FUNCTIONAL OUTCOMES OF RADIAL HEAD ARTHROPLASTY

FUNCTIONAL OUTCOMES OF RADIAL HEAD ARTHROPLASTY IN PEOPLE WITH COMPEX RADIAL HEAD FRACTURES AND ASSOCIATED INJURIES

By

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This thesis is dedicated to my little sister, Amarpreet Kaur

for always believing in me and her unconditional love and support

CONTRIBUTIONS:

The body of this thesis consists of two separate papers, each formatted according to the requirements of the Journal to which they will be submitted. Even though the papers are co-authored by more than one person, Manraj Kaur was responsible for all aspects of the first study which include, designing the protocol, analyses and writing of the manuscript. For the second study, Manraj Kaur was responsible for the statistical analyses and writing of the manuscript. The co-authors on the papers had varying contributions ranging from assistance in data collection, analyses and reviewing the manuscript.

ABSTRACT

Radial head arthroplasty (RHAP) is proposed as the treatment of choice of complex radial head fractures not amenable to reconstruction. With advances in the understanding of elbow biomechanics and subsequently implant designs, low morbidity, few complications and good success has been reported with RHAP compared to internal fixation. Much of the success/complication post RHAP has been attributed to the fracture pattern and presence of associated injuries. While these are important parameters to reflect on, however, the outcome of surgery cannot be solely attributed to the methods of dealing with the radial head fracture. Importantly, the outcomes of RHAP are also influenced by patient factors. Hence, the purpose of this thesis was to assess the existing knowledge of functional outcomes post RHAP and explore the role of acute post surgical pain as a predictor of those outcomes.

The first manuscript in the thesis systematically examines the current available English literature regarding the functional outcomes of metal RHAP. Studies reviewed revealed significant heterogeneity in the study and patient characteristics. Likewise, the method of reporting fracture classification, clinician and patient reported outcomes are inconsistent. Based on the level 4 evidence studies in the review, we concluded that RHAP provides good to excellent outcomes in short-midterm follow up, with no evidence regarding the superiority of one implant over another.

The second manuscript explored the role of acute post surgical pain in development of chronic functional impairment post RHAP using the EVOLVE (Wright Medical Technology, Arlington, Tennessee) implant at 2 years post surgery. A total of 59 adults with complex radial head fractures treated with EVOLVE metal radial head implant were followed for a period of two years. Demographics, American Shoulder and Elbow Surgeon's-Elbow (ASES-e) pain subscale and Disability of Arm, Hand and Shoulder Questionnaire (DASH) data were collected at baseline and two years. Regression analyses revealed that acute post operative pain post RHAP is significantly related to the functional outcome at 2 years post RHAP. An ASES-e pain cut off score of 32/50 predicted the development of chronic functional impairment two years post RHAP.

The results of this thesis highlight the need for prospective longitudinal studies, comparative analyses and standardized methods of reporting concerning effectiveness of RHAP. It also emphasizes the significance of quantifying pain levels in the immediate post operative period and classifying the patient in high/low risk groups for developing chronic functional impairment based on the pain level.

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LIST OF ABBREVIATIONS

RHF- Radial head fractures

RHAP- Radial Head Arthroplasty

ORIF- Open reduction internal fixation

DASH- Disability of Arm Hand and Shoulder

MEPI- Mayo elbow performance index

EFA- Elbow functional Assessment

PREE- Patient rated Elbow evaluation

ASES-e- American Shoulder and Elbow Surgeon-Elbow

SEQUES- Structured Effectiveness quality evaluation scale

CFI- Chronic functional impairment

ICC- Intra-class correlation coefficient

UE- Upper extremity

CI- Confidence interval

WCB- Worker compensation board

ROC- Receiver operating curve

AUC- Area under curve

NR- Not reported

NA- Not available

CHAPTER 1: INTRODUCTION

Radial head fractures

Radial head fractures (RHF) constitute 33% of elbow fractures and 1.5-4% of all fractures (1-3). Most of the individuals who sustain this fracture are between 20-60 (mean 30-40) years, with a male to female ratio of 1:1 (1, 2, 4, 5). Typically, these fractures are caused by a fall on an outstretched arm with the elbow partially flexed and pronated. This results in transmission of axial force from the hand through the wrist and forearm, causing an impaction of the radial head against the capitellum. Though very rare, RHF can also be caused by direct blunt or penetrating trauma (6-8).

One-third of the individuals who sustain RHF also have concurrent injuries to adjacent bones (fractures of the capitellum, coronoid or proximal ulna) and/or ligaments (disruption of lateral or medial collateral ligament or interosseous membrane) (2, 4, 9). Of these concurrent injuries, posterior dislocation of the elbow and coronoid fractures are the most common (2, 4). These associated injuries play a significant role in determining the treatment protocol as well as prognosis of the RHF (4, 10-12).

