. Bredenoord
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
dinsdag 5 april 2022 om 13:00 uur

door

Albert ten Brinke
geboren te Doetinchem

Erasmus University Rotterdam

Promotiecommissie:

Promotor:	Prof.dr. D. Eygendaal
Overige leden:	Prof.dr. S.M.A. Bierma - Zeinstra
	Prof.dr. G.J. Kleinrensink
	Prof.dr. R.G.H.H. Nelissen
Co-promotoren:	Dr. N.M.C. Mathijssen
	Dr. G.A. Kraan

Table of contents

Chapter 1

General introduction

Osteoarthritis

Osteoarthritis - *osteo- (bone), arthr- (joint), -itis (inflammation)* - is a common and complex joint disease characterized by progressive damage to articular cartilage and other joint tissues.[1,2] The term 'osteoarthritis' is, strictly speaking, misleading as inflammation is not the primary or only cause of this joint condition. The correct term for this degenerative joint condition is 'osteoarthrosis' (OA).[3] Osteoarthrosis has traditionally been divided in *primary*, without a specific cause (idiopathic), and *secondary*, with a known cause or predisposing factor as injury (fracture, dislocation, surgery), anatomic abnormalities or chronic inflammation (rheumatoid arthritis (RA)).[4–6] Although 'osteoarthrosis' is still the preferred term in European countries, the term 'osteoarthritis' became deeply integrated in scientific publications under the influence of the Anglo-Saxon literature.[3]

Clinically, OA can lead to gradual progressive pain, loss of function of the affected joint and a decrease in quality of life.[7] Due to the rising prevalence of obesity, ageing and growth of the global population, the prevalence of OA is increasing worldwide with major implications for healthcare systems and socioeconomic costs.[7,8] In the Netherlands, the prevalence of OA is estimated to increase with more than one million to 2.5 million in 2040.[9]

In general, the upper extremity is less susceptible for symptomatic OA compared to the lower extremity.[10,11] Still, OA of the glenohumeral joint (omarthrosis) is the third common form of OA to require joint replacement after the hip and knee.[12] The prevalence of radiological omarthrosis is estimated to be 16-20% in the middle-aged and elderly population.[13–15] Like in the hip and knee joint, primary OA is the most common form of omarthrosis and is mainly seen in patients over 60 years of age, while younger patients more often are diagnosed with secondary OA.[6,16,17]

OA of the elbow is relatively rare. The prevalence of symptomatic primary OA of the elbow is reported to be 0.9% in a Japanese cohort survey.[18] Elbow OA is typically characterized by pain, stiffness and loss of function.[19] Hypertrophic osteophytes act as a mechanical obstruction causing pain at the end range of both flexion and extension. Generally, the radiocapitellar joint is the first region that is affected by OA and preservation of the joint space is common. The latter may account for the good results of non-operative treatment or arthroscopic debridement.[19]

The hand is often involved in OA, especially in older women. Data from the Rotterdam study revealed that radiographic OA is present in more than 60% of the population aged 55 years and older.[20] The highest prevalence of OA was found in the distal interphalangeal (DIP) joints (47.3% at least one DIP joint affected; 6.8-28.6% for separated DIP joints), followed by the trapeziometacarpal (TMC) joint (21.2%).[20] However, OA of the hand is often asymptomatic and the relation between radiographic severity of OA and functional hand disability is poor. The prevalence of symptomatic TMC joint OA is estimated to be 2.7 – 5.7%.[21]

Total Joint Arthroplasty

When non-operative treatment fails, total joint arthroplasty (TJA) is a more than acceptable treatment option for end-stage OA. Although the number of TJA in the upper extremity is considerably lower than for the lower extremity, the number of total shoulder arthroplasty (TSA) is rising and expected to increase in the near future.[22–24] In the Netherlands, the number of TSA has increased with more than 50% between 2014 and 2019 (table 1).[25]

Year	Hip arthroplasty	Knee arthroplasty	Shoulder arthroplasty	Elbow arthroplasty	Wrist arthroplasty	Hand arthroplasty
2014	28.161	26.608	2.091	72		
2015	28.877	26.938	2.498	78		
2016	29.658	27.832	2.603	67		
2017	30.443	29.216	2.888	67	33	177
2018	31.920	29.911	3.047	73	36	190
2019	33.253	30.773	3.253	79	40	257
Growth 14-'19	**18%**	**16%**	**55%**	**10%**	**n.a**	**n.a**

Table 1. Number of registered arthroplasties in The Netherlands between 2014 and 2019.
Data from www.lroi-report.nl

TSA can be broadly divided into anatomic (aTSA) and reverse (rTSA) prostheses. Anatomic prostheses mimic the normal glenohumeral anatomy, while in reverse arthroplasty the ball and socket switch sides. The most common indication for rTSA is glenohumeral OA with severe rotator cuff deficiency. However, indications for rTSA are expanding resulting in a strong increase in the volume of implanted rTSA's.[26]

Although increasing, the number of total elbow arthroplasty (TEA) is still more than 150 times lower than the number of hip and knee replacements.[25,27–29] In contrast to most other joints, inflammatory OA is the most common indication for TEA. However, TEA following acute trauma and primary OA is increasing.[30–32]

Concerning OA of the wrist and hand joints, these days it is possible to replace nearly every joint of the wrist and hand by an artificial joint.[33] However, in addition to joint replacement several other surgical treatment options exist and the optimal treatment for hand and wrist OA is still a topic of debate.[34–42]

The final goal of TJA is to restore a painless, well-functioning joint that ideally lasts for a life time. However, aseptic loosening of implants is still one of the main concerns in TJA of the upper limb. Ten-year survival rates vary between 63 and 97% for TSA,[43–51] 64 - 91% for TEA,[52–56] 71 - 81% for total wrist arthroplasty (TWA)[57–60] and 87 - 94% for TMC joint arthroplasty.[37,61–68] Although long-term survival is increasing over time, survival rates are still inferior to those of THA (96-100%) and TKA (89-95%).[69,70] Consequently, the volume of revision procedures of upper limb TJA is increasing, with high clinical and socioeconomic burden.[22,25]

Survival of orthopaedic implants is generally monitored by clinical survival studies and implant registries. Further, many orthopaedic implants are monitored by the Orthopaedic Data Evaluation Panel (ODEP). ODEP ratings increase with the number of years with available data that support a satisfactory survival and depend on the level of evidence. It was in 2017 that ODEP was introduced for shoulder implants. For TEA first submissions are expected in 2022.[71]

The main disadvantage of implant monitoring by survival studies, registries and ODEP ratings is that implant safety is based on long-term follow-up outcomes. And long-term follow-up takes time. During follow-up, large patient groups are exposed to prostheses with unknown survival rates, awaiting long-term results. Therefore, assessment tools that are able to monitor the performance of orthopaedic implants at an early stage are essential to prevent the exposure of large patient groups to potentially poor performing implants. Moreover, these tools could help to determine whether or not innovative implants or surgical techniques are actually beneficial.

An important factor for long-term success of TJA is initial fixation, either mechanical, using bone cement, or by osseointegration, a structural connection between the implant surface and surrounding bone.[72] Suboptimal fixation, characterized by increased or continuous early migration of the implant relative to the surrounding bone, in the range of tenths of millimeters (mm), is related to aseptic loosening in the mid- to long-term follow-up.[73–77] Therefore, focusing on detection and evaluation of early migration is an important step in the systematic assessment of orthopaedic implants. In daily practice, conventional radiographs are routinely used during TJA follow-up. However, detecting implant migration and loosening using conventional radiographs is imprecise.[78,79] A more accurate method to detect early migration is roentgen stereophotogrammetry.

Radiostereometric Analysis

It was in 1897 that Davidson and Hedley obtained two simultaneously taken radiographs of a pin. They were able to localize the three-dimensional position of the pin by determining the intersection of two pairs of threads from the projected image to the roentgen foci.[80,81] This was the first description of roentgen stereophotogrammetry (Figure 1).

In the early 1970s, Göran Selvik, a Swedish mathematician and anatomist, developed a roentgen stereophotogrammetric method to determine the position of radiopaque markers in an object: Roentgen Stereophotogrammetric Analysis (RSA).[82] Driven by the increasing problem of implant loosening in the late 1970s and 1980s, Selvik further developed the technique enabling accurate measurement of movement between two rigid bodies, i.e. prostheses relative to the surrounding bone.[83] In order to determine the position of implants relative to the bone, radiopaque reference markers had to be inserted into the bone around the prosthesis. Further, markers had to be attached to known positions on the implant by the manufacturer (marker-based RSA).

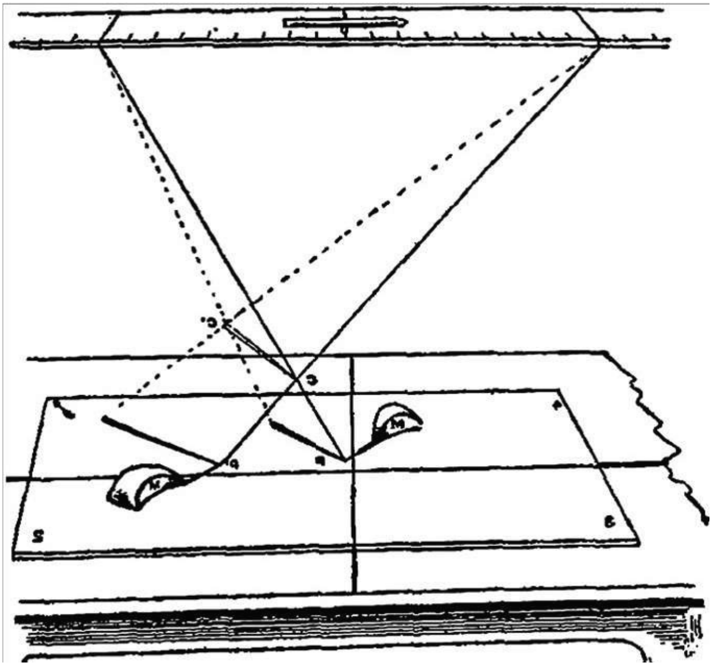


Figure 1. Localizing the three-dimensional position of a pin using an early version of roentgen stereophotogrammetry. First published in: Davidson M. Roentgen rays and localization. An apparatus for exact measurement and localization by means of roentgen rays. Brit Med J. 1898;1:10-14. Reprinted with permission from the British Medical Journal Publishing Group.

Initially, RSA was a largely manually performed, time-consuming and labour-intensive procedure. During the 1990s, it was professor Edward Valstar, an engineer from Leiden, who succeeded in the development of a digital RSA system[84–87]. To overcome the main drawback of attaching markers to the prostheses in marker-based RSA, model-based RSA was developed in the years thereafter.[88–90] In model-based RSA the position of the implant can be estimated by matching a three-dimensional surface model (Computer aided design (CAD) or Reversed engineered (RE) models) with the actual projection of the implant on stereo roentgen images (Figure 2). As a result of further digitization and process automation, RSA has become an easily accessible and applicable method that can be used in almost all orthopaedic departments if the right equipment (software, calibration boxes, roentgen set-up) is available.

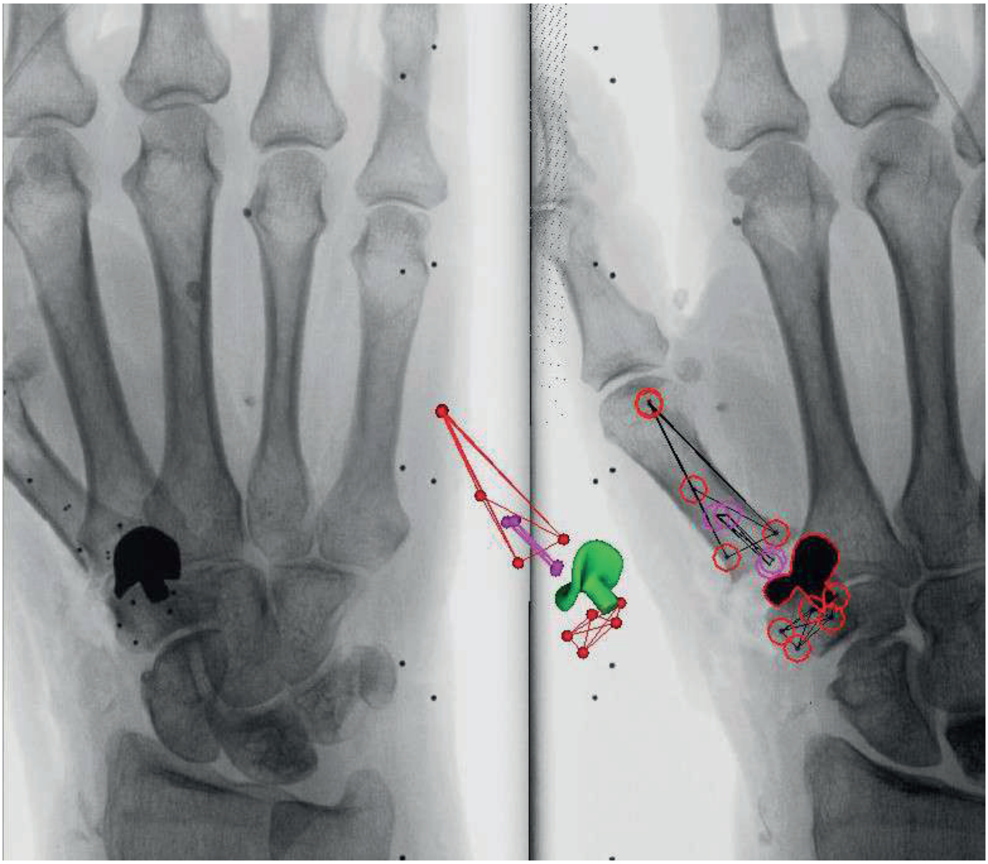


Figure 2. An example of an RSA-scene showing the CAD-model of a TMC joint prosthesis matched with the projection of the implant on stereo roentgen images.

A typical RSA set-up consists of two synchronized X-ray tubes above a detector at a 20° angle to the vertical.[91] A calibration box is positioned between the patient and the detector. This box contains fiducial markers on the bottom of the box to define a coordinate system and to transform the plane of the detector to the lower plane of the box. Control markers, at known positions in the upper surface of the box, are used to determine the exact position of the roentgen foci (Figure 3).

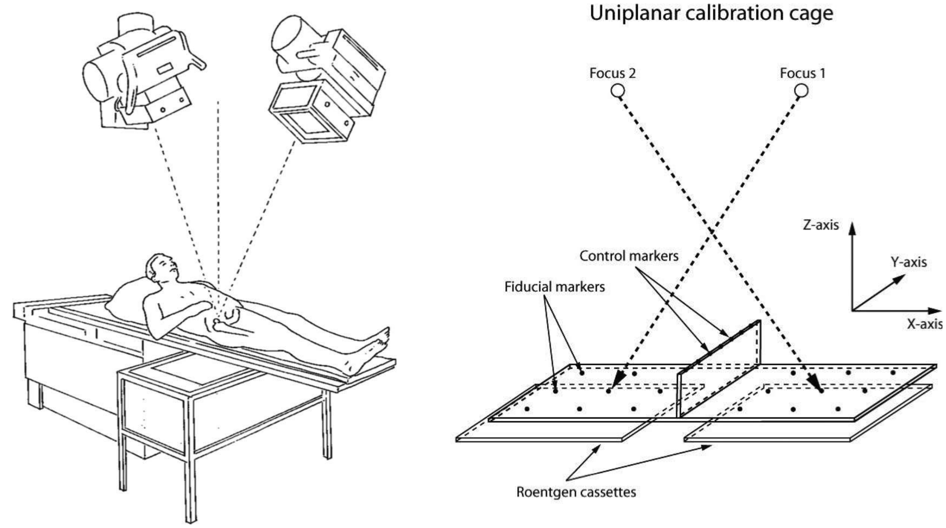


Figure 3. A typical RSA arrangement with two roentgen tubes focused on the joint concerned in an uniplanar set-up. First published in: Valstar ER. et al. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthopaedica 2005;76(4):563-572.Reprinted with permission from Taylor & Francis Group.

Early migration and long-term outcomes

A relation between short-term migration and future implant failure was first described by Grewal et al., Ryd et al. and Kärrholm et al. and later confirmed by Nieuwenhuijse et al. and Hauptfleisch et al.[78,92–95] In 2012, Pijls et al. clearly demonstrated the relation between increased early migration and long-term implant failure in two systematic reviews and meta-analyses.[76,77,96] Migration thresholds for prostheses at risk for loosening of 0.2 – 1.0mm in THA and 0.5 – 1.6mm in TKA were demonstrated. In a recently published implant register based study, Hasan et al. confirmed the value of RSA comparing the all-cause revision rates of non-RSA and RSA-tested TKA designs.[97] Based on data from 26 knee arthroplasty registers, including 339 implant designs, a slightly lower revision rate was shown for RSA-tested implants at five and ten years. Over the last decade, several authors have argued for a phased introduction of new implants in which preclinical tests are followed by clinical RSA trials prior to the widespread introduction of implants to the market.[98–100] The call for a phased introduction was partly based on revision data from national joint registries showing a reduction of 22 – 35% in 5-year revision rates of RSA-tested total knee implants compared to implant designs that have not been assessed using RSA.[98] The concept of phased introduction of new implants has been implemented by the Dutch Orthopaedic Association in the THA guideline, requiring RSA studies of new implant designs before larger clinical trials could be performed.[101]

General aim and outline of this thesis

To date, only a few RSA studies have been published on TJA in the upper extremity. Consequently, the value of early migration, measured using RSA, in the prediction of long-term outcomes of upper extremity implants is unknown. Moreover, data regarding the feasibility and accuracy of the technique when applied in the evaluation of upper limb implants are scarce. Therefore, the **general aim** of this thesis is to investigate the role of RSA in the evaluation of orthopaedic implants in the upper extremity.

Part I of this thesis focuses on the accuracy and precision of RSA in upper limb joints. Given that only a few upper limb RSA studies have been performed and little is known about accuracy and precision of RSA in upper limb TJA, in **chapter 2** we systematically reviewed the existing literature aiming to determine accuracy and precision values of RSA when used in shoulder, elbow and TMC joint arthroplasty.

In **Part II** we evaluate the use of RSA in the TMC joint. **Chapter 3** investigates the in vitro feasibility of RSA in the TMC joint in an experimental pilot study. A surface replacement (SR) TMC joint prosthesis was implanted in five human hand specimens. Ten pairs of RSA radiographs of each hand were used to calculate accuracy and precision of the technique in the TMC joint. In **chapter 4 and 5**, we assess the in vivo feasibility of RSA in the TMC joint. The SR TMC joint prosthesis was implanted in ten patients with end-stage OA of the TMC joint. Mid- and long-term migration patterns and clinical outcomes of this cohort are given.

In **Part III** we evaluate the use of RSA in the assessment of total elbow prostheses. In **Chapter 6** we investigate long-term migration patterns, clinical outcomes and survival of 16 patients after implantation of the Instrumented Bone Preserving (IBP) total elbow prosthesis. Short-term migrations of revised and non-revised implants are evaluated in order to assess the value of early migration in predicting long-term outcomes.

In **Part IV** we aim to investigate fixation and migration patterns of a relatively new concept in TSA. In **chapter 7** we describe the precision of RSA in stemless shoulder arthroplasty and we evaluate short-term migration and clinical outcomes of this implant.

Chapter 8 contains the general discussion of this thesis. We discuss the main findings of this thesis and suggestions for future RSA research are made.

REFERENCES

1. Abramoff B, Caldera F. Osteoarthritis: Pathology, Diagnosis, and Treatment Options. *Med Clin North Am*. 2020;104(2):293-311. doi:10.1016/J.MCNA.2019.10.007
2. Hunter DJ, Bierma-Zeinstra S. Osteoarthritis. *Lancet*. 2019;393(10182):1745-1759. doi:10.1016/S0140-6736(19)30417-9
3. Tanchev V. Osteoarthritis or Osteoarthrosis: Commentary on Misuse of Terms. *Reconstr Rev*. 2017;7(1). doi:10.15438/rr.7.1.178
4. Arden N, Nevitt M. Osteoarthritis: Epidemiology. *Best Pract Res Clin Rheumatol*. 2006;20(1):3-25. doi:10.1016/J.BERH.2005.09.007
5. Denard PJ, Wirth MA, Orfaly RM. Management of glenohumeral arthritis in the young adult. *J Bone Jt Surg - Ser A*. 2011;93(9):885-892. doi:10.2106/JBJS.J.00960
6. Millett PJ, Gobezie R, Boykin RE. Shoulder Osteoarthritis: Diagnosis and Management. *Am Fam Physician*. 2008;78(5):605-611.
7. Hunter D, Schofield D, Callander E. The individual and socioeconomic impact of osteoarthritis. *Nat Rev Rheumatol*. 2014;10(7):437-441. doi:10.1038/NRRHEUM.2014.44
8. Hunter DJ, Bierma-Zeinstra S. Osteoarthritis. *Lancet*. 2019;393(10182):1745-1759. doi:10.1016/S0140-6736(19)30417-9
9. National Institute for Public Health and the Environment. Public Health Foresight Study 2018 (VTV-2018): diseases. 2018. https://www.volksgezondheidtoekomstverkenning.nl/c-vtv/trendscenario-update-2020/ziekten-aandoeningen. Published 2018. Accessed July 27, 2021.
10. Zhang J, Song L, Wei J, et al. Prevalence of and risk factors for the occurrence of symptomatic osteoarthritis in rural regions of Shanxi Province, China. *Int J Rheum Dis*. 2016;19(8):781-789. doi:10.1111/1756-185X.12470
11. Prieto-Alhambra D, Judge A, Javaid MK, Cooper C, Diez-Perez A, Arden NK. Incidence and risk factors for clinically diagnosed knee, hip and hand osteoarthritis: influences of age, gender and osteoarthritis affecting other joints. *Ann Rheum Dis*. 2014;73(9):1659. doi:10.1136/annrheumdis-2013-203355
12. Izquierdo R, Voloshin I, Edwards S, et al. Treatment of glenohumeral osteoarthritis. *J Am Acad Orthop Surg*. 2010;18(6):375-382. doi:10.5435/00124635-201006000-00010
13. Ibounig T, Simons T, Launonen A, Paavola M. Glenohumeral Osteoarthritis: An Overview of Etiology and Diagnostics. *Scand J Surger*. 2020. doi:10.1177/1457496920935018
14. Kobayashi T, Takagishi K, Shitara H, et al. Prevalence of and risk factors for shoulder osteoarthritis in Japanese middle-aged and elderly populations. *J shoulder Elb Surg*. 2014;23(5):613-619. doi:10.1016/J.JSE.2013.11.031
15. Oh J, Chung S, Oh C, et al. The prevalence of shoulder osteoarthritis in the elderly Korean population: association with risk factors and function. *J Shoulder Elb Surg*. 2011;20(5):756-763. doi:10.1016/J.JSE.2011.01.021
16. Boselli K, Ahmad C, Levine W. Treatment of glenohumeral arthrosis. *Am J Sports Med*. 2010;38(12):2558-2572. doi:10.1177/0363546510369250
17. Chillemi C, Franceschini V. Shoulder osteoarthritis. *Arthritis*. 2013;2013:370231. doi:10.1155/2013/370231
18. Nakayama K, Kato H, Ikegami S, et al. Prevalence and associated factors of primary elbow osteoarthritis in the Japanese general elderly population: a Japanese cohort survey randomly sampled from a basic resident registry. *J shoulder Elb Surg*. 2021:S1058-2746(21)00631-5. doi:10.1016/J.JSE.2021.07.015

19. Gramstad GD, Galatz LM. Management of elbow osteoarthritis. *J bone Jt Surg (American vol)*. 2006;88(2):421-430. doi:10.2106/JBJS.E.00568
20. Dahaghin S, Bierma-Zeinstra S, Ginai AZ, Pols HAP, Hazes JMW, Koes BW. Prevalence and pattern of radiographic hand osteoarthritis and association with pain and disability (the Rotterdam study). *Ann Rheum Dis*. 2005;64(5):682-687. doi:10.1136/ARD.2004.023564
21. Niu J, Zhang Y, Lavalley M, Chaisson CE, Aliabadi P, Felson DT. Symmetry and clustering of symptomatic hand osteoarthritis in elderly men and women: the Framingham Study. *Rheumatol*. 2003;42(2):343-348. doi:10.1093/rheumatology/keg110
22. Day J, Lau E, Ong K, Williams G, Ramsey M, Kurtz S. Prevalence and projections of total shoulder and elbow arthroplasty in the United States to 2015. *J shoulder Elb Surg*. 2010;19(8):1115-1120. doi:10.1016/J.JSE.2010.02.009
23. Palsis J, Simpson K, Matthews J, Traven S, Eichinger J, Friedman R. Current Trends in the Use of Shoulder Arthroplasty in the United States. *Orthopedics*. 2018;41(3):E416-E423. doi:10.3928/01477447-20180409-05
24. Padegimas E, Maltenfort M, Lazarus M, Ramsey M, Williams G, Namdari S. Future patient demand for shoulder arthroplasty by younger patients: national projections. *Clin Orthop Relat Res*. 2015;473(6):1860-1867. doi:10.1007/S11999-015-4231-Z
25. Dutch Arthroplasty Register (LROI). LROI Report - 2021. https://www.lroi-report.nl/. Accessed October 23, 2021.
26. Wagner ER, Farley K, Higgins I, Wilson J, Daly C, Gottschalk M. The incidence of shoulder arthroplasty: rise and future projections compared with hip and knee arthroplasty. *J shoulder Elb Surg*. 2020;29(12):2601-2609. doi:10.1016/J.JSE.2020.03.049
27. Jenkins PJ, Watts AC, Norwood T, Duckworth AD, Rymaszewski LA, McEachan JE. Total elbow replacement: outcome of 1,146 arthroplasties from the Scottish Arthroplasty Project. *Acta Orthop*. 2013;84(2):119. doi:10.3109/17453674.2013.784658
28. Kremers H, Larson D, Crowson C, et al. Prevalence of Total Hip and Knee Replacement in the United States. *J bone Jt Surg (American Vol)*. 2015;97(17):1386-1397. doi:10.2106/JBJS.N.01141
29. Triplet J, Kurowicki J, Momoh E, Law T, Niedzielak T, Levy J. Trends in total elbow arthroplasty in the Medicare population: a nationwide study of records from 2005 to 2012. *J shoulder Elb Surg*. 2016;25(11):1848-1853. doi:10.1016/J.JSE.2016.04.021
30. Zhang D, Chen N. Total Elbow Arthroplasty. *J hand Surg (American Vol)*. 2019;44(6):487-495. doi:10.1016/J.JHSA.2018.11.005
31. Samdanis V, Manoharan G, Jordan R, et al. Indications and outcome in total elbow arthroplasty: A systematic review. *Shoulder Elb*. 2020;12(5):353-361. doi:10.1177/1758573219873001
32. Macken A, Prkic A, Kodde I, Lans J, NC C, Eygendaal D. Global trends in indications for total elbow arthroplasty: a systematic review of national registries. *EFORT open Rev*. 2020;5(4):215-220. doi:10.1302/2058-5241.5.190036
33. Papalia R, Tecame A, Torre G, D'Adamio S, Maffulli N, Denaro V. Small joints replacement for hand osteoarthritis: a systematic review. *Br Med Bull*. 2015;116(1):55-68. doi:10.1093/BMB/LDV024
34. Rosenfeld J, Nicholson J. History and design considerations for arthroplasty around the wrist. *Hand Clin*. 2013;29(1):1-13. doi:10.1016/J.HCL.2012.08.017
35. Billig J, Nasser J, Chung K. National Prevalence of Complications and Cost of Small Joint Arthroplasty for Hand Osteoarthritis and Post-Traumatic Arthritis. *J hand Surg (American Vol)*. 2020;45(6):553.e1-553.e12. doi:10.1016/J.JHSA.2019.11.002

36. Li J, Li D, Tian G, Zhang W. Comparison of arthrodesis and arthroplasty of Chinese thumb carpometacarpal osteoarthritis. *J Orthop Surg Res*. 2019;14(1):404. doi:10.1186/S13018-019-1469-2
37. Baek Hansen T. Joint replacement for trapeziometacarpal osteoarthritis: implants and outcomes. *J hand Surg (European Vol)*. 2021;46(2):115-119. doi:10.1177/1753193420917582
38. Neukom L, Marks M, Hensler S, Kündig S, Herren DB, Schindele SF. Silicone arthroplasty versus screw arthrodesis in distal interphalangeal joint osteoarthritis. *J hand Surg (European Vol)*. 2020;45(6):615-621. doi:10.1177/1753193420917818
39. Raj S, Clay R, Ramji S, et al. Trapeziectomy versus joint replacement for first carpometacarpal (CMC 1) joint osteoarthritis: a systematic review and meta-analysis. *Eur J Orthop Surg Traumatol*. 2021. doi:10.1007/S00590-021-03070-5
40. Spaans A, Minnen L, Braakenburg A, Mink van der Molen A. Joint distraction for thumb carpometacarpal osteoarthritis: a feasibility study with 1-year follow-up. *J Plast Surg Hand Surg*. 2017;51(4):254-258. doi:10.1080/2000656X.2016.1241789
41. Laarhoven CMCA van, Ottenhoff JSE, Hoorn BTJA van, Heijl M van, Schuurman AH, Heijden BEPA van der. Medium to Long-Term Follow-Up After Pyrocarbon Disc Interposition Arthroplasty for Treatment of CMC Thumb Joint Arthritis. *J Hand Surg Am*. 2021;46(2):150.e1-150.e14. doi:10.1016/J.JHSA.2020.07.025
42. Froschauer SM, Holzbauer M, Schnelzer RF, et al. Total arthroplasty with Ivory® prosthesis versus resection-suspension arthroplasty: a retrospective cohort study on 82 carpometacarpal-I osteoarthritis patients over 4 years. *Eur J Med Res*. 2020;25(1):13. doi:10.1186/s40001-020-00411-8
43. Sheth MM, Heldt BL, Spell JH, et al. Patient Satisfaction and Clinical Outcomes of Reverse Shoulder Arthroplasty: A Minimum of 10 Years Follow-Up. *J Shoulder Elb Surg*. 2021. doi:10.1016/J.JSE.2021.09.012
44. Märtens N, Heinze M, Awiszus F, Bertrand J, Lohmann CH, Berth A. Long-term survival and failure analysis of anatomical stemmed and stemless shoulder arthroplasties. *Bone Joint J*. 2021;103-B(7):1292-1300. doi:10.1302/0301-620X.103B7.BJJ-2020-0915.R3
45. Evans JP, Batten T, Bird J, Thomas WJ, Kitson JB, Smith CD. Survival of the Aequalis total shoulder replacement at a minimum 20-year follow-up: a clinical and radiographic study. *J Shoulder Elb Surg*. 2021;30(10):2355-2360. doi:10.1016/J.JSE.2021.01.038
46. Magosch P, Lichtenberg S, Habermeyer P. Survival of Stemless Humeral Head Replacement in Anatomic Shoulder Arthroplasty. A prospective Study. *J Shoulder Elb Surg*. 2020;30(7):e343-e355. doi:10.1016/j.jse.2020.09.034
47. Unbehaun D, Rasmussen S, Hole R, et al. Low arthroplasty survival after treatment for proximal humerus fracture sequelae: 3,245 shoulder replacements from the Nordic Arthroplasty Register Association. *Acta Orthop*. 2020;17:1-6. doi:10.1080/17453674.2020.1793548
48. Goldenberg BT, Samuelsen BT, Spratt JD, Dornan GJ, Millett PJ. Complications and implant survivorship following primary reverse total shoulder arthroplasty in patients younger than 65 years: a systematic review. *J Shoulder Elb Surg*. 2020;29(8):1703-1711. doi:10.1016/J.JSE.2020.02.004
49. Singh JA, Sperling JW, Cofield RH. Revision surgery following total shoulder arthroplasty: analysis of 2588 shoulders over three decades (1976 to 2008). *J bone Jt Surg (British Vol)*. 2011;93(11):1513-1517. doi:10.1302/0301-620X.93B11.26938

50. Gadea F, Alami G, Pape G, Boileau P, Favard L. Shoulder hemiarthroplasty: outcomes and long-term survival analysis according to etiology. *Orthop Traumatol Surg Res*. 2012;98(6):659-665. doi:10.1016/j.otsr.2012.03.020
51. Denard PJ, Raiss P, Sowa B, Walch G. Mid- to long-term follow-up of total shoulder arthroplasty using a keeled glenoid in young adults with primary glenohumeral arthritis. *J shoulder Elb Surg*. 2013;22(7):894-900. doi:10.1016/j.jse.2012.09.016
52. Meijering D, Boerboom A, Gerritsma C, et al. Mid-term results of the Latitude primary total elbow arthroplasty. *J shoulder Elb Surg*. 2021. doi:10.1016/J.JSE.2021.08.028
53. Borton ZM, Prasad G, Konstantopoulos G, et al. Mid- to long-term survivorship of the cemented, semiconstrained Discovery total elbow arthroplasty. *J Shoulder Elb Surg*. 2021;30(7):1662-1669. doi:10.1016/J.JSE.2020.12.007
54. Dalemans A, De Smet L, Degreef I. Long-term outcome of elbow resurfacing. *J shoulder Elb Surg*. 2013;22(11):1455-1460. doi:10.1016/j.jse.2013.06.013
55. Tiusanen RE, Tiusanen HT, Saltychev M, Sarantsin PM. Discovery® elbow system arthroplasty: results of 10-year follow-up. *Eur J Orthop Surg Traumatol 2021 316*. 2021;31(6):1207-1213. doi:10.1007/S00590-020-02861-6
56. Plaschke HC, Thillemann TM, Brorson S, Olsen BS. Implant survival after total elbow arthroplasty: a retrospective study of 324 procedures performed from 1980 to 2008. *J shoulder Elb Surg*. 2014;23(6):829-836. doi:10.1016/j.jse.2014.02.001
57. Fischer P, Sagerfors M, Jakobsson H, Pettersson K. Total Wrist Arthroplasty: A 10-Year Follow-Up. *J Hand Surg (American Vol)*. 2020;45(8):780.e1-780.e10. doi:10.1016/J.JHSA.2020.02.006
58. Zijlker HJA, Ritt MJPF, IJsselstein CB. Long-Term Results of Universal 2 Total Wrist Arthroplasty. *J Wrist Surg*. 2019;8(4):317. doi:10.1055/S-0039-1685469
59. Berber O, Garagnani L, Gidwani S. Systematic Review of Total Wrist Arthroplasty and Arthrodesis in Wrist Arthritis. *J Wrist Surg*. 2018;7(5):424. doi:10.1055/S-0038-1646956
60. Krukhaug Y, Lie SA, Havelin LI, Furnes O, Hove LM. Results of 189 wrist replacements. A report from the Norwegian Arthroplasty Register. *Acta Orthop*. 2011;82(4):405-409. doi:10.3109/17453674.2011.588858
61. Martin-Ferrero M. Ten-year long-term results of total joint arthroplasties with ARPE® implant in the treatment of trapeziometacarpal osteoarthritis. *J hand Surg (European Vol)*. 2014;39(8):826-832. doi:10.1177/1753193413516244
62. Martin-Ferrero M, Simón-Pérez C, Coco-Martín MB, Vega-Castrillo A, Aguado-Hernández H, Mayo-Iscar A. Trapeziometacarpal total joint arthroplasty for osteoarthritis: 119 patients with a minimum of 10 years follow-up. *J Hand Surg (European Vol)*. 2020;45(5):443-451. doi:10.1177/1753193419871660
63. Martin-Ferrero MA, Trigueros-Larrea JM, Cal EM la, Coco-Martin B, Simon-Perez C. Long-Term Results of Joint Arthroplasty with Total Prosthesis for Trapeziometacarpal Osteoarthritis in Patients over 65 Years of Age. *Geriatrics*. 2021;6(3). doi:10.3390/GERIATRICS6030065
64. Krukhaug Y, Lie S a., Havelin LI, Furnes O, Hove LM, Hallan G. The results of 479 thumb carpometacarpal joint replacements reported in the Norwegian Arthroplasty Register. *J Hand Surg (European Vol)*. 2014;39:819-825. doi:10.1177/1753193413513988
65. Teissier J, Teissier P, Toffoli A. Trapeziometacarpal prostheses. *Hand Surg Rehabil*. 2021;40:S106-S116. doi:10.1016/J.HANSUR.2020.09.013
66. De Smet A, Vanhove W, Benis S, Verstraete M, Hollevoet N. Ten-year outcomes of the Arpe prosthesis for the treatment of osteoarthritis of the trapeziometacarpal joint. *Acta Orthop Belg*. 2020;86(1):131-136.

