International Orthopaedics (SICOT) (2014) 38:89–93
DOI 10.1007/s00264-013-2074-3

ORIGINAL PAPER

Prosthetic radial head stem pull-out as a mode of failure: a biomechanical study

Dave Shukla · James Fitzsimmons · Kai-Nan An · Shawn O'Driscoll

Received: 12 July 2013 / Accepted: 6 August 2013 / Published online: 17 September 2013

Abstract

Purpose Press-fit cementless radial head implant longevity relies on adequate bone ingrowth. Failed implant osseointegration remains a clinical concern and has been shown to lead to prosthetic failure. The purpose of this study was to test the hypothesis that implants with sufficient initial press-fit stability would be less likely to fail due to implant pull-out, as demonstrated by an increasing amount of energy required to remove the prosthesis from the canal.

Methods Ten cadaveric radii were implanted with five sizes (6–10 mm in 1-mm increments) of grit-blasted, cementless radial head stems. A customised slap hammer was used to measure the energy required to remove each stem. Stem-bone micromotion was also measured.

Results The suboptimally sized stem (Max − 1) (i.e. 1 mm undersized) required less energy (0.5±0 J) to pull out than the optimally sized stem (Max) (1.7±0.3 J) ($p=0.008$). The optimally sized stem demonstrated greater initial stability (45±7 µm) than the suboptimally sized stem (79±12 µm) ($p=0.004$).

Conclusions This investigation demonstrates the importance of obtaining adequate press-fit stability for the prevention of radial head stem pull-out failure. These data add to the relatively scant knowledge in the literature regarding radial head biomechanics. The energy required to remove a prosthetic radial head ingrowth stem decreases in conjunction with diameter. The use of an inadequately sized stem increases the stem's micromotion as well as the risk of prosthetic loosening due to pull-out.

Keywords Radial head implant · Cementless stem failure · Radial head arthroplasty

Introduction

Failure of prosthetic radial heads can theoretically occur by a number of mechanisms. Although the existing literature reporting short- to mid-term results has been generally favourable [1–4], there are currently no guidelines for the diagnosis of a symptomatically loose radial head implant.

Ingrowth of a textured, titanium cementless radial head stem relies on minimising micromotion between the prosthesis and bone. Micromotion in excess of 100~150 µm impairs osseous interdigitation and results in fibrous tissue formation [5, 6]. Several recent biomechanical studies have highlighted the correlation between prosthetic stem diameter and micromotion [7–9]. Specifically, maximising the stem diameter tends to minimise implant micromotion. A recent series reported four cases in which a prosthetic radial head stem pulled out of the radial canal and was pistoning during elbow movement [10]. The authors suggested that stem pull-out as a mode of failure in those instances was likely due to failed osseointegration of the stem within the canal.

We hypothesised that implants with adequate initial press-fit stability (i.e. micromotion < 100 µm) would be less likely to fail due to implant pull-out, as evidenced by an increasing amount of energy required to remove the prosthesis from the canal.

Methods

Ten cadaveric elbows were obtained from our Institutional Cadaver Donor Program. The mean age of the donors was 78 (49–92) years. Specimens were thawed at room temperature overnight prior to dissection. Soft tissue was dissected by

D. Shukla · J. Fitzsimmons · K.-N. An · S. O'Driscoll (✉)
Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN 55905, USA
e-mail: odriscoll.shawn@mayo.edu

layer, and the radius was transected at the junction of the proximal and middle thirds. The bone was potted in an aluminum tube using polymethyl methacrylate. The cement level never extended past the bicipital tuberosity, the visualisation of which was relied on for consistent alignment. Prior to allowing the cement to set, the bone was angled such that the longitudinal axis of the radial neck was oriented vertically. The radial head was excised using a micro-sagittal saw at the junction with the neck, in a horizontal plane.

Radial head implant

Each radius was implanted with a grit-blasted titanium, tapered stem that was 25 mm long with a 4-mm collar (Anatomic Radial Head System, Acumed, Hillsboro, OR, USA). Available stem diameters were 6, 7, 8, 9 and 10 mm. Manually operated rasps were used for canal preparation and were 0.5 mm undersized compared to their designated stem.