Mason's classification of radial head fracture has been the most extensively used, yet also criticised, classification (1). The classification characterises a Type 1 injury as fissure or marginal sector fractures without displacement; Type 2 as marginal sector fractures with displacement; and Type 3 injury as communited fractures involving whole radial head (1). A forth type was added by Johnston (13) as RHF associated with elbow dislocation. The biggest criticism of the Mason's classification of RHF was its inability to capture the associated injuries and/or aid in planning management. Hotchkiss (14) then modified Mason's classification to one that was more treatment oriented. However, the limitation of not taking into account associated ligamentous/osseous injuries remained. Recently, the Mayo group has proposed a classification system to address this by adding a suffix to the fracture type to describe the associated lesion. The suffix indicates the articular injury (c ¼ coronoid, o ¼ olecranon), along with the ligamentous injury (l ¼ lateral collateral ligament, m ¼ medial collateral ligament, d ¼ distal radioulnar joint) (11). The psychometric properties of the Mayo classification of RHF are yet to be assessed (4).

Management of radial head fracture

Regardless of the complexity of the RHF, the goals of treatment include preserving full range of elbow motion, restoring stability and maintaining the length of radius (15, 16). Isolated and minimally displaced fractures are routinely managed non-surgically by closed reduction followed by early mobilization (11, 16, 17). However, the surgeon enters a gray area when the fracture is communited with more than 3 fragments and/or is complicated by associated injuries (15, 18). The decision to resect, fix or replace is made intra-operatively by the surgeon based on the pattern of the fracture (i.e. extent of communition, number of loose fragments and displacement), bone quality and associated injuries (16).

Historically, excision of the radial head was the preferred surgical option for complex RHF (16, 19-21). However, it became less popular as concerns over its long term outcomes were raised (5, 16, 19-21). Biomechanical and cadaveric studies indicated the importance of preserving the radial head (14, 22-25). These studies, along with advancement in technology and surgical techniques, led to an increase in number of open reduction and internal fixation (ORIF) procedures done for complex RHF (12, 26-28). ORIF can yield good results when performed by an experienced surgeon (9, 20). However, there are certain drawbacks to ORIF. First, the surgery time for ORIF is longer. Second, it is technically more demanding on the surgeon. Moreover, the hardware may have to be removed in the future (4, 26). Lastly, avascular necroses of radial head, non-union and displacement of fractures have been reported to be associated with ORIF (12, 15, 26). In such cases, radial head arthroplasty (RHAP) provides a reasonable alternative unless contraindicated by a patient's general condition (17, 29). Overall, RHAP provides satisfactory outcomes. It has shorter learning curves for the surgeons than ORIF and prevents future complications of excision (15). In addition, RHAP also avoids the tenuous fracture fixation in setting of associated injury where maintenance of joint stability would be compromised by inefficient fracture fixation (30, 31).

Radial head arthroplasty (RHAP)

A variety of materials have been used in the fabrication of radial head implants including silicone rubber, vitallium, copper, cobalt-chromium, titanium, and more recently pyrocarbon (15, 32). The use of silicone (33) was discontinued after its mechanical properties were found to be inadequate to counteract the valgus and axial loading at the radiocapitellar joint (34, 35). Some studies have reported implant fracture and inflammatory synovitis in the long term (36-38). Conversely, metal implants were reported to be rigid and capable of withstanding the deforming forces (38, 39). In order to replace the complex and highly variable radial head, two basic conceptual designs evolved and are now most commonly used: (1) polished stem with monopolar or modular head designed to act as a spacer, and (2) rigidly fixed stem with bipolar or monopolar head (18, 40). Bipolar prostheses are as capable as the monoblock prostheses in maintaining congruency of the radial head with the capitellum and sigmoid notch during the elbow's range of motion and restoring the valgus stability (18, 41, 42).

Many trials in the past have examined the outcomes of RHAP (43). Although individual studies differ with respect to the design of implant and study setting, good to excellent outcomes have been consistently achieved by the majority of the patients (43). Concerns over radiological complication of periprosthetic lucency and aseptic loosening have been reported but they have been asymptomatic in short to mid-term studies (43, 44). Long term follow up studies are required to comment on it further.

Assessment of functional status post radial head arthroplasty

The International Classification if Functioning, Disability and Health, known more commonly as ICF defines function as the physiological functions of body systems comprising the physiological system (45). Impairments are the problems in the body structure and functions

for example loss or significant deviation. Functional impairment is assessed in the clinical set up by means of outcome measures (45). These outcome measures can be broadly divided into self report/ patient reported questionnaires or performance measure. Previous literature has shown that self report questionnaires are more accurate indicators of the level of impairment perceived at an individual level (53).

The patient reported outcome assessment instruments used in patients with RHAP range from instruments designed specifically for the elbow joint, to whole upper extremity or to both upper and lower extremities (46). Table 1 summarises the patient reported outcome measure instruments typically used for evaluation of RHAP and their respective psychometric properties. Although considerable data exists regarding the functional outcome measures following shoulder or elbow surgery, there is paucity of data available that is specific to patients with RHAP.