67. Tchurukdichian A, Guillier D, Moris V, See LA, Macheboeuf Y. Results of 110 IVORY® prostheses for trapeziometacarpal osteoarthritis with a minimum follow-up of 10 years. *J Hand Surg (European Vol)*. 2020;45(5):458-464. doi:10.1177/1753193419899843
68. Dehl M, Chelli M, Lippmann S, Benaissa S, Rotari V, Moughabghab M. Results of 115 Rubis II reverse thumb carpometacarpal joint prostheses with a mean follow-up of 10 years: *J Hand Surg (European Vol)*. 2017;42(6):592-598. doi:10.1177/1753193416687508
69. Hallan G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI. Medium- and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register. *J bone Jt Surg (British Vol)*. 2007;89(12):1574-1580. doi:10.1302/0301-620X.89B12.18969
70. Gøthesen O, Espehaug B, Havelin L, et al. Survival rates and causes of revision in cemented primary total knee replacement: a report from the Norwegian Arthroplasty Register 1994-2009. *Bone Joint J*. 2013;95-B(5):636-642. doi:10.1302/0301-620X.95B5.30271
71. Orthopaedic Data Evaluation Panel. Introduction to ODEP. https://www.odep.org.uk/.
72. Shah FA, Thomsen P, Palmquist A. Osseointegration and current interpretations of the bone-implant interface. *Acta Biomater*. 2019;84:1-15. doi:10.1016/J.ACTBIO.2018.11.018
73. Apostu D, Lucaciu O, Berce C, Lucaciu D, Cosma D. Current methods of preventing aseptic loosening and improving osseointegration of titanium implants in cementless total hip arthroplasty: a review. *J Int Med Res*. 2018;46(6):2104-2119. doi:10.1177/0300060517732697
74. Mavrogenis A, Dimitriou R, Parvizi J, Babis G. Biology of implant osseointegration. *J Musculoskelet Neuronal Interact*. 2009;9(2):61-71.
75. Kohli N, Stoddart J, van Arkel R. The limit of tolerable micromotion for implant osseointegration: a systematic review. *Sci Rep*. 2021;11(1). doi:10.1038/S41598-021-90142-5
76. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
77. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
78. Ryd L, Albrektsson BE, Carlsson L, et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J bone Jt Surg (British Vol)*. 1995;77(3):377-383.
79. Reish TG, Clarke HD, Scuderi GR, Math KR, Scott WN. Use of multi-detector computed tomography for the detection of periprosthetic osteolysis in total knee arthroplasty. *J Knee Surg*. 2006;19(4):259-264. doi:10.1055/s-0030-1248116
80. Davidson J, Hedley W. A method of precise localisation and measurement by means of roentgen rays. *Lancet*. 1897;65(16):1001. doi:10.1016/S0140-6736(00)31032-7
81. Davidson M. Roentgen rays and localization. An apparatus for exact measurement and localization by means of roentgen rays. *Brit Med J*. 1898;1:10-14. doi:10.1136/bmj.1.1931.10
82. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl*. 1989;232:1-51.
83. Kärrholm J, Gill RHS, Valstar ER. The history and future of radiostereometric analysis. *Clin Orthop Relat Res*. 2006;448:10-21. doi:10.1097/01.blo.0000224001.95141.fe
84. Vrooman HA, Valstar ER, Brand GJ, Admiraal DR, Rozing PM, Reiber JHC. Fast and accurate automated measurements in digitized stereophotogrammetric radiographs. *J Biomech*. 1998;31:491-498. doi:10.1016/s0021-9290(98)00025-6

85. Nelissen R, Kaptein B, Veeger B. In memoriam. Edward Valstar (1970-2017). *Acta Orthop*. 2017;88(6):701-702. doi:10.1080/17453674.2017.1375341
86. Valstar E. Digital Roentgen Stereophotogrammetry: Development, Validation, and Clinical Application. 2002.
87. Valstar ER, Vrooman HA, Toksvig-Larsen S, Ryd L, Nelissen RG. Digital automated RSA compared to manually operated RSA. *J Biomech*. 2000;33(12):1593-1599.
88. Kaptein B, Valstar E, Spoor C, Stoel B, Rozing P. Model-based RSA of a femoral hip stem using surface and geometrical shape models. *Clin Orthop Relat Res*. 2006;448(448):92-97. doi:10.1097/01.BLO.0000224010.04551.14
89. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC. A new model-based RSA method validated using CAD models and models from reversed engineering. *J Biomech*. 2003;36(6):873-882. doi:10.1016/S0021-9290(03)00002-2
90. Valstar ER, de Jong FW, Vrooman HA, Rozing PM, Reiber JHC. Model-based Roentgen stereophotogrammetry of orthopaedic implants. *J Biomech*. 2001;34(6):715-722. doi:10.1016/S0021-9290(01)00028-8
91. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563-572. doi:10.1080/17453670510041574
92. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. *J bone Jt Surg (British Vol)*. 1994;76:912-917.
93. Grewal R, Rimmer MG, Freeman MA. Early migration of prostheses related to long-term survivorship. Comparison of tibial components in knee replacement. *J bone Jt Surg (British Vol)*. 1992;74(2):239-242.
94. Hauptfleisch J, Glyn-Jones S, Beard D, Gill H, Murray D. The premature failure of the Charnley Elite-Plus stem. *J Bone Jt Surg (British Vol)*. 2006;88(2):179-183. doi:10.1302/0301-620X.88B2.17055
95. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, Nelissen RGHH. Good diagnostic performance of early migration as a predictor of late aseptic loosening of acetabular cups: results from ten years of follow-up with Roentgen stereophotogrammetric analysis (RSA). *J bone Jt Surg (American Vol)*. 2012;94(10):874-880. doi:10.2106/JBJS.K.00305
96. Pijls B. Evidence based introduction of orthopaedic implants. RSA, implant quality and patient safety. 2013.
97. Hasan S, Marang-van de Mheen PJ, Kaptein BL, Nelissen RGHH, Pijls BG. RSA-tested TKA Implants on Average Have Lower Mean 10-year Revision Rates Than Non-RSA-tested Designs. *Clin Orthop Relat Res*. 2020;478(6):1232-1241. doi:10.1097/CORR.0000000000001209
98. Nelissen RGHH, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. *J bone Jt Surg (American Vol)*. 2011;93 Suppl 3:62-65. doi:10.2106/jbjs.k.00907
99. Kärrholm J. Radiostereometric analysis of early implant migration – a valuable tool to ensure proper introduction of new implants. *Acta Orthop*. 2012;83(6):551-552. doi:10.3109/17453674.2012.745352
100. Pijls BG, Nelissen R. The era of phased introduction of new implants. *Bone Jt Res*. 2016;5(6):215-217. doi:10.1302/2046-3758.56.2000653
101. Dutch Orthopaedic Association. *Guideline Total Hip Prosthesis*.; 2019. https://richtlijnendatabase.nl/richtlijn/totale_heupprothese_thp.

PART I

ACCURACY AND PRECISION OF RADIOSTEREOMETRIC ANALYSIS IN TOTAL JOINT ARTHROPLASTY IN THE UPPER EXTREMITY

Chapter 2

The accuracy and precision of radiostereometric analysis in upper limb arthroplasty – a systematic review of 23 RSA studies

B. ten Brinke, A. Beumer, K.L.M. Koenraadt, D. Eygendaal,
G.A. Kraan, N.M.C. Mathijssen

Acta Orthopaedica 2017; 88 (3): 320–325

ABSTRACT

Background and purpose: Radiostereometric analysis (RSA) is an accurate method for measurement of early migration of orthopaedic implants. Since a relation has been shown between early migration and future loosening of total knee and hip prostheses, RSA plays an important role in the development and evaluation of prostheses. However, there have been few RSA studies of the upper limb and the value of RSA of the upper limb is not yet clear. We therefore performed a systematic review to investigate the accuracy and precision of RSA in the upper limb.

Patients and methods: PRISMA guidelines were followed and the protocol for this review was published online at PROSPERO under registration number CRD42016042014. A systematic search of the literature was performed in the databases Embase, Medline, Cochrane, Web of Science, Scopus, Cinahl, and Google Scholar on April 25, 2015 based on the keywords 'radiostereometric analysis', 'shoulder prosthesis', 'elbow prosthesis', 'wrist prosthesis', 'trapeziometacarpal joint prosthesis', 'humerus', 'ulna', 'radius', 'carpus'. Articles concerning RSA for the analysis of early migration of prostheses of the upper limb were included. Quality assessment was performed using the MINORS score, Downs and Black checklist and the ISO RSA standard. Accuracy and precision data were extracted using a predefined extraction form.

Results: 23 studies were included. Precision values were in the 0.06 – 0.88 mm and 0.05 – 10.7° range for the shoulder, the 0.05 – 0.34 mm and 0.16 – 0.76° range for the elbow, and the 0.16 – 1.83 mm and 11 – 124° range for the TMC joint. Accuracy data from marker- and model-based RSA were not reported in the studies included.

Interpretation: RSA is a highly precise method for measurement of early migration of orthopaedic implants in the upper limb. However, the precision of rotation measurement is poor in some components. Challenges with RSA in the upper limb include the symmetrical shape of prostheses and the limited size of surrounding bone, leading to over-projection of the markers by the prosthesis. We recommend higher adherence to RSA guidelines and encourage investigators to publish long-term follow-up RSA studies.

INTRODUCTION

Total joint replacement for severe osteoarthritis (OA) of the shoulder, elbow, wrist or trapeziometacarpal (TMC) joint has become an accepted treatment option. Several implant systems have been developed with ten-year survival rates ranging between 63% and 92% for shoulder arthroplasty,[1–6] 64% and 91% for elbow arthroplasty,[7–9] 60% and 71% for wrist arthroplasty,[10,11] and 91% and 94% for replacement of the TMC joint.[12–14] These long-term survival rates are inferior to those for total knee replacement (89–95%) and total hip replacement (96–100%).[15,16] Improvement of implant survival and implant design in the upper limb is required, including assessment of the influence of implant modifications on survival. However, the number of upper limb implants is relatively low and it can take ten or even more years before signs of loosening become visible on standard radiographs. Radiostereometric analysis (RSA) enables accurate measurement of early migration within the first postoperative year. For hip and knee prostheses, a relation between early migration measured with RSA and future aseptic loosening has been shown.[17–21] Thus, RSA plays an important role in the development, introduction and evaluation of new implant designs. Only a small number of RSA studies have been performed on the upper limb. Implants of the upper extremity are different from knee and hip prostheses in their size, shape and joint kinematics. It is therefore questionable whether the usefulness and precision of RSA of the upper extremity is comparable to that of the lower extremity. To investigate the accuracy and precision of RSA in the upper limb, we performed a systematic review of the literature.

METHODS

Data Sources and search strategy

A research protocol for this review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) was published online at the PROSPERO international prospective register of systematic reviews (http://www.crd.york.ac.uk/prospero) under registration number CRD42016042014.[22] A systematic literature search was performed in the electronic databases Embase, Medline (OvidSP), Cochrane, Web of Science, Scopus, Cinahl (EBSCO), and Google Scholar. The following keywords were used to build the literature search: 'radiostereometric analysis', 'shoulder prosthesis', 'elbow prosthesis', 'wrist prosthesis', 'trapeziometacarpal joint prosthesis', 'humerus', 'ulna', 'radius', 'carpus'. The search was performed on April 25, 2015 and can be found in Appendix A. Reference lists from included articles were screened to include relevant studies that were not directly found with the search. To avoid missing any literature that was published during the drafting of this review, the search was repeated in March 2016.

Inclusion criteria and study selection

Studies were included if they described RSA of prostheses in the shoulder, elbow, wrist, and carpometacarpal joints. All types of study design, both prospective and retrospective, and data retrieved from clinical and experimental studies were included. Studies were excluded if they used RSA for purposes other than measurement of migration of prostheses (e.g. joint kinematics, fracture stability and skeletal growth). Only articles written in English were included. Selection of suitable studies was performed independently by two authors (BB and AB). Disagreements were solved by discussion, and a final decision was made by a third reviewer (GK) if there was disagreement.

Quality assessment

To assess the risk of bias, all articles were scored using fourteen criteria from the revised version of the MINORS score and the Downs and Black checklist (Appendix B).[23,24] For every criterion that was met, one point was given. No points were given if the criterion was not met or in the case that the criterion was not applicable. To assess RSA specific quality, all studies were scored using 11 items from a standard protocol that was developed by the International Organization for Standardization and the European Standards Working Group on Joint Replacement Implants.[25] This protocol was developed to facilitate comparison between different centers and recommends to include all these criteria in publishing RSA results. All the criteria can be found in Appendix C. The maximum score of the RSA specific quality assessment was 20 points. Two authors (BB, KK) assessed the quality independently. If consensus was not reached after discussion, a third reviewer (NM) was consulted.

Data extraction

Data were extracted by one investigator (BB) and extraction was done using a predefined template including the following topics: (1) study information: authors and year of publication; (2) study design: type of study, population size, and follow-up; (3) the joint involved, used prostheses and components; (4) RSA details: marker-based or model-based RSA, use of double examinations, translation data (mm), rotation data (˚), and data on accuracy and precision.

Outcomes

Accuracy can be defined as the closeness of a true value to the most probable value originating from a series of measurements.[26] Thus, accuracy data were collected from studies that determined the accuracy by comparison with another method that calculates migration and that has a resolution substantially better than that of RSA. To investigate the precision of translation and rotation values, we included all results from double examinations in clinical RSA studies. The standard deviation (SD) of the calculated migration using double examinations was used to determine the precision, defined as 1.96 × SD. Precision was calculated separately for the shoulder, elbow, and TMC joint. If prosthesis components were analyzed separately, precision was calculated for each component. If precision was given for all 3 axes (the x-, y-, and z-axis), the lowest precision was used to calculate the mean precision.

RESULTS

Literature search

Our literature search resulted in 214 articles. After screening of titles and abstracts, 35 studies remained. Assessment of the full text resulted in 23 studies being included. Screening of references did not result in any additional inclusions. Repeating the literature search in March 2016 resulted in three additional studies (Figure 1).[27–29]

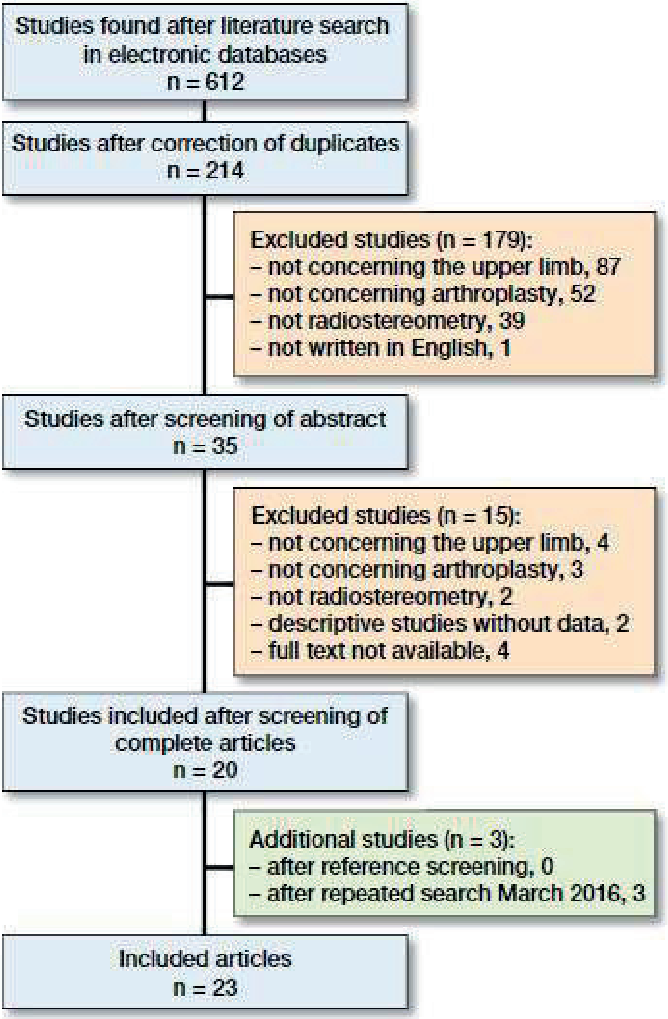


Figure 1. PRISMA flow chart of study selection.

Studies included

Fourteen studies involved the shoulder,[26,28,30–41] four studies involved the elbow,[42–45] and five studies involved the TMC joint.[27,29,46–48] No articles concerning the radiocarpal, distal radioulnar, metacarpophalangeal or interphalangeal joints were found (Appendix D).

Quality assessment

Assessment using the MINORS score and the Downs and Black checklist resulted in a mean quality score of 9 (3–14) points. One study had the maximum score of 14, but eight studies did not achieve more than half of the points (Appendix B). Regarding the RSA-specific quality assessment, the mean score was 12 (Range: 1–17) points on a scale from 0 to 20. None of the included studies met all the criteria. The extent to which the different ISO criteria were met in the RSA studies varied considerably. The cut-off level for rigid body fitting and accuracy data were given in four studies, while only one study presented the cut-off level for the condition number. Other criteria such as follow-up intervals, details of software, translation data and the method of determining the implant position were given in almost all the studies included. All RSA-specific quality scores can be found in Appendix C.

Accuracy

None of the included studies reported accuracy data from marker-based or model-based RSA. In one phantom experiment by Sköldenberg and Odquist,[26] marker-free RSA was compared with standard (i.e. marker-based) RSA to determine the accuracy in a humeral head resurfacing prosthesis. Accuracy of translations of marker-free RSA varied between 0.22 and 0.47 mm. Accuracy of rotations varied between 0.92° and 1.56° compared to marker-based RSA (Appendix D).

Precision

Shoulder – Eight studies on the shoulder reported precision values using double examinations in a clinical setting (five glenoid components, three humeral components).[28,33,35–38,40,41]. Sköldenberg and Odquist described double examinations, although not in a clinical setting but in saw bone models.[26] Two additional studies by Nuttall et al. (2009, 2012) reported precision values from a previous study by the same author and were not included in the precision analysis.[31,38,39] The mean precision of the glenoid component was 0.18 mm for translations and 0.96˚ for rotations. For the humeral component, mean precision was 0.61 mm for translations and 5.34˚ for rotations.

Elbow – All four elbow studies gave precision values for the RSA technique. Van der Lugt et al. reported precision data from a previous study by Valstar et al. and was not included, so that three studies remained in the precision analysis (one humeral component, one ulnar component, and one both components).[44,49] No double examinations were performed in the study by Valstar et al. since permission for double examinations was not given by the institution's ethics committee.[49] To calculate the precision in this study, the first postoperative RSA radiograph was scanned and analyzed repeatedly. Despite the fact that no double examinations were performed, precision values from this study were included in our analysis. The mean precision was 0.29 mm for translations of the humeral component and 0.66˚ for rotations. For the ulnar component, mean precision was 0.12 mm for translations and 0.56˚ for rotations.

TMC joint – Precision analysis of the trapezium component of the TMC joint prosthesis using clinical double examinations was described in two studies by Hansen et al.[46,48] In the first study, two trapezium cup designs were analyzed using double examinations in both a phantom and a clinical study.[46] Only precision data obtained from the clinical experiments were included in this review. The mean precision of translations in the trapezium component was 0.93 mm. Precision of rotation measurements could only be given in the first study by Hansen et al. and varied between 43° and 124°.[46] Clinical double examinations concerning the metacarpal stem were reported in one study.[46] Precision of translation measurements varied between 0.22 mm and 0.50 mm. Precision values for rotations varied between 11° and 25°.

DISCUSSION

Main results

The purpose of this systematic review was to evaluate the accuracy and precision of RSA of prostheses in the upper limb. We found that RSA is a highly precise technique for detection of early migration of orthopaedic implants in the upper limb. Precision values of translation measurements were comparable with those from RSA of total hip and knee arthroplasties.[50–53] On the whole, precision of rotations was lower than that of translation measurements. With regard to the shoulder, it is notable that precision of rotations was lower in the humeral component than in the glenoid component. Especially studies on humeral head resurfacing prostheses showed poor precision values.[33,41] This might be due to the symmetrical shape of the implant, which constitutes a challenge when calculating rotations. Other implant designs with a highly symmetrical shape such as the trapezium Elektra screw cup and all-polyethylene cup were also found to have poor precision values.[46] The small size of the surrounding bone, especially in the trapezium bone, and the small number of markers that can be inserted around the prosthesis might lead to over-projection of the bone markers by the prosthesis and to a lack of detectable markers.[29] On the other hand, a cadaver study by Ooms et al. showed a higher precision than in clinical studies for both the trapezium and the metacarpal component of the TMC joint prosthesis.[27] Although analysis can be performed in a more controlled environment in a cadaver study, these results indicate that migration measurement of the TMC joint prosthesis with higher precision should be possible. Thus, clinical research concerning the TMC joint should be done with a high diligence. RSA radiographs should be evaluated immediately, so that radiographs could be repeated in case of occluded markers.

The accuracy of RSA in the upper limb has barely been described. On the other hand, the accuracy of the technique with total hip and knee prostheses has been studied more extensively. Since the RSA technique in the lower limb and the upper limb is similar, accuracy data from hip and knee RSA studies might be extrapolated to the upper limb. The predictive value of early migration for future loosening in upper limb arthroplasty did not fall within the scope of this review, as not enough data are available. The only scientific basis for the relation between early postoperative motion of the prosthesis and future outcomes is described in a study by Streit et al.[28] The authors noted a correlation between higher migration in the first three postoperative years and mean VAS pain scores. Furthermore, they found that radiolucencies were observed in approximately two-thirds of the prostheses in the high-motion group and in around one-fifth in the low-motion group. Although the role of radiolucent lines is still debated, the authors suggested the possibility of early micromotion where there are radiolucencies.

Quality of the studies included

A limitation of this review is the low number of articles included. Regarding the quality of the studies included, it can be noted that the adherence to existing guidelines was poor.[25,54] As recommended in the ISO standard, precision should be assessed in each clinical RSA study using double examinations. Several studies did not report double examinations or referred to precision values from previous studies.[29,31,32,39,44] For example, Nuttall et al. presented a study on the humeral component in TSA and referred to precision values of the glenoid component.[38,39] None of the studies that were included followed all the guidelines from the ISO standard. The most frequently ignored items were rigid body fitting error, cut-off levels for condition numbers, accuracy details, and radiological details. These findings are in accordance with the findings of Madanat et al. who described the low adherence to RSA guidelines in RSA studies on knee and hip arthroplasty.[55] To improve the methodological quality and to make it easier to compare the results of studies from different centers, better adherence to the guidelines is recommended for future studies.

Future directions

Future research should focus on three main topics. First, to learn more about precision and accuracy of RSA it is important to increase the number of RSA studies in shoulder, elbow, wrist and hand arthroplasty. Secondly, long-term results are required to evaluate migration patterns in orthopaedic implants and to investigate the predictive value of early migration for future loosening. The follow-up time in all but four studies included in this review was two years or less. We therefore encourage the authors of the included RSA studies to re-assess their patient cohorts after five and ten years, in order to provide adequate follow-up data. Thirdly, given the predictive value of early migration in total knee and hip arthroplasty, RSA is an important tool in the development, introduction, and evaluation of orthopaedic implants. This predictive value has not yet been proven in the upper limb, so the value of RSA in upper limb arthroplasty is not yet clear. Future research should therefore concentrate on the predictive value of early migration for loosening of prostheses in the upper limb.

CONCLUSION

RSA is a highly precise method for measurement of early migration of orthopaedic implants in the upper limb. However, the precision of rotation in several components has been poor. Challenges of RSA in the upper limb include the symmetrical shape of some components and the limited size of surrounding bone, leading to over-projection of the markers by the prosthesis. We recommend higher adherence to RSA guidelines and encourage investigators to present long-term follow-up RSA studies.

REFERENCES

1. Singh JA, Sperling JW, Cofield RH. Revision surgery following total shoulder arthroplasty: analysis of 2588 shoulders over three decades (1976 to 2008). *J bone Jt Surg (British Vol)*. 2011;93(11):1513-1517. doi:10.1302/0301-620X.93B11.26938
2. Gadea F, Alami G, Pape G, Boileau P, Favard L. Shoulder hemiarthroplasty: outcomes and long-term survival analysis according to etiology. *Orthop Traumatol Surg Res*. 2012;98(6):659-665. doi:10.1016/j.otsr.2012.03.020
3. Denard PJ, Raiss P, Sowa B, Walch G. Mid- to long-term follow-up of total shoulder arthroplasty using a keeled glenoid in young adults with primary glenohumeral arthritis. *J shoulder Elb Surg*. 2013;22(7):894-900. doi:10.1016/j.jse.2012.09.016
4. Fevang BTS, Nystad TW, Skredderstuen A, Furnes ON, Havelin LI. Improved survival for anatomic total shoulder prostheses. *Acta Orthop*. 2015;86(1):63-70. doi:10.3109/17453674.2014.984113
5. Voorde PC Ten, Rasmussen J V, Olsen BS, Brorson S. Resurfacing shoulder arthroplasty for the treatment of severe rheumatoid arthritis. *Acta Orthop*. 2015;86(3):293-297. doi:10.3109/17453674.2015.1018761
6. Swedish Shoulder Arthroplasty Registry. Annual report 2015. http://www.ssas.se/axel/reports.php.
7. Dalemans A, De Smet L, Degreef I. Long-term outcome of elbow resurfacing. *J shoulder Elb Surg*. 2013;22(11):1455-1460. doi:10.1016/j.jse.2013.06.013
8. Mansat P, Bonnevialle N, Rongières M, Mansat M, Bonnevialle P. Experience with the Coonrad-Morrey total elbow arthroplasty: 78 consecutive total elbow arthroplasties reviewed with an average 5 years of follow-up. *J Shoulder Elbow Surg*. 2013;22(11):1461-1468. doi:10.1016/j.jse.2013.07.042
9. Plaschke HC, Thillemann TM, Brorson S, Olsen BS. Implant survival after total elbow arthroplasty: a retrospective study of 324 procedures performed from 1980 to 2008. *J shoulder Elb Surg*. 2014;23(6):829-836. doi:10.1016/j.jse.2014.02.001
10. Krukhaug Y, Lie SA, Havelin LI, Furnes O, Hove LM. Results of 189 wrist replacements. A report from the Norwegian Arthroplasty Register. *Acta Orthop*. 2011;82(4):405-409. doi:10.3109/17453674.2011.588858
11. Ward CM, Kuhl T, Adams BD. Five to ten-year outcomes of the Universal total wrist arthroplasty in patients with rheumatoid arthritis. *J bone Jt Surg (American Vol)*. 2011;93(10):914-919. doi:10.2106/JBJS.H.01614
12. Krukhaug Y, Lie S a., Havelin LI, Furnes O, Hove LM, Hallan G. The results of 479 thumb carpometacarpal joint replacements reported in the Norwegian Arthroplasty Register. *J Hand Surg (European Vol)*. 2014;39:819-825. doi:10.1177/1753193413513988
13. Martin-Ferrero M. Ten-year long-term results of total joint arthroplasties with ARPE® implant in the treatment of trapeziometacarpal osteoarthritis. *J hand Surg (European Vol)*. 2014;39(8):826-832. doi:10.1177/1753193413516244
14. Semere A, Vuillerme N, Corcella D, Forli A, Moutet F. Results with the Roseland(®) HAC trapeziometacarpal prosthesis after more than 10 years. *Chir Main*. 2015;34(2):59-66. doi:10.1016/j.main.2015.01.004
15. Hallan G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI. Medium- and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register. *J bone Jt Surg (British Vol)*. 2007;89(12):1574-1580. doi:10.1302/0301-620X.89B12.18969

16. Gøthesen O, Espehaug B, Havelin L, et al. Survival rates and causes of revision in cemented primary total knee replacement: a report from the Norwegian Arthroplasty Register 1994-2009. *Bone Joint J*. 2013;95-B(5):636-642. doi:10.1302/0301-620X.95B5.30271
17. Grewal R, Rimmer MG, Freeman MA. Early migration of prostheses related to long-term survivorship. Comparison of tibial components in knee replacement. *J bone Jt Surg (British Vol)*. 1992;74(2):239-242.
18. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. *J bone Jt Surg (British Vol)*. 1994;76:912-917.
19. Ryd L, Albrektsson BE, Carlsson L, et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J bone Jt Surg (British Vol)*. 1995;77(3):377-383.
20. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
21. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
22. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *J Clin Epidemiol*. 2009;62(10):1006-1012. doi:10.1016/j.jclinepi.2009.06.005
23. Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological Index for Non-Randomized Studies (Minors): Development and Validation of a New Instrument. *ANZ J Surg*. 2003;73(May):712-716.
24. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health*. 1998;52(6):377-384. doi:10.1136/jech.52.6.377
25. International Organisation for Standardization. *Implants for Surgery — Roentgen Stereophotogrammetric Analysis for the Assessment of Migration of Orthopaedic Implants*.; 2013.
26. Sköldenberg O, Odquist M. Measurement of migration of a humeral head resurfacing prosthesis using radiostereometry without implant marking: an experimental study. *Acta Orthop*. 2011;82(2):193-197. doi:10.3109/17453674.2011.566133
27. Ooms EM, ten Brinke B, Mathijssen NMC, Blom IF, Deijkers RLM, Kraan G a. Feasibility of model-based Roentgen Stereophotogrammetric Analysis to evaluate early migration of the trapeziometacarpal joint prosthesis. *BMC Musculoskelet Disord*. 2015;16(1):295. doi:10.1186/s12891-015-0747-3
28. Streit JJ, Shishani Y, Green ME, et al. Analysis of Glenoid Component Motion After Total Shoulder Arthroplasty. *Orthopedics*. 2015;38(10):891-897. doi:10.3928/01477447-20151002-56
29. ten Brinke B, Mathijssen NMC, Blom I, Deijkers RLM, Ooms EM, Kraan G a. Model-based roentgen stereophotogrammetric analysis of the surface replacement trapeziometacarpal total joint arthroplasty. *J Hand Surg (European Vol)*. 2016;41:925-929. doi:10.1177/1753193416629070
30. Szerlip B, Muh S, Streit JJ, Gobezie R. Humeral Fixation in Shoulder Arthroplasty: Does Stem Geometry Matter? *Semin Arthroplast*. 2012;23:103-105. doi:10.1053/j.sart.2012.03.008
31. Nuttall D, Haines JF, Trail IA. The early migration of a partially cemented fluted pegged glenoid component using radiostereometric analysis. *J Shoulder Elb Surg*. 2012;21:1191-1196. doi:10.1016/j.jse.2011.07.028

32. Nuttall D, Birch A, Haines JF, Trail IA. Radiostereographic analysis of a shoulder surface replacement: does hydroxyapatite have a place? *Bone Joint J*. 2014;96-B(8):1077-1081. doi:10.1302/0301-620X.96B8.30534
33. Mechlenburg I, Klebe TM, Dossing K V, Amstrup A, Soballe K, Stilling M. Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: Two-year results of a randomized controlled clinical trial. *J Shoulder Elb Surg*. 2014;23:1427-1436. doi:10.1016/j.jse.2014.05.012
34. Jónsson E, Lidgren L, Mjöberg B, Rydholm U, Selvik G. Humeral cup fixation in rheumatoid shoulders. Roentgen stereophotogrammetry of 12 cases. *Acta Orthop Scand*. 1990;61:116-117. doi:10.3109/17453679009006500
35. Nagels J, Valstar ER, Stokdijk M, Rozing PM. Patterns of loosening of the glenoid component. *J bone Jt Surg (British Vol)*. 2002;84(1):83-87.
36. Rahme H, Mattsson P, Larsson S. Stability of cemented all-polyethylene keeled glenoid components. A radiostereometric study with a two-year follow-up. *J bone Jt Surg (British Vol)*. 2004;86:856-860. doi:10.1016/S1551-7977(08)70036-0
37. Rahme H, Mattsson P, Wikblad L, Larsson S. Cement and press-fit humeral stem fixation provides similar results in rheumatoid patients. *Clin Orthop Relat Res*. 2006;448:28-32. doi:10.1097/01.blo.0000224007.25636.85
38. Nuttall D, Haines JF, Trail II. A study of the micromovement of pegged and keeled glenoid components compared using radiostereometric analysis. *J Shoulder Elb Surg*. 2007;16:65-70. doi:10.1016/j.jse.2006.01.015
39. Nuttall D, Haines JF, Trail IA. The effect of the offset humeral head on the micromovement of pegged glenoid components: A comparative study using radiostereometric analysis. *J Bone Jt Surg Ser B*. 2009;91:757-761. doi:10.1302/0301-620x.91b6.22060
40. Rahme H, Mattsson P, Wikblad L, Nowak J, Larsson S. Stability of cemented in-line pegged glenoid compared with keeled glenoid components in total shoulder arthroplasty. *J bone Jt Surg (American Vol)*. 2009;91:1965-1972. doi:10.2106/JBJS.H.00938
41. Stilling M, Mechlenburg I, Amstrup A, Soballe K, Klebe T. Precision of novel radiological methods in relation to resurfacing humeral head implants: Assessment by radiostereometric analysis, DXA, and geometrical analysis. *Arch Orthop Trauma Surg*. 2012;132:1521-1530. doi:10.1007/s00402-012-1580-x
42. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis: 21 Elbows followed for 2 years. *Acta Orthop Scand*. 2002;73:264-272. doi:10.1080/000164702320155220
43. Rahme H, Mattsson P, Larsson S. Stable fixation of the ulnar component in the Kudo elbow prosthesis. A radiostereometric (RSA) study of 13 prostheses with 2-year follow-up. *Acta Orthop*. 2005;76(1):104-108. doi:10.1080/00016470510030418
44. van der Lugt JCT, Valstar ER, Witvoet-Braam SW, Nelissen RGHH. Migration of the humeral component of the Souter-Strathclyde elbow prosthesis: a long-term RSA study. *J bone Jt Surg (British Vol)*. 2010;92(2):235-241. doi:10.1302/0301-620X.92B2.22636
45. DeVos MJ, Verdonschot N, Luites JWH, Anderson PG, Eygendaal D. Stable fixation of the IBP humeral component implanted without cement in total elbow replacement: A radiostereometric analysis study of 16 elbows at two-year follow-up. *Bone Jt J*. 2014;96 B(2):229-236. doi:10.1302/0301-620X.96B2

46. Hansen TB, Larsen K, Bjergelund L, Stilling M. Trapeziometacarpal joint implants can be evaluated by roentgen stereophotogrammetric analysis. *J hand Surg (European Vol)*. 2010;35(6):480-485. doi:10.1177/1753193409355627
47. Hansen TB, Meier M, Moller MC, Larsen K, Stilling M. Primary cup fixation with different designs of trapeziometacarpal total joint trapezium components: a radiostereometric analysis in a pig bone model. *J hand Surg (European Vol)*. 2011;36:285-290.
48. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. A randomized clinical RSA study with 2-year follow-up. *Acta Orthop*. 2013;84(1):98-105. doi:10.3109/17453674.2013.765625
49. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis 21 elbows followed for 2 years. *Acta Orthop Scand*. 2002;73(3):264-272. doi:10.1080/000164702320155220
50. Ryd L. Micromotion in knee arthroplasty. A roentgen stereophotogrammetric analysis of tibial component fixation. *Acta Orthop Scand Suppl*. 1986;220:1-80.
51. Vrooman HA, Valstar ER, Brand GJ, Admiraal DR, Rozing PM, Reiber JHC. Fast and accurate automated measurements in digitized stereophotogrammetric radiographs. *J Biomech*. 1998;31(5):491-498. doi:10.1016/S0021-9290(98)00025-6
52. Ryd L, Yuan X, Löfgren H. Methods for determining the accuracy of radiostereometric analysis (RSA). *Acta Orthop Scand*. 2000;71(4):403-408. doi:10.1080/000164700317393420
53. Valstar ER, Vrooman HA, Toksvig-Larsen S, Ryd L, Nelissen RG. Digital automated RSA compared to manually operated RSA. *J Biomech*. 2000;33(12):1593-1599.
54. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563-572. doi:10.1080/17453670510041574
55. Madanat R, Mäkinen T, Aro HT, Bragdon C, Malchau H. Adherence of hip and knee arthroplasty studies to RSA standardization guidelines. A systematic review. *Acta Orthop*. 2014;85(5):447-455. doi:10.3109/17453674.2014.934187

SUPPLEMENTAL DATA

Appendix A The full literature search strategy for EMBASE database.

(‘radiostereometric analysis’/exp OR Stereoradiography/exp OR ((stereometry/exp OR stereophotogrammetry/exp) AND (radiography/exp OR radiodiagnosis/de OR ‘X ray system’/de OR ‘x ray’/de OR ‘radiological procedures’/exp)) OR (radiostereomet* OR radiostereograph* OR radiostereophotogrammet* OR ((radio* OR rontgen* OR roentgen* OR X-ray OR X-rays) NEAR/3 (stereomet* OR stereophotogrammet*)) OR Stereoradiogra*):ab,ti) AND (arm/exp OR ‘bones of the arm and hand’/exp OR shoulder/exp OR ‘shoulder girdle’/exp OR ‘shoulder surgery’/exp OR ‘arm disease’/exp OR ‘arm movement’/exp OR ‘carpometacarpal joint’/exp OR ‘arm prosthesis’/exp OR ‘elbow prosthesis’/exp OR ‘shoulder prosthesis’/exp OR ‘wrist prosthesis’/exp OR ‘humerus head’/exp OR ((upper NEXT/1 (extremit* OR limb*)) OR arm OR arms OR forearm* OR hand OR hands OR finger* OR wrist OR shoulder* OR elbow* OR glenohumer* OR humeroscapul* OR scapulohumer* OR ((scapulo OR gleno) NEXT/1 humer*) OR trapeziometacarp* OR carpometacarp* OR scapula* OR clavicle* OR sternum* OR humer* OR metacarp* OR phalang* OR dorsopalmar* OR radioulnar* OR ‘rotator cuff’ OR scaphotrapez* OR trapez* OR ulna OR ulnar OR radius OR radial OR carpus OR carpal OR capitate* OR hamate* OR lunate* OR pisiform* OR scaphoid* OR triquetrum* OR radiolunate OR radiocapitate OR ulnocapitate OR radiotriquetral):ab,ti)

Appendix B Quality assessment criteria according to the MINORS Score and the Downs and Black checklist.