Kinetic energy measurements

We tested all five stem diameters using a protocol designed to simulate an actual intraoperative technique. Implants were inserted using a previously described customised slap hammer[7, 8, 11]. The removable weights (0.5, 0.75 and 1 kg) and height options from which the weight was dropped (0.1 or 0.15 m) allowed for quantification of the kinetic energy required for rasp and stem insertion. The following formula was used to calculate the rasp and stem insertion energy:

$$\text{Potential energy} = \mathrm{M}g\mathrm{H}$$
$$\mathrm{M} = \text{mass [Kg]}\, g = 9.8\ \mathrm{m/s^2}\ \mathrm{H} = \text{Height [m]}$$

Each testing sequence was initiated with the minimum value of each weight (0.5 kg) and height (0.1 m). If rasp or stem insertion did not occur after 12 taps, the first variable increased was the height, from 0.1 to 0.15 m. The same weight was dropped until insertion occurred, or until 12 taps had elapsed. If insertion did not occur, the weight was then increased from 0.5 to 0.75 kg and dropped again from 0.1 m. This cycle of sequentially increasing first the height, then the weight, was repeated until the rasp or stem was fully inserted or until the maximum values of each parameter were reached (1 kg, 0.15 m). The rasp was considered fully inserted when it had reached a marking on the instrument that was pre-designated by the manufacturer. We considered the stem fully inserted when the collar was flush against the radial neck.

Energy required for stem pull-out

The energy required to remove the stem after full insertion (pull-out energy) was measured using the same slap hammer used for rasp and stem insertion, though in a different manner. The slap hammer was machined so that it was able to firmly screw onto the non-inserting end of the stem. After insertion of the stem and micromotion testing, the specimen was turned upside down and securely clamped to a stand. After securing the slap hammer (now also upside down) onto the end of the stem, removal proceeded in a manner identical to that of insertion, i.e. the removal sequence was initiated with the minimal weight (0.5 kg) and the lowest height (0.1 m), with both the weight and height increasing as described above until stem removal occurred.

Micromotion testing

Micromotion was measured using a previously reported device [7, 12, 13]. Following stem insertion, a metal dish (10 mm thickness, 100 mm diameter) was secured around the top of the radial head and locked with a screw. The plate-specimen construct was rigidly fixed into the device using a steel sleeve and two collar clamps. A 100-N, pneumatically applied load delivered to the stem's centre acted as a joint compressive force, minimising any other motion within the system. A second load cell-equipped pneumatic device applied an eccentric load of 10 N to a point 4.5 cm from the plate's centre. This load provided the bending moment (45 N cm) that produced the measured micromotion. A mounted laser sensor 180° opposite from the eccentric load at a point 4.5 cm from the stem's centre recorded vertical displacement of the plate. We were able to derive micromotion of the stem's tip from displacement of the plate using simple geometry.

Size designation

We used a uniform size designation to make clinically relevant comparisons. The stem sizes were categorised in relation to the 'maximum'. We used the term 'Max' to define the largest diameter of stem that fit the canal without causing cortical disruption. If a crack occurred in the radial neck, that stem was oversized and was labelled as 'Max+1'. The following is an example of the manner in which we categorised a specimen that experienced fracture at 10 mm: 6 mm (Max − 3), 7 mm (Max − 2), 8 mm (Max − 1), 9 mm (Max) and 10 mm (Max+1).

Statistical analysis

All data were reported as the mean ± standard error. The data were modelled with the use of one-factor repeated measures analysis and means contrast comparisons where appropriate, with a significance level of $p \leq 0.05$. Correlation between the energy required to remove the stem and micromotion was assessed using a non-parametric measure of correlation (Spearman's rank correlation).