Acute post-operative pain as a predictor of functional outcome in individuals with RHAP

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (47). Acute pain post RHAP is usually a manifestation of tissue damage inflicted at the time of injury and surgery (48, 49). The location and severity of pain, along with other non-clinical factors have been proposed as the risk factors for chronic pain and impairment after surgery (50-52). Previous research has established the role of acute pain in the development of chronic pain (51); however, the relationship between acute pain and chronic impairment has not been extensively studied. Suboptimal functional outcomes post surgery can have many psychological and socioeconomic implications ranging from emotional distress, catastrophizing, reduced productivity at work and subsequent burden on the health care system (48, 52, 53). Acute post-operative pain can be measured and managed within hours after surgery with the help of interdisciplinary teams. Hence, if a relationship between acute post-surgical pain and chronic functional impairment is found, it may assist healthcare professionals with in early identification of the patients at risk and help them to design a treatment plan accordingly.

Thesis Rationale

When the literature was examined concerning the effectiveness of metallic RHAP, it was found that substantial heterogeneity existed with respect to the type of setting and implant, study design, patient population, outcome measures and follow up times, making it difficult to determine the overall effectiveness of the procedure. Furthermore, since many of these studies were retrospective, the possibility of bias is increased. Finally, the majority of the studies neither considered factors that might mediate the outcomes nor adjusted for these in their analyses. This makes it difficult to attribute differences across studies to identified differences in the studied populations or procedures. Given these considerations, a systematic review of literature on treatment effectiveness provides the best mechanism for describing the variation across studies and synthesizing information to have a clear sense of the overall outcome.

Previous outcomes research following surgical interventions has indicated that pain experiences, either prior to surgery or in the early postoperative period, can indicate elevated risk for future long term pain and functional problems (48, 51, 52). A number of non-modifiable factors have been identified in literature to predict outcomes following arthroplasty of other joints and include: age, gender, educational status and severity of injury (54-56). Conversely, post-operative acute pain is a modifiable and quantifiable risk factor. If acute pain is found to be related to suboptimal outcome post RHAP, the postoperative rehabilitation of these patients can be modified to achieve better prognosis.

Assessing functional outcome and a better understanding of acute post-operative pain may help to identify the long term risk factors associated with RHAP. Better understanding and management of this pain may help to reduce the economic burden on the health care system associated with joint replacements.

Thesis objectives

In summary, there has been major progress in the understanding of biomechanics, biomaterials and implant designs along with the surgical technique of RHAP. These advances combined with shorter surgical times, less complex surgical procedures and more favourable outcomes over ORIF have made RHAP a reasonable alternative for an increasing number of patients. The demand by younger and more active patients for this procedure is expected to rise as the failure rates for this procedure diminish. Therefore, it is in the best interest of clinicians and patients to evaluate the outcomes of RHAP for the management of complex RHF. Further, if it can be demonstrated that the early postoperative pain experience can predict risk of chronic pain then this should be taken into consideration in the postoperative rehabilitation. Thus the objectives of the thesis were:

1. To examine the consistency of functional improvement following radial head arthroplasty (Chapter 2).
2. To explore the relationship between acute post-surgical pain and functional outcomes at 2 years following radial head arthroplasty (Chapter 3)

Table 1 – Patient reported functional outcome measures used in Radial Head Arthroplasty

Outcome instrument	Anatomic region	Measures	Dimensions- Total score of the items	Psychometrics	Additional comments
Disability of Arm, Shoulder and Hand Questionnaire (DASH)(57)	Shoulder, Arm and Hand	Function (Bilaterally)	Daily activities- 21 Symptoms- 5 Social Function-1 Work Function- 1 Sleep- 1 Confidence- 1 Total- 30	Validated- Yes(58-62) Test retest reliability (elbow):ICC=0.92(62) MCID=10-17(63) Time taken by patient to complete = 6min(64)	Most validated measure of Upper extremity functional status, higher score equals poor outcome. Frequently used as comparative standard in the design of joint specific instruments for UE(46)
Mayo Elbow Performance Index (MEPI)(65)	Elbow	Pain, Motion, stability and Daily function	Pain- 45 Motion- 20 Stability- 10 Functional tasks- 25 Total- 100	Validated- Yes(62) High correlation with other elbow measures (Broberg and Morrey, Hospital Scoring System) and moderate correlation with Visual analgoue scale for pain(66) MCID - 15 (elbow arthroplasty and synovectomy)(67) Time to complete by patient-NR	Raw scores categorized as Excellent (90-100), Good (75-89), Fair (60-74) and Poor (<60). Less training, low costs (46, 62). No strength or deformities are included in the content of the scale (62).
Broberg and Morrey Elbow Scale(68)	Elbow	Pain, Motion, stability and Strength	Pain- 35 Motion- 40 Stability- 5 Strength- 20 Total- 100	Validated- Yes (62) Time to complete by patient: NR(46) MCID- NR(46)	Raw scores categorised as Excellent (95-100), Good (80-94), Fair (60-79) and Poor (≤60)
Elbow Functional Assessment (EFA)(69)	Elbow	Pain, Activities of Daily life, Motion	Pain - 30 ADL- 35 Motion- 35 Total - 100	Validated - Yes(69) Reliability: ICC = >0.88(69) MCID: not reported Time to complete by patient - NR	Validated in Rheumatoid arthritis. Not extensively used in trauma population
American Shoulder and	Elbow	Pain, function,	Pain - 6 Function - 12	Validated - Yes(71) Reliability:	Higher score indicates worse functioning; Not