	DeVos 2014	Hansen 2010	Hansen 2011	Hansen 2013	Jonsson 1990	Mechlenburg 2014	Nagels 2002	Nutall 2007	Nutall 2009	Nutall 2012	Nutall 2014	Rahme 2004	Rahme 2005	Rahme 2006	Rahme 2009	Sköldenberg 2011	Stilling 2012	Szerlip 2012	Valstar 2002	Van der Lugt 2010	Streit 2012	Ten Brinke 2016	Ooms 2015
1	1	1	1	1	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1
2	1	1	1	1	0	1	0	0	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1
3	1	0	0	0	0	0	1	0	0	0	0	0	1	1	1	0	1	0	0	1	0	1	0
4	1	0	0	1	0	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	0
5	0	0	0	1	0	1	0	1	1	0	1	0	0	1	1	0	1	0	0	0	0	0	0
6	0	0	0	1	0	1	0	1	0	0	1	0	0	1	1	0	1	0	0	0	0	0	0
7	0	0	0	1	0	1	0	1	0	0	1	1	0	1	1	0	1	0	0	0	0	0	0
8	0	0	0	1	0	1	0	1	1	0	1	0	0	0	1	0	1	0	0	0	0	0	0
9	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	1	1	0	1	0
10	0	0	1	1	0	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0
11	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
12	1	0	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1
13	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
14	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
TOTAL	**9**	**6**	**7**	**13**	**3**	**13**	**7**	**9**	**8**	**7**	**10**	**9**	**10**	**13**	**14**	**7**	**13**	**5**	**8**	**8**	**7**	**8**	**6**

1 Is the aim of the study clearly described?
2 Are the endpoints appropriate to the aim of the study?
3 Does the study noted the inclusion of consecutive patients?
4 Are the characteristics of the patients included clearly described?
5 Did the authors select an adequate control group?
6 Did the authors studied contemporary groups?
7 Where the patients in different intervention groups or were the cases and controls recruited from the same population?
8 Are the baseline equivalence of groups clearly described?
9 Have the characteristics of patients lost to follow-up been described?
10 Is the prospective calculation of study size described?
11 Is the follow up time appropriate to the aim of the study?
12 Were the statistical tests used to assess the main outcome appropriate?
13 Are the interventions of interest clearly described?
14 Does the study provide estimates of the random variability in the data for the main outcome?

Appendix C RSA specific quality assessment using criteria from the ISO standard (ISO 16087:2013(E))

	DeVos 2014	Hansen 2010	Hansen 2011	Hansen 2013	Jonsson 1990	Mechlenburg 2014	Nagels 2002	Nutall 2007	Nutall 2009	Nutall 2012	Nutall 2014	Rahme 2004	Rahme 2005	Rahme 2006	Rahme 2009	Sköldenberg 2011	Stilling 2012	Szerlip 2012	Valstar 2002	Van der Lugt 2010	Streit 2015	Ten Brinke 2016	Ooms 2015
1A	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1B	1	1	0	0	0	1	0	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1
2A	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
2B	1	1	1	1	0	1	1	1	0	0	0	1	1	1	1	1	1	0	1	0	1	0	1
2C	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2D	0	1	0	1	0	1	0	1	1	1	1	0	0	0	0	1	1	0	0	0	1	0	1
3	0	1	0	1	0	1	1	0	0	0	0	1	1	1	1	1	1	0	1	0	1	0	1
4	1	0	0	1	0	0	1	1	1	1	0	1	1	1	1	0	0	0	1	1	1	0	0
5A	1	1	0	1	0	1	1	0	0	0	1	0	0	0	0	1	1	0	1	1	0	0	0
5B	1	1	0	1	0	1	1	0	0	0	1	0	0	0	0	1	1	0	1	1	0	0	0
6A	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1
6B	1	1	1	1	0	1	0	1	1	1	0	0	0	0	0	1	1	0	0	0	1	0	1
7	1	1	1	1	0	0	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1
8	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1
9A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
9B	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	0
10A	1	1	1	1	0	1	1	1	0	0	0	1	1	1	1	1	1	0	0	0	1	0	1
10B	1	1	1	1	0	1	1	1	0	0	0	1	1	1	1	1	1	0	0	0	1	0	1
11A	1	1	0	1	0	1	1	1	0	0	0	1	1	1	1	1	1	0	1	1	1	1	1
11B	1	1	0	0	0	0	0	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1
TOTAL	**15**	**16**	**9**	**16**	**1**	**14**	**13**	**14**	**10**	**10**	**7**	**13**	**13**	**13**	**13**	**17**	**14**	**2**	**14**	**12**	**17**	**9**	**14**

1A	Translation is expressed in millimetres
1B	Rotation is expressed in degrees
2A	Accuracy values are presented
2B	Precision values are presented
2C	Follow-up intervals are mentioned
2D	Type of cage and use of reference plates are given
3	Experimental setup is standardized or described in detail
4	The coordinate systems are described
5A	Method of image acquisition is described
5B	Scanner or system details are described
6A	Software name is stated
6B	Software version is stated
7	Size of marker beads used are given
8	Method of determining the position of implant (marker/model-based) is stated
9A	Cut-off level for condition number is stated
9B	Cut-off level for rigid body fitting error is stated
10A	Precision by double examination is presented
10B	Double examinations are performed in a sufficient number of patients
11A	Migration data are given in terms of translation (3 degrees of freedom)
11B	Migration data are given in angular rotations (3 degrees of freedom)

Appendix D Precision and accuracy data of included RSA studies

RCT, Randomized Controlled Trial; n/a, not available; TMC, trapeziometacarpal; N, number of participants.

	Author (year)	Type of implant	Study design	RSA Method	*N*	Time of follow-up (months)	Precision translation (mm)	Precision rotation (˚)	Accuracy translation (mm)	Accuracy rotation (˚)
Shoulder (glenoid component)	Nagels et al. (2002)	Polyethylene glenoid comp. (Biomet Inc, Warsaw, Indiana)	Cohort Study	Not described	5	36	0,35	n/a	n/a	n/a
	Rahme et al. (2004)	3M Modular (Smiths & Nephew, Memphis, Tennessee)	Cohort Study	Marker based	14	24	0,11-0,21	1,02-1,27	n/a	n/a
	Nutall et al. (2007)	Global shoulder arthroplasty system (DePuy, Leeds, UK)	RCT	Marker based	20	24	0,13	1,2	n/a	n/a
	Rahme et al. (2009)	Bigliani/Flatow total shoulder prosthesis (Zimmer, Warsaw, Indiana)	RCT	Marker based	26	24	0,04-0,07	n/a	n/a	n/a
	Nutall et al. (2012)	Global shoulder arthroplasty system (DePuy, Leeds, UK)	Cohort Study	Marker based	11	24	Nutall (2007)	Nutall (2007)	n/a	n/a
	Streit et al. (2015)	Polyethylene glenoid comp. (Arthrex, Naples, USA) or pegged glenoid comp. (Tornier, Edina, USA)	Cohort Study	Model based	11	36	0,06-0,14	0,55-0,88	n/a	n/a
Shoulder (humeral component)	Jonsson et al. (1990)	Scan Shoulder cups (MITAB, Sjöbo, Sweden)	Cohort Study	Model based	12	12	n/a	n/a	n/a	n/a
	Rahme et al. (2006)	3M Modular (Smiths & Nephew, Memphis, Tennessee)	RCT	Marker based	25	24	n/a	0,52-0,89	n/a	n/a
	Nutall et al. (2009)	Global shoulder arthroplasty system (DePuy, Leeds, UK)	RCT	Marker based	22	24	Nutall (2007)	Nutall (2007)	n/a	n/a

	Author (year)	Type of implant	Study design	RSA Method	*N*	Time of follow-up (months)	Precision translation (mm)	Precision rotation (˚)	Accuracy translation (mm)	Accuracy rotation (˚)
	Sköldenberg et al. (2011)	Copeland HHRI (biomet, Warsaw, Indiana)	Phantom study	Marker based	3	-	0,03-0,10	0,05-0,31	n/a	n/a
			Phantom study	Marker-free	3	-	0,14-0,20	0,86-0,61	0,20-0,44	0,85-1,45
	Stilling et al.(2012)	Copeland HHRI (biomet, Warsaw, Indiana) and Global CAP HHRI (DePuy, Leeds, UK)	RCT	Model based	21	6	0,60-0,88	10,67	n/a	n/a
	Szerlip et al. (2012)	Aequalis Press-Fit Shoulder Prosthesis (Tornier, Edina, USA) and Univers II (Arthrex, Naples, USA)	Cohort study	Marker based	29	24	n/a	n/a	n/a	n/a
	Nutall et al. (2014)	Global CAP HHRI (DePuy, Leeds, UK)	RCT	Model based	20	24	0,16	n/a	n/a	n/a
	Mechlenburg et al. (2014)	Copeland HHRI (biomet, Warsaw, Indiana) and Global CAP HHRI (DePuy, Warsaw, Indiana)	RCT	Model based	32	24	0,24-0,45	4,51	n/a	n/a
Elbow (humeral component)	Valstar et al. (2002)	Souter-Strathclyde (Stryker, Kalamazoo, USA)	Cohort Study	Marker based	18	24	0,13-0,34*	0,23-0,56*	n/a	n/a
	Van der Lugt et al. (2010)	Souter-Strathclyde (Stryker, Kalamazoo, USA)	Cohort Study	Marker based	18	98 (12-136)	Valstar (2002)	Valstar (2002)	n/a	n/a
	De Vos et al. (2014)	IBP (Biomet, Bridgend, UK)	Cohort Study	Marker based	16	24	0,08-0,23	0,38-0,76	n/a	n/a
Elbow (ulnar component)	Valstar et al. (2002)	Souter-Strathclyde (Stryker, Kalamazoo, USA)	Cohort Study	Marker based	15	24	0,05-0,17	0,16-0,68	n/a	n/a
	Rahme et al. (2005)	Kudo (Biomet, South Glamorgan, UK)	Cohort Study	Marker based	13	24	0,07-0,08	0,41-0,60	n/a	n/a

	Author (year)	Type of implant	Study design	RSA Method	*N*	Time of follow-up (months)	Precision translation (mm)	Precision rotation (˚)	Accuracy translation (mm)	Accuracy rotation (˚)
	Vander Lugt et al. (2010)	Souter-Strathclyde (Stryker, Kalamazoo, USA)	Cohort Study	Marker based	15	98 (12-136)	Valstar (2002)	Valstar (2002)	n/a	n/a
TMC-joint (trapezium component)	Hansen et al. (2010)	Elektra screw cup (Small Bone Innovations, Les Bruyères, France)	Phantom Study	Model based	10	-	0,06-0,26	2,32-18,27	n/a	n/a
			Cohort Study	Model based	5	0	0,28-0,45	43,30 - 123,92	n/a	n/a
		DLC all-polyethylene cup (Small Bone Innovations, Les Bruyères, France)	Phantom Study	Marker based	10	-	0,06-0,16	0,77-1,28	n/a	n/a
			Cohort Study	Marker based	6	0	0,89-1,83	70,15 - 115,95	n/a	n/a
	Hansen et al. (2011)	Elektra screw cup, DLC polyethylene cup (Small Bone Innovations, Les Bruyères, France) and MOTEC screw cup (Swemac AB, Linköbing, Sweden)	Animal study	Marker and Model based	36	-	n/a	n/a	n/a	n/a
	Hansen et al. (2013)	Elektra screw cup (Small Bone Innovations, Les Bruyères, France)	RCT	Model based	10	24	0,16-0,73	n/a	n/a	n/a
		DLC all-polyethylene cup (Small Bone Innovations, Les Bruyères, France)	RCT	Marker based	10	24	0,26-0,59	n/a	n/a	n/a
	Ooms et al. (2015)	SR TMC prosthesis (Avanta, San Diego, USA)	Cadaver Study	Model based	5	-	0,11-0,29	1,47-3,59	n/a	n/a

	Author (year)	Type of implant	Study design	RSA Method	*N*	Time of follow-up (months)	Precision translation (mm)	Precision rotation (˚)	Accuracy translation (mm)	Accuracy rotation (˚)
	Ten Brinke et al. (2016)	SR TMC prosthesis (Avanta, San Diego, USA)	Cohort Study	Model based	9	60	Ooms et al. (2015)	Ooms et al. (2015)	n/a	n/a
TMC-joint (metacarpal component)	Hansen et al. (2010)	Elektra metacarpal stem (Small Bone Innovations, Les Bruyères, France)	Phantom Study	Model based	10	-	0,18-1,52	0,85-25,65	n/a	n/a
			Cohort Study	Model based	11	0	0,22-0,50	10,84-24,88	n/a	n/a
	Ooms et al. (2015)	SR TMC prosthesis (Avanta, San Diego, USA)	Cadaver Study	Model based	5	-	0,19-0,35	2,10-3,45	n/a	n/a

PART II

RSA IN THE TRAPEZIOMETACARPAL JOINT

Chapter 3

Feasibility of model-based Roentgen Stereophotogrammetric Analysis to evaluate early migration of the trapeziometacarpal joint prosthesis

E.M. Ooms, B. ten Brinke, N.M.C. Mathijssen, I.F. Blom,
R.L.M. Deijkers, G.A. Kraan

BMC Musculoskeletal Disorders 2015; 16: 295

ABSTRACT

Background: The purpose of this study was to determine the feasibility of Roentgen Stereophotogrammetric Analysis (RSA) in total joint arthroplasty of the trapeziometacarpal (TMC) joint of the thumb.

Methods: In five cadaveric hands the TMC joint was replaced by the Surface Replacement Trapeziometacarpal prosthesis (SR™ TMC prosthesis; Avanta, San Diego, CA) and tantalum beads of 0.8 mm were implanted for RSA. RSA radiographs in two directions were made in ten positions to calculate the measurement error. Migration values from zero are indicative for the measurement error. The number of detected markers was recorded.

Results: Accuracy analysis showed that for translations the mean measurement error varied between 0.003 mm (SD 0.057) and 0.055 mm (SD 0.133). For the rotations values ranged from 0.034° (SD 1.759) to 0.502° (SD 1.617).

Conclusions: RSA of the SR TMC prosthesis is feasible. The measurement error is good for translations but high for rotations. The latter is due to the close position of the markers relative to each other.

BACKGROUND

Osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is a disabling disease. The prevalence of trapeziometacarpal OA is estimated to be 2.2% in women and 0.62% in men. A high prevalence is found in older women (70–74 years) with an estimate of 5.3%.[1] Restoration of thumb function with a pain free, stable and mobile joint while preserving strength is the main goal of surgical treatment.[2,3] Several implant designs for TMC joint replacement have been used with variable success rates, but early failure remains an important issue.[4,5] These failures are mainly due to aseptic loosening caused by implant instability.[6] A relatively new prosthesis design, the surface replacement (SR) TMC prosthesis (Avanta, San Diego, CA), is a resurfacing joint replacement that closely duplicates the anatomy of the articular surfaces of the first metacarpal and trapezium (Figure 1).[7] This prosthesis might perform better in terms of survival, which is highly dependent on implant stability.[8] Clinical reports of the SR TMC prosthesis however show loosening rates from 0 to 55%.[5,9,10]

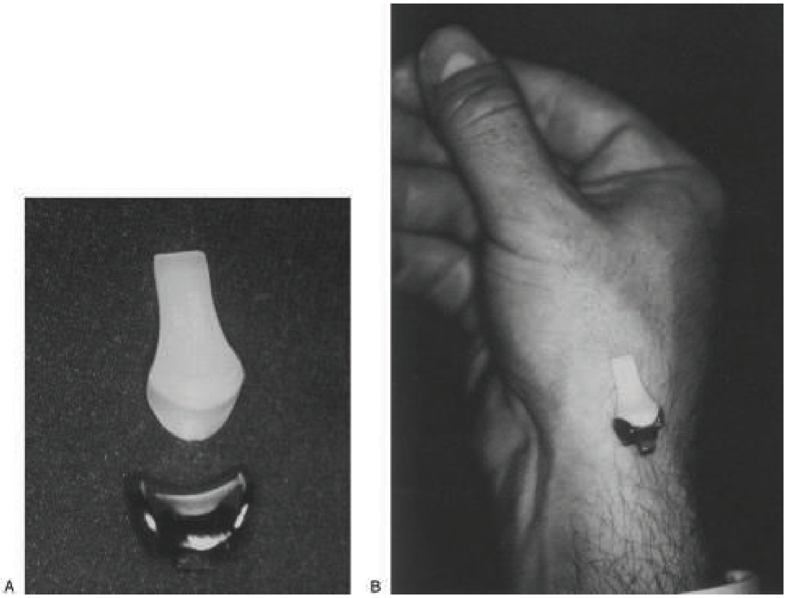


Figure 1. The surface replacement TMC Joint prosthesis in front of the TMC joint.

In all studies concerning TMC joint replacement, aseptic loosening is scored when radiolucency or gross displacement is seen while comparing subsequent radiographs.[4,5,11,12] However, this method is far from accurate. In larger joints, implant stability can be assessed with high accuracy using Roentgen Stereophotogrammatric Analysis (RSA).[13] The usefulness of RSA in larger joints as the knee and the hip has been shown in two recent systematic reviews and RSA has become the gold standard for research on prosthesis migration.[14–16] Hansen et al. described the use of RSA in the TMC joint in a phantom study.[17] Their research showed that RSA might be clinically useful for detection of implant loosening up to two years.[18] However, since only one phantom study and one clinical study have been performed using RSA in the TMC joint, we may state that the experience is limited in this field. Furthermore, only the cemented metacarpal cup (DLC cup, Small Bone Innovations Inc.) and the Elektra trapezium screw cup (Small Bone Innovations Inc) were analyzed by Hansen et al. and not the saddle formed SR TMC joint prosthesis as used in this study. Moreover, accuracy of rotation values was poor in the research that has been done so far.[17,18]

Before new clinical RSA studies should be performed, we first performed an RSA cadaver study using the SR TMC joint. RSA of the TMC joint can be challenging because of the limited surgical exposure and the small available bone stock for placement of RSA beads. Therefore, the purpose of this study was to determine whether RSA is feasible in TMC joint replacement using the SR TMC prosthesis and if so, what the measurement error is when using this technique.

METHODS

In five cadaveric hands the TMC joint was replaced by the SR TMC prosthesis according to the standard implantation technique as described by the manufacturer (Avanta orthopaedics, San Diego, USA) (Figure 2). Tantalum beads of 0.8 mm were implanted in the trapezium and first metacarpal bone without the need for extension of the skin incision or extending the standard surgical exposure. In general, three beads were implanted via the 1 mm drilled hole for the prosthetic peg and two more were inserted through the exposed radial cortex. In the first metacarpal two beads were placed in metaphyseal bone as distal as possible via the reamed intramedullary cavity. Additionally one more bead was inserted in the ulnar trabecular bone of the metacarpal base and one or two beads were secured in the exposed radial cortex. The metacarpal prosthesis component was provided with three or four 0.5 mm beads, two at the tip and one or two at the base of the component. Insertion of the beads was performed with a combined instrument of a 0.7 or 1.1 gauge i.v. needle and the trocart of a 1.1 gauge spinal needle.

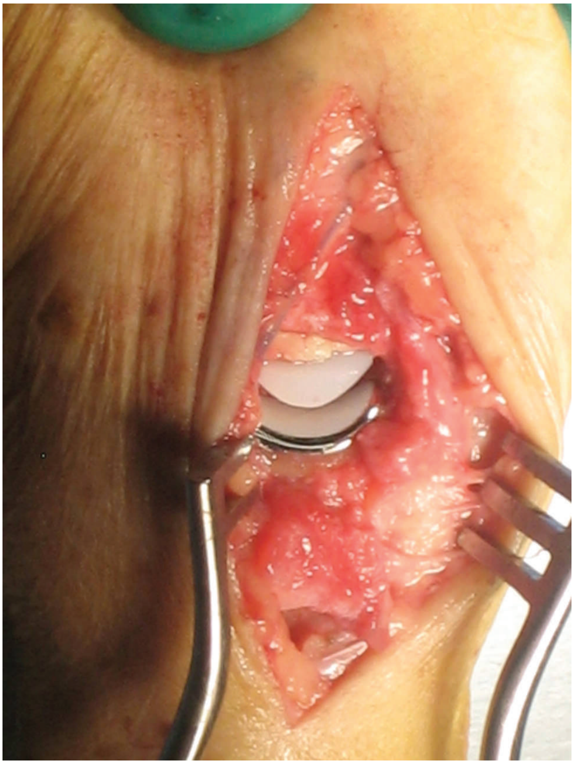


Figure 2. Implanted SR TMC joint prosthesis

A reversed engineered (RE) three-dimensional surface model of the trapezium component of the SR TMC prosthesis was prepared for model-based RSA (Introtech, Nuenen, The Netherlands).[19] After the surgical procedure, RSA radiographs were made using a carbon fibre calibration box (Medis specials, Leiden, The Netherlands) and two synchronized roentgen tubes. RSA radiographs were performed of all hands in two commonly used positions for imaging of the TMC joint (Robert view and lateral view). The number of visually detected markers for each bone or implant was recorded. Of each hand, ten pairs of RSA radiographs were made. After each radiograph, the hand was replaced and rotated a few degrees. The radiographs were imported in a software program for model-based RSA (Model-based RSA 3.11, Medis specials, Leiden, The Netherlands) and the 'migration' of the prosthesis between the RSA radiographs was calculated (Figure 3). All markers (i.e. fiducial, control and intra-ossal) and the prosthesis were marked manually in both planes. Paired migrations were performed to calculate the 'migration' between all ten positions of each hand. To obtain the accuracy of the performed technique, mean errors and standard deviations were calculated for all translations and rotations.

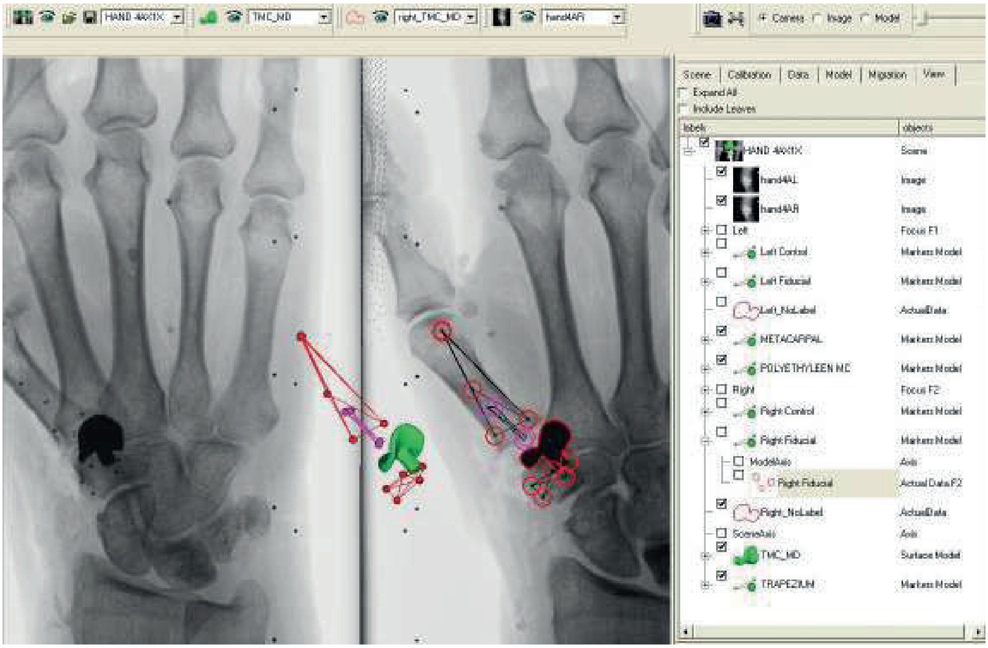


Figure 3. Model-based RSA scene of the SR TMC prosthesis. The three-dimensional reconstruction shows the position of the trapezium component (green), markers in the polyethylene metacarpal component (purple) and the bone markers (first metacarpal and trapezium, red).

The study protocol has been assessed by the regional Medical Ethical Committee (METC Zuidwest Holland). No ethical approval was necessary, since this study did not fall under the scope of the Medical Research Involving Human Subjects Act.

RESULTS

For the metacarpal bone, all beads were visible in all positions and in both RSA radiographs. For the polyethylene metacarpal component, one of the five specimen had an over-projection of the proximal bead by the metal trapezium prosthesis component. If five beads were used in the trapezium, at least three beads were visible in all positions. The accuracy analysis showed that for translations the measurement error varied between 0.003 mm (SD 0.057) and 0.055mm (SD 0.133). For rotations, measurement errors ranged from 0.034° (SD 1.759) to 0.502° (SD 1.617). The accuracy analysis is presented in Table 1.

Table 1. Measurement errors of model-based RSA of the metacarpal and trapezium component of the SR™TMC prosthesis after repeated measurements of five cadaveric hands in ten different positions.

Metacarpal component	**Tx (mm)**	**Ty(mm)**	**Tz(mm)**	**Rx (°)**	**Ry (°)**	**Rz (°)**
Mean	0.006	-0.003	0.055	-0.034	0.502	0.043
SD	0.098	0.181	0.133	1.759	1.617	1.069
Min	-0.156	-0.272	-0.150	-3.495	-1.699	-2.242
Max	0.152	0.319	0.225	2.958	3.295	0.830
Trapezium component	**Tx (mm)**	**Ty(mm)**	**Tz(mm)**	**Rx (°)**	**Ry (°)**	**Rz (°)**
Mean	0.025	0.003	-0.034	-0.148	-0.045	-0.474
SD	0.093	0.057	0.082	0.749	0.762	1.085
Min	-0.057	-0.077	-0.117	-1.272	-0.703	-2.666
Max	0.253	0.104	0.142	1.157	1.830	1.045

SD: Standard deviation; Tx, Ty, Tz: translations along the x-axis (medial- lateral), y-axis (distal-proximal) and z-axis (posterior-anterior). Rx, Ry, Rz: rotations around the x-axis (flexion-extension), y-axis (internal-external) and z-axis (abduction-adduction).

DISCUSSION

This is the first study in which the accuracy of RSA was measured and analyzed in TMC joint arthroplasty using the SR TMC prosthesis. In surgical procedures that do not occur frequently, as TMC joint replacement, the high accuracy of RSA is essential whereas only small patient cohorts can be achieved to evaluate the effect on prosthetic fixation due to changes in implant design, addition of coatings, surgical placement technique or new bone cements.[20] As suggested by Valstar et al. validation of the accuracy of RSA systems is important.[16] Therefore, we performed this phantom study on cadaveric hands. The results of this study can be used for clinical studies on TMC joint arthroplasty. We conclude that with the amount and the diameters of the tantalum beads as used in this study, RSA radiographs can be made that could be easily and accurately interpreted. The bead placement does not influence the extent of the surgical procedure, although a somewhat longer operation time is inevitable. The reported accuracy of RSA in literature (expressed as the standard deviations of repeated measurements) ranges between 0.08 and 0.22 mm for translations and between 0.15° and 0.52° for rotations.[21] Regarding the accuracy of RSA in the TMC joint, standard deviations varied between 0.03 and 0.77mm for translations and 0.40°-13.08° for rotations in a phantom study.[17] In a clinical study the highest standard deviations were 0.25 mm for translations and 12.69° for rotations.[18] Measured accuracy in our study is comparable to previous accuracy results, with respect to the translation. Standard deviations of rotation values were also high (highest SD 1.759°), but not as high as in the phantom study of Hansen et al. This could be due to the asymmetrical shape of the SR TMC prosthesis in contrast to the symmetry along the Y-axis of the Elektra HA stem. The low accuracy of rotation values in our study is expected to be due to the close position of the markers relative to each other in the first metacarpal and the trapezium prosthesis component. Further, the high measurement errors of rotations could be the result of selecting different sets of beads during the analysis of RSA radiographs, since not all five beads were visible in each direction. To decrease the measurement error in future (clinical) studies, the distance between the markers should be enlarged. Besides, beads should be placed in a triangular fashion in the metacarpal component, instead of four in a rectangle.

In joint replacement surgery aseptic loosening is the main reason for long-term revision. It might be caused by wear particles from the articular surface that causes osteolytic activity around the prosthesis. Another cause of loosening could be insufficient bone-prosthesis fixation or high stresses on the bone-prosthesis interface due to a bad design of the implant.[4,6,22,23] Aseptic loosening generally starts with micro migration of the prosthesis relative to the bone in the range of 0.2 to 1.0 mm. Since implant loosening starts with micro migration, knowledge on migration is important as it could potentially predict future loosening or gain more insight about implant fixation.[24] These insights could possible contribute to further improvement of TMC prosthesis designs.

CONCLUSIONS

RSA of the SR TMC prosthesis is feasible. The measurement error is low for translations but high for rotations. The latter is due to the close position of the markers relative to each other.

REFERENCES

1. Wolf JM, Turkiewicz A, Atroshi I, Englund M. Prevalence of Doctor-Diagnosed Thumb Carpometacarpal Joint Osteoarthritis: An Analysis of Swedish Health Care. *Arthritis Care Res*. 2014;66(6):961-965. doi:10.1002/ACR.22250
2. Shuler M, Luria S, Trumble T. Basal Joint Arthritis of the Thumb. *J Am Acad Orthop Surg*. 2008;16(7):418-423. doi:10.5435/00124635-200807000-00007
3. Badia A, Sambandam SN. Total joint arthroplasty in the treatment of advanced stages of thumb carpometacarpal joint osteoarthritis. *J Hand Surg (American Vol)*. 2006;31:1605-1614. doi:10.1016/j.jhsa.2006.08.008
4. Wachtl SW, Guggenheim PR, Sennwald GR. Cemented and non-cemented replacements of the trapeziometacarpal joint. *J bone Jt Surg (British Vol)*. 1998;80(1):121-125. doi:10.1302/0301-620X.80B1.7941
5. Pérez-Úbeda MJ, García-López A, Martinez FM, Vilanova EJ, Molina Martos M, López-Duran Stern L. Results of the Cemented SR Trapeziometacarpal Prosthesis in the Treatment of Thumb Carpometacarpal Osteoarthritis. *J Hand Surg (American Vol)*. 2003;28(6):917-925. doi:10.1016/S0363-5023(03)00378-2
6. Naidu SH, Kulkarni N, Saunders M. Titanium basal joint arthroplasty: a finite element analysis and clinical study. *J hand Surg (American Vol)*. 2006;31(5):760-765.
7. Uchiyama S, Cooney WP, Niebur G, An KN, Linscheid RL. Biomechanical analysis of the trapeziometacarpal joint after surface replacement arthroplasty. *J Hand Surg (American Vol)*. 1999;24(3):483-490. doi:10.1053/jhsu.1999.0483
8. Linscheid RL. Implant arthroplasty of the hand: Retrospective and prospective considerations. *J Hand Surg (American Vol).* 2000;25(5):796-816. doi:10.1053/jhsu.2000.4166
9. Pendse A, Nisar A, Shah SZ, Bhosale A, Freeman J V, Chakrabarti I. Surface replacement trapeziometacarpal joint arthroplasty--early results. *J hand Surg (European Vol)*. 2009;34(6):748-757. doi:10.1177/1753193409343750
10. van Rijn J, Gosens T. A cemented surface replacement prosthesis in the basal thumb joint. *J Hand Surg (American Vol)*. 2010;35(4):572-579. doi:10.1016/j.jhsa.2009.12.026
11. De Smet L, Sioen W, Spaepen D, Van Ransbeeck H. Total joint arthroplasty for osteoarthritis of the thumb basal joint. *Acta Orthop Belg*. 2004;70(1):19-24.
12. van Cappelle HG, Elzenga P, van Horn JR. Long-term results and loosening analysis of de la Caffinière replacements of the trapeziometacarpal joint. *J hand Surg (American Vol)*. 1999;24(3):476-482. doi:10.1053/jhsu.1999.0476
13. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl*. 1989;232:1-51.
14. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
15. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
16. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563-572. doi:10.1080/17453670510041574

17. Hansen TB, Larsen K, Bjergelund L, Stilling M. Trapeziometacarpal joint implants can be evaluated by roentgen stereophotogrammetric analysis. *J hand Surg (European Vol)*. 2010;35(6):480-485. doi:10.1177/1753193409355627
18. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. A randomized clinical RSA study with 2-year follow-up. *Acta Orthop*. 2013;84(1):98-105. doi:10.3109/17453674.2013.765625
19. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC. A new model-based RSA method validated using CAD models and models from reversed engineering. *J Biomech*. 2003;36(6):873-882. doi:10.1016/S0021-9290(03)00002-2
20. Valstar ER, Nelissen RGHH, Reiber JHC, Rozing PM. The use of Roentgen stereophotogrammetry to study micromotion of orthopaedic implants. *ISPRS J Photogramm Remote Sens*. 2002;56:376-389. doi:10.1016/S0924-2716(02)00064-3
21. Valstar ER, de Jong FW, Vrooman HA, Rozing PM, Reiber JHC. Model-based Roentgen stereophotogrammetry of orthopaedic implants. *J Biomech*. 2001;34(6):715-722. doi:10.1016/S0021-9290(01)00028-8
22. Jones L, Frondoza C, Hungerford D. Effect of PMMA particles and movement on an implant interface in a canine model. *J bone Jt Surg (British Vol)*. 2001;83(3):448-458. doi:10.1302/0301-620X.83B3.10734
23. Aspenberg P, Herbertsson P. Periprosthetic bone resorption. Particles versus movement. *J bone Jt Surg (British Vol)*. 1996;78(4):641-646.
24. Aspenberg P, Van der Vis H. Migration, particles, and fluid pressure. A discussion of causes of prosthetic loosening. *Clin Orthop Relat Res*. 1998;352:75-80.

Chapter 4

Model-based roentgen stereophotogrammetric analysis of the surface replacement trapeziometacarpal total joint arthroplasty

B. ten Brinke, N.M.C. Mathijssen, I.F. Blom, R.L.M. Deijkers
E.M. Ooms, G.A. Kraan

Journal of Hand Surgery (European Vol) 2016; 41 (9): 925-929

ABSTRACT

Objectives: The primary aim of this clinical and radiostereometric study was to evaluate the migration pattern of the surface replacement trapeziometacarpal joint prosthesis (SR TMC, Avanta®, San Diego, CA). The secondary aims were to assess patient-related outcomes and implant survival five years after surgery.

Methods: Ten patients received the prosthesis. Radiostereometric radiographs were obtained six weeks, six months, one year and five years postoperatively and were analyzed using model-based software. All patients completed the Disabilities of the Arm, Shoulder and Hand (DASH) and Nelson Hospital scores at these follow-up moments.

Results: Mean translations varied between 0.0 and 0.5 mm after five years. Rotation values could be calculated in six patients and mean rotations varied between −0.3 and 2.3°, although the precision of rotation measurements was poor. The five-year survival rate was 80%. Mean pre-operative DASH and Nelson Hospital scores were 53 (SD 14) and 51 (SD 13), respectively. Six months post-operatively, the DASH and Nelson Hospital scores improved significantly to 25 (SD 20) and 74 (SD 18) and remained high after 5 years.

Conclusion: Implant stability measured using RSA was good after five years of follow-up, although the accuracy of rotation values seems to be poor. Early migration did not predict implant failure in this study. The five-year survival rate of the SR^{TM}TMC prosthesis is 80%, with a high patient satisfaction.

INTRODUCTION

Osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is a common problem that leads to pain, weakness and adduction deformity of the thumb.[1] When conservative treatment fails, surgical treatment might be considered.[2] In the last decades, total joint arthroplasty of the TMC joint has become an increasingly used procedure for OA of the thumb although the outcomes of the various implants have been variable.[3–5] The surface replacement (SR) TMC joint prosthesis (SR TMC, Avanta®, San Diego, CA) is a resurfacing prosthesis that closely duplicates the saddle-shaped anatomy of the TMC joint (Figure 1).

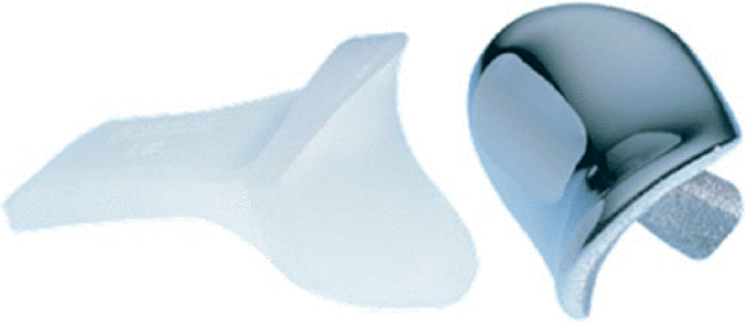


Figure 1. The SR TMC^{MC} joint prosthesis, Avanta®

It consists of a polyethylene metacarpal component and a trapezium component made of cobalt chrome.[6] Reported loosening rates of the SR TMC prosthesis vary between 0% and 55%, with a maximum follow-up time of 36 months.[7–10] In these studies, aseptic loosening was scored by comparing subsequent radiographs for radiolucency or gross displacement. However, aseptic implant loosening generally starts with early micromotion, which cannot be detected with conventional radiographs.[11] Early micromotion can be detected accurately with roentgen stereophotogrammetric analysis (RSA).[12,13] Tantalum beads are inserted in the surrounding bone during surgery. Stereoradiographs are taken direct post-operatively, using two roentgen tubes placed at an angle of 20° and centered at a calibration box. RSA-radiographs are analyzed using model-based RSA software, calculating the three-dimensional positions of both the bone markers and the prosthesis. Determining the three-dimensional position of the prosthesis relative to the surrounding bone at several follow-up moments makes it possible to calculate migration of the implant that occurred between follow-up moments. The technique is frequently used to determine early micromotion of hip and knee prostheses.[14,15] However, only two studies have described the use of RSA to evaluate the early migration of TMC joint prostheses.[16,17] In this prospective cohort study, we evaluated the stability of the SR TMC joint prosthesis using RSA. The primary objective was to determine the migration pattern of the trapezial component of the TMC prosthesis. Secondary objectives were the patient-related outcomes and long-term survival of the prosthesis, with a follow-up time of five years.