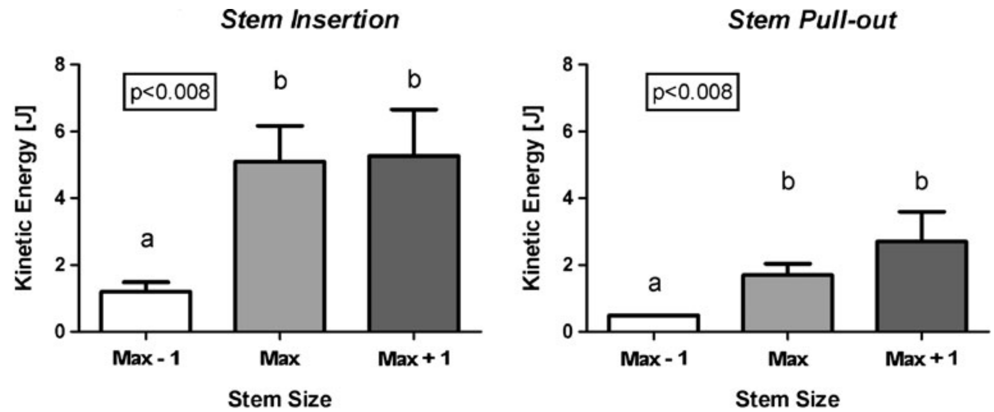

Fig. 1 The mean energy required for the insertion (*left*) and pull-out (*right*) of the prosthetic stems. Greater energy was required to both insert and remove the optimally sized stem as compared to the undersized stem. Undersized stems (*Max − 1*) required significantly less energy to insert (*left*) and also to pull out (*right*) than did the optimally sized stems (*Max*) or the oversized stems (*Max+ 1*) that caused radial neck fracture. Data shown are the means ± standard error of the means (*error bars*). *Lower-case letters* indicate the results of repeated measures analysis. Columns with letters in common are not statistically different from one another ($p \leq 0.05$)

Results

Fracture

All fractures in both groups were longitudinally oriented and occurred in a hoop-stress pattern. By intentionally and sequentially increasing the stem size beyond which the radial canal could accommodate, fractures were achieved in nine of ten specimens. This allowed us to determine which stem diameter was optimal for each individual specimen. The most common location for a crack to develop was the lateral aspect (six specimens), followed by the medial aspect (two specimens). There was an equal incidence (one specimen each) of fractures in the posterior, posterolateral, posteromedial and anterior aspects. Twelve fracture lines developed in nine specimens, as some specimens developed more than one fracture line.

Energy required for insertion

Increasing the stem size did have a significant effect on the energy required to insert the rasp ($p < 0.008$) (Fig. 1). Over four times the amount of energy was required to insert the optimally sized stem (Max) (5.1±1.1) as compared to the energy required to insert the stem which was undersized by 1 mm (Max − 1) (1.2±0.3) (Fig. 1).

Energy required for removal (pull-out)

We were able to pull out the suboptimally sized stem (Max − 1) using significantly less force (0.5±0 J) than was required to pull out the optimally sized stem (Max) (1.7±0.3 J) ($p = 0.008$) (Fig. 1). Additionally, the mean micromotion of the suboptimally sized stem (79±12 μm) approached the threshold for impaired osseointegration and was significantly greater than the mean micromotion value of the optimally sized stem (45±7 μm) ($p = 0.004$) (Fig. 2). Oversizing the stem did not significantly improve micromotion or resistance to pull-out. The energy required to pull out the oversized stem (Max+1) was 2.7±0.9 J and was not different from the optimally sized stem group's value ($p = 0.2$). Additionally, the mean micromotion observed in the oversized stem group (56±9 μm) was not significantly different from the optimally sized stem group ($p = 0.3$).

A reverse correlation between the pull-out force and micromotion was observed (Spearman's $\rho = -0.57$, $p = 0.0001$), and a threshold effect was observed for the submaximally sized stem (Fig. 3).

Discussion

This study showed that obtaining adequate initial press-fit stability of an ingrowth radial head prosthesis is important in

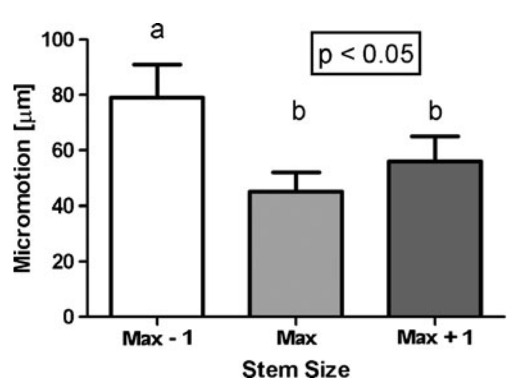

Fig. 2 Stem micromotion values for the optimally sized (*Max*) and oversized implants (*Max+ 1)* were significantly less than for the undersized implants (*Max − 1*) ($p < 0.05$). Data shown are the means ± standard error of the means (*error bars*). *Lower-case letters* indicate the results of repeated measures analysis. Columns with letters in common are not statistically different from one another ($p < 0.05$).