Elbow Surgery-Elbow (ASES-e)(70)		satisfaction	Satisfaction - 1 Total-19	ICC=0.89 (range: 0.8-0.9)(71) Time to complete patient section - 3 minutes(70) MCID-NR	been extensively used in trauma population
Patient Rated Elbow Evaluation (PREE)(71)	Elbow	Pain, function, specific activities	Pain - 5 Specific activities -11 Usual Activities - 4 Total - 20	Validated - Yes Reliability: Pain - ICC = 0.76-0.87, Function - ICC = 0.6 - 0.88 Test-retest reliability: ICC = 0.88 - 0.89(71) Time to complete – NR	Higher score indicates worse functioning; Not been extensively used in trauma population

Abbreviations: ICC, Intra class correlation coefficient; MCID, Minimally Clinical important difference; UE, Upper extremity; NR, Not reported

References

1. Mason ML. Some observations on fractures of the head of the radius with a review of one hundred cases. Br J Surg. 1954 Sep;42(172):123-32.

2. Kaas L, van Riet RP, Vroemen JP, Eygendaal D. The incidence of associated fractures of the upper limb in fractures of the radial head. Strategies Trauma Limb Reconstr. 2008 Sep;3(2):71-4.

3. Conn JJ, Wade PA. Injuries of the elbow: A ten year review. The Journal of trauma, J Trauma. 1961;1(3):248-68.

4. van Riet RP, Morrey BF, O'Driscoll SW, Van Glabbeek FD. Associated injuries complicating radial head fractures: A demographic study. Clinical Orthopaedics & Related Research. 2005 December;441:351-5.

5. Fuchs S, Chylarecki C. Do functional deficits result from radial head resection? Journal of Shoulder and Elbow Surgery. 1999;8(3):247-51.

6. Amis AA, Miller JH. The mechanisms of elbow fractures: An investigation using impact tests in vitro. Injury. 1995;26(3):163-8.

7. McGinley JC, Hopgood BC, Gaughan JP, Sadeghipour K, Kozin SH. Forearm and elbow injury: The influence of rotational position. The Journal of Bone and Joint Surgery (American). 2003 December 1;85(12):2403-9.

8. Ring D, Jupiter JB. Current concepts review - fracture-dislocation of the elbow. The Journal of Bone and Joint Surgery (American). 1998 April 1;80(4):566-80.

9. Itamura J, Roidis N, Mirzayan R, Vaishnav S, Learch T, Shean C. Radial head fractures: MRI evaluation of associated injuries. Journal of Shoulder and Elbow Surgery. 2005 0;14(4):421-4.

10. Morrey BF, editor. Radial head fracture. Morrey BF (ed) ed. Philadelphia: WB Saunders; 2000.

11. Kumar V, Wallace WA. Radial head fractures – update on classification and management. Orthopaedics and Trauma. 2012 201204;26(2):124-31.

12. VanBeek C, Levine WN. Radial Head—Resect, fix, or replace. Operative Techniques in Orthopaedics. 2010 201003;20(1):2-10.

13. Johnston GW. A follow-up of one hundred cases of fracture of the head of the radius with a review of the literature. Ulster Med J. 1962 Jun 1;31:51-6.

14. Hotchkiss R. Displaced fractures of the radial head: Internal fixation or excision? Journal of the American Academy of Orthopaedic Surgeons. 1997 January 01;5(1):1-10.

15. Calfee R, Madom I, Weiss AC. Radial head arthroplasty. J Hand Surg. 2006 2;31(2):314-21.

16. King GJ. Management of comminuted radial head fractures with replacement arthroplasty. Hand Clin. 2004 Nov;20(4):429,41, vi.

17. Monica JT, Mudgal CS. Radial head arthroplasty. Hand Clin. 2010 vii; Aug;26(3):403-10.

18. Madsen J, Flugsrud G. Radial head fractures: Indications and technique for primary arthroplasty. European Journal of Trauma and Emergency Surgery. 2008;34(2):105-12.

19. Coleman DA, Blair WF, Shurr D. Resection of the radial head for fracture of the radial head. long-term follow-up of seventeen cases. J Bone Joint Surg Am. 1987 Mar;69(3):385-92.