METHODS

Between June and October 2008, ten consecutive patients with OA of the TMC joint received the SR TMC implant system and were included in this study. All patients were operated by the same orthopaedic surgeon (R. D.). During surgery, five or six tantalum beads of 0.5 and 0.8 mm diameter were inserted into the trapezium in order to allow RSA measurements.

The study was approved by the local Medical Ethics Committee and written informed consent was obtained from all patients. Patients had to be 18 years or older and of American Society of Anesthesiologists (ASA) classification I or II.[18] Conservative treatment for OA had to be failed, the Eaton and Littler stage had to be 2 to early 4. Patients had to be willing and able to participate in a postoperative rehabilitation schedule and to complete the functional assessments.[19] Exclusion criteria were: severe instability of the TMC joint, non-isolated TMC OA, previous TMC surgical procedures, recent myocardial infarct or cerebrovascular accidents, mentally disabled patients, recent major surgical procedure, active infection, current malignancy, uncontrolled hypertension or a history of alcohol or drugs abuse.

Patients were assessed at six weeks, six months, one year and five years postoperatively. At each assessment, conventional and RSA radiographs were obtained. RSA radiographs on the third post-operative day were used as the reference examination. Model- based software (Medis, RSAcore, Leiden, The Netherlands) was used to analyze the RSA radiographs and to calculate migration of the prostheses. Migration was defined as translation along and rotations around the x-, y- and z-axes. Translations were expressed in millimeters and rotations in degrees. In addition, patients were asked to complete the disabilities of the arm, shoulder and hand (DASH) and Nelson Hospital Score questionnaires at six months, one year and five years post-operatively.[20,21] The DASH score decreases with functional improvement, whereas the Nelson Hospital score increases.

Before this study, a cadaver study using the SR TMC prosthesis was carried out to determine the accuracy of RSA in the TMC joint.[22] In this study, the SR TMC prosthesis was implanted in five cadaveric hands. Ten consecutive RSA radiographs of each hand were obtained with the hand in ten different positions. To determine the systematic measurement error, defined as the standard deviation of repeated measurements, 'migration' values between the ten radiographs were calculated. Accuracy analysis showed a systematic measurement error between 0.06 and 0.13mm for translations and between 1.75° and 1.62° for rotations.

Statistics

The quantitative variables obtained from the DASH and Nelson Hospital questionnaires were tabulated and analyzed as mean, standard deviation, minimum and maximum scores. These scores were analyzed using linear mixed models for repeated measurements.[23] The level of significance was set at $p < 0.05$. For the migration data of the SR TMC implant system, descriptive analysis was used since the number of patients was not enough to apply statistical tests.

RESULTS

Clinical results

There were nine female patients and one male. The five-year survival of the implants was 80%. In two patients, the prosthesis was removed after one and two years, respectively, because of pain and loss of function. The mean pre-operative DASH and Nelson Hospital scores were 53 (Standard deviation (SD) 14) and 51 (SD 13), respectively. Six months postoperatively, the DASH and Nelson Hospital scores improved significantly to 25 (SD 20; p = 0.003) and 75 (SD 18; p = 0.004), respectively. There were no significant differences between the scores at six months and five years (DASH p = 0.28; Nelson p = 0.26). All results are summarized in Figure 2. The mean pre-operative DASH and Nelson Hospital scores of the two patients who underwent a revision of the prosthesis were 52 and 54. The scores of these patients did not improve after surgery; their DASH and Nelson Hospital scores after six months were, respectively, 50 (p = 0.95) and 54 (p = 1.0). Scores one year postoperatively were 49 (p = 0.93) and 58 (p = 0.82).

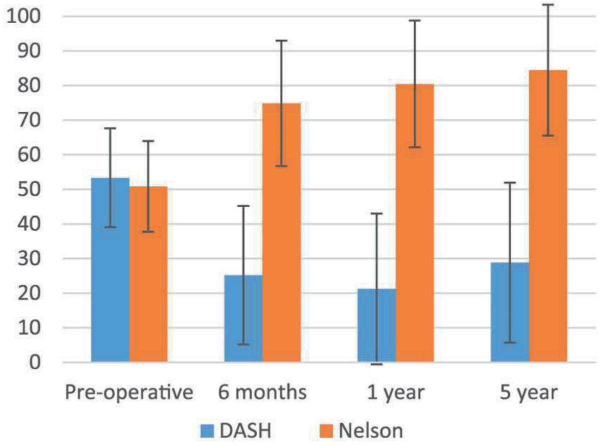


Figure 2. Mean DASH and Nelson Hospital scores of patients pre-operatively and 6 months, 1 year and 5 years after placement of the SR TMC prosthesis. The error bars represent the standard deviations.

RSA results

One patient received a 'small' sized prosthesis. This size could not be analyzed by the RSA software and therefore migration calculation was not possible in this patient, so that nine patients were analyzed. In all but two of the RSA radiographs, at least three beads were visible. One of these two radiographs belonged to the patient who received the small-sized prosthesis and was not included in the analysis. Rotation values of a second patient could not be calculated because of a lack of visible markers. Despite the fact that at least three beads were visible in all other patients, rotation values of four patients could not be calculated at each follow-up point. In these patients, the visible markers on the first radiograph did not correspondent to the detected markers on the second radiograph because of over projection of the markers by the prosthesis. In two patients, the post-operative examination could not be analyzed because of motion artefacts and RSA radiographs taken six weeks postoperatively were used as the reference examination.

The mean translations of the SR TMC joint prosthesis were 0.24 mm (SD 0.94), 0.48 mm (SD 0.67) and 0.00 mm (SD 0.37) for translations along the x-, y- and z-axes after five years of follow-up. The mean rotation values after five years were 2.3° (SD 7.4), 1.2° (SD 3.1) and 0.3 (SD 9.97) for rotations around the x-, y- and z-axes. The translation and rotation patterns are shown in Figures 3 and 4.

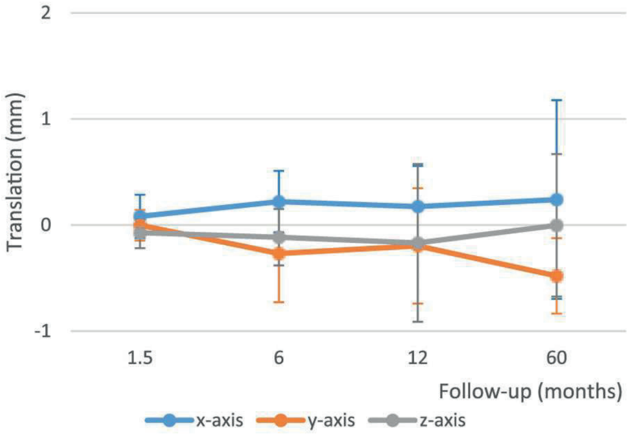


Figure 3. Mean translation of the SR TMC prosthesis after placement in nine patients with OA of the TMC joint. The error bars represent the standard deviations.

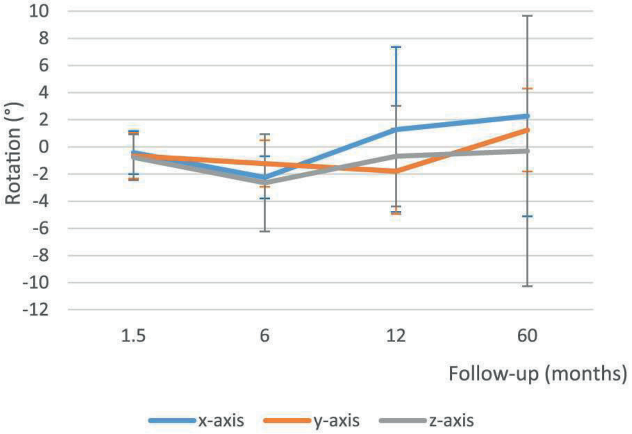


Figure 4. Mean rotation of the SR TMC prosthesis after placement in nine patients with OA of the TMC joint. The error bars represent the standard deviations.

DISCUSSION

Radiostereometric studies investigating prostheses in the upper extremity with a long-term follow-up are scarce. To gain more insight into migration patterns of orthopaedic implants in the upper limb and into the predictive value of early migration for long-term outcomes it is important to expand RSA research in this field. To the best of our knowledge, this is the first study using radiostereometry to analyze the migration pattern of the saddle-shaped SR TMC prosthesis.

In a previous study by Van Rijn and Gosens, 15 SR TMC joint prostheses were implanted and one failure occurred.[10] No radiographic loosening was described. Perez-Ubeda et al. noted a revision rate of 20%, comparable with our results.[9] Nisar et al. followed 72 prostheses with a mean follow-up time of 36 months.[7] Six prostheses were revised and lucencies were seen on plain radiographs in eight additional joints, without loss of function.

One clinical RSA study regarding the TMC joint has been published by Hansen and Stilling.[17] In this study, migration of the uncemented Elektra screw cup and the cemented DLC all-polyethylene cup (both manufactured by Small Bone Innovations Inc., Les Bruyères, France) were compared. Mean total translations of 0.80 mm (SD 2.0) for the uncemented Elektra screw cup and 0.36 mm (SD 0.43) for the cemented DLC all-polyethylene cup were found after two years of follow-up. Translation results were comparable with the translations found in the present study after six weeks, six months and one year. Translation results with a follow-up time of five years have not been described in literature before. Hansen and Stilling suggest that implants with a translation of above 1 mm could be regarded as loose implants. In our study two prostheses were revised, of which one translated more than 1 mm after one year. However, in three non-revised prostheses, there was a translation of more than 1 mm, without loosening or any symptoms. Therefore, the cut-off point for implant loosening, as suggested by Hansen and Stilling, has to be studied further. Hansen and Stilling did not measure rotations because of a poor accuracy. In our study, we found increased rotation values after five years with high standard deviations. In spite of these high rotation values, the DASH and Nelson Hospital scores were still good. Looking at one of the outliers, a rotation of 13° was found, although the DASH and Nelson Hospital scores were still excellent after five years (9 and 96, respectively). Given the high standard deviations, the precision of rotation values seems to be poor. The reasons for this poor precision could be the small size of the bone and the low number of markers.[24] Because of the close position of the markers relative to each other and to the prosthesis, not all the markers were visible in all radiographs. In five patients, rotation values could not be calculated in all radiographs due to a lack of detectable markers or because visible markers on the first radiograph did not correspond with the visible markers on the second radiograph. Calculating migration using different sets of beads obviously leads to high measurement errors. For future RSA studies of the TMC joint, we recommend the insertion of additional markers. To prevent over projection by the trapezial component of the prosthesis, beads should be placed as far as possible from the prosthesis and more proximally in the trapezium to have at least three markers visible in both RSA radiographs.

Regarding the knee and the hip joint, a relation between early migration and future implant loosening has clearly been demonstrated in two systematic reviews.[14,15] Total knee prostheses with a migration between 0.5 mm and 1.6 mm in the first year postoperatively were at risk for future loosening.[15] In total hip arthroplasty, cups with a translation between 0.2 mm and 1.0 mm in the first year postoperatively were considered to be at risk.[14] In our study, no relation between early migration and future loosening could be demonstrated for the SR TMC prosthesis, since the number of patients in this study was too small to show significant differences between the migration of the two revised prostheses and the non-revised prostheses. Despite the low patient numbers, the migration rates of the revised and non-revised prostheses appear to be similar in both groups. One may therefore argue that micromotion of the SR TMC prosthesis is not predictive for future loosening with a follow-up time of five years. However, the number of patients included in this study is small and a follow-up time of five years is relatively short. In a study by Martin-Ferrero with a follow-up time of ten years in 64 patients with unconstrained uncemented ARPE arthroplasties (Biomet, Spain Orthopedics SL, Valencia, Spain), the survival of implants decreased only after five years.[25] Therefore, it would be valuable to reassess this cohort after ten years to investigate whether there is a relation between early migration and future loosening.

The DASH and Nelson Hospital scores improved significantly six months after surgery. Franchignoni et al. described a minimal clinically important difference (MCID) of 10.8 points for the DASH score.[26] In our study, an increase of 28 points was measured in the first six months postoperatively. No further improvement in DASH and Nelson Hospital scores was seen after one and five years. In two patients who underwent a revision of the prosthesis, the DASH and Nelson Hospital scores did not improve postoperatively. Therefore, one may argue that the DASH and Nelson Hospital scores after six months are predictive for patient-related outcomes in the long term.

Conclusion

Implant stability measured using RSA was good after five years of follow-up, although the accuracy of rotation values seems to be poor. Early migration did not predict implant failure in this study. The five-year survival rate of the SRTMTMC prosthesis is 80%, with a high patient satisfaction.

REFERENCES

1. Pelligrini VD. Osteoarthritis of the trapeziometacarpal joint: the pathophysiology of articular cartilage degeneration. II. Articular wear patterns in the osteoarthritic joint. *J hand Surg (American Vol)*. 1991;16(6):975-982.
2. Martou G, Veltri K, Thoma A. Surgical treatment of osteoarthritis of the carpometacarpal joint of the thumb: a systematic review. *Plast Reconstr Surg*. 2004;114(2):421-432.
3. Ulrich-Vinther M, Puggaard H, Lange B. Prospective 1-Year Follow-Up Study Comparing Joint Prosthesis With Tendon Interposition Arthroplasty in Treatment of Trapeziometacarpal Osteoarthritis. *J Hand Surg (American Vol)*. 2008;33(8):1369-1377. doi:10.1016/j.jhsa.2008.04.028
4. Vermeulen GM, Slijper H, Feitz R, Hovius SER, Moojen TM, Selles RW. Surgical management of primary thumb carpometacarpal osteoarthritis: A systematic review. *J Hand Surg (American Vol)*. 2011;36(1):157-169. doi:10.1016/j.jhsa.2010.10.028
5. Huang K, Hollevoet N, Giddins G. Thumb carpometacarpal joint total arthroplasty: a systematic review. *J Hand Surg (European Vol)*. 2015;40E(4):338-350.
6. Uchiyama S, Cooney WP, Niebur G, An KN, Linscheid RL. Biomechanical analysis of the trapeziometacarpal joint after surface replacement arthroplasty. *J Hand Surg (American Vol)*. 1999;24(3):483-490. doi:10.1053/jhsu.1999.0483
7. Nisar A, Pendse A, Bhosale A, Chakrabarti I. Avanta trapeziometacarpal joint arthroplasty - results after two and half years. *Orthop Proc*. 2011;93-B(supp I).
8. Pendse A, Nisar A, Shah SZ, Bhosale A, Freeman J V, Chakrabarti I. Surface replacement trapeziometacarpal joint arthroplasty--early results. *J hand Surg (European Vol)*. 2009;34(6):748-757. doi:10.1177/1753193409343750
9. Pérez-Úbeda MJ, García-López A, Martinez FM, Vilanova EJ, Molina Martos M, López-Duran Stern L. Results of the Cemented SR Trapeziometacarpal Prosthesis in the Treatment of Thumb Carpometacarpal Osteoarthritis. *J Hand Surg (American Vol)*. 2003;28(6):917-925. doi:10.1016/S0363-5023(03)00378-2
10. van Rijn J, Gosens T. A cemented surface replacement prosthesis in the basal thumb joint. *J Hand Surg (American Vol)*. 2010;35(4):572-579. doi:10.1016/j.jhsa.2009.12.026
11. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. *J bone Jt Surg (British Vol)*. 1994;76:912-917.
12. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl*. 1989;232:1-51.
13. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563-572. doi:10.1080/17453670510041574
14. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
15. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
16. Hansen TB, Larsen K, Bjergelund L, Stilling M. Trapeziometacarpal joint implants can be evaluated by roentgen stereophotogrammetric analysis. *J hand Surg (European Vol)*. 2010;35(6):480-485. doi:10.1177/1753193409355627

17. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. A randomized clinical RSA study with 2-year follow-up. *Acta Orthop*. 2013;84(1):98-105. doi:10.3109/17453674.2013.765625
18. Fitz-Henry J. The ASA classification and peri-operative risk. *Ann R Coll Surg Engl*. 2011;93(3):185. doi:10.1308/147870811X565070A
19. Eaton R, Littler J. Ligament Reconstruction for the Painful Thumb Carpometacarpal Joint. *J Bone Jt Surg (American Vol)*. 1973;55(8):1655-1666.
20. Veehof MM, Sleegers EJA, Van Veldhoven NHMJ, Schuurman AH, Van Meeteren NLU. Psychometric qualities of the Dutch language version of the disabilities of the arm, shoulder, and hand questionnaire (DASH-DLV). *J Hand Ther*. 2002;15(4):347-354. doi:10.1016/S0894-1130(02)80006-0
21. Citron N, Hulme CE, Wardle N. A self-administered questionnaire for basal osteoarthritis of the thumb. *J Hand Surg (European Vol)*. 2007;32(5):524-528. doi:10.1016/j.jhse.2007.03.015
22. Ooms EM, ten Brinke B, Mathijssen NMC, Blom IF, Deijkers RLM, Kraan G a. Feasibility of model-based Roentgen Stereophotogrammetric Analysis to evaluate early migration of the trapeziometacarpal joint prosthesis. *BMC Musculoskelet Disord*. 2015;16(1):295. doi:10.1186/s12891-015-0747-3
23. West B. Analyzing longitudinal data with the linear mixed models procedure in SPSS. *Eval Heal Prof*. 2009;32(3):207-228. doi:10.1177/0163278709338554
24. Ryd L, Yuan X, Löfgren H. Methods for determining the accuracy of radiostereometric analysis (RSA). *Acta Orthop Scand*. 2000;71(4):403-408. doi:10.1080/000164700317393420
25. Martin-Ferrero M. Ten-year long-term results of total joint arthroplasties with ARPE® implant in the treatment of trapeziometacarpal osteoarthritis. *J hand Surg (European Vol)*. 2014;39(8):826-832. doi:10.1177/1753193413516244
26. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). *J Orthop Sports Phys Ther*. 2014;44(1):30-39. doi:10.2519/jospt.2014.4893

Chapter 5

A radiostereometric and clinical long-term follow-up study of the surface replacement trapeziometacarpal joint prosthesis

B. ten Brinke, N.M.C. Mathijssen, I.F. Blom, L.A. Koster, G.A. Kraan

BMC Musculoskelet Disorders 2021; 22(1): 148

ABSTRACT

Background: The aim of this study was to determine long-term survival and clinical outcomes of the surface replacement trapeziometacarpal joint prosthesis (SR TMC) and to evaluate implant migration using radiostereometric analysis (RSA).

Methods: In this clinical long-term follow-up study outcomes of ten patients who received the SR™TMC joint prosthesis were evaluated using the Disability of the Arm, Shoulder and Hand (DASH) and Nelson scores, Visual Analogue Scale (VAS) of pain, and key pinch strength. RSA-radiographs were obtained direct postoperatively and six months, one year, five years and ten years postoperatively and were analyzed using model-based RSA software.

Results: During follow-up, two early revisions took place. Mean pre-operative DASH and Nelson scores were 54 (SD 15) and 54 (SD 17), improved significantly after six months (DASH 25 (SD 20), Nelson 75 (SD 18)) and remained excellent during long-term follow-up in all patients with a stable implant. At final follow-up, clinical scores deteriorated clearly in two patients with a loose implant in situ.

Conclusions: Long-term survival of the SR™TMC joint prosthesis is relatively poor. However, clinical outcomes improved significantly in the short-term and remained excellent in the long-term in those patients with a stable implant, but deteriorated clearly in case of loosening. The role of RSA in TMC joint arthroplasty is potentially valuable but needs to be further investigated. Several challenges of RSA in the TMC joint have been addressed by the authors and suggestions to optimize RSA-data are given.

INTRODUCTION

The two most widely used surgical procedures for the treatment of osteoarthritis (OA) of the trapeziometacarpal (TMC) joint are the trapeziectomy and TMC joint arthroplasty. In recently published research it is hypothesized that TMC joint arthroplasty is superior compared to trapeziectomy in terms of pain, strength, range of motion (ROM), satisfaction and recovery.[1–5] However, most studies present short-term follow-up and thus long-term data are of interest.

Previously, our group presented the five-year results of a radiostereometric analysis (RSA) of the Surface Replacement (SR) TMC joint prosthesis (SR TMC, Avanta®, San Diego, CA).[6] This study showed a survival of eight out of ten prostheses with satisfying clinical outcomes.

The experience with RSA in the TMC joint is limited: two experimental and two small clinical studies have been published up to now.[6–9] These studies have learned us that RSA of the TMC joint is feasible with high precision for translations, but that precision for rotation measurement is poor. Long-term RSA studies of the TMC joint have not been published before and thus long-term migration data of TMC joint prostheses are unknown.

The aim of the present study is to determine long-term survival and clinical outcomes of the SR TMC joint prosthesis ten years after placement and to evaluate the migration of the prosthesis during follow-up.

METHODS

Design and participants

Ten consecutive patients (nine women) with OA of the TMC joint received an SR TMC joint prosthesis between June and October 2008 and were prospectively followed with a follow-up time of ten years. Details of the original study are described in our previous paper.[6] All participants of our previous study with the prosthesis in situ were invited to visit our clinic to undergo clinical and RSA examination and to complete patient reported outcome measures (PROMs).

Clinical outcomes

To evaluate clinical outcomes, patients were asked to complete the Dutch version of the Disabilities of the Arm, Shoulder and Hand (DASH) and the Dutch translation of the Nelson Hospital Score.[10,11] The DASH score decreases with functional improvement, whereas the Nelson Hospital score increases. Further, the Visual Analogue Scale (VAS) ranging from 0 to 100 was used to evaluate pain. Unlike in our short-term study, lateral pinch strength (key pinch) was measured at long-term follow-up (Mechanical Pinch Gauge, Sammons Preston, Bolingbrook, IL).

Radiostereometric analysis

RSA radiographs were obtained using two synchronized roentgen tubes (DigitalDiagnost and the MobileDiagnost wDR (Philips, Best, The Netherlands)) positioned 1.2 m above the roentgen detector. The palm of the hand was placed on top of a Perspex calibration box (Medis, Leiden, the Netherlands). For each patient, all available RSA acquisitions were used to calculate migration with a model-based approach (Model-based RSA software version 4.2, RSAcore, Leiden, The Netherlands). Migration is defined as translation (T; in mm) of the trapezium component with respect to the trapezium bone along the radial-ulnar (Tx), proximal-distal (Ty) and volar-dorsal (Tz) axis (Figure 1).

Figure 1. Detail of a model-based RSA scene analyzing migration of the SR TMC joint prosthesis. Three bone markers (red spheres) show a poor three-dimensional spatial distribution (CN 1016) resulting in poor rotational precision. The arrows indicate the three-dimensional coordinate system. Positive migration along the X-, Y-, and Z-axis indicates radial, distal and dorsal translation of the prosthesis with respect to the trapezial bone.

Migration at all available follow-up moments was calculated with respect to the reference RSA acquisition taken direct postoperatively. In order to include as much data as possible, translations were calculated using the three-dimensional model of the implant as the reference object and the center of gravity of the bone markers as migrating object. As much as possible identical bone markers that could be detected in the RSA radiographs and meeting the International Organisation of Standardization (ISO) criterion for marker stability (Mean error (ME) < 0.35 mm) were used for translation measurements, even if the rigid body did not meet the ISO criterion for acceptable three-dimensional distribution (Condition Number (CN) < 150).[12] The occluded markers model was applied to include bone markers not visible in particular RSA radiographs.[13] The calculated translations are multiplied with − 1 to express the results as translations of the implant with respect to the bone. Total translation (TT, mm) was calculated using the Pythagorean theorem ($\sqrt{(Tx^2 + Ty^2 + Tz^2)}$). Rotations were considered as inaccurate and not reported.

For all patients attending the ten-year follow-up, a double RSA examination was acquired to determine the precision of the technique. Precision was defined as 1.96 x standard deviation (SD) of 'migration' between two examinations taken at ten-year follow-up.

Statistical analysis

Descriptive analysis was used to give an overview of survival rate. In order to investigate differences in DASH and Nelson scores a Wilcoxon signed-rank test was used. VAS pain scores, key pinch grip and migrations were described using descriptive analysis.

RESULTS

Survival

Mean age at ten-year follow-up was 72 years (Range: 59-82). As reported in our previous paper two patients (patient 1 and 3) underwent a revision respectively two and three years postoperatively because of persistent pain, without radiological signs of loosening. In one patient, progressive scaphotrapezial OA was seen on conventional radiographs. In the other patient, the reason for persistent pain remained unclear. A trapeziectomy was performed in both patients. During revision surgery, both implants turned out to be well fixated. No additional prostheses were revised during follow-up. However, at ten-year follow-up two prostheses were clinically suspicious for loosening (patient 5 and 9), based on pain and loss of function. Single photon emission computed tomography (SPECT) showed increased uptake of technetium around the implant in both patients, indicating loosening. Conventional radiographs did not show any signs of loosening. Both patients were treated conservatively with a splint.

Clinical outcomes

Of the ten patients enrolled in this study, eight patients with the prosthesis in situ completed ten-year follow-up. Mean pre-operative DASH and Nelson Hospital scores were 54 (Standard deviation (SD): 15) and 54 (SD 17). We previously found a statistically and clinically significant improvement in mean DASH and Nelson scores after six months (DASH 25 (SD 20), $p = 0.04$; Nelson 75 (SD 18), $p = 0.02$). Scores did not further improve or deteriorate between six months and five years (15 (SD 18), $p = 0.4$; 84 (SD 19), $p = 0.4$) nor between six months and ten years (20 (SD 23), $p = 1.0$; 87 (SD 18), $p = 0.3$). VAS pain scores varied from 0 to 3 in rest and from 0 to 44 during activity on a 100-points scale in patients without clinical suspicion of loosening. As expected, DASH, Nelson and VAS pain scores worsened substantially in both patients with a suspicion of a loosening. Key pinch strength was remarkable high in our study population. Clinical scores are summarized in Table 1 and Figure 2.

Table 1. Patient characteristics and clinical results ten years after implantation of the SR TMC joint prosthesis.

Patient ID	Age at surgery	Sex	Side	VAS pain (rest)	VAS pain (activity)	Key pinch strength (kg)
1[a]	64	F	L	.	.	.
2	67	F	R	3	20	6
3[a]	70	F	R	.	.	.
4	59	M	R	0	0	13
5[b]	56	F	L	75	74	3
6	61	F	R	0	0	9
7	49	F	R	2	44	9
8	59	F	L	0	0	8
9[b]	58	F	L	45	66	4
10	72	F	R	1	1	3

a) patients who underwent revision surgery; b) patients with loose implant at ten-year follow-up

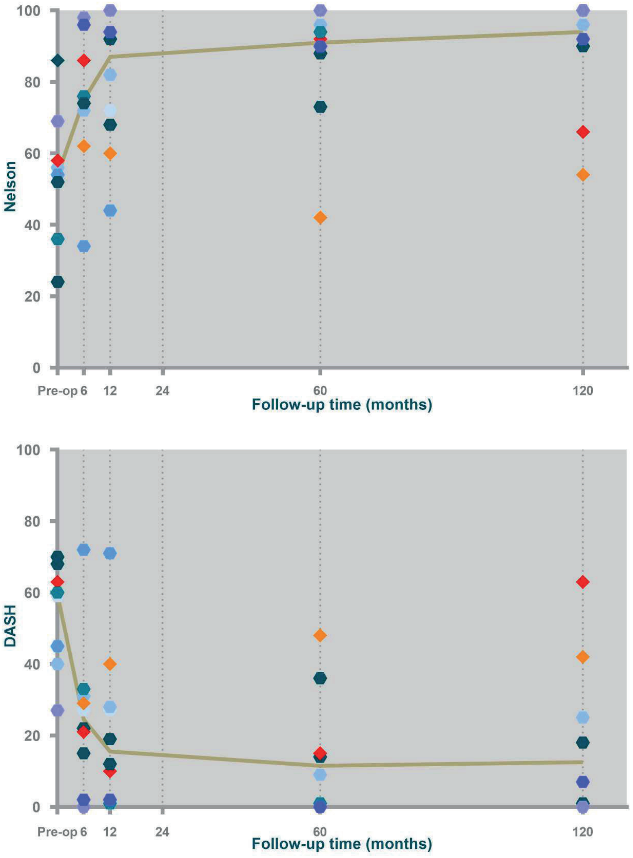


Figure 2. Median DASH and Nelson scores in ten patients with the SR TMC joint prosthesis. Median DASH and Nelson scores are indicated by the curve. Single patients are expressed as markers. Patients with a loose implant are expressed as orange (patient 5) and red (patient 9) diamonds.

RSA results

Of the eight patients who completed ten-year follow-up, RSA radiographs were taken in seven patients. One patient received a ‘small’ sized implant, of which no Computer-aided design (CAD) model was available in the software and thus RSA radiographs were not acquired. Double examinations could be used in six patients to determine precision of RSA. One patient had not enough markers visible in the double examination. Precision values of translations along the x-, y- and z-axis are given in Table 2.

Table 2. Precision measurement using double examinations in six patients with the SR TMC joint prosthesis *in situ.*

	Tx	Ty	Tz	Total translation
Min	-0.09	-0.01	-0.15	0.04
Max	0.08	0.13	0.12	0.19
Median	0.01	0.02	0.01	0.11
Mean	0.01	0.03	0.00	0.11
SD	0.06	0.05	0.10	0.06
Upper 95% CI	0.14	0.13	0.20	0.22

SD: standard deviation; CI: confidence interval; Tx, Ty, Tz: translation along the x-, y- and z-axis

In four patients we were able to calculate translations of the implants up to ten years of follow-up. In the other patients, translations were calculated up to the last follow-up moment with analyzable RSA radiographs, but not up to ten years postoperatively because of revision of the implant ($n = 2$), lack of visible bone markers ($n = 1$) or unstable bone markers ($ME > 0.35$, $n = 2$). An overview of all translations is shown in Figure 3. A stable migration pattern was seen in three implants. In one of the patients clinically suspicious for implant loosening (patient 9) RSA confirmed increased migration of the implant (Figure 3), despite negative conventional radiographs. In the second patient with a clinically suspicious loose implant (patient 5) RSA radiographs could not be analyzed because of unstable markers.

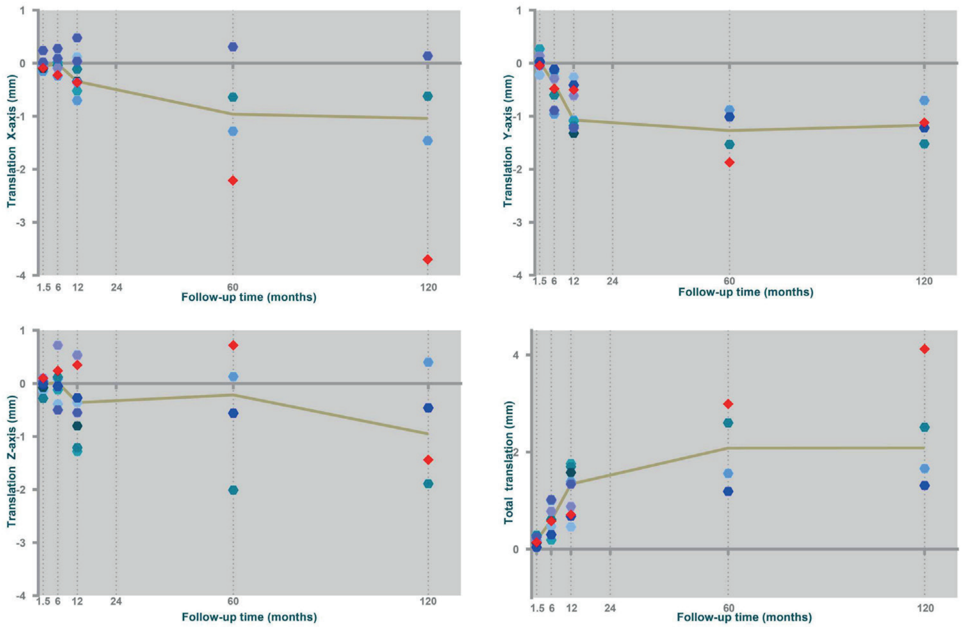


Figure 3. Median translations along the X-, Y- and Z- axis and Total Translation of the trapezium component of the SR TMC joint prosthesis with respect to the trapezium bone during 10 years of follow-up. Median translation values are indicated by the curve. Single patients are expressed as markers. Patients with a loose implants (patient 5 and 9) are expressed as red diamonds.

DISCUSSION

In this first long-term RSA-study of the TMC joint we present ten-year survival rate, clinical outcomes and migration of the SR TMC joint prosthesis. After ten years of follow-up, two out of ten prostheses were revised and two additional loose implants were found at the ten-year follow-up moment. Long-term survival is worse compared to recently published long-term results of the Roseland®, ARPE®, Ivory® and Rubis II prostheses, varying from 85 to 95%.[14–19] This is mainly explained by two early revisions. Migration analysis of these implants showed a stable fixation of the trapezium component in the first 12 months postoperatively and both implants turned out to be well fixated during revision surgery. Therefore, both revisions were not considered as loose implants. No additional implants were revised during further follow-up. However, at ten-year follow-up, two patients (patient 5 and 9) had clinical signs of loosening including pain and loss of function. Clinical suspicion was supported in patient 9 by RSA as we found the implant migrating substantially, while conventional radiographs did not show any sign of loosening. Loosening could not be confirmed by RSA in patient 5 since analysis of the RSA radiographs was inaccurate as a result of unstable markers.

Six patients were highly satisfied with high DASH and Nelson scores and low VAS pain scores. Especially key pinch grip was high in these patients and comparable with pinch grip in the normal population corrected for sex and age.[20] These satisfying results are comparable with previously published long-term results.[14–19]

Several studies have been published comparing total joint arthroplasty with trapeziectomy, but only reporting short-term results.[1–5] Jager et al. described higher satisfaction, mobility, strength, pain reduction and functional scores in favor of the MAIA® total joint prosthesis.[1] Robles-Molina et al. reported similar pain relief and functional improvement, but superior pinch strength and range of motion in the ARPE group.[2] Besides a significantly better ROM, pinch strength, DASH, pain relief and satisfaction, Cebrian-Gomez et al. described a faster return to work in the Ivory prosthesis group.[3] Unlike the results of Cebrian-Gomez et al., Thorkildsen and Røkkum did not find any significant difference in DASH scores between TMC joint arthroplasty and trapeziectomy but did find better motion and strength in the prosthesis group.[4] On the other hand, most studies show higher complication and revision rates in total joint arthroplasty. Taking this into consideration, together with the assumed higher costs of TMC joint arthroplasty in comparison with trapeziectomy, the optimal surgical treatment for TMC joint OA remains a topic of debate. In our opinion further research should be done to investigate which individual patients do actually have benefit from the described advantages of total joint arthroplasty and which do not.

Worth noticing is that all controlled trials comparing trapeziectomy and total joint arthroplasty have investigated ball-and-socket design implants and not saddle-shaped SR implants as used in this study. The SR TMC joint prosthesis has been developed to preserve normal anatomy and kinematics of the thumb, striving for better survival.[21] Although controlled trials comparing the two implants have not been performed, short-term survival of the SR implant appeared to be inferior to ball-and-socket implants whereafter the prosthesis was withdrawn from the market.[22] Apart from our study, no long-term results of the SR TMC joint prosthesis are available to compare with long-term results of ball-and-socket designs. Given the lack of long-term survival data and the absence of controlled studies, no firm conclusions can be drawn about superiority of one of both implants in the long term.

Concerning the role of RSA in TMC joint arthroplasty scientific support is limited. RSA studies analyzing TMC joint prostheses are sparse and patient cohorts are small. Furthermore, the technique faces some significant challenges that have to do with the small size of the joint. As in previously published studies, it was not possible to calculate rotations of the implant in our study. The main reason for this is the lack of stable ($ME < 0.35$), sufficient ($N > 2$) and well three-dimensional spread ($CN < 150$) markers. Using marker rigid bodies containing unstable and poor spread markers results in large and incorrect rotations. Simply ignoring these rotations is not the right strategy since rotations do affect translation calculation. An incorrect rotational alignment of the reference model can lead to incorrect rotations and hence inaccurate translation measurement. This effect of rotation on translation is explained by Beardsley et al. and Van Hamersveld et al.[23,24] Therefore, striving for a well three-dimensional spread and stable rigid body as a reference for migration calculation is still important, even if rotations are left out of consideration. However, the small size of the surrounding bone makes it difficult to ensure this in the TMC joint. In cases were

RSA data cannot be analyzed due to said reasons the alternative strategy of *reversed migration* calculation as applied in this study may be a better option for two reasons. First, when the implant is used as the reference model, RSA scenes with only two bone markers can be used for translation calculation. The reference model can be used to correct for the different positions of the TMC joint with respect to the calibration cage in different RSA acquisitions. With only two markers in the reference model, this cannot be accurately done since two markers create a line around which the implant model can be rotated 360 degrees, resulting in potentially inaccurate migrations. Secondly, for marker rigid bodies with a CN > 150 similar issue arises. The higher the CN, the more the markers in the rigid body are aligned in a column like fashion, resulting in similar rotational inaccuracies as described above (Figure 1). The strategy of reversed migration calculation will not solve all marker-related problems but does allow for more data to be analyzed. Furthermore, an improvement can be expected in translation measurements when marker rigid bodies have a high CN.

