

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

The Journal of Hand Surgery (European Volume) XXE(X) 1–5 © The Author(s) 2016 Reprints and permissions: sagepub.co.uk/journalsPermissions.nav DOI: 10.1177/1753193416629070 jhs.sagepub.com



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Abstract

The primary aim of this clinical and radiostereometric study was to study 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 prosthesis survival 5 years after surgery. Ten patients received the prosthesis. Radiostereometric radiographs were obtained 6 weeks, 6 months, 1 year and 5 years post-operatively and were analysed using model-based software. All patients completed DASH and Nelson Hospital scores at these follow-ups. Mean translations varied between 0.0 and 0.5 mm after 5 years. Rotation values could be calculated in six patients and mean rotations varied between −0.3 and 2.3°, although the precision of rotation values seems to be poor. The 5-year survival rate was 80%. Mean pre-operatively, the DASH and Nelson Hospital scores were 53 (SD 14) and 51 (SD 13), respectively. Six months post-operatively, the DASH and Nelson Hospital scores had both significantly improved to 25 (SD 20) and 74 (SD 18) and remained high after 5 years. Implant stability was good 5 years post-operatively, and early migration did not predict implant failure in this study.

Level of Evidence: IV.

Keywords

Roentgen stereophotogrammetric analysis, trapeziometacarpal joint, total joint arthroplasty, migration, prosthesis survival

Date received: 25th May 2015; revised: 23rd December 2015; accepted: 4th January 2016

Introduction

Osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is a common problem that leads to pain, weakness and adduction deformity of the thumb (Pelligrini, 1991). When conservative treatment fails, surgical treatment might be considered (Martou et al., 2014). In the last decades, total joint arthroplasty of the TMC joint has become an increasingly used procedure for OA of the thumb (Ulrich-Vinther et al., 2008; Vermeulen et al., 2001) although the outcomes of the various implants have been variable (Huang et al., 2015). The surface replacement TMC joint prosthesis (SRTMTMC, Avanta[®], San Diego, CA) is a resurfacing prosthesis

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that closely duplicates the saddle-shaped anatomy of the TMC joint (Figure 1). It consists of a polyethylene metacarpal component and a trapezium component made of cobalt chrome (Uchiyama et al., 1999). Reported loosening rates of the SR[™]TMC prosthesis vary between 0% and 55%, with a maximum followup time of 36 months (Nisar et al., 2011; Pendse et al., 2009; Perez-Ubeda et al., 2003; Van Rijn and Gosens, 2010). In these studies, aseptic loosening was scored by comparing subsequent radiographs for radiolucency or gross displacement. However, aseptic loosening of the prosthesis generally starts with early micromotion, which cannot be detected with conventional radiographs (Kärrholm et al., 1994). Early micromotion can be detected with roentgen stereophotogrammetric analysis (RSA) (Selvik, 1989; Valstar et al., 2005). RSA is a very accurate method for detecting early micromotion of prostheses. Tantalum beads are inserted in the surrounding bone at operation. Stereotactic radiographs are taken post-operatively, using two X-ray tubes placed at an angle of 20° and centred at a calibration box. These two images are analysed using model-based RSA software, so that the three-dimensional positions of the beads and the prostheses can be calculated. Analysis of RSA radiographs taken over intervals makes it possible to determine migration that occurred between follow-up points. The technique is frequently used to determine early micromotion of hip or knee prostheses (Pijls et al., 2012a, 2012b). However, only two studies have described the use of RSA to evaluate the early migration of TMC joint prostheses (Hansen and Stilling, 2013; Hansen et al., 2010).

In this prospective cohort study, we studied the stability of the SRTMTMC 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 5 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



Figure 1. The SR[™]TMC, Avanta[®] TMC joint prosthesis.

(Fitz-Henry, 2011). Conservative treatment for OA had failed, the Eaton and Littler (1973) stage had to be 2 to early 4, patients had to be willing and able to comply with post-operative functional assessment and be able to participate in a rehabilitation schedule.