20. Rokjaer M, Knudsen H. Fractures of the head and neck of the radius treated by excision. Acta Chir Scand. 1972;138(8):793-7.

21. Wallenbock E, Potsch F. Resection of the radial head: An alternative to use of a prosthesis? J Trauma. 1997 Dec;43(6):959-61.

22. Beingessner DM, Dunning CE, Gordon KD, Johnson JA, King GJ. The effect of radial head excision and arthroplasty on elbow kinematics and stability. J Bone Joint Surg Am. 2004 Aug;86-A(8):1730-9.

23. Esser RD, Davis S, Taavao T. Fractures of the radial head treated by internal fixation: Late results in 26 cases. J Orthop Trauma. 1995;9(4):318-23.

24. Furry KL, Clinkscales CM. Comminuted fractures of the radial head. arthroplasty versus internal fixation. Clin Orthop Relat Res. 1998 Aug;(353)(353):40-52.

25. Hotchkiss RN, Weiland AJ. Valgus stability of the elbow. J Orthop Res. 1987;5(3):372-7.

26. Ikeda M, Sugiyama K, Kang C, Takagaki T, Oka Y. Comminuted fractures of the radial head. comparison of resection and internal fixation. J Bone Joint Surg Am. 2005 Jan;87(1):76-84.

27. Morrey BF, Chao EY, Hui FC. Biomechanical study of the elbow following excision of the radial head. J Bone Joint Surg Am. 1979 Jan;61(1):63-8.

28. Pfaeffle HJ, Stabile KJ, Li ZM, Tomaino MM. Reconstruction of the interosseous ligament unloads metallic radial head arthroplasty and the distal ulna in cadavers. J Hand Surg Am. 2006 Feb;31(2):269-78.

29. Ashwood N, Bain GI, Unni R. Management of mason type-III radial head fractures with a titanium prosthesis, ligament repair, and early mobilization. J Bone Joint Surg Am. 2004 Feb;86-A(2):274-80.

30. Pike JM, Athwal GS, Faber KJ, King GJ. Radial head fractures--an update. Journal of Hand Surgery - American Volume. 2009 Mar;34(3):557-65.

31. Ring D. Displaced, unstable fractures of the radial head: Fixation vs. replacement--what is the evidence? Injury. 2008 Dec;39(12):1329-37.

32. Stuffmann E, Baratz ME. Radial head implant arthroplasty. Journal of Hand Surgery - American Volume. 2009 Apr;34(4):745-54.

33. Swanson AB, Jaeger SH, La Rochelle D. Comminuted fractures of the radial head. the role of silicone-implant replacement arthroplasty. J Bone Joint Surg Am. 1981 Sep;63(7):1039-49.

34. Trepman E, Ewald FC. Early failure of silicone radial head implants in the rheumatoid elbow. A complication of silicone radial head implant arthroplasty. J Arthroplasty. 1991 Mar;6(1):59-65.

35. Morrey BF, Askew L, Chao EY. Silastic prosthetic replacement for the radial head. J Bone Joint Surg Am. 1981 Mar;63(3):454-8.

36. Gordon M, Bullough PG. Synovial and osseous inflammation in failed silicone-rubber prostheses. J Bone Joint Surg Am. 1982 Apr;64(4):574-80.

37. Vanderwilde RS, Morrey BF, Melberg MW, Vinh TN. Inflammatory arthritis after failure of silicone rubber replacement of the radial head. J Bone Joint Surg Br. 1994 Jan;76(1):78-81.

38. Gupta GG, Lucas G, Hahn DL. Biomechanical and computer analysis of radial head prostheses. J Shoulder Elbow Surg. 1997 Jan-Feb;6(1):37-48.

39. Ring D. Load-sharing at the wrist following radial head replacement with a metal implant. A cadaveric study. J Bone Joint Surg Am. 2004 Nov;86-A(11):2569; author reply 2569-70.

40. Doornberg JN, Parisien R, van Duijn PJ, Ring D. Radial head arthroplasty with a modular metal spacer to treat acute traumatic elbow instability. J Bone Joint Surg Am. 2007 May;89(5):1075-80.

41. Judet T, Garreau de Loubresse C, Piriou P, Charnley G. A floating prosthesis for radial-head fractures. J Bone Joint Surg Br. 1996 Mar;78(2):244-9.

42. Popovic N, Lemaire R, Georis P, Gillet P. Midterm results with a bipolar radial head prosthesis: Radiographic evidence of loosening at the bone-cement interface. J Bone Joint Surg Am. 2007 Nov;89(11):2469-76.

43. Charalambous CP, Stanley JK, Mills SP, Hayton MJ, Hearnden A, Trail I, et al. Comminuted radial head fractures: Aspects of current management. J Shoulder Elbow Surg. 2011 Sep;20(6):996-1007.

44. Van Riet RP, Van Glabbeek F, Verborgt O, Gielen J. Capitellar erosion caused by a metal radial head prosthesis. A case report. J Bone Joint Surg Am. 2004 May;86-A(5):1061-4.