To avoid the problem of invisible or unstable markers, an RSA methods based on Computed Tomography (CT) has been developed with comparable accuracy and precision to that of RSA of the hip.[25] More recently, Broden et al. described the use of a CT-based method to calculate migration of shoulder implants.[26] In an experimental setting, accuracy and precision were comparable to that of RSA with similar effective doses. Given the mentioned marker-related problems, accuracy and precision of CT-based migration calculation is worth to be investigated in the TMC joint.

Considering the proved predictive value of early migration in hip- and knee arthroplasty for future loosening, RSA plays an important role in the introduction and surveillance of orthopedic implants.[27–29] However, the relation between early migration and future loosening has not yet been proved in other joints than the hip and knee. If existent, this relation will be difficult to demonstrate in TMC joint arthroplasty because of small patient numbers. Thus, the question arises ‘What to do with RSA in the TMC joint?’

An important principle in total joint replacement is to strive for the best possible fixation of implants into the surrounding bone. Although the predictive value of early migration of TMC joint implants is unclear, RSA remains the most accurate method available to assess implant migration and fixation. Comparing different implant designs, RSA may play an important role in the early distinction of good and bad performing implants preventing implants with suboptimal fixation coming into the market.

A not so often discussed feature of RSA is the use of the technique as a diagnostic tool in individual cases. In daily practice, confirming clinical suspicion of loosening may be challenging, expensive and time consuming. Generally, the first step in the diagnostic algorithm of implant failure is taking conventional radiographs. However, the value of conventional radiographs in diagnosing loosening is limited.[30] Magnetic Resonance Imaging (MRI) and CT scans to assess implant loosening are more expensive and generally difficult to read because of metal artefacts.[31] Additional bone scintigraphy and SPECT may be helpful but are expensive and time consuming.

In our study we found two patients with clinical symptoms of loosening. Conventional radiographs did not show signs of loosening, while RSA enabled us to easily confirm implant migration in one of both patients. Although the numbers in this study are too small to come to conclusions, future research comparing diagnostic accuracy and cost-effectiveness of RSA versus other diagnostic modalities in the detection of implant loosening could be interesting. The diagnostic value of RSA could be investigated in patients who are already involved in RSA studies and could undergo both RSA examinations and other diagnostic tests in case of loosening. Alternatively, tantalum beads could be implanted in new patient cohorts undergoing total joint arthroplasty. After obtaining two postoperative RSA radiographs as reference and to demonstrate stabilization of implants, RSA radiographs could be repeated in case of clinically suspicion of loosening during follow-up.

CONCLUSION

Long-term survival of the SR TMC joint prosthesis is relatively poor. Clinical outcomes improved significantly in the short-term and remained excellent in the long-term in those patients with a stable implant, but deteriorated clearly in case of loosening. The role of RSA in TMC joint arthroplasty is potentially valuable but needs to be further investigated.

REFERENCES

1. Jager T, Barbary S, Dap F, Dautel G. Evaluation of postoperative pain and early functional results in the treatment of basal joint arthritis. Comparative prospective study of trapeziectomy vs. MAIA1 prosthesis in 74 female patients. *Chir Main*. 2013;32:55-62. doi:10.1016/j.main.2013.02.004
2. Robles-Molina MJ, López-Caba F, Gómez-Sánchez RC, Cárdenas-Grande E, Pajares-López M, Hernández-Cortés P. Trapeziectomy With Ligament Reconstruction and Tendon Interposition Versus a Trapeziometacarpal Prosthesis for the Treatment of Thumb Basal Joint Osteoarthritis. *Orthopedics*. 2017;40(4):e681-e686. doi:10.3928/01477447-20170503-03
3. Cebrian-Gomez R, Lizaur-Utrilla A, Sebastia-Forcada E, Lopez-Prats FA. Outcomes of cementless joint prosthesis versus tendon interposition for trapeziometacarpal osteoarthritis: a prospective study. *J hand Surg (European Vol)*. 2019;44(2):151-158. doi:10.1177/1753193418787151
4. Thorkildsen RD, Røkkum M. Trapeziectomy with LRTI or joint replacement for CMC1 arthritis, a randomised controlled trial. *J Plast Surg Hand Surg*. 2019;53:361-369. doi:10.1080/2000656X.2019.1635490
5. Froschauer SM, Holzbauer M, Schnelzer RF, et al. Total arthroplasty with Ivory® prosthesis versus resection-suspension arthroplasty: a retrospective cohort study on 82 carpometacarpal-I osteoarthritis patients over 4 years. *Eur J Med Res*. 2020;25(1):13. doi:10.1186/s40001-020-00411-8
6. ten Brinke B, Mathijssen NMC, Blom I, Deijkers RLM, Ooms EM, Kraan G a. Model-based roentgen stereophotogrammetric analysis of the surface replacement trapeziometacarpal total joint arthroplasty. *J Hand Surg (European Vol)*. 2016;41:925-929. doi:10.1177/1753193416629070
7. Hansen TB, Larsen K, Bjergelund L, Stilling M. Trapeziometacarpal joint implants can be evaluated by roentgen stereophotogrammetric analysis. *J hand Surg (European Vol)*. 2010;35(6):480-485. doi:10.1177/1753193409355627
8. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. A randomized clinical RSA study with 2-year follow-up. *Acta Orthop*. 2013;84(1):98-105. doi:10.3109/17453674.2013.765625
9. Ooms EM, ten Brinke B, Mathijssen NMC, Blom IF, Deijkers RLM, Kraan G a. Feasibility of model-based Roentgen Stereophotogrammetric Analysis to evaluate early migration of the trapeziometacarpal joint prosthesis. *BMC Musculoskelet Disord*. 2015;16(1):295. doi:10.1186/s12891-015-0747-3
10. Veehof MM, Sleegers EJA, Van Veldhoven NHMJ, Schuurman AH, Van Meeteren NLU. Psychometric qualities of the Dutch language version of the disabilities of the arm, shoulder, and hand questionnaire (DASH-DLV). *J Hand Ther*. 2002;15(4):347-354. doi:10.1016/S0894-1130(02)80006-0
11. Citron N, Hulme CE, Wardle N. A self-administered questionnaire for basal osteoarthritis of the thumb. *J Hand Surg (European Vol)*. 2007;32(5):524-528. doi:10.1016/j.jhse.2007.03.015
12. International Organisation for Standardization. *Implants for Surgery — Roentgen Stereophotogrammetric Analysis for the Assessment of Migration of Orthopaedic Implants*.; 2013.
13. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC. A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. *J Biomech*. 2005;38(11):2330-2334. doi:10.1016/j.jbiomech.2004.09.018

14. Semere A, Vuillerme N, Corcella D, Forli A, Moutet F. Results with the Roseland(®) HAC trapeziometacarpal prosthesis after more than 10 years. *Chir Main*. 2015;34(2):59-66. doi:10.1016/j.main.2015.01.004
15. Dehl M, Chelli M, Lippmann S, Benaissa S, Rotari V, Moughabghab M. Results of 115 Rubis II reverse thumb carpometacarpal joint prostheses with a mean follow-up of 10years. *J Hand Surg (European Vol)*. 2017;42:524-528. doi:10.1177/1753193416687508
16. Martin-Ferrero M, Simón-Pérez C, Coco-Martín MB, Vega-Castrillo A, Aguado-Hernández H, Mayo-Iscar A. Trapeziometacarpal total joint arthroplasty for osteoarthritis: 119 patients with a minimum of 10 years follow-up. *J Hand Surg (European Vol)*. 2020;45(5):443-451. doi:10.1177/1753193419871660
17. De Smet A, Vanhove W, Benis S, Verstraete M, Hollevoet N. Ten-year outcomes of the Arpe prosthesis for the treatment of osteoarthritis of the trapeziometacarpal joint. *Acta Orthop Belg*. 2020;86(1):131-136.
18. Dumartinet-Gibaud R, Bigorre N, Raimbeau G, Jeudy J, Saint Cast Y. Arpe total joint arthroplasty for trapeziometacarpal osteoarthritis: 80 thumbs in 63 patients with a minimum of 10 years follow-up. *J Hand Surg (European Vol)*. 2020;45(5):465-469. doi:10.1177/1753193420909198
19. Tchurukdichian A, Guillier D, Moris V, See LA, Macheboeuf Y. Results of 110 IVORY® prostheses for trapeziometacarpal osteoarthritis with a minimum follow-up of 10 years. *J Hand Surg (European Vol)*. 2020;45(5):458-464. doi:10.1177/1753193419899843
20. Puh U. Age-related and sex-related differences in hand and pinch grip strength in adults. *Int J Rehabil Res*. 2010;33(1):4-11. doi:10.1097/MRR.0b013e328325a8ba
21. Lerebours A, Marin F, Bouvier S, Egles C, Rassineux A, Masquelet AC. Trends in Trapeziometacarpal Implant Design: A Systematic Survey Based on Patents and Administrative Databases. *J Hand Surg (American Vol)*. 2020;45(3):223-238. doi:10.1016/j.jhsa.2019.11.015
22. Pendse A, Nisar A, Shah SZ, Bhosale A, Freeman J V, Chakrabarti I. Surface replacement trapeziometacarpal joint arthroplasty--early results. *J hand Surg (European Vol)*. 2009;34(6):748-757. doi:10.1177/1753193409343750
23. Beardsley CL, Paller DJ, Peura GD, Brattbakk B, Beynnon BD. The effect of coordinate system choice and segment reference on RSA-based knee translation measures. *J Biomech*. 2007;40(6):1417-1422. doi:10.1016/j.jbiomech.2006.05.005
24. van Hamersveld KT, Marang–van de Mheen PJ, Koster LA, Nelissen RGHH, Toksvig-Larsen S, Kaptein BL. Marker-based versus model-based radiostereometric analysis of total knee arthroplasty migration: a reanalysis with comparable mean outcomes despite distinct types of measurement error. *Acta Orthop*. 2019;90(4):366-372. doi:10.1080/17453674.2019.1605692
25. Scheerlinck T, Polfliet M, Deklerck R, Van Gompel G, Buls N, Vandemeulebroucke J. Development and validation of an automated and marker-free CT-based spatial analysis method (CTSA) for assessment of femoral hip implant migration In vitro accuracy and precision comparable to that of radiostereometric analysis (RSA). *Acta Orthop*. 2016;87(2):139-145. doi:10.3109/17453674.2015.1123569
26. Brodén C, Giles JW, Popat R, et al. Accuracy and precision of a CT method for assessing migration in shoulder arthroplasty: an experimental study. *Acta Radiol*. 2020;61:776-782. doi:10.1177/0284185119882659
27. Nelissen RGHH, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. *J bone Jt Surg (American Vol)*. 2011;93 Suppl 3:62-65. doi:10.2106/jbjs.k.00907

28. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
29. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
30. Reish TG, Clarke HD, Scuderi GR, Math KR, Scott WN. Use of multi-detector computed tomography for the detection of periprosthetic osteolysis in total knee arthroplasty. *J Knee Surg*. 2006;19(4):259-264. doi:10.1055/s-0030-1248116
31. Burge AJ, Konin GP, Berkowitz JL, Lin B, Koff MF, Potter HG. What is the Diagnostic Accuracy of MRI for Component Loosening in THA? *Clin Orthop Relat Res*. 2019;477(9):2085-2094. doi:10.1097/CORR.0000000000000772

PART III

RSA IN THE ELBOW JOINT

Chapter 6

Long-term outcomes after Instrumented Bone Preserving total elbow arthroplasty: a radiostereometric study with a minimum follow-up of 10 years

B. ten Brinke, N.M. Kosse, P.E. Flikweert, M. van der Pluijm, D. Eygendaal

Journal of Shoulder and Elbow Surgery 2020; 29(1): 126-131

ABSTRACT

Background: Aseptic loosening is a main concern in elbow arthroplasty. Evaluation of implant migration using radiostereometric analysis (RSA) might increase understanding of implant loosening. Previously, two-year RSA results of 16 Instrumented Bone Preserving (IBP) elbow prostheses showed migration of the humeral component in the first weeks but stabilization of most components within six months postoperatively. The present study evaluated long-term survival, the relation between early migration and survival and the long-term migration and clinical outcomes.

Methods: Sixteen patients who received an IBP prosthesis were prospectively followed with a median follow-up time of 136 months (range 82 – 165). Migration was measured using RSA. Clinical results were described using the Elbow Function Assessment (EFA), Broberg and Morrey Elbow Functional Rating Index (EFRI), Oxford Elbow Score (OES) and Visual Analogue Scale (VAS) for pain and satisfaction.

Results: Four patients underwent a revision within ten years, two more were planned for revision surgery after 14 years. Five patients died during follow-up with their prosthesis in situ. Early migration was not associated with implant survival. Long-term migration patterns varied widely. Median EFA score was 58.5, EFRI was 50 and OES was 32. Median VAS score for pain was 2 and 7.5 for satisfaction.

Conclusion: Ten-year survival of the IBP total elbow prosthesis was 75%, decreasing to 63% after 14 years of follow-up. Long-term implant failure could not be predicted by two-year migration results in this study. Although short-term clinical results were promising, long-term outcomes worsened in all patients.

INTRODUCTION

Total joint replacement has become an accepted treatment option for symptomatic osteoarthritis (OA) or rheumatoid arthritis (RA) of the elbow joint. Several total elbow implant designs have been developed and show ten-year survival rates varying between 64 and 91%.[1–5] Although survival rates are improving, they do not match the long-term survival results of hip and knee arthroplasty and aseptic loosening is still one of the main concerns in replacement of the elbow joint.[6] The Instrumented Bone Preserving Elbow System (IBP; Biomet Merck Ltd, Bridgend, United Kingdom) was introduced in 2001. This implant was designed to preserve intercondylar bone and to improve initial fixation and stability of the implant.[7] Kleinlugtenbelt et al. described one implant failure in 19 patients together with satisfactory short-term clinical results.[8] However, ten-year follow-up data showed increased revision rates up to 25%.[1] These data demonstrate the necessity to improve implant survival and to expand the knowledge about the process of loosening in elbow arthroplasty.

Numerous studies have been performed to assess migration of prostheses using radiostereometric analysis (RSA). RSA enables accurate migration measurement in small patient cohorts.[9,10] In primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), early implant migration is related with long-term implant failure resulting in revision.[11–13] This technique could therefore be of great interest in elbow arthroplasty. However, RSA-studies in this field are scarce. Based on the precision of RSA in the knee joint, Valstar et al. hypothesized that elbow implants at risk for loosening had more than 0.4mm translation and/or 1 degree of rotation two years postoperatively.[14] However, long-term outcomes of this cohort showed that these cut off scores did not predict implant loosening.[15]

Previously, our group presented the two-year results of an RSA study with 16 IBP elbow prostheses.[7] The results revealed a stable fixation in 14 out of 16 implants after two years. In contrast to knee and hip prostheses, there is currently no information available concerning the relation between early migration of elbow implants and survival. Therefore, the aim of the present study was to determine the long-term survival rate of the IBP total elbow prosthesis, to investigate a possible relation between early migration and long-term survival and to evaluate the migration of the humeral component of the prosthesis and the clinical and functional outcomes in the long-term with a minimum follow-up period of 11 years.

METHODS

Design and participants

This study is a follow-up study of a single-centre prospective study performed between June 2003 and February 2006. Sixteen patients (12 women, 4 men) received a unilateral IBP total elbow prosthesis (Biomet Merck Ltd, Bridgend, United Kingdom) in the Sint Maartenskliniek, Nijmegen. Details of the original study are described in the previously published paper by DeVos et al.[7] Patients with the prosthesis still in situ and alive were invited to visit the outpatient clinic of the Sint Maartenskliniek in Nijmegen. Patients underwent a clinical examination and were asked to fill out patient reported outcome measurements. RSA radiographs were obtained.

All included patients gave their written informed consent to participate in this study. Ethical approval was given by the Medical Ethics Review Committee of Slotervaart en Raede (NL59132.048.16) and the local hospital's investigation board.

Survival

Survival data of all 16 patients could be obtained. We defined two endpoints to describe survival: 1) 'failure' defined as the revision of the humeral component of the IBP total elbow prosthesis and 2) 'died' defined as dead with the prosthesis in situ.

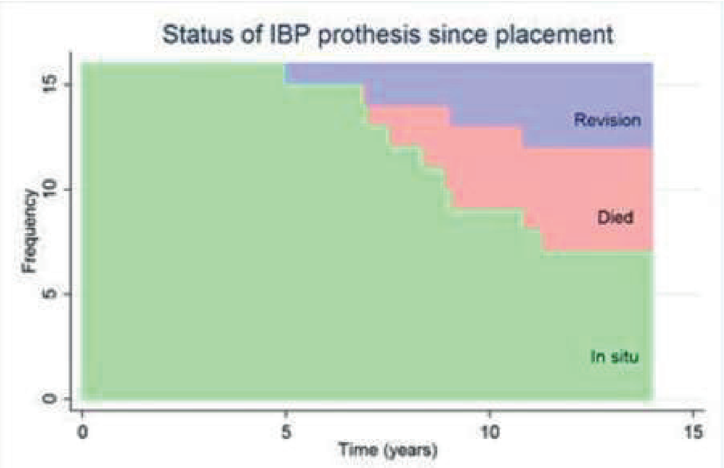


Figure 1. Number of Instrumented Bone Preserving prostheses *in situ*, the number of patients that died (with the prosthesis *in situ*) and the number of revisions, over the years.

Radiological assessment

RSA radiographs were taken using a Digital Radiography (DR) system (Digital Diagnost Valueroom (2014) and MobileDiagnost wDR (2014)) and 2 synchronized roentgen tubes positioned 1.1 meter above the X-ray cassette. A perspex calibration box was placed under the elbow. Migration, defined as translations (T; in mm) and rotations (R; in ˚), is the change in position and orientation of the humeral component with respect to the distal humerus over time around the medial-lateral (x), proximal-distal (y) and anterior-posterior (z) axis. Migration was calculated by comparing the current position of the implant with the position directly after the operation (the reference radiograph). Migration results are presented as total translation ($TT=\sqrt{(Tx^2+Ty^2+Tz^2)}$) and total rotation ($TR=\sqrt{(Rx^2+Ry^2+Rz^2)}$). The maximum acceptable condition number (CN) was 150. The maximum mean error (ME) of rigid body was 0.42. Compared to the previous study, new model-based RSA-software (Model-based RSA, RSAcore, Leiden, The Netherlands) was used. Therefore, both the reference radiographs and the radiographs taken 24 months postoperatively were recalculated.

Clinical outcomes

Clinician reported outcome measures included the passive range of motion (ROM) in flexion-extension and pronation-supination, the Elbow Function Assessment (EFA) and the Broberg and Morrey Elbow Functional Rating Index (EFRI). The EFA ranges from 0 to 100 points and includes patient-reported pain, activities of daily living (ADL) and ROM and the EFRI ranges from 0 to 100 points.

Patient reported outcome measures included the Oxford Elbow Score (OES) and the visual analogue scale (VAS) to evaluate pain and patient satisfaction. The OES ranges from 0 to 48 and contains 12 questions concerning elbow function, pain and social-psychological items. The VAS ranges from 0 to 100. For all scores, higher scores indicate better outcomes, except for the VAS pain scores.

Statistical Analysis

Descriptive statistics were used to give an overview of patient characteristics, survival and the predictive value of early migration for implant failure. In addition, a Mann-Whitney U test was performed in order to investigate the differences in two-year migration between participants with and without a revised implant. Given the small number of patients, clinical results were reported using descriptive analysis.

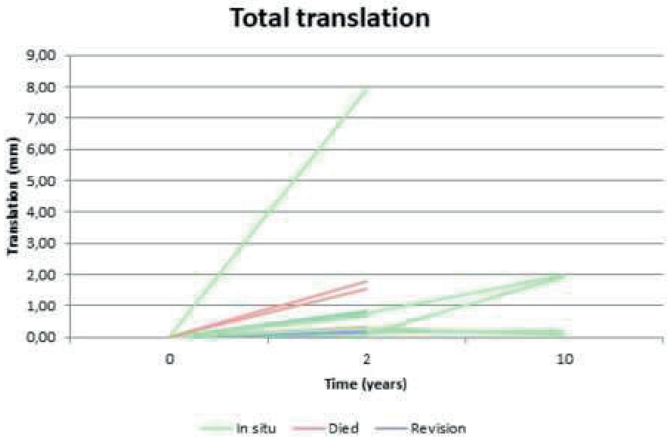


Figure 2. Total translation of the Instrumented Bone Preserving total elbow prosthesis during follow-up.

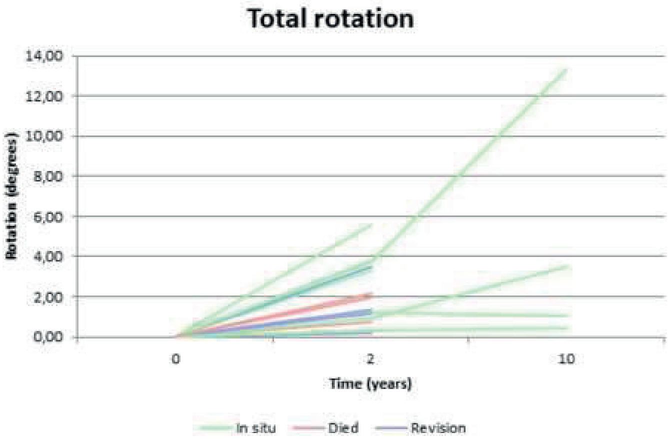


Figure 3. Total rotation of the Instrumented Bone Preserving total elbow prosthesis during follow-up.

RESULTS

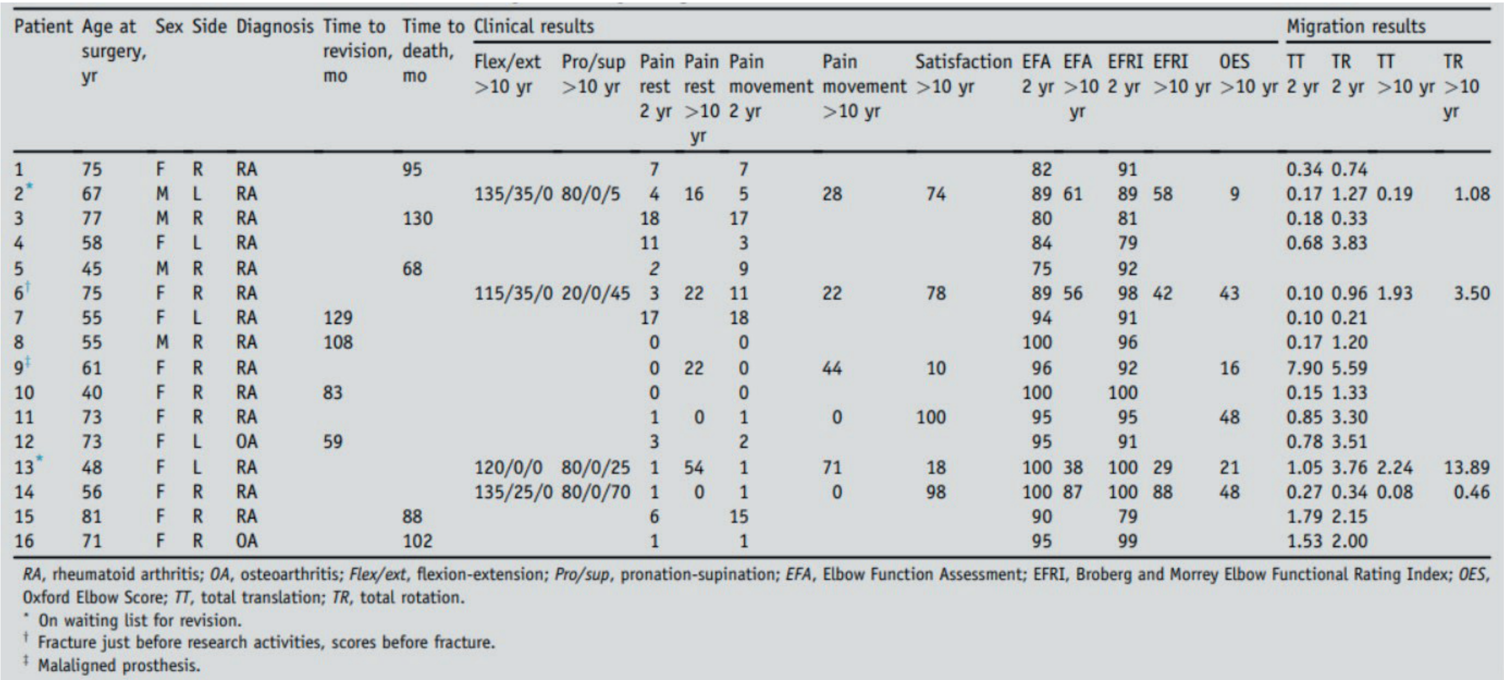
Eleven of the 16 patients who completed the two-year follow-up, where still alive at the time of the present study, seven patients with their prosthesis in situ. Six of them were willing to participate in this study. Four patients visited the hospital between December 2016 and April 2017 at a median follow-up time of 145.5 months (range 134-165). Two patients were unable to visit the hospital but filled out the patient reported outcome measures. The median age of the six participating patients was 77 years (range 58-87) at the time of research activities, including one man and six women.

Survival

Four patients underwent a revision within ten years of follow-up. The median time to revision was 95.5 months (range 59-129). Five patients died with their prosthesis in situ. Figure 1 presents an overview of the survival of the prostheses over the years.

RSA results

In four patients who underwent a revision, median total translation (TT) and total rotation (TR) was 0.2mm (range 0.1-0.8) and 1.3˚ (range 0.2-3.5) 2 years postoperatively. In 11 non-revised patients median TT and TR was 0.7mm (range 0.1-7.9) and 2.0˚ (range 0.3-5.6). There was no difference in the amount of migration between the revised and non-revised prostheses (TT: $p = 0.07$; TR: $p = 0.50$). Two patients with a prosthesis that was classified as unstable after two years of follow-up did not undergo a revision of the implant. One patient died after a follow-up time of 68 months with the prosthesis in situ. The second patient did not undergo a revision despite of poor VAS satisfaction and OES scores ten years postoperatively. Long-term migration patterns varied widely between the four patients (Table 1, Figures 2 and 3). We found high migration values in one patient (patient 6) who suffered a posttraumatic periprosthetic fracture of the lateral epicondyle just before the outpatient visit. Further, loosening of the humeral component was shown in patient 13.



Patient	Age at surgery, yr	Sex	Side	Diagnosis	Time to revision, mo	Time to death, mo	Clinical results												Migration results			
							Flex/ext >10 yr	Pro/sup >10 yr	Pain rest 2 yr	Pain rest >10 yr	Pain movement 2 yr	Pain movement >10 yr	Satisfaction >10 yr	EFA 2 yr	EFA >10 yr	EFRI 2 yr	EFRI >10 yr	OES >10 yr	TT 2 yr	TR 2 yr	TT >10 yr	TR >10 yr
1	75	F	R	RA		95			7		7			82		91			0.34	0.74		
2*	67	M	L	RA			135/35/0	80/0/5	4	16	5	28	74	89	61	89	58	9	0.17	1.27	0.19	1.08
3	77	M	R	RA		130			18		17			80		81			0.18	0.33		
4	58	F	L	RA					11		3			84		79			0.68	3.83		
5	45	M	R	RA		68			2		9			75		92						
6†	75	F	R	RA			115/35/0	20/0/45	3	22	11	22	78	89	56	98	42	43	0.10	0.96	1.93	3.50
7	55	F	L	RA	129				17		18			94		91			0.10	0.21		
8	55	M	R	RA	108				0		0			100		96			0.17	1.20		
9‡	61	F	R	RA					0	22	0	44	10	96		92		16	7.90	5.59		
10	40	F	R	RA	83				0		0			100		100			0.15	1.33		
11	73	F	R	RA					1	0	1	0	100	95		95		48	0.85	3.30		
12	73	F	L	OA	59				3		2			95		91			0.78	3.51		
13*	48	F	L	RA			120/0/0	80/0/25	1	54	1	71	18	100	38	100	29	21	1.05	3.76	2.24	13.89
14	56	F	R	RA			135/25/0	80/0/70	1	0	1	0	98	100	87	100	88	48	0.27	0.34	0.08	0.46
15	81	F	R	RA		88			6		15			90		79			1.79	2.15		
16	71	F	R	OA		102			1		1			95		99			1.53	2.00		

RA, rheumatoid arthritis; *OA*, osteoarthritis; *Flex/ext*, flexion-extension; *Pro/sup*, pronation-supination; *EFA*, Elbow Function Assessment; EFRI, Broberg and Morrey Elbow Functional Rating Index; *OES*, Oxford Elbow Score; *TT*, total translation; *TR*, total rotation.

* On waiting list for revision.

† Fracture just before research activities, scores before fracture.

‡ Malaligned prosthesis.

Table 1. Patient characteristics and an overview of two and ten-year year migration values and clinical outcomes.

Clinical outcomes

Clinician reported outcome measures were completed in four patients. Six patients completed the patient reported outcome measures. Results varied largely among the participants (table 1). Compared to the two-year follow-up, EFA, EFRI and OES scores decreased in all patients and approached the preoperative situation.

During clinical assessment, two patients (2 and 13) were found to have a loose prosthesis and were put on the waiting list to undergo a revision. One because of loosening of the ulnar component and one because of loosening of the humeral component with a spontaneous fracture of the lateral epicondyle. Another patient (6) had suffered a posttraumatic periprosthetic fracture of the lateral epicondyle just before the outpatient visit. This patient was treated conservatively. The given clinical scores of this patient concern the clinical situation just before the fracture. One patient (9) had a known malaligned prosthesis and although two-year VAS pain scores, EFA and EFRI scores were excellent, long-term outcomes worsened substantially.

DISCUSSION

The aim of the present study was to report the long-term survival rate of the IBP total elbow prosthesis, to investigate the predictive value of early migration for long-term implant survival and to evaluate long-term migration and clinical outcomes.

The survival rate of the IBP prosthesis was 75% after ten years of follow-up. This is in line with previous studies concerning elbow joint replacement reporting ten-year survival rates between 70.7% and 90%.[1–3,16–20] Survival rates decreased to 62.5% after 14 years of follow-up, which is slightly worse compared to recently published long-term survival ranging between 70.6% and 99%.[3,20,21] However, these studies were retrospective or register-based. Actively inviting patients to our clinic, leading to two additional revisions, might explain the higher revision rate.

Although this study is underpowered to demonstrate a relation between early migration and survival, a descriptive analysis is performed to investigate any possible relation. In accordance with the results of Van der Lugt et al, who described the long-term follow-up of 18 Souter-Strathclyde elbow prostheses, our data do not support the existence of a relation between early migration and long-term implant survival.[14] It should be noted, though, that implant failure is often defined as implant revision. However, there might be several reasons why loosening of elbow prostheses does not always lead to revision. First, loosening does not always result in clinically relevant symptoms of the elbow. In this study, two patients turned out to have a loose prosthesis during research activities and were planned for an implant revision. Asymptomatic loosening could partially be explained by the fact that compared to the hip and knee joint, the elbow is mechanically less stressed during the day.[15] Second, patients found to have a loose implant might decide to reject a revision because of high age, comorbidity or a less-demanding lifestyle. Finally, patients are able to spare the affected elbow using the contralateral arm, which theoretically reduces the need for revision. Considering these aspects, long-term survival defined as revision of the implant might not be the right endpoint to study the relation between early migration and long-term survival in elbow arthroplasty. In future research to the predictive role of early migration for long-term outcomes, the endpoints of survival should be reconsidered and more focused on clinical outcomes instead of revision alone.

Clinical results in our study worsened substantially over time, which is in line with Dalemans et al, who found a deterioration of clinical outcomes after 174 months of follow-up.[1] A possible factor that contributes to this deterioration might be loosening of implants which are not revised, despite of complaints. In addition, deterioration of clinical outcome scores is possibly influenced by multiple factors like aging and comorbidities that are not all related to the elbow implant, however, they should be taken into account during the evaluation of the elbow implant.

An important limitation of our study is the small number of patients included for long-term follow-up. Therefore, no general conclusions could be drawn concerning long-term migration or long-term clinical outcomes. The high loss to follow-up is mainly explained by the death of a relatively large number of subjects. Nevertheless, both early migration data and long-term survival data of all 16 patients were completely available.

CONCLUSION

This study demonstrated the long-term results of the IBP total elbow prosthesis with a long-term survival rate of 75% after 10 years of follow-up. A relation between early migration and late revision could not be demonstrated in this study. Although short-term clinical results were promising, long-term outcomes worsened in most patients. In future research survival outcomes should be reconsidered bringing the focus more on clinical outcomes instead of revision alone.

REFERENCES

1. Dalemans A, De Smet L, Degreef I. Long-term outcome of elbow resurfacing. *J shoulder Elb Surg*. 2013;22(11):1455-1460. doi:10.1016/j.jse.2013.06.013
2. Kodama A, Mizuseki T, Adachi N. Kudo type-5 total elbow arthroplasty for patients with rheumatoid arthritis. *Bone Joint J*. 2017;99-B(6):818-823. doi:10.1302/0301-620X.99B6.BJJ-2016-1033.R2
3. Krukhaug Y, Hallan G, Dybvik E, Lie SA, Furnes ON. A survivorship study of 838 total elbow replacements: a report from the Norwegian Arthroplasty Register 1994-2016. *J shoulder Elb Surg*. 2018;27(2):260-269. doi:10.1016/j.jse.2017.10.018
4. Mansat P, Bonnevialle N, Rongières M, Mansat M, Bonnevialle P. Experience with the Coonrad-Morrey total elbow arthroplasty: 78 consecutive total elbow arthroplasties reviewed with an average 5 years of follow-up. *J Shoulder Elb Surg*. 2013;22(11):1461-1468. doi:10.1016/j.jse.2013.07.042
5. Plaschke HC, Thillemann TM, Brorson S, Olsen BS. Implant survival after total elbow arthroplasty: a retrospective study of 324 procedures performed from 1980 to 2008. *J shoulder Elb Surg*. 2014;23(6):829-836. doi:10.1016/j.jse.2014.02.001
6. Prkic A, Welsink C, The B, van den Bekerom MPJ, Eygendaal D. Why does total elbow arthroplasty fail today? A systematic review of recent literature. *Arch Orthop Trauma Surg*. 2017;137(6):761-769. doi:10.1007/s00402-017-2687-x
7. DeVos MJ, Verdonschot N, Luites JWH, Anderson PG, Eygendaal D. Stable fixation of the IBP humeral component implanted without cement in total elbow replacement: A radiostereometric analysis study of 16 elbows at two-year follow-up. *Bone Jt J*. 2014;96 B(2):229-236. doi:10.1302/0301-620X.96B2
8. Kleinlugtenbelt I V, Bakx PAGM, Huij J. Instrumented Bone Preserving elbow prosthesis in rheumatoid arthritis: 2-8 year follow-up. *J shoulder Elb Surg*. 2010;19(6):923-928. doi:10.1016/j.jse.2010.05.003
9. Kärrholm J, Herberts P, Hultmark P. Radiostereometry of Hip Prostheses: Review of Methodology and Clinical Results. *Clin Orthop Relat Res*. 1997;344:94-110.
10. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl*. 1989;232:1-51.
11. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
12. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
13. Pijls BG, Plevier JWM, Nelissen RGHH. RSA migration of total knee replacements. *Acta Orthop*. 2018;89(3):320-328. doi:10.1080/17453674.2018.1443635
14. van der Lugt JCT, Valstar ER, Witvoet-Braam SW, Nelissen RGHH. Migration of the humeral component of the Souter-Strathclyde elbow prosthesis: a long-term RSA study. *J bone Jt Surg (British Vol)*. 2010;92(2):235-241. doi:10.1302/0301-620X.92B2.22636
15. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis 21 elbows followed for 2 years. *Acta Orthop Scand*. 2002;73(3):264-272. doi:10.1080/000164702320155220

16. Barco R, Streubel PN, Morrey BF, Sanchez-Sotelo J. Total Elbow Arthroplasty for Distal Humeral Fractures. *J Bone Jt Surg*. 2017;99(18):1524-1531. doi:10.2106/JBJS.16.01222
17. Nestorson J, Rahme H, Adolfsson L. Arthroplasty as primary treatment for distal humeral fractures produces reliable results with regards to revisions and adverse events: a registry-based study. *J Shoulder Elb Surg*. 2019;28(4):e104-e110. doi:10.1016/j.jse.2018.07.035
18. Pham TT, Delclaux S, Huguet S, Wargny M, Bonnevialle N, Mansat P. Coonrad-Morrey total elbow arthroplasty for patients with rheumatoid arthritis: 54 prostheses reviewed at 7 years' average follow-up (maximum, 16 years). *J Shoulder Elb Surg*. 2018;27(3):398-403. doi:10.1016/j.jse.2017.11.007
19. Rausch V, Hackl M, Leschinger T, Müller LP, Wegmann K. Ellenbogenprothese bei rheumatischen Erkrankungen. *Z Rheumatol*. 2018;77(10):899-906. doi:10.1007/s00393-018-0539-x
20. Welsink CL, Lambers KTA, van Deurzen DFP, Eygendaal D, van den Bekerom MPJ. Total Elbow Arthroplasty. *JBJS Rev*. 2017;5(7):e4. doi:10.2106/JBJS.RVW.16.00089
21. Nishida K, Hashizume K, Nasu Y, et al. Mid-term results of alumina ceramic unlinked total elbow arthroplasty with cement fixation for patients with rheumatoid arthritis. *Bone Joint J*. 2018;100-B(8):1066-1073. doi:10.1302/0301-620X.100B8.BJJ-2017-1451.R1

PART IV

RSA IN THE SHOULDER JOINT

Chapter 7

Early fixation of the humeral component in stemless total shoulder arthroplasty: a radiostereometric and clinical study with 24-month follow-up

B. ten Brinke, B. Hesseling, D. Eygendaal, M.A. Hoelen, N.M.C. Mathijssen

Bone and Joint Journal 2022;104-B(1):76-82

ABSTRACT

Aims: Stemless humeral implants have been developed to overcome stem-related complications in total shoulder arthroplasty. However, stemless implant designs may hypothetically result in less stable initial fixation potentially affecting long-term survival. The aim of this study is to investigate early fixation and migration patterns of the stemless humeral component of the Simpliciti Shoulder System and to evaluate clinical outcomes.