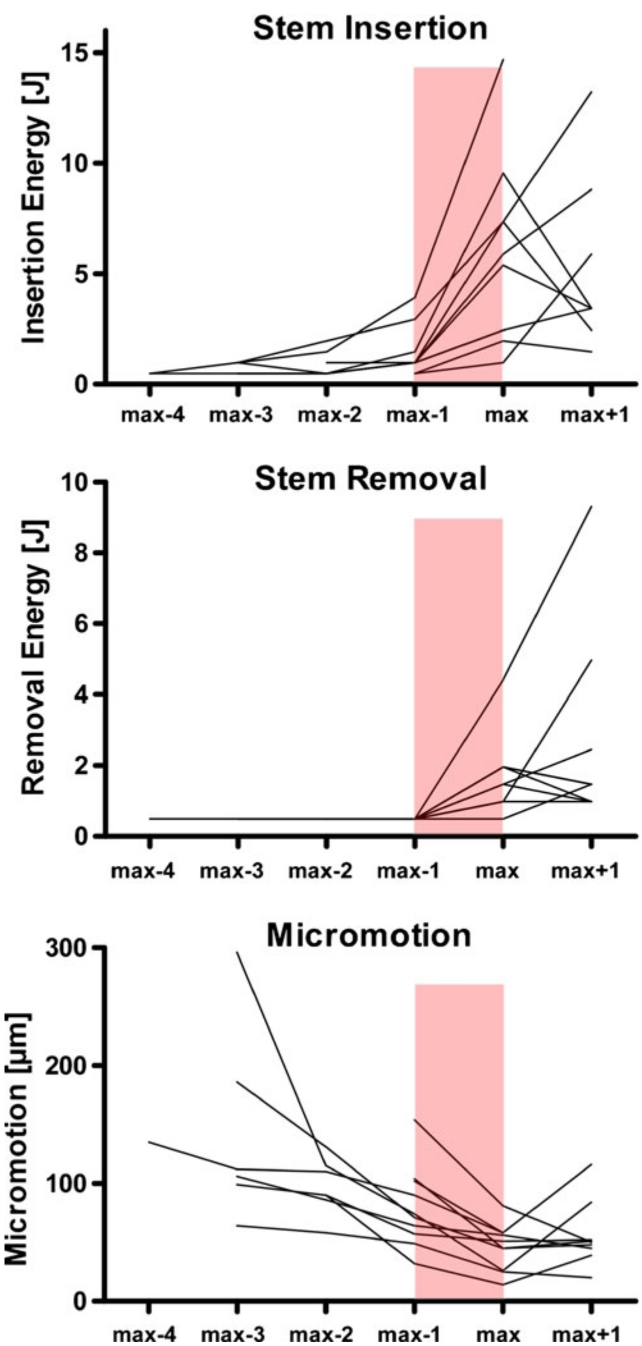

Fig. 3 A threshold effect was observed for the submaximally sized (*max-1*) stem. As the energy required for stem insertion (*top*) and removal (*middle*) increased, a corresponding decrease in micromotion (*bottom*) was observed. Each *line* represents individual specimens

preventing stem pull-out and implant failure. It is known that minimising stem micromotion promotes osseointegration [6].

O'Driscoll and Herald reported aseptic loosening of radial head implants by pistoning (pull-out) of the prosthesis in the radial canal [10]. The authors concluded that mechanical instability resulted from failed bony ingrowth. Our findings support the observations of that study in that a decreasing energy required to remove the stem correlated with greater implant micromotion (decreasing stability).

These data add to the relatively scant knowledge we have regarding radial head implant biomechanics. The effects of several aspects of prosthetic radial head stems have been studied, including the type and extent of surface coating [8, 12], stem diameter [9] and stem length [13]. Studies have shown that the amount of energy required to fully insert the rasp and stem can be used as a guide to assess the appropriateness of implant diameter [7, 8, 11].

Two aspects of our study support observations of a previous investigation regarding hoop-stress fractures of the radial neck that occur during insertion of oversized stems [11]. The authors demonstrated that micromotion of an implant that is 1-mm too big, measured after a fracture occurred, was not different from the micromotion measured with optimally sized stems. Given the maintenance of stability after a hoop-stress crack occurred, the authors advised not removing the oversized stem, also citing the fact that extraction would be difficult and cause risk of bone damage. Our data support the theory postulated in that study, in that the energy required for removal of the oversized stem (Max+1) was the same as the energy needed to pull out the optimally sized stem (Max), and greater than that needed to remove the suboptimally sized stem (Max − 1) ($p<0.008$). Additionally, we also observed that stability was not affected by a fracture occurring during stem insertion, as no difference was observed between micromotion values of the oversized stems (56±9 μm) and the optimally sized stems (45±7 μm).