45. Stucki G, Cieza A. The International Classification of Functioning, Disability and Health (ICF) Core Sets for rheumatoid arthritis: a way to specify functioning. Ann Rheum Dis 2004 Nov;63 Suppl 2:ii40-ii45.

46. Smith MV, Calfee RP, Baumgarten KM, Brophy RH, Wright RW. Upper extremity-specific measures of disability and outcomes in orthopaedic surgery. J Bone Joint Surg Am. 2012 Feb 1;94(3):277-85.

47. Crombie IK. Epidemiology of pain: A report of the task force on epidemiology of the international association for the study of pain. Seattle: IASP Press; 1999.

48. Young Casey C, Greenberg MA, Nicassio PM, Harpin RE, Hubbard D. Transition from acute to chronic pain and disability: A model including cognitive, affective, and trauma factors. Pain. 2008 Jan;134(1-2):69-79.

49. Carr DB, Goudas LC. Acute pain. The Lancet. 1999 6/12;353(9169):2051-8.

50. Perkins FMMD, Kehlet HMD, Ph.D. Chronic pain as an outcome of surgery: A review of predictive factors. Anesthesiology. 2000 October;93(4):1123-33.

51. Macrae WA. Chronic post-surgical pain: 10 years on. Br J Anaesth. 2008 2008;101(1):77-86.

52. Weigl M, Cieza A, Cantista P, Reinhardt JD, Stucki G. Determinants of disability in chronic musculoskeletal health conditions: A literature review. Eur J Phys Rehabil Med. 2008 Mar;44(1):67-79.

53. Woby SR, Watson PJ, Roach NK, Urmston M. Are changes in fear-avoidance beliefs, catastrophizing, and appraisals of control, predictive of changes in chronic low back pain and disability? European Journal of Pain. 2004;8(3):201-10.

54. Chung KC, Kotsis SV, Kim HM. Predictors of functional outcomes after surgical treatment of distal radius fractures. J Hand Surg Am. 2007 Jan;32(1):76-83.

55. Brown KR, Jean-Claude J, Seabrook GR, Towne JB, Cambria RA. Determinates of functional disability after complex upper extremity trauma. Ann Vasc Surg. 2001 Jan;15(1):43-8.

56. Jones CA, Voaklander DC, Suarez-Alma ME. Determinants of function after total knee arthroplasty. Phys Ther. 2003 Aug;83(8):696-706.

57. Hudak PL, Amadio PC, Bombardier C, Beaton D, Cole D, Davis A, et al. Development of an upper extremity outcome measure: The DASH (disabilities of the arm, shoulder, and head). Am J Ind Med. 1996;29(6):602-8.

58. Atroshi I, Gummesson C, Andersson B, Dahlgren E, Johansson A. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: Reliability and validity of the swedish version evaluated in 176 patients. Acta Orthop Scand. 2000 Dec;71(6):613-8.

59. Beaton DE. Measuring the wole or the parts? Journal of Hand Therapy. 2001 200104/06;14(2):128-42.

60. Offenbächer M, Ewert T, Sangha O, Stucki G. Validation of a german version of the ’Disabilities of arm, shoulder and hand‘ questionnaire (DASH-G). Zeitschrift für Rheumatologie. 2003;62(2):168-77.

61. SooHoo NF, McDonald AP, Seiler III JG, McGillivary GR. Evaluation of the construct validity of the DASH questionnaire by correlation to the SF-36. J Hand Surg. 2002 5;27(3):537-41.

62. Turchin DC, Beaton DE, Richards RR. Validity of observer-based aggregate scoring systems as descriptors of elbow pain, function, and disability. The Journal of Bone & Joint Surgery. 1998 February 1;80(2):154-62.

63. Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. J Clin Epidemiol. 2004 10;57(10):1008-18.

64. Mock, Charles M, Ellen J, Gregory B, Andrew C, Brad d, et al. Determinants of disability after lower extremity fracture. Journal of Trauma-Injury Infection & Critical Care. 2000 December;49(6):1002-11.

65. Morrey B, Adams R. Semiconstrained arthroplasty for the treatment of rheumatoid arthritis of the elbow. J Bone Joint Surg Am. 1992 04;74(4):479-90.

66. Doornberg JN, Ring D, Fabian LM, Malhotra L, Zurakowski D, Jupiter JB. Pain dominates measurements of elbow function and health status. J Bone Joint Surg Am. 2005 Aug;87(8):1725-31.

67. de Boer YA, Hazes JM, Winia PC, Brand R, Rozing PM. Comparative responsiveness of four elbow scoring instruments in patients with rheumatoid arthritis. The Journal of Rheumatology. 2001 December 01;28(12):2616-23.

68. Broberg MA, Morrey BF. Results of delayed excision of the radial head after fracture. J Bone Joint Surg Am. 1986 Jun;68(5):669-74.