Patients and Methods: In this prospective cohort study RSA-radiographs were obtained in 24 patients one day postoperatively and six weeks, six months, one year and two years postoperatively. Migration was calculated using model-based RSA. Clinical outcomes were evaluated using the visual analogue scale (VAS) for pain, the Oxford Shoulder Score (OSS), the Constant-Murley Score (CMS) and the Disabilities of the Arm, Shoulder and Hand (DASH) score.

Results: At two years, median translation (Interquartile range (IQR)) along the x-, y- and z-axis was -0.12mm (-0.18 – 0.02), -0.17mm (-0.27 – -0.09) and 0.09mm (0.02 – 0.31). Median rotation (IQR) around the x-, y- and z-axis was 0.12° (-0.50 – 0.57), -0.98° (-1.83 – 1.23) and 0.09° (-0.76 – 0.30). Twenty prostheses stabilised within 12 months postoperatively. Four prostheses showed continuous migration between 12 and 24 months. At two years of follow-up, all clinical scores improved significantly (median difference (IQR) VAS at rest: -3.0 (-1.5 – -6.0); OSS: 22.0 (15.0 – 25.0); CMS: 29.5 (15.0 – 35.75); DASH: -30,0 (-20.6 – -41.67) (all $p<0.001$). One prosthesis was revised because of instability.

Conclusion: In conclusion, we found that 20 out of 24 implants stabilised within 12 months postoperatively. The significance of continuous migration in four implants is unclear and future research on the predictive value of early migration for future loosening in TSA is required. Clinical results improved clinically relevant.

INTRODUCTION

Traditionally, total shoulder arthroplasty (TSA) has been designed as a stemmed implant relying on intramedullary fixation of the humeral component. Although complications related to the humeral component are rare, stemmed humeral implants have important drawbacks as well, including intraoperative fractures, stress shielding, stress risers (in case of ipsilateral elbow arthroplasty) and periprosthetic fractures.[1–6] Furthermore, revision of stemmed humeral implants is technically demanding and extraction of stem and cement may lead to additional bone loss and intraoperative fractures.[7]

In order to reduce stem-related complications and to make implant revision less complex, several stemless implant designs have been developed in the last decade.[8,9] Theoretical advantages of stemless implants include a better preservation of humeral bone stock and a reduced fracture risk intra- and postoperatively. Furthermore, stemless implants could be valuable in cases with challenging deformities of the metaphyseal part of the proximal humerus.

Recently, the non-inferiority of stemless implants compared to stemmed implants in the short- to mid-term follow up has been demonstrated in several high-quality studies.[9–16] However, only two studies have been published with a minimum of ten years of follow-up. Magosch et al. demonstrated a survival of 96.5% in 75 shoulders.[17] Märtens et al. demonstrated that clinical long-term outcomes did not differ between stemless and stemmed implants.[18] Although not significant, ten-year implant survival was lower in the stemless group (91.5% vs 95.3%). To carefully assess implant safety we are convinced that more long-term follow-up is essential. Even though short-term results are satisfactory, one of the most important potential drawbacks of stemless implants might evolve in the long-term, namely aseptic loosening.

One of the main factors for long-term success is initial fixation of the implant. The uncemented humeral component of the Simpliciti Stemless Shoulder System consists of a collar and a three-fin nucleus. In order to achieve a stable fixation in the metaphyseal bone, the collar and nucleus are treated with a porous sintered titanium (cp-Ti) coating to allow bone ingrowth into the implant.[8] In contrast to stemmed implants, fixation of stemless implants completely relies on cancellous instead of cortical bone. Fixation in cancellous bone has been shown to be worse compared to cortical bone in a recent experimental study using pig bones.[19] Combined with a reduced contact area between the prosthesis and the surrounding bone, especially in case of osteoporotic bone, this may lead to suboptimal fixation of the prosthesis potentially affecting the long-term implant survival.

A proven method to assess in vivo micromotion is Radiostereometric Analysis (RSA).[20,21] Nelissen et al. recommended that new orthopaedic implants should be analyzed using RSA.[22] However, although stemless humeral implants have been widely used, early migration has never been assessed using RSA. Investigating early migration and initial fixation of this relatively new implant will provide earlier evaluation of this class of prostheses while awaiting long-term follow-up data.

The aim of this prospective, single-centre study was to identify fixation and migration patterns of the Simpliciti stemless shoulder system using model-based RSA (MB-RSA) and to evaluate clinical outcomes with a follow-up time of two years. We hypothesized that early migration of this stemless humeral component will stabilize within the first year after placement. Moreover, we expected a significant improvement in clinical scores two years postoperatively in comparison with preoperative scores.

METHODS

In this single-center prospective cohort study all consecutive patients receiving the stemless Simpliciti shoulder system between March 2014 and October 2017 were included if they met the following inclusion criteria: end-stage osteoarthritis (OA), posttraumatic OA, rheumatoid arthritis (RA) of the glenohumeral joint or avascular necrosis (AVN) of the humeral head in patients aged 45 years and older. Patients had to be able to speak and write the Dutch language. Patients were excluded in the event of accompanied fractures, post-septic OA, glenohumeral instability, BMI > 35 kg/m^2, or any active infection. All included patients gave their written informed consent to participate in this study. This study was registered in the Netherlands Trial Register (NL6632). Ethical approval was given by the Medical Ethical Committee Zuidwest Holland (NL45412.098.13).

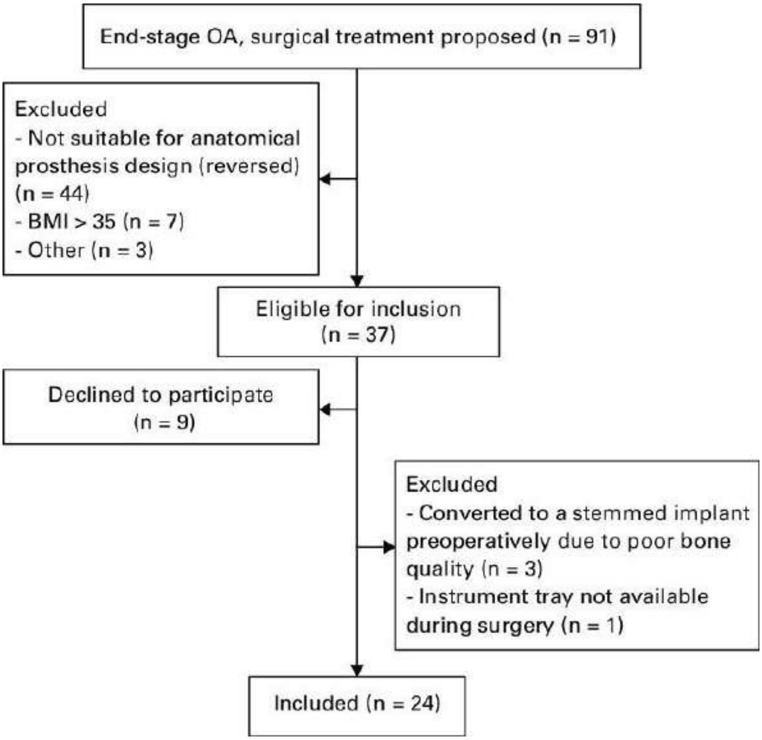


Figure 1. Flow chart showing enrolment of patients available for analysis. OA,osteoarthritis.

During the study period, 28 patients were eligible for inclusion and willing to participate in our study. However, four patients had to be excluded during surgery (Figure 1) leaving 24 participants (24 shoulders) in the study (16 women) with a mean age 67.5 years (49 to 82). Indication for surgery was primary OA in 23 patients and AVN of the humeral head in one patient. Median operating time was 111.5 minutes (interquartile range (IQR) (101.0 to 119.8) in hemiarthroplasty (n = 6) and 116.0 minutes (IQR 104.5 to 121.8) in TSA (n = 18).

Technique

All operations were performed by the same orthopaedic surgeon experienced in shoulder surgery (M.H.) through a deltopectoral approach with the patient positioned in a beach chair position. The humeral head was dislocated anteriorly and after removal of osteophytes, resection of the humeral head was performed. The metaphysis and fin tracks were then prepared. After preparation and placement of the glenoid component (in TSA), the appropriate humeral head size was determined and the final prosthesis was implanted. Subscapularis repair was performed using both transtendinous and transosseous sutures. Postoperative care was standardized and consisted of an abduction pillow for four weeks followed by a sling for another two weeks. Patients were allowed to perform pendulum exercises. After four weeks, patients started active assisted shoulder range-of-motion exercises. External rotation was limited to 0° during the first six weeks.

Radiostereometric analysis

During surgery eight to 12 tantalum beads (1mm diameter) were inserted in the proximal humerus, taking into account a sufficient dispersal of the beads. Two synchronized roentgen tubes (DigitalDiagnost and MobileDiagnost wDR (Philips, Best, The Netherlands)) were used to obtain RSA radiographs at the first day postoperatively (reference radiograph) and six weeks, six months, one year and two years postoperatively. Migration was calculated using model-based RSA software (Model-based RSA, Version 4.2, RSAcore, Leiden, The Netherlands). Migration was defined as the change in 3D position of the nucleus of the humeral component with respect to the humeral bone (represented by the inserted bone markers) between the postoperative (reference) and follow-up radiographs. An implant-based coordinate system was used to calculate translations along (T; in mm) and rotations around (R; in degrees) the medial-lateral (x), cranial-caudal (y) and ventral-dorsal (z) axes. Detected bone markers were used for analysis if they met the International Organisation of Standardization (ISO) criteria for marker stability (mean error of rigid body fitting (ME) < 0.35 mm) and 3D distribution (condition number (CN) <150).[23]

We assumed that implants should stabilize within 12 months after implantation. To demonstrate either stabilization or continuous migration of the implants, migration was calculated in all patients between 12 and 24 months.

In order to determine precision of migration measurement, double examinations were performed in 19 patients at one-year follow up. Precision is presented as 1.96 x standard deviation (SD) of the measured 'migration' between the RSA-examinations.

Outcomes

The primary outcome of this study was the fixation and migration pattern of the humeral component of the stemless Simpliciti shoulder system using MB-RSA. Secondary outcome measures were the Constant-Murley Score (CMS),[24] the Oxford Shoulder Score (OSS),[25] the Disability of the Arm, Shoulder and Hand (DASH) score[26] and the Visual Analogue Scale (VAS) for pain at rest and during activity (0 to 10) with a follow-up time of two years. Number of complications, additional surgeries and operative time were recorded.

Statistical analysis

To assess normal distribution of the CMS, OSS, DASH and VAS scores a Shapiro-Wilk test was performed. Since no normal distribution could be assumed, all clinical data were analyzed using nonparametric statistics. Friedman tests were used to compare pre- and postoperative clinical scores over time. Additionally, post-hoc Bonferroni corrections were performed for multiple testing. Mann-Whitney U tests were used to compare clinical outcomes of implants with and without continuous migration. For all comparisons, results were considered to be statistically significant at $p < 0.05$. Given the high accuracy of RSA, patient numbers in RSA-studies are generally set at 25.[27]

RESULTS

RSA

Double examinations were performed in 19 patients. One patient was excluded from precision measurement because the CN of the double examination scene exceeded 150. An overview of precision measurements is given in Table 1.

Table 1. Precision measurements using double examinations in 18 patients at one-year follow-up.

Measurement	Median (IQR)	Mean (SD; range)	Precision
Tx, mm	0.02 (-0.03 to 0.05)	0.03 (0.1; -0.12 to 0.32)	0.19
Ty, mm	0.03 (-0.03 to 0.09)	0.01 (0.27; -0.91 to 0.49)	0.54
Tz, mm	0.00 (-0.04 to 0.10)	0.04 (0.17; -0.28 to 0.55)	0.34
Rx, °	0.01 (-0.09 to 0.19)	0.28 (0.86; -0.34 to 3.28)	1.68
Ry, °	0.16 (-0.40 to 1.02)	0.03 (2.16; -5.95 to 3.49)	4.23
Rz, °	-0.06 (-0.15 to 0.06)	-0.12 (0.53; -2.01 to 0.52)	1.03

IQR, interquartile range; SD, standard deviation

RSA radiographs were available and analyzed at every follow-up review in all but one patient. This patient underwent a revision 17 months after implantation for pain and instability. Migration of this patient was calculated up to one year postoperatively. All migration data are presented in Figure 2.

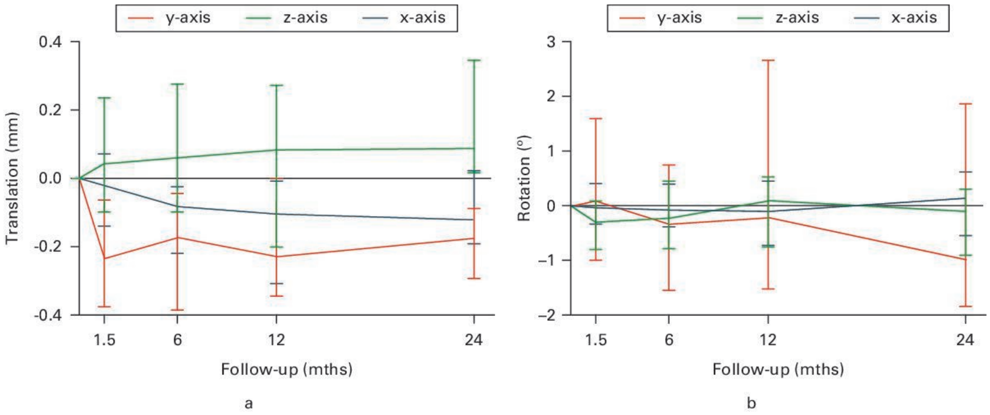


Figure 2. Median translation values (a) along the x-, y-, and z-axis of 24 humeral components and median rotation values (b) around the x-, y-, and z-axis of 24 humeral components of the Simpliciti shoulder system. Error bars represent the interquartile range.

Median continuous translation (i.e. translation between 12 and 24 months (IQR)) along the x-, y- and z-axis was -0.01 mm (IQR -0.09 – 0.05), 0.04 mm (IQR -0.03 – 0.11) and 0.03mm (IQR -0.03 – 0.15). Median continuous rotation around theses axes was 0.05° (IQR -0.21 – 0.23), -0.62° (IQR -1.32 – 1.30) and 0.06° (IQR -0.10 – 0.25). In 19 patients, migration between 12 and 24 months approached zero, indicating that these implants stabilized within the first 12 months of follow-up. In one patient, continuous translation between 12 and 24 months could not be determined due to a revision after 17 months. In this patient, the implant was found to have stabilized between six and 12 months. Four outliers (three women, mean age 69.3 (62 – 76)) were identified with remarkable high migration values between 12 and 24 months (patient 6,8,12 and 23; Table 2). Of these, three were total joint replacements and one hemiarthroplasty. Indication for surgery was primary OA in all four cases. Conventional radiographs of these four patients showed no radiolucent lines or other signs of loosening.

Table 2. Calculated migration between 12 and 24 months postoperatively to demonstrate stabilization or continuous migration of implants.

Patient ID	Tx	Ty	Tz	Rx	Ry	Rz
1	.	.	.	.	.	.
2	.	.	.	.	Y	.
3	.	.	.	.	.	.
4	.	.	.	.	Y	.
5	.	.	.	.	.	.
6	.	*y*	Z	.	.	.
7	.	.	.	.	Y	.
8	.	*y*	*z*	X	.	Z
9						
10	.	.	.	.	.	.
11	.	.	.	.	.	.
12	*x*	.	Z	X	.	*z*
13	.	.	.	.	.	.
14	.	.	.	.	.	.
15	.	.	.	.	Y	.
16	.	.	.	.	.	.
17	.	.	.	.	*y*	.
18	.	.	.	.	Y	.
19	.	.	.	.	*y*	.
20	.	.	.	.	.	.
21	.	.	.	.	*y*	.
22	.	.	.	.	*y*	.
23	*x*	*y*	Z	.	Y	Z
24	.	.	.	.	*y*	.

. = tranlation < 0,5 mm or rotation < 1,5 degree

x, y, z = translation 0.5 - 1.0mm or rotation 1.5 - 2.0 degrees

X, Y, Z = translation > 1.0mm or rotation > 2.0 degrees

Clinical outcomes

All but one patient completed final follow-up as one patient underwent a revision of the humeral head. Median CMS, OSS, DASH and VAS scores improved significantly from baseline to two-year follow-up (Table 3). Significant improvement of VAS pain scores occurred in the first six weeks postoperatively (VAS rest $p=0.024$; VAS active $p=0.011$, Friedman's test) and did not further improve after six weeks (VAS rest $p=0,690$; VAS active $p=0.059$, Friedman's test)). Other clinical outcome measurements did not improve between baseline and six weeks follow-up (OSS $p > 0.999$; DASH $p > 0.999$, Friedman's test) but improved significantly in the first six months postoperatively (CMS $p=0.002$; OSS $p=0.002$; DASH $p=0.001$, Friedman's test). No further improvement was found between six months and two years (CMS $p=0.589$; OSS $p=0.932$; DASH $p > 0.999$, Friedman's test).

Concerning the four outliers with high continuous migrations between 12 and 24 months, clinical scores at 24 months did not differ from patient with stable implants ($p > 0.05$ for all clinical scores, Mann-Whitney U test).

Table 3. Median (IQR) clinical scores of 24 patients after implantation of the Simpliciti Stemless Shoulder System.

	Pre-op	6 weeks	6 months	12 months	24 months	P – value*
CMS	43.0		66.5	73.5	69.0	< 0.001
	(32.0-52.5)		(53.5-71.0)	(63.8-80.3)	(66.3-78.8)	
OSS	21.0	22.0	36.5	37.5	42.0	< 0.001
	(17.8-25.0)	(17.8-27.3)	(32.3-42.3)	(33.8-43.3)	(37.5-45.0)	
DASH	45.8	42.1	15.0	17.1	13.8	< 0.001
	(32.7-59.4)	(33.3-56.7)	(10.8-26.0)	(6.5-22.5)	(7.5-20.4)	
VAS pain	4.0	1.0	0.0	0.0	0.0	< 0.001
(rest)	(3.0 -6.0)	(0.8-3.0)	(0.0-1.0)	(0.0-1.0)	(0.0-1.0)	
VAS pain	8.0	3.0	1.0	1.0	1.0	< 0.001
(active)	(6.0-8.0)	(1.8-4.3)	(0.0-3.0)	(0.0-2.3)	(0.0-2.0)	

CMS: constant-Murley Score; OSS: Oxford Shoulder Score; DASH: Disabilities of the Arm, Shoulder and Hand; VAS: Visual Analogue Scale. * pre-operatively vs. 24 months, Friedman's test

Complications

One patient underwent a revision of the humeral head 17 months postoperatively because of persistent pain and instability. After revision of the humeral head to a larger component the patient was satisfied. In another patient, a deep venous thrombosis was diagnosed four weeks postoperatively. A third patient suffered a traumatic rupture of the subscapularis tendon four months postoperatively. Initially, the patient underwent an open tendon repair nine months postoperatively. After a re-rupture 23 months postoperatively, the patient was planned for a revision of the prosthesis to a reversed prosthesis which was outside the follow-up period of this study.

DISCUSSION

The primary aim of this study was to determine fixation and migration patterns of the Simpliciti Stemless Shoulder System using model-based RSA. We found that 20 out of 24 prostheses stabilized within the first 12 months postoperatively. Four prostheses showed continuous migration between 12 and 24 months postoperatively.

From total hip- (THA) and knee arthroplasty (TKA) we know that increased early migration is a strong predictor for future loosening.[28,29] Following this thought, one could argue that based on the results of our study, one out of every six implanted humeral components is theoretically at risk for aseptic loosening. This could potentially lead to the exposure of large patient groups to early revision surgery. However, the predictive value of early migration for future loosening as it is demonstrated in THA and TKA has not been validated in TSA. Moreover, migration thresholds to detect prostheses at risk for loosening have not been defined so far. Pijls et al. described a migration threshold of 0.2 – 1.0mm in THA and of 0.5 – 1.6mm in TKA in the first 24 months for prostheses at risk for loosening.[28,29] Except that these thresholds have been determined for THA and TKA only, they have been specifically demonstrated for proximal migration along the y-axis (THA) and maximum total point of motion (TKA). Therefore, these thresholds might not be applicable to migrations along individual axes in TSA.

In contrast, suggestions that early migration does also affect long-term outcomes in TSA have been described. Mechlenburg et al. used precision of translations (0.37 mm) as a migration threshold in their RSA study comparing 18 Global C.A.P. humeral head resurfacing implant (HHRI) and 14 Copeland HHRI's.[30] They found that three out of five revised implants exceeded this threshold, whereas four of 24 non-revised implants migrated above this limit. Further, total translation (TT) between 12 and 24 months of follow-up was significantly higher in the revised group (TT 0.58 vs 0.22 mm). Rahme et al. compared early migration of 13 keeled and 14 pegged glenoid components of the Bigliani/Flatow total shoulder prosthesis (Zimmer, USA). In this prospective randomized study no differences in total migration were found. A wide and pragmatic margin of the minimally detectable migration limit (1.0 mm and 2.0°) was used as a threshold for acceptable migration.[31] The reliability of this threshold could not be assessed as long-term follow-up of this cohort has not been published so far. However, Streit et al. used the thresholds as proposed by Rahme et al. in a prospective study evaluating nine keeled ultra-high-molecular-weight polyethylene (UHMWPE) (Arthrex, USA) and two UHMWPE pegged components (Tornier, USA) and found a significant increase in VAS pain score in six patients who surpassed this threshold.[32] This may indicate that early migration is predictive for future clinical outcomes. However, given the small number of patients, the study is probably underpowered to support this conclusion.

Considering the limited data to support clearly defined migration thresholds for prostheses at risk in TSA, we have not attempted to distinguish prostheses at risk and not at risk for future loosening based on our two-year migration data. However, out of 24 implants we identified four outliers (17%) with remarkable high continuous migration (Table 2). Although short-term outcomes in these patients were good, the significance of this continuous migration for long-term outcomes in unclear. Nevertheless, given the clear relation between early migration and long-term survival in THA and TKA, the level of continuous migration found in our study raises concern. To understand the value of continuous migration better in TSA, further research after migration patterns of stemless shoulder arthroplasty is required, ideally comparing different stemless and stemmed implant designs. Moreover, long-term outcomes of implants with known short-term migrations should be evaluated in order to investigate the existence of a relationship between early migration and long-term outcomes. We intend to present five- and ten-year outcomes of this cohort to establish the effect of continuous migrations on long-term outcomes in the outliers.

High rotation values were found around the y-axis. Precision of rotations around the y-axis is low and explains these unreliable high migration values around this axis (Table 2, Figure 2b). Poor precision in this axis can be explained by the symmetrical shape of the implant and is consistent with previous published precision measurements of, in particular, symmetrical, stemless resurfacing prostheses.[30,33,34]

This is the first RSA study analyzing migration of a stemless shoulder prosthesis. Several other stemless implants have been developed, with slightly different design features.[35] In short, there are two different types of fixation; one by the impaction of a fin system comparable with the Simpliciti and one with a central threaded cortical cage. Comenda et al. concluded that implant design is relevant to postoperative bone adaptation based in 3D finite element (FE) modelling.[36] Implants with a threaded cage cause the most bone loss, whereas the bone adaptation was the most marked in the Shoulder Modular Arthroplasty (Lima, Italy). Therefore, our findings concerning migration of the Simpliciti shoulder system cannot be extrapolated to other stemless designs as differences in their designs may affect the response of the bone, implant fixation, migration patterns and long-term results. Additional RSA studies for different designs are desirable.

As mentioned, patient numbers in RSA studies are generally set at 25.[27] As a result of four exclusions during surgery, we included 24 patients, one fewer than intended (Figure 1). However, given our high precision values, we do not expect this missing inclusion to affect our conclusions.

The secondary aim of this study was to evaluate clinical outcomes after implantation of the Simpliciti Shoulder System. All clinical outcome measurements improved significantly within six months after implantation. No further improvement was seen after six months. Regarding clinical relevance, minimal clinically important difference (MCID) values are known to be highly variable and generally assessed in heterogeneous patient groups undergoing different interventions.[37] If compared with published MCID values investigated in patients with OA or RA undergoing TSA (CMS 16.6; OSS 6.9; DASH 10.1; VAS 1.4 – 3.0), all clinical scores demonstrated in our study showed improvement beyond the established MCID values.[38,39] It should be noted that this study was not powered for the analysis of secondary outcomes. Although our results correspond to previous short-term follow-up studies, clinical outcomes should be interpreted with caution.[9–16]

Stemless shoulder systems have been developed in order to reduce stem-related problems, to preserve more bone stock and to make revision surgery less complex. In our study, we reported one revision and no periprosthetic fractures. In a recent systematic review and meta-analysis including 1,564 anatomical stemless TSA's, Willems et al. reported a humeral-related complication rate of 0.6%, which is comparable with stemmed implants.[1,2,9] Concerning bone stock preservation, Willems et al. described that osteolysis at the proximal humerus is lower compared to stemmed arthroplasty, corresponding with the results of a FE model described by Razfar et al.[40] Data concerning revision after primary stemless implants are lacking. Overall, short-term clinical results of stemless implants have been shown to be comparable to stemmed implants. However, suggested benefits of stemless implants over traditional, stemmed prostheses have only been described in a limited fashion. Considering this, in combination with migration values demonstrated in our study, critical assessment of long-term outcomes is essential before a safe continuation of the widespread use of this stemless concept can be guaranteed.

The most important limitation of our study is the absence of a control group. As long as migration values cannot be related to established acceptable migration limits, interpreting migration results of single patient cohorts is difficult, and firm conclusions about implant safety cannot be drawn. Until a relationship between early migration and late outcomes has been established, it is more valuable to compare early migration of relatively new implants with implants with known, satisfactory long-term outcomes. For stemless implants, early migration should be compared with established stemmed implants with known longterm survival. However, the only clinical RSA study analyzing a stemmed humeral component was published more than 15 years ago.[41] In this study, Rahme et al. compared two-year migration of the 3M Modular Prosthesis (Smith & Nephew, Memphis, TN) after press-fit or cemented fixation. No differences were found between the two groups. Mean migration values were slightly higher compared to our results. However, continuous migration between 12 and 24 months was not reported. Recently, Nyring et al. published a study protocol of a randomized controlled trial comparing migration of stemless and stemmed implants.[42] Results of this study will, depending on migration values of stemless with respect to stemmed implants, either support or discourage the widespread use of stemless implants awaiting long-term survival data.

A second limitation of our study is that we did not assess bone density. As mentioned before, fixation of stemless humeral implants relies on cancellous bone. Favre et al. demonstrated that in vitro micromotion of stemless shoulder implants is strongly dependent on cancellous bone quality.[43] Quental et al. demonstrated that micromotion increased when low bone density was present in an experimental setting.[44] This relation does not apply to stemmed implants.[45] Of note is that we excluded three patients because of poor bone quality (Figure 1). Migration values reported in our study are therefore determined in above-average bone quality patients and could not be extrapolated to patients with poor bone quality. Future research is required to investigate the influence of bone density on migration and long-term survival of stemless implants.

CONCLUSION

In conclusion, early migration of stemless humeral components can be measured with high precision using RSA. We found that 20 out of 24 stemless Simpliciti Shoulder Systems stabilized within 12 months postoperatively. The significance of continuous migration in four implants (17%) is unclear and future research on the predictive value of early migration in TSA is required. Clinical results improved clinically relevant in all patients.

REFERENCES

1. Bohsali KI, Bois AJ, Wirth MA. Complications of shoulder arthroplasty. *J Bone Jt Surg (American Vol)*. 2017;99(3):256-269. doi:10.2106/JBJS.16.00935
2. Athwal GS, Sperling JW, Rispoli DM, Cofield RH. Periprosthetic humeral fractures during shoulder arthroplasty. *J Bone Jt Surg (American Vol)*. 2009;91(3):594-603. doi:10.2106/JBJS.H.00439
3. Raiss P, Edwards TB, Deutsch A, et al. Radiographic changes around humeral components in shoulder arthroplasty. *J Bone Jt Surg (American Vol)*. 2014;96(7):e54. doi:10.2106/JBJS.M.00378
4. Denard PJ, Raiss P, Gobezie R, Edwards TB, Lederman E. Stress shielding of the humerus in press-fit anatomic shoulder arthroplasty: review and recommendations for evaluation. *J Shoulder Elb Surg*. 2018;27(6):1139-1147. doi:10.1016/j.jse.2017.12.020
5. Sahota S, Sperling JW, Cofield RH. Humeral windows and longitudinal splits for component removal in revision shoulder arthroplasty. *J Shoulder Elb Surg*. 2014;23(10):1485-1491. doi:10.1016/j.jse.2014.02.004
6. Parada SA, Flurin P-H, Wright TW, et al. Comparison of complication types and rates associated with anatomic and reverse total shoulder arthroplasty. *J Shoulder Elb Surg*. 2021;30(4):811-818. doi:10.1016/J.JSE.2020.07.028
7. Somerson JS, Hsu JE, Neradilek MB, Matsen FA. Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016. *J Shoulder Elb Surg*. 2018;27(11):1978-1986. doi:10.1016/J.JSE.2018.03.025
8. Churchill RS, Athwal GS. Stemless shoulder arthroplasty—current results and designs. *Curr Rev Musculoskelet Med*. 2016;9(1):10-16. doi:10.1007/s12178-016-9320-4
9. Willems JIP, Hoffmann J, Sierevelt IN, Bekerom MPJ va. den, Alta TDW, Noort A van. Results of stemless shoulder arthroplasty: a systematic review and meta-analysis. *EFORT Open Rev*. 2021;6(1):35-49. doi:10.1302/2058-5241.6.200067
10. Upfill-Brown A, Satariano N, Feeley B. Stemless shoulder arthroplasty: review of short and medium-term results. *JSES Open Access*. 2019;3(3):154-161. doi:10.1016/j.jses.2019.07.008
11. Peng W, Ou Y, Wang C, Wei J, Mu X, He Z. The short- To midterm effectiveness of stemless prostheses compared to stemmed prostheses for patients who underwent total shoulder arthroplasty: A meta-analysis. *J Orthop Surg Res*. 2019;14(1):469. doi:10.1186/s13018-019-1515-0
12. Liu EY, Kord D, Horner NS, Leroux T, Alolabi B, Khan M. Stemless anatomic total shoulder arthroplasty: a systematic review and meta-analysis. *J Shoulder Elb Surg*. 2020;29(9):1928-1937. doi:10.1016/j.jse.2019.12.022
13. Wiater JM, Levy JC, Wright SA, et al. Prospective, Blinded, Randomized Controlled Trial of Stemless Versus Stemmed Humeral Components in Anatomic Total Shoulder Arthroplasty: Results at Short-Term Follow-up. *J Bone Joint Surg Am*. 2020;102(22):1974-1984. doi:10.2106/JBJS.19.01478
14. Rasmussen J V., Harjula J, Arverud ED, et al. The short-term survival of total stemless shoulder arthroplasty for osteoarthritis is comparable to that of total stemmed shoulder arthroplasty: a Nordic Arthroplasty Register Association study. *J Shoulder Elb Surg*. 2019;28(8):1578-1586. doi:10.1016/j.jse.2019.01.010
15. Romeo AA, Erickson BJ, Costouros J, et al. Eclipse stemless shoulder prosthesis vs. Univers II shoulder prosthesis: a multicenter, prospective randomized controlled trial. *J Shoulder Elb Surg*. 2020;29(11):2200-2212. doi:10.1016/j.jse.2020.07.004

16. Karssiens TJ, Gill JR, Kumar KHS, Sjolin SU. Clinical results and survivorship of the Mathys Affinis Short, Short Stem Total Shoulder Prosthesis. *Bone Jt Open*. 2021;2(1):58. doi:10.1302/2633-1462.21.BJO-2020-0184
17. Magosch P, Lichtenberg S, Habermeyer P. Survival of Stemless Humeral Head Replacement in Anatomic Shoulder Arthroplasty. A prospective Study. *J Shoulder Elb Surg*. 2020;30(7):e343-e355. doi:10.1016/j.jse.2020.09.034
18. Märtens N, Heinze M, Awiszus F, Bertrand J, Lohmann CH, Berth A. Long-term survival and failure analysis of anatomical stemmed and stemless shoulder arthroplasties. *Bone Joint J*. 2021;103-B(7):1292-1300. doi:10.1302/0301-620X.103B7.BJJ-2020-0915.R3
19. Thillemann JK, Dremstrup L, Hansen TB, Stilling M. The mechanical fixation of a cementless conical cup in cortical versus cancellous trapezial bone: an experimental study. *J Hand Surg (European Vol)*. 2021;46(2):146-153. doi:10.1177/1753193420963255
20. Valstar ER, de Jong FW, Vrooman HA, Rozing PM, Reiber JHC. Model-based Roentgen stereophotogrammetry of orthopaedic implants. *J Biomech*. 2001;34(6):715-722. doi:10.1016/S0021-9290(01)00028-8
21. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl*. 1989;232:1-51.
22. Nelissen RGHH, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. *J bone Jt Surg (American Vol)*. 2011;93 Suppl 3:62-65. doi:10.2106/jbjs.k.00907
23. International Organisation for Standardization. *Implants for Surgery — Roentgen Stereophotogrammetric Analysis for the Assessment of Migration of Orthopaedic Implants*.; 2013.
24. Constant C, Murley A. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res*. 1987;214:160-164.
25. Dawson J, Rogers K, Fitzpatrick R, Carr A. The Oxford shoulder score revisited. *Arch Orthop Trauma Surg 2008 1291*. 2008;129(1):119-123. doi:10.1007/S00402-007-0549-7
26. Veehof MM, Sleegers EJA, Van Veldhoven NHMJ, Schuurman AH, Van Meeteren NLU. Psychometric qualities of the Dutch language version of the disabilities of the arm, shoulder, and hand questionnaire (DASH-DLV). *J Hand Ther*. 2002;15(4):347-354. doi:10.1016/S0894-1130(02)80006-0
27. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005. doi:10.1080/17453670510041574
28. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
29. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
30. Mechlenburg I, Klebe TM, Dossing K V, Amstrup A, Soballe K, Stilling M. Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: Two-year results of a randomized controlled clinical trial. *J Shoulder Elb Surg*. 2014;23:1427-1436. doi:10.1016/j.jse.2014.05.012
31. Rahme H, Mattsson P, Wikblad L, Nowak J, Larsson S. Stability of cemented in-line pegged glenoid compared with keeled glenoid components in total shoulder arthroplasty. *J bone Jt Surg (American Vol)*. 2009;91:1965-1972. doi:10.2106/JBJS.H.00938

32. Streit JJ, Shishani Y, Green ME, et al. Analysis of Glenoid Component Motion After Total Shoulder Arthroplasty. *Orthopedics*. 2015;38(10):891-897. doi:10.3928/01477447-20151002-56
33. Stilling M, Mechlenburg I, Amstrup A, Soballe K, Klebe T. Precision of novel radiological methods in relation to resurfacing humeral head implants: Assessment by radiostereometric analysis, DXA, and geometrical analysis. *Arch Orthop Trauma Surg*. 2012;132:1521-1530. doi:10.1007/s00402-012-1580-x
34. Ten Brinke B, Beumer A, Koenraadt KLM, Eygendaal D, Kraan GA, Mathijssen NMC. The accuracy and precision of radiostereometric analysis in upper limb arthroplasty. *Acta Orthop*. 2017;88(3):320-325. doi:10.1080/17453674.2017.1291872
35. Wodarek J, Shields E. Stemless Total Shoulder: A Review of Biomechanical Fixation and Recent Results: *J shoulder Elb Arthroplast*. 2021. doi:10.1177/24715492211008408
36. Comenda M, Quental C, Folgado J, Sarmento M, Monteiro J. Bone adaptation impact of stemless shoulder implants: a computational analysis. *J Shoulder Elb Surg*. 2019;28(10):1886-1896. doi:10.1016/j.jse.2019.03.007
37. Hao Q, Devji T, Zeraatkar D, et al. Minimal important differences for improvement in shoulder condition patient-reported outcomes: A systematic review to inform a BMJ Rapid Recommendation. *BMJ Open*. 2019;9(2). doi:10.1136/bmjopen-2018-028777
38. Christie A, Dagfinrud H, Garratt AM, Ringen Osnes H, Hagen KB. Identification of shoulder-specific patient acceptable symptom state in patients with rheumatic diseases undergoing shoulder surgery. *J Hand Ther*. 2011;24(1):53-61. doi:10.1016/j.jht.2010.10.006
39. Simovitch R, Flurin PH, Wright T, Zuckerman JD, Roche CP. Quantifying success after total shoulder arthroplasty: the minimal clinically important difference. *J Shoulder Elb Surg*. 2018;27(2):298-305. doi:10.1016/j.jse.2017.09.013
40. Razfar N, Reeves J, Langohr D, Willing R, Athwal GS, Johnson JA. Comparison of proximal humeral bone stresses between stemless, short stem, and standard stem length: a finite element analysis. *J shoulder Elb Surg*. 2016;25(7):1076-1083. doi:10.1016/J.JSE.2015.11.011
41. Rahme H, Mattsson P, Wikblad L, Larsson S. Cement and press-fit humeral stem fixation provides similar results in rheumatoid patients. *Clin Orthop Relat Res*. 2006;448:28-32. doi:10.1097/01.blo.0000224007.25636.85
42. Nyring MRK, Olsen BS, Yilmaz M, Petersen MM, Flivik G, Rasmussen J V. Early migration of stemless and stemmed humeral components after total shoulder arthroplasty for osteoarthritis-study protocol for a randomized controlled trial. *Trials*. 2020;21(1):830. doi:10.1186/s13063-020-04763-8
43. Favre P, Seebeck J, Thistlethwaite PAE, et al. In vitro initial stability of a stemless humeral implant. *Clin Biomech*. 2016;32:113-117. doi:10.1016/j.clinbiomech.2015.12.004
44. Quental C, Folgado J, Comenda M, Monteiro J, Sarmento M. Primary stability analysis of stemless shoulder implants. *Med Eng Phys*. 2020;81:22-29. doi:10.1016/j.medengphy.2020.04.009
45. Peppers TA, Jobe CM, Dai QG, Williams PA, Libanati C. Fixation of humeral prostheses and axial micromotion. *J Shoulder Elb Surg*. 1998;7(4):414-418. doi:10.1016/S1058-2746(98)90034-9

Chapter 8

General discussion and future perspectives

The general aim of this thesis was to investigate the role of Radiostereometric Analysis (RSA) in the evaluation of orthopaedic implants in the upper extremity. In this section, the current state of RSA in shoulder, elbow, wrist and hand total joint arthroplasty will be discussed, as well as the feasibility, precision and accuracy of the technique when used in the upper extremity. Challenges we faced during our research will be addressed and future perspectives of RSA in evaluating upper extremity total joint arthroplasties will be discussed.