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 6weeks, 6months, 1 year and 5 years post-operatively. At each assessment, conventional and RSA radiographs were obtained. RSA radiographs on the third post-operative day were used as the reference examination. Modelbased software (Medis, RSAcore, Leiden, The Netherlands) was used to analyse the RSA radiographs and to calculate migration of the prostheses. Migration was defined as translation along and rotations about the x-, y- and z-axes. Translations were expressed in millimetres and rotations in degrees. In addition, patients were asked to complete the disabilities of the arm, shoulder and hand (DASH) (Veehof et al., 2002) and Nelson Hospital Score (Citron et al., 2007) questionnaires at 6 months, 1 year and 5 years post-operatively. The DASH score decreases with functional improvement, whereas the Nelson Hospital score increases.

Before this study, a cadaver study using the SRTMTMC prosthesis was carried out to determine the accuracy of RSA in the TMC joint (Ooms et al., 2015). In this study, the SRTMTMC 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 0.13 mm 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 analysed as mean, standard deviation, minimum and maximum scores. These scores were analysed using linear mixed models for repeated measurements (West, 2009). The level of significance was set at p < 0.05. For the migration data of the SRTMTMC 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 5-year survival of the implants was 80%. In two patients, the prosthesis was removed after 1 and 2 years, respectively, because of pain and loss of function. The 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 had 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 6 months and 5 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 6 months were, respectively, 50 (p=0.95) and 54 (p=1.0). Scores 1 year postoperatively were 49 (p=0.93) and 58 (p=0.82).

RSA results

One patient received a 'small' sized prosthesis. This size could not be analysed by the RSA software and therefore migration calculation was not possible in this patient, so that nine patients were analysed.

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 were not the same as the detected markers on the second radiograph because some markers were hidden by the prosthesis.

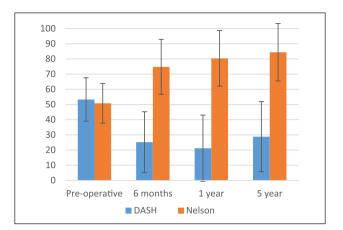


Figure 2. Mean DASH and Nelson Hospital scores of patients pre-operatively and 6 months, 1 year and 5 years after placement of the SR™TMC prosthesis. The error bars represent the standard deviations.

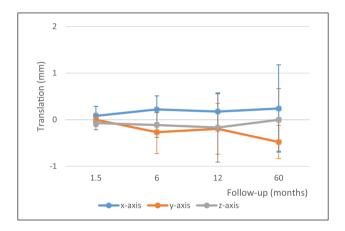


Figure 3. Mean translation of the SR^{TMTMC} prosthesis after placement in nine patients with OA of the TMC joint. The error bars represent the standard deviations.

In two patients, the post-operative examination could not be analysed because of motion artefacts and RSA radiographs taken 6 weeks post-operatively were used as the reference examination.

The mean translations of the SRTMTMC implant system 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 5 years of follow-up. The mean rotation values after 5 years were 2.3° (SD 7.4), 1.2° (SD 3.1) and 0.3 (SD 9.97) for rotations about the *x*-, *y*- and *z*-axes. The translation and rotation patterns are shown in Figures 3 and 4.

Discussion

Radiostereometric studies investigating prostheses of the upper limb with a long-term follow-up are scarce. To gain more insight into the migration patterns of

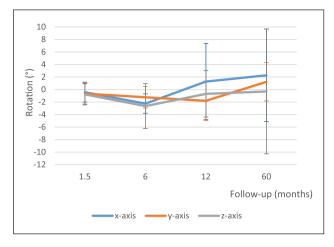


Figure 4. Mean rotation of the SRTMTMC prosthesis after placement in nine patients with OA of the TMC joint. The error bars represent the standard deviations.

orthopaedic implants of the upper limb and the predictive value of early migration it is important to expand RSA research in this field.