69. de Boer YA, van den Ende CH, Eygendaal D, Jolie IM, Hazes JM, Rozing PM. Clinical reliability and validity of elbow functional assessment in rheumatoid arthritis. J Rheumatol. 1999 Sep;26(9):1909-17.

70. Research Committee,American Shoulder and Elbow Surgeons, King GJW, Richards RR, Zuckerman JD, Blasier R, Dillman C, et al. A standardized method for assessment of elbow function. Journal of Shoulder and Elbow Surgery. 1999;8(4):351-4.

71. MacDermid JC. Outcome evaluation in patients with elbow pathology: Issues in instrument development and evaluation. Journal of Hand Therapy. 2001 200104/06;14(2):105-14.

CHAPTER 2: STUDY ONE

Functional outcomes of radial head arthroplasty: Systematic review

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Functional outcomes of Radial head arthroplasty: A systematic review

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Abstract

Purpose: This study was conducted to determine the quality and content of research on the functional outcomes post radial head arthroplasty (RHAP).

Methods: A comprehensive search of medical databases for English language studies reporting on functional outcomes of patients undergoing metallic RHAP was conducted. Additional relevant studies were identified through bibliographic review of all included studies and review articles. Two reviewers evaluated each study to determine its eligibility for inclusion and data of interest was recorded. The Structured Effectiveness Quality Evaluation Scale (SEQES) was used to evaluate the quality of the studies. Rater agreement was determined. Data extraction on functional outcomes was conducted; and a narrative synthesis performed.

Results: We identified 21, Sackett's level IV studies reporting on 391 radial heads. The mean duration of follow up was found to be 47.2 months, with mean age of patients between 48.4±6.9 years. The male to female ratio was found to be 1.05:1 and the dominant arm was involved in 54% of the patients. When the functional outcomes achieved post RHAP were compared to the normative scores the comparison suggested that RHAP has good to excellent functional outcomes in short to midterm follow up. The weighted mean Mayo elbow performance score was 85.8±4.1 (95%CI, 85.3-86.3).

Conclusions: The heterogeneity of the type of implant, patient characteristic and outcome measures used along with the inadequate reporting of details restrict definitive conclusions regarding the effectiveness of RHAP is supported by weak scientific quality of evidence. However evidence is consistent that high levels of function are obtained with this procedure. There is no direct evidence on the superiority of one implant versus another. Well designed prospective, randomised trials comparing different implant designs or alternative methods of treatment (internal fixation) are required. There is also a need for better reporting standards in RHAP.

Background

Radial head arthroplasty (RHAP) has been performed in patients with communited radial head fractures (Mason type 3/ 4) associated with bony and/or ligamentous injuries (1). The development of radial head prosthesis began in 1950s as an alternative to resection (2). Although Swanson's silicone prosthesis gained some popularity initially (3-5), it was associated with long term failure due to fracture of the implant and development of inflammatory synovitis (6-10), causing substantial uncertainty with respect to the potential benefits of replacement surgery.

Biomechanical studies of the elbow joint complex and review of failed silicone implants encouraged the development of more rigid metallic prosthesis with various modifications, including monoblock to modular, monopolar to bipolar and cemented to uncemented stem fixations available today (2). Although several case series have evaluated the benefits of a particular type of implant, the relative benefits of one design or surgical technique over another has not been evaluated in the literature. The purpose of this systematic review was to identify if there are adequate objective data of effectiveness in literature to advocate for radial head arthroplasty.

The focus of this systematic review was to obtain an estimate of the functional outcomes of radial head arthroplasty, expected complications and radiological findings post RHAP as well as to critically appraise the identified studies using a methodological scoring system.

Methodology

Search Strategy and Eligibility Criteria

A literature search of PubMed, OVID and EMBASE databases using the terms "radial head" and "metal" and "arthroplasty" or "replacement" and "functional outcomes" was conducted. No date limitations were applied to the search. The search was developed and conducted by the author KM and was last updated in February 2012.

After the duplicates and non-English language studies were excluded, a manual reference check of all retrieved studies and the recent reviews was performed to identify any additional potentially relevant studies and complement the electronic search. We only included the articles published in peer reviewed journals and excluded any conference abstracts or proceedings of meeting, editorials, monographs, textbook chapters, letters to editor or case reports. For a study to meet the inclusion criteria, the authors had to have reported on (1) primary metal radial head replacement surgery, and (2) at least one functional outcome post radial head arthroplasty. Studies that reported on revision arthroplasty were excluded; however studies in which all of the patients were treated with delayed replacement of radial head were included in the review. Literature reviews, cadaveric and biomechanical studies were excluded. Both of the reviewers (MK and JMD) reached a consensus with respect to the studies that were included or excluded prior to the data extraction. All clinical study designs were included in the review, including randomised control trials, retrospective and prospective observational studies, and uncontrolled case series. Secondary studies, if any, were not included in the review in order to avoid double counting of the patients.