RSA in the upper extremity: where do we stand?

In contrast to the lower extremity, the experience of RSA in the upper extremity is limited. With this in mind, we systematically reviewed the existing literature on RSA in total joint arthroplasty (TJA) of the upper extremity in 2017 (**chapter 2)**. In this review, 23 studies were available for analysis, including experimental phantom studies and animal studies. Since then, less than twenty new RSA studies related to upper extremity implants have been published (accessed September 2021), of which a substantial part still consists of experimental or feasibility studies with small patient cohorts. Hence, one may conclude that the implementation of RSA in the upper extremity is still at a very early stage compared to the lower extremity. There might be several reasons for this difference. First, although increasing, the absolute numbers of implanted prostheses in shoulder, elbow, wrist and hand are much lower than in THA and TKA (**chapter 1**), resulting in less implants that are actually available for RSA. In line with these low numbers, another factor that could contribute to the low number of RSA studies is financial interest. Orthopaedic implant companies will benefit more from a proven successful and safe hip prosthesis than from, for instance, a new elbow prosthesis. Further, when used in upper extremity TJA, RSA has several technical challenges. This might discourage orthopaedic surgeons, researches and also manufacturers from initiating clinical RSA studies. However, considering that survival rates of orthopaedic implants in the upper extremity are still inferior compared to the lower extremity, we believe that more attention should be paid to the assessment of initial fixation and early migration of upper limb implants using RSA.

Accuracy, precision and feasibility

Accuracy and precision

What does the existing RSA literature have taught us about accuracy– *the agreement of a particular measurement with an accepted standard* – and precision – *the level of agreement of a particular measurement with itself when it is repeated* – in the shoulder, elbow, hand and wrist? According to the ISO RSA Standard, accuracy of RSA has to be determined by comparison with another method with a substantially better resolution than that of RSA.[1] In studies assessing the accuracy of RSA the implant is often attached to a micrometer. Precision has to be determined using clinical double examinations at one follow-up moment. Assuming that the implant will not move within the short interval between two radiographs, any migration measured between the two examinations will be due to measurement errors.

In **Chapter 2** we summarized data on accuracy and precision from previous literature up to 2017. Since then, several studies have been added to the existing literature reporting on accuracy and precision of RSA in the shoulder. Van der Kleut et al. demonstrated high accuracy of RSA in migration and wear measurements in reverse total shoulder arthroplasty (rTSA).[2,3] In addition, Fraser et al. showed high accuracy and precision values for migration measurement of the glenoid component in rTSA.[4,5] Concerning anatomic shoulder arthroplasty (aTSA), high precision of translations has been demonstrated, varying between 0.03 and 0.88mm, comparable with RSA in THA and TKA.[6–12] Regarding rotations of TSA, precision was generally high, but was poor for rotations around one particular axis in two studies concerning humeral head resurfacing implants (HHRI).[13,14] Similarly, in our RSA study analyzing a stemless humeral component (**chapter 7**) we found poor precision values for rotations around the y-axis whereas precision of rotation around the other axes was high. This might be explained by the symmetrical shape of both the HHRI and the stemless implant. Rotations around the axis of symmetry cannot be accurately detected as the shape of the implant remains unchanged during rotation.[15] The same phenomenon has been shown in total wrist arthroplasty (TWA). Holm-Glad et al. demonstrated high accuracy and precision values in two total wrist implant designs. However, rotations around the y-axis could not be calculated in the symmetrical Motec ® implant.[16]

Precision of RSA in the elbow has been described in three clinical studies.[17–19] Although experience of RSA in the elbow is relatively low, precision values were remarkable high: 0.05 - 0.34mm for translation measurement and 0.16 - 0.76° for rotation measurement in both the humerus and the ulna.

In TMC-joint arthroplasty, precision of RSA was found to be poor, in particular for rotations. This applied to both a symmetrical ball-and-socket design and the asymmetrical saddle-shaped surface replacement (SR) TMC-joint prosthesis as described in this thesis.[20,21] Although precision of RSA was promising in an experimental study analyzing the SR TMC joint prosthesis in five human hand specimens (**chapter 3**), rotations could not be reasonable measured in a clinical RSA study (**chapter 4** and **5**). In contrast to rotations, translations could be measured with high precision.

Feasibility

One should keep in mind that high accuracy and precision is not the same as feasibility - *the possibility that something can be made, done, achieved or is reasonable*. Precision of RSA is generally determined using clinical double examinations or repeated measurements in at least a minimum of 25% of the patients or fifteen patients in small cohorts[1]. Reported precision values in literature are therefore by definition determined in those RSA radiographs that are suitable for analysis. However, these values do not provide information about RSA radiographs that are, for any reason, not suitable for analysis. For example, Valstar et al. described high precision values (0.05 – 0.34 mm and 0.16 – 0.68°) analyzing the Souter-Strathclyde elbow prosthesis based on repeated measurements.[17] However, despite high precision, rotation could be calculated in only eight humeral and five ulnar components out of 21 implants at two-year follow-up because of technical problems analyzing the remaining RSA radiographs. Similar issues have been described for RSA in the TMC-joint and in lesser extend for the wrist.[16]

In general, most of the problems using RSA in the upper limb are related to the small size of the surrounding bone and can be divided in two main problems: the position of the bone markers in relation to the implant and the position of the markers relative to each other. A close position of the markers in relation to the implant may result in over projection of the bone markers by the prosthesis, leading to less detectable markers during analysis. For rotation measurements, at least three but rather more than three corresponding markers are required. A lack of visible markers will lead to non-analyzable RSA scenes and loss of migration data. Positioning bone markers too close to each other will result in a poor three-dimensional spread of marker rigid bodies, defined by a high Condition Number (CN). The higher the CN, the more the markers are aligned in a linear configuration leading to inaccurate rotation values around the axis parallel to this linear shaped marker rigid body.

Concerning the shoulder, above mentioned problems are expected to be less of an issue given the larger size of the glenoid and proximal humerus. In **chapter 7** we described the results of an RSA study examining implant migration of a stemless humeral component. Obtained RSA radiographs could indeed be analyzed in all patients at all follow-up moments in this study with acceptable CN's. Looking at previous RSA studies concerning TSA, only one study reports that the limit for acceptable CN had to be increased for the glenoid component because of a relatively poor three-dimensional marker distribution.[11] This indicates that also in TSA, attention should be paid to the distribution of bone markers in the glenoid.

In contrast to TSA, problems related to marker distribution are more pronounced in small bones as the ulna and the trapezium bone. In **chapter 4 and 5** we describe the results of a clinical RSA study reporting mid- and long-term migration data of the SR TMC-joint prosthesis. We had a considerable loss of analyzable RSA scenes at five- and ten-year follow-up because of a lack of stable and visible bone markers. Furthermore, to reach a well distributed marker rigid body turned out to be difficult, leading to high CN's and unreliable rotation values. Therefore, only translations measurements could be presented.

In an attempt to overcome the problem of occluded bone markers, Marker Configuration (MC) model-based RSA was applied.[22] MC-models describe the three-dimensional position of the bone markers. In case of occluded bone markers during follow-up, the position of the marker rigid body can still be estimated, allowing for more RSA scenes suitable for analysis. Furthermore, we used the technique of reversed migration calculation, in which not the marker rigid body but the implant model is used as the reference model to correct for the different positions of the joint with respect to the calibration box. With only two bone markers available for the reference marker rigid body, this cannot be accurately done since two markers create a line around which the implant model can be rotated. For marker rigid bodies with a poor three-dimensional spread similar issue arises. Applying these techniques allowed us to calculate translations in initial unusable RSA radiographs. However, despite the use of these techniques, rotation measurement in TMC-joint arthroplasty has not been possible so far.

If rotations could not be calculated accurately, simply ignoring these rotations is not the right strategy since rotations do affect translation calculation. An incorrect rotational alignment of the reference model can lead to inaccurate rotations and hence incorrect translation measurement.[23] Therefore, striving for a well three-dimensional spread and stable rigid body as a reference for migration calculation is still important, even if rotations are left out of consideration. Considering this, the feasibility of RSA in small joints as the TMC-joint is doubtful. To measure migration of small joints implants, further research is required to investigate methods that are less dependent on bone markers.

In summary, the ability of measuring implant migration with high accuracy and precision has been demonstrated in total shoulder, elbow and wrist arthroplasty. In TMC-joint arthroplasty, sufficient precision values have only been demonstrated for translation measurements. Notwithstanding high accuracy and precision, concerns about the feasibility of RSA in the elbow, wrist and TMC-joint have to do with the small size of the surrounding bone. Therefore, we suggest further RSA studies concerning these joints to be focused on the optimization of the technique first.

Predictive value

In order to define implants at risk for future loosening in THA and TKA, clear migration thresholds have been defined. Pijls et al. described a migration threshold of 0.2 – 1.0mm along the y-axis in THA and a maximum total point of motion (MTPM) of 0.5 – 1.6mm in TKA in the first 24 months.[24,25] Implants that migrate beyond these thresholds are at risk for loosening. However, it is unknown whether these thresholds are applicable in shoulder, elbow, wrist and hand arthroplasty.

Several attempts have been done in literature to distinguish stable and unstable implants based on short-term migration. Mechlenburg et al. used a threshold of 0.37 mm based on minimally detectable migration limits in their RSA study comparing the Global C.A.P. HHRI and the Copeland HHRI.[13] They found that three out of five revised and four out of 24 non-revised implants exceeded this threshold. Further, total translation (TT) between 12 and 24 months was significantly higher in the revised group (TT 0.58 vs 0.22 mm). Further, higher TT was reported for the Global C.A.P. HHRI compared to the Copeland HHRI at two years of follow-up. Looking at long-term survival of both implants, high revision rates have been reported for the Global C.A.P. HHRI (23% after 5-8 years) whereas satisfactory long-term survival of 95% after 18 years have been described for the Copeland HHRI.[26–28] In order to divide potential stable and unstable implants, Rahme et al. used a wide and pragmatic margin of the minimally detectable migration limit (1.0 mm and 2.0°).[8] The reliability of this threshold could not be assessed as long-term follow-up of this cohort has not been published so far. Nevertheless, Streit et al. used the thresholds as proposed by Rahme et al. and found a significant increase in VAS pain score in six patients who surpassed this threshold.[11] However, this study probably was underpowered to support this conclusion. In **chapter 7** we present the short-term RSA results of the stemless Simpliciti Shoulder System. Assuming that physiological implant migration takes place in the first weeks to months postoperatively, continuous migration between one and two years was calculated in order to assess initial implant stability. We found that four out of 24 prostheses showed remarkable high continuous migration. Whether this continuous migration affects long-term survival has to become clear after long-term follow-up is available. However, given the clear relation between early migration and long-term survival in THA and TKA, these migration values definitely raise concerns.

Concerning the elbow, two patient cohorts have been described with both short-term migrations and long-term outcomes available. Valstar et al. defined implants at risk if they exceeded migration of 0.4 mm or 1.0° in the second year postoperatively, based on RSA data from TKA.[29,30] After 121 months, one out of eight humeral components at risk was revised. Three implants not at risk were loose at long-term follow-up.[31] De Vos et al. described early migration of 16 humeral components of the Instrumented Bone Preserving (IBP) total elbow prosthesis.[18] To define acceptable migration limits, they referred to the above-mentioned study of Valstar et al.[17] Fourteen of the 16 humeral components were defined as stable. In **chapter 6** we described long-term outcomes of this cohort. Of the stable implants, four prostheses were revised during follow-up. Regarding the potential unstable prostheses, no revisions were performed. Total rotation (TR) and total translation (TT) at two-year follow-up did not differ significantly between the revised and the non-revised implants. Based on the results of these two cohorts, the predictive value of early migration could not be shown. However, patient and implant numbers are too low to come to conclusions.

Only one long-term RSA study concerning the TMC-joint has been described in literature (**chapter 5**). Early migrations of this cohort are presented in **chapter 4**. Because of the low number of implants analyzed using RSA and the technical challenges of the technique in its current form, no conclusions could be drawn about potential migration thresholds in TMC-joint arthroplasty.

In TWA, no long-term survival data of RSA-examined implants exist. Hence, the relation between early migration and long-term outcomes cannot be investigated.

In summary, the number of RSA studies and analyzed implants in shoulder, elbow, wrist and TMC joint arthroplasty is not sufficient to demonstrate the value of early migration in predicting the risk of long-term loosening. Migration thresholds for implants at risk are therefore not available. In TSA, several clues for a possible relation between early migration and long-term loosening have been described and have to be confirmed in future studies.

RSA in the upper extremity: where do we go?

Predicting long-term outcomes

Given the high accuracy of RSA and considering the predictive value of early migration for long-term survival in THA and TKA, RSA can be considered as an important, objective instrument to examine newly developed orthopaedic implants. However, notwithstanding the introduction of a multitude of new implant designs in the last decades, most of the currently used implants in the upper extremity have never been evaluated in RSA studies. On the one hand, this is defensible as data supporting the relation between early migration and the risk of long-term failure of upper limb prostheses are lacking. On the other hand, the absence of data does not mean that the relation between early migration and long-term survival does not exist. Given the value of RSA in the evaluation of THA and TKA, further research to determine the relevance of RSA in upper limb TJA is definitely worthwhile. This applies in particular to TSA, as several clues have yet been described suggesting that increased early migration could affect long-term outcomes.

However, in order to assess the predictive value of RSA in the upper extremity large numbers of implants are required. Established migration thresholds in THA and TKA are based on dozens of RSA studies including hundreds of implants. In contrast, the use of RSA in upper extremity implants is still at an early stage. Hence, the first step to investigate the predictive value of early migration measured using RSA is to increase the number of implant designs that is analyzed using RSA.

Apart from an increase in RSA studies, long-term follow-up and data from clinical studies and orthopaedic registries are essential to assess the value of measured early migration in predicting long-term outcomes. However, collecting long-term follow-up data takes time. To speed up the research process on the predictive value of early migration, it could be helpful to measure early migration of implant designs of which long-term follow-up is known. In other words, RSA should not only be used in new implants, but could also be helpful in measuring and comparing early migration of currently used, ‘gold standard’ implants with known long-term survival.

Availability and standardization of RSA data

When increasing the number of RSA studies, more and more data will become available. In order to facilitate comparison and meta-analysis of migration data from different studies and research groups, it is of great importance to present these data in a consistent and homogeneous way. A great step in the direction of presenting RSA outcomes in a standardized way was initiated by Valstar et al. who published guidelines for standardization of RSA.[32] Following this publication, Madanat et al. demonstrated that quality of RSA-studies increased after publication of the guidelines, but that adherence to the guidelines was still relatively low[33]. In our systematic review (**chapter 2**), we have shown that adherence to the guidelines was poor in almost all RSA studies of the upper limb. In accordance with Madanat et al, the most frequently ignored items were details on rigid body fitting error, cut-off values for condition numbers and details of images acquisition, while the importance of these ignored items have been demonstrated in this thesis. It is therefore that we recommend strict adherence to existing guidelines in future RSA studies of the upper limb. Even better should be the registration of RSA trials in a special RSA registry and to share migration outcomes in a standardized way enabling merging of data. Combining migration data from an RSA registry with clinical outcome measurements and survival data from (inter)national implant registries may be useful in further research regarding the relation between early migration and long-term implant failure in upper limb arthroplasty. For future RSA studies we recommend to report complete migration values along all individual axes including standard deviations, instead of a selection of data (i.e. TT, maximum total point of motion (MTPM)) as it is yet unclear which values will be useful in determining migration thresholds for prostheses at risk for early failure. Further, detailed information concerning accuracy, precision and the number of analyzable radiographs as well as the used coordinate systems should be described.

Factors influencing migration patterns in the upper extremity

Apart from simply increasing the number of RSA studies, several issues should be taken into account in future research investigating the relation between early migration and long-term failure in upper limb implants.

First, a relation between increased early migration and future revision assumes that loosening of orthopaedic implants starts with early micro motion.[30,34] However, the question is whether this theory also applies to loosening of implants in the upper extremity. Substantial biomechanical differences in weight-bearing, range of motion and the magnitude and direction of joint forces exist between upper and lower extremity joints and might result in different migration and loosening patterns. Whereas axial compression forces are by far the greatest factor acting on hips and knees, Klemt et al. demonstrated considerable shear forces in the glenohumeral joint.[35,36] Suboptimal positioning of the glenoid component in TSA could even increase these shear forces, leading to eccentric loading of the glenoid component, which is considered as an imported cause for loosening (rocking horse phenomenon).[37–39] Concerning TEA, lifting activities lead to shear distraction forces on the bone-implant junction.[40] Experimental studies investigating the failure behavior of polymethylmethacrylate (PMMA) bone cement, showed that PMMA has a weak capability to support tension and shear loading compared with compression loading.[41] Obviously, this may affect long-term implant survival of upper limb implants. The question is whether this also affects early migration, detectable using RSA.

Concerning loosening patterns of TEA, the influence of rheumatoid arthritis (RA) should also be taken into consideration. Although RA as the indication for TEA is decreasing, a substantial part of TEA is still performed in patients with RA.[42,43] Böhler et al. demonstrated that higher inflammatory disease activity is a risk factor for radiographic loosening after THA and TKA.[44] Considering this, increased disease activity at some point during follow-up may attribute to aseptic loosening, even in initially stable implants. This will of course influence the results when investigating the relation between early migration and long-term loosening.

Second, it is of great importance to define a clear endpoint of implant failure when investigating the predictive value of early migration. In scientific research, the endpoint in survival analysis is generally defined as revision. However, implant revision is a joint decision of the patient and the treating physician and thus not an objective endpoint for implant failure. In daily practice, implant loosening does not always lead to implant revision in upper extremity TJA. Whereas a painful, loose hip or knee prosthesis leads to a severe limitation of mobility and the need for a walking aid or wheelchair, patients with loose implants in the elbow and TMC-joints are able to spare the joint for example by using splints. This theoretically reduces the need for revision, especially in old patients with comorbidities and a less demanding lifestyle. In future research on the predictive value of early migration for long-term failure, the endpoints of survival should be reconsidered and more focused on clinical outcomes.

Possible technical solutions

It should be clear that RSA of upper limb implants has several technical challenges, which have to do with bone markers. Further research has to focus on methods that are less dependent on markers. Two of these methods include *markerless* RSA and CT-based RSA. Classical marker-based RSA relied on the placement of tantalum markers both on the implant and in the surrounding bone. Model-based RSA, as used in the studies presented in this thesis, utilizes three-dimensional surface models created by reversed engineering (RE) to determine the position of the implant, but still needs bone markers to determine the position of the surrounding bone. Completely marker-less RSA methods use image processing techniques to determine the position of both the implant and the surrounding bone.[45–47] However, this method has never been used in small joints as the elbow, wrist and TMC-joint and requires further research.

Another promising method to avoid marker-related problems is CT-based RSA, which enables migration measurement using the surface anatomy of the bone. Accuracy and precision of CT-based RSA have been shown to be comparable with that of model-based RSA of THA in both experimental and clinical studies.[48–51] Recently, Broden et al. also demonstrated that CT-based RSA was comparable with the accuracy and precision of RSA in TSA.[52] An additional advantage of CT-based techniques is the availability of CT-scans in daily practice. Future studies are required to assess the applicability of CT-based RSA in the smaller joints that particularly face marker-related problems.

Clinical implications and recommendations

The role of RSA in predicting long-term outcomes of arthroplasty in the upper limb needs to be further investigated. The question raises what the place of RSA could be in the period awaiting more insight in the relation between early migration and long-term outcomes.

For TSA, we recommend routine evaluation using RSA of all new implants released. We believe that RSA is an accurate, safe and minimal invasive method that is potentially able to prevent the exposure of large patient numbers to possible poor performing implants. Although the predictive value of RSA has not yet been proven in TSA, we believe that based on the current literature and data from this thesis excessive migration in the first two years after implantation should be a cause for concern and justifies critical examination before further distribution of implants should take place. At the same time, further research to confirm or to negate the relation between early migration of TSA and long-term implant survival should be continued.

Concerning TEA and TMC-joint arthroplasty, in our opinion it is yet unreliable to draw general conclusions based on implant migrations measured using current RSA techniques. We recommend to investigate the feasibility of marker-less RSA methods in these joints, such as CT-based RSA.

RECOMMENDATIONS FOR FUTURE RSA RESEARCH IN THE UPPER EXTREMITY

- We recommend routine assessment of early migration of new shoulder implants with RSA prior to the widespread use of these implants.

- To investigate the predictive value of early migration for long-term outcomes in total shoulder arthroplasty, we recommend the assessment of early migration of implants with known long-term survival rates, and to publish long-term survival studies of implants with known early migration values.

- Comparing early migration of new implants with migration values of implants with known (satisfactory) long-term survival, could add to a more reliable assessment of implant safety in total shoulder arthroplasty.

- When investigating the predictive value of early migration in upper extremity implants, the endpoint of implant failure should also be focused on clinical outcomes instead of revision alone.

- To facilitate pooling of migration data, it is of great importance to present migration data in a consistent and uniform way, according to previously published guidelines.

- Complete migration data along all individual axes, including standard deviations, precision and accuracy data, the number of analyzable radiographs and the used coordinate systems should be reported.

- The introduction of an international RSA registry to collect standardized migration data could contribute to comparison and meta-analysis of migration data of upper extremity implants.

- In order to avoid marker-related problems, the next step in RSA research in elbow and TMC-joint arthroplasty is to evaluate the feasibility of CT-based RSA methods.

References

1. International Organisation for Standardization. *Implants for Surgery — Roentgen Stereophotogrammetric Analysis for the Assessment of Migration of Orthopaedic Implants*.; 2013.
2. Van de Kleut M, Yuan X, Athwal GS, Teeter M. Validation of radiostereometric analysis in six degrees of freedom for use with reverse total shoulder arthroplasty. *J Biomech*. 2018;68:126-131. doi:10.1016/j.jbiomech.2017.12.027
3. Van de Kleut M, Yuan X, Athwal GS, Teeter M. Validation of In Vivo Linear and Volumetric Wear Measurement for Reverse Total Shoulder Arthroplasty Using Model-Based Radiostereometric Analysis. *J Orthop Res*. 2019;37(7):1620-1627. doi:10.1002/JOR.24294
4. Fraser A, Tsukanaka M, Fjalestad T, Madsen J, Röhrl S. Model-based RSA is suitable for clinical trials on the glenoid component of reverse total shoulder arthroplasty. *J Orthop Res*. 2018;36(12):3299-3307. doi:10.1002/JOR.24111
5. Fraser A, Bøe B, Fjalestad T, Madsen J, Röhrl S. Stable glenoid component of reverse total shoulder arthroplasty at 2 years as measured with model-based radiostereometric analysis (RSA). *Acta Orthop*. 2021;1:1-7. doi:10.1080/17453674.2021.1943932
6. Rahme H, Mattsson P, Larsson S. Stability of cemented all-polyethylene keeled glenoid components. A radiostereometric study with a two-year follow-up. *J bone Jt Surg (British Vol)*. 2004;86:856-860. doi:10.1016/S1551-7977(08)70036-0
7. Rahme H, Mattsson P, Wikblad L, Larsson S. Cement and press-fit humeral stem fixation provides similar results in rheumatoid patients. *Clin Orthop Relat Res*. 2006;448:28-32. doi:10.1097/01.blo.0000224007.25636.85
8. Rahme H, Mattsson P, Wikblad L, Nowak J, Larsson S. Stability of cemented in-line pegged glenoid compared with keeled glenoid components in total shoulder arthroplasty. *J bone Jt Surg (American Vol)*. 2009;91:1965-1972. doi:10.2106/JBJS.H.00938
9. Nuttall D, Haines JF, Trail II. A study of the micromovement of pegged and keeled glenoid components compared using radiostereometric analysis. *J Shoulder Elb Surg*. 2007;16:65-70. doi:10.1016/j.jse.2006.01.015
10. Nuttall D, Birch A, Haines JF, Trail IA. Radiostereographic analysis of a shoulder surface replacement: Does hydroxyapatite have a place? *Bone Jt J*. 2014;96 B:1077-1081. doi:10.1302/0301-620x.96b8.30534
11. Streit JJ, Shishani Y, Green ME, et al. Analysis of Glenoid Component Motion After Total Shoulder Arthroplasty. *Orthopedics*. 2015;38(10):891-897. doi:10.3928/01477447-20151002-56
12. Skoldenberg O, Odquist M. Measurement of migration of a humeral head resurfacing prosthesis using radiostereometry without implant marking: An experimental study. *Acta Orthop*. 2011;82:193-197. doi:10.3109/17453674.2011.566133
13. Mechlenburg I, Klebe TM, Dossing K V, Amstrup A, Soballe K, Stilling M. Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: Two-year results of a randomized controlled clinical trial. *J Shoulder Elb Surg*. 2014;23:1427-1436. doi:10.1016/j.jse.2014.05.012
14. Stilling M, Mechlenburg I, Amstrup A, Soballe K, Klebe T. Precision of novel radiological methods in relation to resurfacing humeral head implants: Assessment by radiostereometric analysis, DXA, and geometrical analysis. *Arch Orthop Trauma Surg*. 2012;132:1521-1530. doi:10.1007/s00402-012-1580-x

15. Seehaus F, Emmerich J, Kaptein BL, Windhagen H, Hurschler C. Dependence of model-based RSA accuracy on higher and lower implant surface model quality. *Biomed Eng Online*. 2013;12(1):32. doi:10.1186/1475-925X-12-32
16. Holm-Glad T, Reigstad O, Tsukanaka M, Røkkum M, Röhrl S. High precision and accuracy of model-based RSA for analysis of wrist arthroplasty. *J Orthop Res*. 2018;36(11):3053-3063. doi:10.1002/JOR.24063
17. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis: 21 Elbows followed for 2 years. *Acta Orthop Scand*. 2002;73:264-272. doi:10.1080/000164702320155220
18. DeVos MJ, Verdonschot N, Luites JWH, Anderson PG, Eygendaal D. Stable fixation of the IBP humeral component implanted without cement in total elbow replacement: A radiostereometric analysis study of 16 elbows at two-year follow-up. *Bone Jt J*. 2014;96 B(2):229-236. doi:10.1302/0301-620X.96B2
19. Rahme H, Mattsson P, Larsson S. Stable fixation of the ulnar component in the Kudo elbow prosthesis. A radiostereometric (RSA) study of 13 prostheses with 2-year follow-up. *Acta Orthop*. 2005;76:104-108. doi:10.1080/00016470510030418
20. Hansen TB, Larsen K, Bjergelund L, Stilling M. Trapeziometacarpal joint implants can be evaluated by roentgen stereophotogrammetric analysis. *J hand Surg (European Vol)*. 2010;35(6):480-485. doi:10.1177/1753193409355627
21. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. *Acta Orthop*. 2013;84:98-105. doi:10.3109/17453674.2013.765625
22. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC. A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. *J Biomech*. 2005;38(11):2330-2334. doi:10.1016/j.jbiomech.2004.09.018
23. Beardsley CL, Paller DJ, Peura GD, Brattbakk B, Beynnon BD. The effect of coordinate system choice and segment reference on RSA-based knee translation measures. *J Biomech*. 2007;40(6):1417-1422. doi:10.1016/j.jbiomech.2006.05.005
24. Pijls BG, Nieuwenhuijse MJ, Fiocco M, et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. *Acta Orthop*. 2012;83(6):583-591. doi:10.3109/17453674.2012.745353
25. Pijls BG, Valstar ER, Nouta K-A, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop*. 2012;83(6):614-624. doi:10.3109/17453674.2012.747052
26. von Gerhardt A, Willems JIP, Geervliet PC, Spruyt P, Noort A van, Visser CPJ. Long-term results of the uncemented resurfacing shoulder hemiarthroplasty (Global C.A.P.). *J shoulder Elb Surg*. 2021:S1058-2746(21)00693-5. doi:10.1016/J.JSE.2021.08.021
27. Geervliet PC, van den Bekerom MPJ, Spruyt P, Curvers M, van Noort A, Visser CPJ. Outcome and revision rate of uncemented glenohumeral resurfacing (C.A.P.) after 5–8 years. *Arch Orthop Trauma Surg*. 2017;137(6):771-778. doi:10.1007/S00402-017-2688-9
28. Rai P, Davies O, Wand J, Bigsby E. Long-term follow-up of the Copeland mark III shoulder resurfacing hemi-arthroplasty. *J Orthop*. 2015;13(1):52-56. doi:10.1016/J.JOR.2015.09.003
29. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis 21 elbows followed for 2 years. *Acta Orthop Scand*. 2002;73(3):264-272. doi:10.1080/000164702320155220

30. Ryd L, Albrektsson BE, Carlsson L, et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J bone Jt Surg (British Vol)*. 1995;77(3):377-383.
31. van der Lugt JCT, Valstar ER, Witvoet-Braam SW, Nelissen RGHH. Migration of the humeral component of the Souter-Strathclyde elbow prosthesis: a long-term RSA study. *J bone Jt Surg (British Vol)*. 2010;92(2):235-241. doi:10.1302/0301-620X.92B2.22636
32. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563-572. doi:10.1080/17453670510041574
33. Madanat R, Mäkinen T, Aro HT, Bragdon C, Malchau H. Adherence of hip and knee arthroplasty studies to RSA standardization guidelines. A systematic review. *Acta Orthop*. 2014;85(5):447-455. doi:10.3109/17453674.2014.934187
34. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. *J bone Jt Surg (British Vol)*. 1994;76:912-917.
35. Luepongsak N, Amin S, Krebs D, McGibbon C, Felson D. The contribution of type of daily activity to loading across the hip and knee joints in the elderly. *Osteoarthritis*. 2002;10:353-359. doi:10.1053/joca.2000.0511
36. Klemt C, Prinold J, Morgans S, et al. Analysis of shoulder compressive and shear forces during functional activities of daily life. *Clin Biomech*. 2018;54:34-41. doi:10.1016/J.CLINBIOMECH.2018.03.006
37. Geraldes D, Hansen U, Jeffers J, Amis A. Stability of small pegs for cementless implant fixation. *J Orthop Res*. 2017;35(12):2765-2772. doi:10.1002/JOR.23572
38. Karelse A, Van Tongel A, Verstraeten T, Poncet D, De Wilde L. Rocking-horse phenomenon of the glenoid component: the importance of inclination. *J shoulder Elb Surg*. 2015;24(7):1142-1148. doi:10.1016/J.JSE.2014.12.017
39. Braun S, Schroeder S, Mueller U, Sonntag R, Buelhoff M, Kretzer J. Influence of joint kinematics on polyethylene wear in anatomic shoulder joint arthroplasty. *J shoulder Elb Surg*. 2018;27(9):1679-1685. doi:10.1016/J.JSE.2018.02.063
40. Prkić A, van Bergen C, The B, Eygendaal D. Total elbow arthroplasty is moving forward: Review on past, present and future. *World J Orthop*. 2016;7(1):44-49. doi:10.5312/WJO.V7.I1.44
41. Khellafi H, Bouziane MM, Djebli A, et al. Investigation of Mechanical Behaviour of the Bone Cement (PMMA) under Combined Shear and Compression Loading. *J Biomimetics, Biomater Biomed Eng*. 2019;41:37-48. doi:10.4028/www.scientific.net/JBBBE.41.37
42. Fevang B, Lie S, Havelin L, Skredderstuen A, Furnes O. Results after 562 total elbow replacements: a report from the Norwegian Arthroplasty Register. *J shoulder Elb Surg*. 2009;18(3):449-456. doi:10.1016/J.JSE.2009.02.020
43. Gay D, Lyman S, Do H, Hotchkiss R, Marx R, Daluiski A. Indications and reoperation rates for total elbow arthroplasty: an analysis of trends in New York State. *J bone Jt Surg (American vol)*. 2012;94(2):110-117. doi:10.2106/JBJS.J.01128
44. Böhler C, Weimann P, Alasti F, Smolen J, Windhager R, Aletaha D. Rheumatoid arthritis disease activity and the risk of aseptic arthroplasty loosening. *Semin Arthritis Rheum*. 2020;50(2):245-251. doi:10.1016/J.SEMARTHRIT.2019.07.011
45. Seehaus F, Olender G, Kaptein B, Ostermeier S, Hurschler C. Markerless Roentgen Stereophotogrammetric Analysis for in vivo implant migration measurement using three dimensional surface models to represent bone. *J Biomech*. 2012;45(8):1540-1545. doi:10.1016/J.JBIOMECH.2012.03.004

46. de Bruin PW, Kaptein BL, Stoel BC, Reiber JHC, Rozing PM, Valstar ER. Image-based RSA: Roentgen stereophotogrammetric analysis based on 2D-3D image registration. *J Biomech*. 2008;41:155-164. doi:10.1016/j.jbiomech.2007.07.002
47. Börlin N, Röhrl S, Bragdon C. RSA wear measurements with or without markers in total hip arthroplasty. *J Biomech*. 2006;39(9):1641-1650. doi:10.1016/J.JBIOMECH.2005.05.004
48. Scheerlinck T, Polfliet M, Deklerck R, Van Gompel G, Buls N, Vandemeulebroucke J. Development and validation of an automated and marker-free CT-based spatial analysis method (CTSA) for assessment of femoral hip implant migration In vitro accuracy and precision comparable to that of radiostereometric analysis (RSA). *Acta Orthop*. 2016;87(2):139-145. doi:10.3109/17453674.2015.1123569
49. Brodén C, Olivecrona H, Maguire GQ, Noz ME, Zeleznik MP, Sköldenberg O. Accuracy and Precision of Three-Dimensional Low Dose CT Compared to Standard RSA in Acetabular Cups: An Experimental Study. *Biomed Res Int*. 2016;2016. doi:10.1155/2016/5909741
50. Brodén C, Sandberg O, Sköldenberg O, et al. Low-dose CT-based implant motion analysis is a precise tool for early migration measurements of hip cups: a clinical study of 24 patients. *Acta Orthop*. 2020;91(3):260-265. doi:10.1080/17453674.2020.1725345
51. Brodén C, Sandberg O, Olivecrona H, Emery R, Sköldenberg O. Precision of CT-based micromotion analysis is comparable to radiostereometry for early migration measurements in cemented acetabular cups. *Acta Orthop*. 2021. doi:10.1080/17453674.2021.1906082
52. Brodén C, Giles JW, Popat R, et al. Accuracy and precision of a CT method for assessing migration in shoulder arthroplasty: an experimental study. *Acta Radiol*. 2020;61:776-782. doi:10.1177/0284185119882659

APPENDICES

Summary

Since the 1970s, radiostereometric analysis (RSA) has been used to measure (early) migration of orthopaedic implants. RSA is a highly accurate roentgen technique which enables us to determine implant micro motion of tenths of millimeters. **Chapter 1** of this thesis gives a brief overview of the history of RSA and a short explanation of the technique behind implant migration analysis. RSA has extensively been used to measure migration of total hip and total knee arthroplasties. Precision and accuracy of the technique have been clearly described as well as the relation between early implant migration, measured using RSA in the first two years postoperatively, and long-term implant survival. However, it is unclear whether RSA, when applied in the upper extremity, is as accurate and precise as in the lower extremity. Further, it is uncertain whether the predictive value of early migration for the risk of future loosening also applies to total joint arthroplasty in the upper extremity. Therefore, the aim of this thesis is to investigate the role of RSA in the evaluation of orthopaedic implants in the upper extremity.