This investigation is limited in that only one type of implant was studied. Although several options of stem length and surface coating are available, we examined a grit-blasted implant that was 25 mm in length. Also, pull-out was only tested to failure and not cyclically. Clinical failure is likely to be due to cyclical loading, rather than a single load to failure.

Conclusions

The energy required to remove a grit-blasted titanium ingrowth radial head implant stem decreases in conjunction with stem diameter. The use of an inadequately sized stem increases the implant micromotion and the risk of prosthetic loosening due to pull-out.

Acknowledgements This study was funded by the Mayo Foundation. The prosthetic components used in this study were provided by Acumed, LLC. This study was not supported by any outside funding or grants. The Mayo Clinic Institutional Review Board (IRB) that convened on 17 December 2010 approved the project, entitled "Prosthetic Radial Head Stability" (IRB protocol number 01–008186).

Conflict of interest The authors would like to disclose that the senior author (SOD) and the Mayo Foundation receive royalties from commercial entities related to the subject of this article.

References

1. Grewal R, MacDermid JC, Faber KJ, Drosdowech DS, King GJ (2006) Comminuted radial head fractures treated with a modular metallic radial head arthroplasty. Study of outcomes. J Bone Joint Surg Am 88(10):2192–2200. doi:10.2106/JBJS.E.00962
2. Ashwood N, Bain GI, Unni R (2004) Management of Mason type-III radial head fractures with a titanium prosthesis, ligament repair, and early mobilization. J Bone Joint Surg Am 86-A(2):274–280
3. Moro JK, Werier J, MacDermid JC, Patterson SD, King GJ (2001) Arthroplasty with a metal radial head for unreconstructible fractures of the radial head. J Bone Joint Surg Am 83-A(8):1201–1211
4. Burkhart KJ, Mattyasovszky SG, Runkel M, Schwarz C, Küchle R, Hessmann MH, Rommens PM, Lars MP (2010) Mid- to long-term results after bipolar radial head arthroplasty. J Shoulder Elbow Surg 19(7):965–972. doi:10.1016/j.jse.2010.05.02
5. Ling RS (1986) Observations on the fixation of implants to the bony skeleton. Clin Orthop Relat Res 210:80–96
6. Pilliar RM, Lee JM, Maniatopoulos C (1986) Observations on the effect of movement on bone ingrowth into porous-surfaced implants. Clin Orthop Relat Res 208:108–113
7. Moon JG, Berglund LJ, Domire Z, An KN, O'Driscoll SW (2009) Stem diameter and micromotion of press fit radial head prosthesis: a biomechanical study. J Shoulder Elbow Surg 18(5):785–790. doi:10.1016/j.jse.2009.02.014
8. Chanlalit C, Fitzsimmons JS, Shukla DR, An KN, O'Driscoll SW (2011) Micromotion of plasma spray versus grit-blasted radial head prosthetic stem surfaces. J Shoulder Elbow Surg 20(5):717–722. doi:10.1016/j.jse.2010.11.010
9. Ferreira LM, Stacpoole RA, Johnson JA, King GJ (2010) Cementless fixation of radial head implants is affected by implant stem geometry: an in vitro study. Clin Biomech (Bristol, Avon) 25(5):422–426. doi:10.1016/j.clinbiomech.2010.02.001
10. O'Driscoll SW, Herald JA (2012) Forearm pain associated with loose radial head prostheses. J Shoulder Elbow Surg 21:92–97. doi:10.1016/j.jse.2011.05.008
11. Chanlalit C, Shukla DR, Fitzsimmons JS, An KN, O'Driscoll SW (2011) Effect of hoop stress fracture on micromotion of textured ingrowth stems for radial head replacement. J Shoulder Elbow Surg 21(7):949–954. doi:10.1016/j.jse.2011.05.001
12. Chanlalit C, Fitzsimmons JS, Moon JG, Berglund LJ, An KN, O'Driscoll SW (2011) Radial head prosthesis micromotion characteristics: partial versus fully grit-blasted stems. J Shoulder Elbow Surg 20(1):27–32. doi:10.1016/j.jse.2010.05.030
13. Shukla DR, Fitzsimmons JS, An KN, O'Driscoll SW (2012) Effect of stem length on prosthetic radial head micromotion. J Shoulder Elbow Surg 21(11):1559–1564. doi:10.1016/j.jse.2011.05.009