To the best of our knowledge, this is the first study using radiostereometry to analyse the migration pattern of the saddle-shaped SR[™]TMC prosthesis. In the study of Van Rijn and Gosens (2010) of the SR[™]TMC prosthesis, 15 prostheses were implanted and one failure occurred. No radiographic loosening was described. Perez-Ubeda et al. (2003) noted a revision rate of 20%, comparable with our results. Nisar et al. (2011) followed 72 prostheses with a mean follow-up time of 36 months. Six prostheses were revised and in eight surviving joints lucencies were seen on plain radiographs, without loss of function.

One clinical RSA study regarding the TMC joint has been done. It compared the uncemented Elektra screw cup and the cemented DLC all-polyethylene cup (both manufactured by Small Bone Innovations Inc., Les Bruyères, France) (Hansen and Stilling, 2013). 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 2 years of follow-up. Translation results were comparable with the translations found in this study after 6 weeks, 6 months and 1 year. However, translation results for a TMC joint prosthesis after 5 years of follow-up have not been described before. Hansen and Stilling (2013) suggest that implants with a translation of above 1mm could be regarded as loose implants. In our study two prostheses were revised, of which one translated more than 1mm after 1 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 (2013), has to be studied further.

Hansen and Stilling (2013) did not measure rotations because of a poor accuracy. In our study, we found an increase in rotation values after 5 years with high standard deviations. In spite of the 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 5 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 (Ryd et al., 2000). 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 were not visible on the second radiograph, so that the detected markers on both RSA radiographs did not correspond with each other. The latter situation results in the RSA software calculating the migration of the prostheses using different sets of beads, which obviously leads to high measurement errors. For future RSA studies of the TMC joint, we recommend inserting more markers. To prevent overprojection by the trapezial component of the prosthesis, beads should not be placed too close to the prosthesis and more proximally in the trapezium to have at least three markers that are visible in both RSA radiographs.

For the knee and the hip joint, the association between early migration and future loosening of implants has clearly been demonstrated in two systematic reviews (Pijls et al., 2012a, 2012b). Total knee prostheses with a migration between 0.5mm and 1.6 mm in the first year were at risk for future revision (Pijls et al., 2012a). For total hip arthroplasty, cups with a translation between 0.2 mm and 1.0 mm in the first year were considered to be at risk (Pijls et al., 2012b). 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 SRTMTMC prosthesis is not predictive for future loosening with a follow-up time of 5 years. However, the number of patients included in this study is small and a follow-up time of 5 years is relatively short. In a study by Martin-Ferrero (2014) with a follow-up time of 10 years in 64 patients with unconstrained uncemented ARPE arthroplasties (Biomet, Spain Orthopedics SL, Valencia, Spain), the survival of implants decreased only after 5 years. Therefore, it would be valuable to reassess this cohort after 10 years to investigate whether there is a relation between early migration and future loosening.

The DASH and Nelson Hospital scores improved significantly 6 months after surgery. Franchignoni et al. (2014) described a minimal clinically important difference (MCID) of 10.8 points for the DASH score. In our study, an increase of 28 points was measured from pre-operatively to 6 months after surgery, and therefore hand function, measured with DASH, improved beyond the minimal clinically important difference. No further improvements in DASH and Nelson Hospital scores were seen after 1 and 5 years. In the two patients who had the prosthesis removed, the DASH and Nelson Hospital scores did not improve postoperatively. Therefore, one may argue that the DASH and Nelson Hospital scores after 6 months are predictive for patient-related outcomes in the long term.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The research foundation of the orthopaedic department of Reinier de Graaf Hospital receives a grant from Biomet-Zimmer. N. M. C. Mathijssen and G. A. Kraan do not personally receive financial support from Biomet-Zimmer.

Ethical approval

Ethical approval for this study was given by the Medical Ethics Review Committee.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Informed consent

Informed consent of all included patients has been obtained.

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