PART I – Accuracy and precision of RSA in the upper extremity

In **Chapter 2** we systematically reviewed the literature in order to examine the accuracy and precision of RSA in shoulder, elbow, wrist and hand arthroplasty. Fourteen studies concerning the shoulder, four studies on the elbow and five studies on trapeziometacarpal (TMC) joint arthroplasty were included. Precision values for RSA in the shoulder varied between 0.06 – 0.88mm for translations and between 0.05 – 10.7° for rotations. In the elbow joint, precision varied between 0.05 – 0.34mm and 0.16 – 0.76° and in the TMC joint between 0.16–1.83mm and 11 – 124°. Accuracy data were not reported in included studies. Adherence to existing RSA guidelines was poor in nearly all studies, leading to heterogeneously reported data. This systematic review demonstrated that RSA is a highly precise technique to assess migration of orthopaedic implants in the upper extremity. However, precision of rotation measurement is less precise around the axis of symmetry in symmetrical implants as humeral head resurfacing implants (HHRI). Moreover, precision of RSA is poor when used in small joints as the TMC joint due to the limited size of the surrounding bone and poor three-dimensional spread markers.

PART II – RSA in the trapeziometacarpal joint

In **Chapter 3** we performed an experimental study to assess the feasibility of RSA of a surface replacement (SR) TMC joint prosthesis. The TMC joint of five human hand specimens was replaced by the prosthesis. Of each hand, ten pairs of RSA radiographs were made. Implant migration relative to the surrounding bone during the time inbetween the different radiographs was assumed to be zero. As a result, measured migration between these RSA scenes was considered as the measurement error of the technique. ‘Accuracy of zero motion’ varied between 0.11 and 0.26mm for translations and between 1.47 and 3.72° for rotations. This study showed the in vitro feasibility of RSA in the TMC joint with high precision for translations. Lower precision for rotations was attributed to the close position of the markers relative to each other and to the prosthesis.

The aim of the clinical pilot study described in **Chapter 4** was to evaluate *in vivo* migration patterns of the SR TMC joint prosthesis. Secondary aims were to assess patient-related outcomes (DASH, Nelson) and implant survival after five years. Mean translations of the prosthesis varied between 0.00 and 0.50 mm five years postoperatively. Mean rotation values varied between 0.3 and 2.3°, but high standard deviations indicated poor precision. Two patients underwent an early revision because of pain, without signs of loosening. Clinical outcomes in the other patients improved significantly.

Long-term follow-up of this cohort is described in **Chapter 5**. The purpose of this study was to determine long-term survival and clinical outcomes ten years after implantation of the SR TMC joint prosthesis and to evaluate implant migration during follow-up. Although no additional revisions took place, two patients had a loose implant at final follow-up. DASH and Nelson scores deteriorated clearly in these two patients. Long-term clinical outcomes remained excellent in patients with a stable implant in terms of pain, range of motion and strength. Precision of RSA of the TMC joint prosthesis was determined in a clinical setting using double examinations. High precision values were found for translations, ranging from 0.10 and 0.12 mm. Rotations could not be calculated because of a lack of stable and well three-dimensional spread markers. In this chapter we extensively discuss several technical challenges of RSA in small joints like the TMC joint. Possible solutions as marker configuration (MC) models and reversed migration calculation are discussed.

PART III – RSA in the elbow joint

Concerning the elbow joint, only a few short-term RSA studies have been published and knowledge about the influence of early migration on long-term outcomes is lacking. The aim of **chapter 6** was to evaluate long-term survival of sixteen Instrumented Bone Preserving (IBP) total elbow prostheses. This implant was designed to preserve intercondylar bone and to improve initial fixation and stability. To investigate the relation between early migration and long-term outcomes, previously published short-term migration values were compared between revised and non-revised implants. Further, long-term migration and clinical outcomes (Elbow Function Assessment (EFA), Broberg and Morrey Elbow Functional Rating Index (EFRI), Oxford Elbow Score (OES) and Visual Analog Scale (VAS) for pain) of the IBP prostheses were reported with a minimal follow-up time of ten years. Ten-year survival was 75%, decreasing to 63% after fourteen years of follow-up. Known short-term migration values did not differ between revised and non-revised implants, however the number of patients in this study was not sufficient to draw conclusions about the potential relation between early migration and long-term outcomes. Long-term migration values could be calculated in four patients and varied widely. Clinical outcomes worsened substantially over time in almost all patients. Several patients with loose prostheses at final follow-up refrained from revision surgery, indicating that implant revision might not be the right endpoint in studies investigating the relation between early migration and long-term loosening in total elbow arthroplasty.

PART IV – RSA in the shoulder joint

In **Chapter 7** we evaluated fixation and migration patterns and clinical outcomes of the Simpliciti stemless shoulder system. Stemless humeral implants have been developed to overcome stem-related complications like fractures and complex revisions. Based on theoretical advantages and promising short-term results, stemless implants gained popularity and the number of stemless implants will soon surpass stemmed arthroplasty. In our study, patient reported outcome measures improved significantly in all patients at two-year follow-up, in accordance with existing literature. Fixation of stemless humeral components completely relies on cancellous metaphyseal bone. This may potentially lead to suboptimal fixation affecting long-term implant survival. We found that twenty out of 24 implants stabilized within 12 months postoperatively, but that four implants showed continuous migration between 12 and 24 months and did not stabilize during follow-up. Although a relation between increased early migration and long-term failure has not been demonstrated so far, the level of migration found in this study raises concern and critical assessment of long-term outcomes in stemless shoulder arthroplasty is of vital importance.

PART V – General discussion

In **chapter 8** we discuss the main findings of this thesis. These days, assessment of early migration of orthopaedic implants in upper limb arthroplasty is sporadically performed. In recent years however, the ability of highly precise migration measurement of upper extremity implants has been demonstrated, particularly for TSA. Although the number of RSA studies is not sufficient to investigate the relation between early migration and long-term outcomes, several clues for the predictive value of early migration in TSA have been described. Based on current literature and data from this thesis, we suggest routine migration assessment using RSA of all new shoulder implants prior to market release. Further investigation of the predictive value of RSA in TSA requires an increase in the number of studies evaluating short-term migration and long-term follow-up. Further standardization of reporting migration outcomes is essential to facilitate comparison and pooling of data. In this chapter we discuss several factors that should be taken into account in the further evaluation of migration patterns in the upper extremity, including biomechanical differences between upper and lower limb joints, the influence of rheumatoid arthritis (RA) on migration and the importance of determining the right endpoint for implant failure. Notwithstanding high accuracy and precision in TEA, TWA and TMC joint arthroplasty, concerns about the feasibility of RSA have to do with the small size of the surrounding bone. Before further RSA studies will be performed using model-based RSA, we recommend to examine the feasibility of newly developed techniques as CT-based RSA in small joints of the upper extremity.

Nederlandse Samenvatting

Vanaf de jaren ’70 wordt (vroege) migratie van orthopedische implantaten gemeten met behulp van radiostereometrische analyse (RSA), een zeer nauwkeurige röntgentechniek die het mogelijk maakt om microbewegingen tot tienden van millimeters vast te leggen. **Hoofdstuk 1** van dit proefschrift geeft een beknopt overzicht van de geschiedenis van RSA en een korte uitleg over de techniek achter het meten van migraties. De hoge accuratesse en precisie van RSA is uitgebreid beschreven voor het meten van migratie van totale heup- (THP) en totale knieprotheses (TKP). Daarnaast is er een duidelijke relatie aangetoond tussen gemeten migratie in de eerste twee jaar na de operatie en het risico op vroegtijdige loslating van protheses. Het is echter onduidelijk of RSA net zo accuraat en precies is wanneer de techniek wordt toegepast in de bovenste extremiteit. Ook is niet duidelijk of de voorspellende waarde van vroege migratie voor loslating op de langere termijn ook geldt voor schouder-, elleboog-, pols- of handprothesiologie. Het doel van dit proefschrift is dan ook de rol van RSA te onderzoeken in het beoordelen van orthopedische implantaten in de bovenste extremiteit.

DEEL I – Accuratesse en precisie van RSA in de bovenste extremiteit

Hoofdstuk 2 beschrijft een systematisch literatuuronderzoek naar de accuratesse en precisie van RSA in schouder-, elleboog-, pols- en handprothesiologie. Veertien studies betreffende de schouder, vier over de elleboog en vijf studies over de duimbasis (of: het trapeziometacarpale (TMC) gewricht) konden worden geïncludeerd. Precisie van RSA van de schouder varieerde van 0.06 – 0.88mm voor translaties en van 0.05 – 10.7° voor rotaties. In de elleboog varieerde de precisie van 0.05 – 0.34mm en van 0.16 – 0.76° en in het TMC gewricht van 0.16 – 1.83mm en van 11 – 124°. De accuratesse van RSA werd niet beschreven in de geïncludeerde studies. In veruit de meeste studies werden aanbevelingen uit bestaande RSA richtlijnen onvolledig toegepast, resulterend in een heterogene presentatie van data. Dit systematisch literatuuronderzoek toont aan dat RSA een zeer precieze methode is om migratie van orthopedische implantaten in de bovenste extremiteit te meten. Echter is de precisie lager voor het meten van rotaties rond de symmetrieas in symmetrische implantaten zoals de zogenaamde *resurfacing* schouderimplantaten. Ook vonden we een lagere precisie wanneer RSA wordt toegepast in kleinere gewrichten zoals het TMC gewricht. Dit kan worden verklaard door een slechte drie-dimensionele spreiding van botmakers als gevolg van de beperkte omvang van het omliggende bot.

DEEL II – RSA in het trapeziometacarpale gewricht

In **hoofdstuk 3** onderzoeken we in een experimentele studie de uitvoerbaarheid van RSA in het TMC gewricht. Hiertoe werd in vijf anatomische preparaten van de hand het TMC gewricht vervangen door een *surface replacement* (SR) TMC prothese. Van elke hand werden tien RSA opnames gemaakt waarbij werd verondersteld dat er geen migratie van de prothese ten opzichte van het bot zou optreden in de tijd tussen de verschillende opnames. Gemeten migratie tussen de verschillende RSA opnames werd dan ook als meetfout beschouwd. De "zero motion" accuratesse varieerde van 0.11 – 0.26mm voor translaties en van 1.47 – 3.72° voor rotaties. In deze studie hebben we aangetoond dat RSA in het TMC gewricht mogelijk is in een experimentele setting met een hoge precisie voor het meten van translaties. De lagere precisie voor rotaties van de prothese is het gevolg van een slechte drie-dimensionale spreiding van de geplaatste botmakers.

Het doel van de in **hoofdstuk 4** beschreven pilotstudie was het meten van de migratie van de SR TMC prothese in een klinische setting. De SR TMC prothese werd geïmplanteerd in tien patiënten met artrose van het duimbasisgewricht. Secundaire uitkomstmaten waren patiënt gerapporteerde uitkomsten (DASH, Nelson Score) en survival van de prothese na vijf jaar follow-up. Vijf jaar na implantatie was de gemiddelde translatie van de prothese 0.0-0.5mm en de gemiddelde rotatie 0.3-2.3°. Hoge standaarddeviaties wijzen echter op een matige precisie van gemeten rotatiewaarden. Twee patiënten ondergingen een vroege revisie van de prothese in verband met pijnklachten, zonder tekenen van loslating. Klinische uitkomsten in de andere acht patiënten verbeterden significant.

De lange termijn follow-up van dit cohort is beschreven in **hoofdstuk 5**. Het doel van deze studie was het onderzoeken van klinische uitkomsten en overleving van de prothese met een follow-up duur van tien jaar. Daarnaast werd de lange termijn migratie in kaart gebracht. Ondanks dat er in deze studie geen extra revisies werden gerapporteerd, bleek er tijdens de 10-jaar follow-up wel sprake van loslating van de prothese in twee patiënten. De klinische resultaten van deze twee patiënten verslechterden aanzienlijk. Klinische uitkomsten in de patiënten met een stabiele prothese bleven zeer goed. Om de precisie van RSA in het TMC gewricht te bepalen in een klinische setting, werd gebruik gemaakt van *double examinations:* twee op hetzelfde moment genomen röntgenfoto's waartussen de 'migratie' gemeten werd. De precisie van translaties was goed en varieerde van 0.10 – 0.12m. Rotaties konden in deze studie niet worden bepaald als gevolg van instabiele markers en een matig drie-dimensionele spreiding van de markers. Tot slot worden in dit hoofdstuk de technische uitdagingen benoemd die komen kijken bij het gebruik van RSA in kleinere gewrichten als het TMC gewricht. Mogelijke oplossingen als *marker configuration* (MC) en *reversed migration calculation* worden besproken.

DEEL III – RSA in de elleboog

Migratie van totale elleboogprotheses, gemeten met RSA, is slechts beschreven in een handvol studies met overwegend korte-termijn follow-up. Over de invloed van vroege migratie van elleboogprotheses op lange-termijn uitkomsten is dan ook weinig bekend. Het doel van **hoofdstuk 6** was het onderzoeken van de lange-termijn overleving van de *Instrumented Bone Preserving* (IBP) totale elleboogprothese, een prothese die ontwikkeld is met het doel zoveel mogelijk intercondylair bot te behouden en daarmee fixatie en stabiliteit van de prothese te optimaliseren. Om de invloed van vroege migratie op lange-termijn uitkomsten te onderzoeken werden korte-termijn migratiewaarden vergeleken tussen gereviseerde en niet-gereviseerde implantaten. Klinische uitkomsten ((Elbow Function

Assessment (EFA), Broberg and Morrey functional rating index (EFRI, Oxford Elbow Score (OES) en de Visual Analog Scale (VAS) voor pijn) en migratie van de IBP werden beschreven met een follow-up duur van ten minste tien jaar. Tien-jaar overleving van de prosthese was 75%, dalend naar 63% na veertien jaar. Er was geen verschil in korte-termijn migratie tussen gereviseerde en niet-gereviseerde implantaten, echter was het aantal patiënten in deze studie niet voldoende om conclusies te kunnen trekken over het mogelijke verband tussen vroege migratie en lange-termijn uitkomsten. Lange-termijn migratie kon worden gemeten in vier patiënten en was zeer variabel. Meerdere patiënten in deze studie zagen in het geval van loslating van hun prothese af van een revisie van de prothese. Dit betekent dat revisie van de prothese mogelijk niet het juiste eindpunt is in verder onderzoek naar het verband tussen vroege migratie en lange-termijn uitkomsten in elleboogprothesiologie.

DEEL IV – RSA in de schouder

In **hoofdstuk 7** presenteren we de resultaten van een RSA studie waarin we de initiële fixatie, migratie en klinische uitkomsten van 24 steelloze humeruscomponenten van de Simpliciti Schouderprothese onderzoeken. De steelloze humeruscomponent van de totale schouderprothese is ontwikkeld om problemen gerelateerd aan de humerussteel (fracturen, complexe revisies) te voorkomen. Gestoeld op theoretische voordelen en veelbelovende korte-termijn uitkomsten heeft dit type implantaat snel aan populariteit gewonnen en zullen er op korte termijn wereldwijd meer steelloze dan gesteelde humerusimplantaten worden ingebracht. Steelloze humerusimplantaten vinden hun fixatie in spongieus metafysair bot. Dit zou in theorie kunnen leiden tot een suboptimale fixatie met invloed op lange-termijn overleving van de prothese. In deze studie toonden we aan dat twintig van de 24 implantaten stabiliseerden binnen de eerste twaalf maanden postoperatief. Echter was er in vier (17%) protheses sprake van continue migratie tussen twaalf en 24 maanden. De klinische uitkomsten verbeterden klinisch en statistisch significant in alle patiënten. Ondanks dat een relatie tussen vroege migratie en lange-termijn uitkomsten niet is aangetoond in schouderprothesiologie, vormen de hoge migratiewaarden uit deze studie een reden tot zorg. Het kritisch beoordelen van de lange-termijn resultaten van dit type implantaat is dan ook van groot belang.

Algemene discussie

In **hoofdstuk 8** worden de belangrijkste bevindingen van dit proefschrift besproken. Migratie van orthopedische implantanten in de bovenste extremiteit is slechts sporadisch onderzocht. Recent onderzoek heeft echter aangetoond dat het wel degelijk mogelijk is om migratie van protheses in de bovenste extremiteit op een betrouwbare manier te meten. Dit geldt met name voor prothesiologie van de schouder. Ondanks dat het aantal onderzochte implantaten niet voldoende is om een eventuele relatie tussen vroege migratie en lange-termijn uitkomsten betrouwbaar te kunnen onderzoeken, is er in de literatuur wel degelijk een aantal aanwijzingen beschreven voor de voorspellende waarde van vroege migratie van schouderprotheses. Op grond van de huidige literatuur en data uit dit proefschrift is het advies om alle nieuwe schouderprotheses te analyseren middels RSA in kleine patiëntengroepen alvorens deze toe te laten tot de markt. Vervolgonderzoek naar de voorspellende waarde van vroege migratie in schouderprotheses vraagt uitbreiding van het aantal studies dat vroege migratie en lange-termijn uitkomsten onderzoekt. Het gestandaardiseerd rapporteren van migratie uitkomsten is essentieel voor het vergelijken en het samenvoegen van data in de toekomst. In dit hoofdstuk worden verschillende factoren besproken die belangrijk zijn om in ogenschouw te nemen tijdens verder onderzoek naar migratiepatronen in de bovenste extremiteit: verschillen in biomechanica tussen de bovenste en de onderste extremiteit, de invloed van reumatische artritis op migratie en het belang van het definiëren van het juiste eindpunt voor het falen van een prothese. Ondanks dat er in de literatuur een hoge precisie van RSA is beschreven voor prothesiologie van de elleboog, pols en het TMC gewricht, staat de uitvoerbaarheid van RSA in deze gewrichten ter discussie door technische uitdagingen als gevolg van de beperkte omvang van de gewrichten. Wij raden dan ook aan om, voordat nieuwe RSA studies in deze gewrichten worden gestart met de huidige *model-based* RSA software, eerst verder onderzoek te doen naar de haalbaarheid van nieuwe ontwikkelingen als bijvoorbeeld RSA gebaseerd op CT-onderzoek.

Abbreviations

3D	Three dimensional
ASA	American society of anesthesiologists
aTSA	Anatomic total shoulder arthroplastly
AVN	Avascular necrosis
BMI	Body mass index
CAD	Computer aided design
CMS	Constant-murley score
CN	Condition number
CT	Computed tomography
DASH	Disabilities of the arm, shoulder and hand
DIP	Distal interphalangeal
EFA	Elbow function assessment
EFRI	Elbow functional rating index
FE	Finite element
HHRI	Humeral head resurfacing implants
IBP	Instrumented bone preserving
ISO	International organization for standardization
IQR	Interquartile range
MB-RSA	Model-based radiostereometric analysis
MC	Marker configuration
MCID	Minimal clinically important difference
ME	Mean error
METC	Medisch ethische toetsingscommissie, Medical ethical committee
Mm	Millimeter
MRI	Magnetic resonance imaging
MTPM	Maximum total point of motion
OA	Osteoarthritis, osteoarthrosis
ODEP	Orthopaedic data evaluation panel
OES	Oxford elbow score
OSS	Oxford shoulder score
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
PROM	Patient reported outcome measures
RA	Rheumatoid arthritis
RE	Reversed engineered
ROM	Range of motion
RSA	Radiostereometric analysis

rTSA	Reverse total shoulder arthroplasty
SD	Standard deviation
SPECT	Single photon emission computed tomography
SR	Surface replacement
TEA	Total elbow arthroplasty
THA	Total hip arthroplasty
TJA	Total joint arthroplasty
TKA	Total knee arthroplasty
TMC	Trapeziometacarpal
TSA	Total shoulder arthroplasty
TT	Total translation
TR	Total rotation
TWA	Total wrist arthroplasty
VAS	Visual analogue scale

PhD Portfolio

Name PhD Student:	A. (Bart) ten Brinke
Erasmus MC Department:	Orthopaedic Surgery
Promotor:	Prof.dr. D. Eygendaal
Co-promotoren:	Dr. N.M.C. Mathijssen, Dr. G.A. Kraan

PhD training

General Courses	Year	ECTS
Scientific Writing in English for publication in biomedical journals – *Dordrecht*	2017	1.5
Introduction epidemiology – *Delft*	2018	0.7
Basisdidactiek voor docenten / Teach the teacher I – *Rotterdam*	2020	0.7
Research Integrity – *Rotterdam*	2021	0.5
BROK (Basiscursus Regelgeving Klinisch Onderzoek) / Good Clinical Practice – *Rotterdam*	2021	1.5
Specific Courses	**Year**	**ECTS**
Model-based RSA (basic) – *Leiden*	2015	0.5
Hand and Wrist Arthroscopy & Arthroplasty – *Utrecht*	2016	0.3
BIRG Cadaver course: PIP Joint replacement, Ulna head replacement, radius and forearm reconstruction – *Amsterdam*	2018	0.3
Model-based RSA (advanced) – *Aarhus*	2019	0.5
Proximal humerus fractures – *Rotterdam*	2020	0.3

Podium Presentations	Location	ECTS
Model-based Roentgen Stereophotogrammetric Analysis of the Surface Replacement Trapeziometacarpal total joint arthroplasty: A clinical RSA study with 5-year follow up	Wetenschapsdag, ROGO Rotterdam 2014	0.5
Model-based Radiostereometrische Analyse voor het berekenen van micromigratie van de Surface Replacement trapeziometacarpale prothese	NOV jaarcongres 2016	0.5
Accuracy and precision of Radiostereometric Analysis in shoulder, elbow and TMC-joint arthroplasty – a systematic review of 23 RSA-studies	FESSH Congress Santander 2016	0.5
The role of Radiostereometric Analysis in the evaluation of orthopaedic implants in the upper limb	5th RSA Conference Adelaide 2017	0.5
Long-term outcomes of the SR-TMC total joint prosthesis: an RSA study with 10-year follow-up	Wetenschapsdag ROGO Rotterdam 2018	0.5
Long-term outcomes of the SR-TMC total joint prosthesis: an RSA study with 10-year follow-up	6th RSA Conference Aarhus 2019	0.5
Stable fixation of the stemless humeral component of the Simpliciti Shoulder System: a radiostereometric study with 12 months of follow-up	6th RSA Conference Aarhus 2019	0.5
Stable Fixation Of The Stemless Humeral Component Of The Simpliciti Shoulder System: A Radiostereometric Study With 24 Months Of Follow-Up	Virtual SECEC Congress 2020	0.5
Stable fixation of the stemless humeral component of the simpliciti shoulder system: A radiostereometric study with 24 months of follow-up	Virtual EFORT Congress 2020	0.5
Vroege fixatie van de Simpliciti schouderprothese: een radiostereometrische (RSA) en klinische studie met 2 jaar follow-up	Virtueel NOV Voorjaarscongres 2021	0.5

Poster Presentations	Location	ECTS
Feasibility of model-based RSA in trapeziometacarpal joint replacement.	4th RSA Conference Bologna 2015	0.5
Model-based Roentgen Stereophotogrammetric Analysis of the Surface Replacement Trapeziometacarpal total joint arthroplasty: A clinical RSA study with 5-year follow up	4th RSA Conference Bologna 2015	0.5
Long-term follow-up after instrumented bone preserving total elbow arthroplasty using RSA	5th RSA Conference Adelaide 2017	0.5

Teaching activities	Year	ECTS
University Teacher Qualification Erasmus MC Rotterdam	2020 – 2021	4.0
Supervising medical interns	2017 – 2021	2.5

Other	Year	ECTS
Organizing Journal Club *Evidence-based Espresso* Erasmus MC Rotterdam	2019 – 2021	2.0

List of publications

Book chapters

B. ten Brinke, A. Beumer, D. Eygendaal
Anatomy of the elbow
In: Pederzini LA, Eygendaal D, Denti M. Elbow and Sport. Berlin Heidelberg: Springer-Verlag 2016. ISBN 978-3-662-48740-2

Peer reviewed publications

B. ten Brinke, P.T.P.W. Burgers, M.M.M. Bruijninckx. *Een man met een pijnlijke zwelling in het bovenbeen.* Nederlands Tijdschrift voor Traumatologie 2013; 21(3): 98.

B. ten Brinke, P.J. Klitsie, R. Timman, J.J. Busschbach, J.F. Lange, G-J. Kleinrensink. *Anatomy Education and classroom versus laparoscopic dissection based training: a randomized study at one medical school.* Academic Medicine 2014; 89(5): 806-10.

B. ten Brinke, L.J. de Haan, K.L.M. Koenraadt, R.C.I. van Geenen. *Medial femoral condyle fracture as an intraoperative complication of Oxford unicompartmental knee replacement: a case report.* Knee Surgery, Sports Traumatology, Arthroscopy 2014; 24(10): 3191-3193.

B.R.J. Aerts, **B. ten Brinke**, T.S.C. Jakma, B.J. Punt. *Classification of tibial tuberosity fractures in children: four clinical cases*. Injury 2015; 46(8): 1680-1683.

E.M. Ooms, **B. ten Brinke**, N.M. Mathijssen, I. Blom, R. Deijkers, G.A. Kraan. *Feasibility of model-based roentgen stereophotogrammetric analysis to evaluate early migration of the trapeziometacarpal joint prosthesis.* BMC Musculoskeletal Disorders 2015; 16: 295.

B. ten Brinke, N.M.C. Mathijssen, I.F. Blom, R. Deijkers, E. Ooms, G.A. Kraan. *Model-based Roentgen Stereophotogrammetric Analysis of the Surface Replacement Trapeziometacarpal total joint arthroplasty.* Journal of Hand Surgery (European Vol.) 2016; 41(9): 925-929.

C.J.A. van Bergen, K.I.M. van den Ende, **B. ten Brinke**, D. Eygendaal. *Osteochondritis dissecans of the capitellum in adolescents.* World Journal of Orthopedics 2016; 7(2): 102-108.

P.J. Klitsie, **B. ten Brinke**, R. Timman, J.J. Busschbach, J.F. Lange, G-J. Kleinrensink. *Training for endoscopic surgical procedures should be performed in the dissection room: a randomized study.* Surgical Endoscopy 2017; 31(4): 1754-1759.

B. ten Brinke, A. Beumer, K.L.M. Koenraadt, G.A. Kraan, N.M.C. Mathijssen. *Accuracy and precision of Radiostereometric Analysis in shoulder, elbow and TMC-joint arthroplasty – a systematic review of 23 RSA-studies.* Acta Orthopaedica 2017; 88(3): 320-325.

B. ten Brinke, N. Kosse, P. Flikweert, M. van der Pluijm, D. Eygendaal. *Long-term outcomes after Instrumented Bone Preserving Total Elbow Arthroplasty: A radiostereometric study with a minimum follow-up of 10 years*. Journal of Shoulder and Elbow Surgery 2020; 29(1): 126-131.

I.F. Blom, L.A. Koster, **B. ten Brinke**, N.M.C. Mathijssen. *Effective radiation dose in radiostereometric analysis of the hip.* Acta Orthopaedica 2020; 91(4): 390-395.

B. ten Brinke, N.M.C. Mathijssen, I.F. Blom, L.A. Koster, G.A. Kraan. *A radiostereometric and clinical long-term follow-up study of the surface replacement trapeziometacarpal joint prosthesis.* BMC Musculoskelet Disorders 2021; 22(1):148.

B. ten Brinke, B. Hesseling, D. Eygendaal, M.A. Hoelen, N.M.C. Mathijssen. *Early fixation of the humeral component in stemless total shoulder arthroplasty: a radiostereometric and clinical study with 24 months of follow-up*. Bone and Joint Journal 2022;104-B(1):76-82

R. Keijsers, **B. ten Brinke**, L.J. de Haan, R.L.A.W. Bleys, M.P.J. van den Bekerom. *Multiple perforations of the ECRB tendon using an innovative standardized, reproducible technique; a cadaveric study on accuracy and prospective clinical safety assessment pilot study. No adverse effects in the first 122 patients with lateral epicondylitis.* Accepted for publication in The Archives of Bone & Joint Surgery

Dankwoord

"Een van de allerzoetste vormen van waanzin echter is ongetwijfeld het pronken met andermans veren"

Desiderius Erasmus, Lof der Zotheid (1511)

Gedurende de afgelopen jaren zijn tal van mensen in meer of mindere mate, direct of indirect, betrokken geweest bij de totstandkoming van dit proefschrift. Hen wil ik graag in het laatste hoofdstuk van dit proefschrift bedanken.

Prof. dr. D. Eygendaal, beste Denise. Jij was de eerste die in mijn prille onderzoek een proefschrift zag. En dat is maar goed ook, want zelf zag ik het toen nog niet. Ik wil je ontzettend bedanken voor het vertrouwen dat je mij steeds hebt gegeven, als dokter en als onderzoeker. Dank voor je enthousiasme, je oprechte betrokkenheid en je altijd optimistische blik vooruit. "Hoe mooi zou het zijn als..." is ongetwijfeld een van jouw meest gebruikte zinnen. En hoe mooi ís het dat dit proefschrift dankzij jouw transfer van 020 naar 010 in de blessuretijd van mijn promotietraject alsnog een Rotterdams proefschrift is geworden!

Dr. N.M.C. Mathijssen, beste Nina. Je weet welke zin er nu gaat komen. "Ik heb nog een project liggen dat je tijdens je coschap Orthopedie mooi kan afronden." Hier ligt het dan. Acht jaar later. Maar het ligt er. En dat heb ik aan jou te danken. Dank voor de perfecte balans tussen het kritisch kijken naar mijn concepten en de ruimte die je liet voor eigen invulling. Dank voor de tijd die je altijd maakte om even te bellen, te brainstormen of om een boompje op te zetten over welk *coördinate system* we nou weer hadden gebruikt.

Dr. G.A. Kraan, beste Gerald. Zonder jouw pathologisch optimisme was dit proefschrift in de kiem gesmoord. Maar jij overtuigde mij ervan dat het wel degelijk mogelijk is om een artikel te publiceren over 15 duimbasisgewrichten en wat botmarkers. Het werden er zelfs drie. Dank daarvoor, want daarmee was de basis voor dit proefschrift gelegd. Dank voor de energie die jij in mij en in dit proefschrift gestoken hebt! Ik kijk uit naar de rest van mijn opleiding in het Reinier waar ik van geluk mag spreken met jou als opleider.

Geachte overige leden van de promotiecommissie, **prof.dr. S.M.A. Bierma-Zeinstra**, **prof.dr. G.J. Kleinrensink**, **prof.dr. R.G.H.H. Nelissen**, **prof.dr. F. Stockmans**, **dr. P.J.C. Heesterbeek** en **dr. J.W. Colaris**. Hartelijk dank voor het beoordelen van dit proefschrift en voor uw aanwezigheid tijdens de verdediging ervan.

Ian Blom, werden alle RSA foto's maar door jou gemaakt. Dank voor jouw tomeloze inzet en het vele monnikenwerk achter de RSA-laptop. Dank voor je reacties op mijn appjes om één uur 's nachts, vaak binnen een minuut. Ik kijk met veel plezier terug naar onze reisjes naar Adelaide en Aarhus. En nogmaals excuses voor het hardlooprondje in Aarhus dat Godzijdank niet je laatste werd.

Mannen van RSA*Core*, **Bart Kaptein** en **Lennard Koster**. Hartelijk dank voor jullie inbreng. Zodra jullie aan boord waren, kwam dat de kwaliteit altijd ten goede.

Veel dank ben ik verschuldigd aan het team van het onderzoeksbureau in het Reinier de Graaf: **Brechtje Hesseling**, **Rianne Oomen** en **Nicole de Esch**. Dank voor al jullie hulp!

Alle nog niet genoemde mede-auteurs wil ik hartelijk danken voor hun expertise: **Edwin Ooms**, **Ruud Deijkers**, **Annechien Beumer**, **Koen Koenraadt**, **Nienke Kosse**, **Petra Flikweert**, **Marco van der Pluijm** en **Max Hoelen**.

Alle collega A(N)IOS, stafleden en opleiders van de **ROGO Rotterdam**. Dank voor een prachtige regio waar opleiding hoog in het vaandel staat. **Koen Bos**, dank voor de tijd en de gelegenheid die ik heb gekregen dit proefschrift af te ronden. Binnenkort maar de EPA Wetenschap aftekenen?

Herjan Mijderwijk, dat jij naast me zou staan tijdens de verdediging van dit proefschrift was geen vraag. Naast jaargenoten, studiegenoten, teamgenoten en huisgenoten nu ook allebei gepromoveerd. We hebben veel gemeen en dat maakt een gesprek al gauw een goed gesprek. Zoals men ijzer scherpt met ijzer, zo scherpt een mens zijn medemens. Dank voor je vriendschap en dat je daarin blijft investeren ook vanuit Duitsland.

Jeroen de Goffau, wat goed om jou naast me te hebben staan als paranimf. Onze vriendschap is haar tweede lustrum inmiddels ruimschoots voorbij. Ik kijk terug op een mooie studententijd samen. Ik heb je nooit kunnen overhalen om orthopedisch chirurg te worden, en dat is maar goed ook. Mooi om te zien hoe goed je op je plek zit als (bijna) huisarts in Zeeland. Dank dat ik je altijd lastig kan vallen als ik weer eens een figuur nodig had met meer dan 300 dpi. Speciale dank voor het ontwerpen van de kaft van dit proefschrift!

David Mak en **Reinier Kuijsten**, dank voor jullie waardevolle vriendschap! Mooi om al zoveel jaren samen op te trekken. Dank voor de vele mooie herinneringen, goede gesprekken en scherpe vragen die helpen om ook dit proefschrift in het juiste perspectief te plaatsen.

Lieve **buren**, dank voor jullie indirecte bijdrage aan dit proefschrift. Dank voor alle momenten die mij ervan weerhielden achter de laptop te gaan zitten. De borrels, de winterbarbecue, tuinoverstijgende klusprojecten, de bijna dagelijkse bakkies op de stoep. Wat is het heerlijk wonen aan De Dijk!

TVL 5. Bedankt dat ik bij jullie lid mocht worden. Dank voor jullie betrokkenheid en zorg. Dank voor alle ontspannen weekenden in Groningen, die vaak voelen als vakantie. Bedankt dat jullie altijd voor ons kloar staan!

Papa en mama, bedankt voor de sterke basis die jullie me hebben gegeven. Bij jullie was er altijd de ruimte en het vertrouwen om nieuwe dingen te gaan ontdekken. Verantwoordelijkheid, doorzettingsvermogen en niet bang zijn voor het onbekende zijn waarden die ik van jullie heb meegekregen en die me zeker hebben geholpen als dokter en onderzoeker. **Gerhard, Geke, Arienke, Job, Joanne** en **Wessel**, dank voor een mooi en veelzijdig gezin!

Lieve **Elin** en **Lasse**. Wetenschap is eigenlijk niets meer dan de nieuwsgierigheid naar het onbekende. Wat dat betreft zijn jullie allebei professor! Wat is het heerlijk om me samen met jullie steeds weer te verwonderen over de kleine ontdekkingen die het leven biedt! Nu het boekje af is ("papa, moet je vandaag ook op de *comjoeter* werken?") kijk ik uit naar nog meer tijd met jullie. Ik hou van jullie!

Lieve **Joanne**, dank voor alles wat je voor me betekent. Bedankt dat je altijd achter me stond de afgelopen jaren tijdens het werken aan dit proefschrift, ook als dat soms veel vroeg van jou en het gezin. Dank dat je me altijd steunt in al de plannen die ik heb, behalve als jij denkt dat je een beter plan hebt. Ik ben benieuwd naar de plannen die we samen nog gaan maken en kijk uit naar de toekomst met jou! Ik hou van je!

Curriculum Vitae

Bart ten Brinke (1988) was born in Doetinchem, the Netherlands, and spent several years of his childhood in Lubumbashi, Congo. After graduating from high school (GSR, Rotterdam) he studied medicine at the Erasmus University Medical Center in Rotterdam. During his studies he traveled several times to the south-east of Nigeria to visit the department of orthopaedics and traumatology of the NKST Rehabilitation Hospital in Mkar. It was there that his interest in orthopaedic surgery and traumatology was born. During his elective internship at the department of orthopaedics in Reinier de Graaf, Delft, he became involved in RSA research. As little was known about the role of RSA in the upper extremity, he decided to continue this scientific research, which has eventually led to this thesis.

After he obtained his medical degree in 2014 he worked successively in the Albert Schweitzer Hospital in Dordrecht (general surgery) and in the Amphia Hospital in Breda (orthopaedic surgery), where he met his promotor Prof. dr. D. Eygendaal. In 2017 Bart started his orthopaedic residency which took him to the department of general surgery of the Albert Schweitzer Hospital in Dordrecht (dr. P.W. Plaisier) and to the orthopaedic departments of Reinier de Graaf in Delft (dr. G.A. Kraan) and Erasmus Medical Center Rotterdam (dr. P.K. Bos). Apart from orthopaedic surgery, Bart is interested in medical education and during his time in Rotterdam he completed the University Teaching Qualification. In 2021 he visited the orthopaedic department of the Amphia Hospital to gain more experience in elbow pathology (dr. B. The). He will finish his residency in Reinier de Graaf in Delft in January 2024.

Bart currently enjoys living in Rotterdam together with his wife Joanne and their two children, Elin (2017) and Lasse (2019).