Data extraction and quality appraisal

Information about the study sample, intervention, and outcomes was extracted by one reviewer and checked for accuracy by a second reviewer. The quality of the studies was assessed using the Structured Effectiveness Quality Evaluation Scale (SEQES) (11) (Appendix1) and Sackett's Level of Evidence (12)(Appendix 2). SEQES is a 24-item scale; where each item is allocated a score between 0 (criterion not met) to 2 (criterion completely met). The first section assesses if sufficient background information was provided to frame the study question. The next section has seven questions that evaluate the study design with respect to nature of data collection, randomisation of patients and presence of an independent evaluator. The third section contains information pertaining to the enrollment and follow up of participants. The comprehensiveness of information given on the interventions and outcomes is determined in the fourth and fifth section of SEQES. The section on the statistical analyses consists of 5 questions and is based on the appropriateness and reporting of the statistical tests performed. The agreement of the conclusion with the objectives and results of the study was determined in the last section based on one question. A higher score corresponds to a better quality of study. The studies were classified independently by the two reviewers based on their overall score as low (0-16), moderate (17-32) or high (33-48) quality studies (11). Any disparities in the final scores between the two raters were identified, a consensus was reached by discussion and level of agreement was calculated.

Statistical Analysis

The patient and treatment characteristics were summarised using descriptive statistics. The data on the outcomes were pooled and confidence interval (95% CI) & weighted means (weighted by sample size) were calculated across studies when possible. All the calculations were performed using the SPSS software (version 20.0, Chicago, Illinois)

Results

We identified 21 studies that accounted for a total of 391 radial head implants published between 1993 and 2012 for the quantitative synthesis in this review (Table 1). All included studies that reported on the functional outcomes of RHAP were graded as Level 4 evidence (12) (Table 2). The majority of the studies were published between 1990-2000 and 2006-2008 reflecting the time during which new implants were being designed and tested. As such, most of these studies have reported on only short to medium term follow-up. Most of the studies were done in Europe (13-22) (47.62%) and North America (23-28) (33.33%) followed by South East Asia, predominantly China (29-31) (14.29%) and Australia (32) (4.76%). The implants used varied in design with respect to their modularity and component mobility. The studies reviewed included evaluation of the Judet (13-16, 18, 20, 21) 24.74% (96), EVOLVE (19, 24, 25, 28, 30) 23.45% (91), Titanium (26-28, 31, 32) 17.53% (68), Vitallium (17, 17, 23, 23, 29, 29) 13.66% (53), Katalyst (33) (30) 7.73% and Link (18) (22) 4.64% prostheses. Shore et al. (28) did not report on the distribution of the type of prosthesis reviewed, hence the study was not included in this calculation.

There was a wide range of follow up duration, with a mean duration of 47.2 months (95% CI, 34.7 – 59.8) (lower quartile, 30.85; median, 39; upper quartile, 57.6). The study by

Harrington et al. (26) had the longest duration of follow up in the RHAP literature with a mean follow up of 12.1 years (minimum, maximum: 6, 29 years). The patient recruitment rate of all the studies included was greater than 90%. The mean age for the participants was 48.4 ± 6.9 years (95%CI, 45.4-51.4years). There were 185 male and 175 female participants with a male: female ratio of 1.05:1. This male female ratio is consistent with the ratio reported in the literature (34). There was most agreement that the indication for acute RHAP was complex radial head fractures (Mason Type 3 & 4) along with concomitant elbow injuries that threatened the stability of the elbow joint. Residual pain and stiffness from previous failed resection or internal fixation was found to be the indication for delayed replacements. Less common indications included traumatic elbow instability, previously failed excision or fixation, failed silicone replacement, and non-union or mal-union. Contraindications that have been reported for the use of RHAP include open fractures with risk of infection, chondral lesion or avascular necrosis of capitellum and known allergy to metal used in the implant. The most common mechanism of injury was a fall on outstretched hand (68.4%) followed by fall from height (>6 feet) (14%) and motor vehicle accident (9.2%). There were a few direct injuries to the elbow (7.6%) and only 2 cases (0.8%) of sports related injuries. The dominant hand was involved in 54.3% of participants in 13 (13-15, 17, 19, 21, 23-29, 31, 32) studies that reported hand dominance.

The surgical technique was described in all the studies with posterolateral Kocher's approach being the most commonly used. The rationale for the size of radial head prosthesis was given with respect to the specific type of implant. The protocol for postoperative rehabilitation included immediate mobilization under the supervision of a hand therapist, within 1-2 days of surgery, supplemented with an extension splint at night. Only 2 studies, Link(22) and Katalyst(33) implants reported immobilisation for 7-10 days followed by supervised assisted active range of motion exercises. The active and passive stretching and strengthening were initiated within 6-8 weeks after the surgery depending on the type of initial injury and other repairs around the elbow joint.

Range of motion (ROM) was documented in 20 out of 21 studies (except Brinkman et al. (18)) and was measured either with a manual goniometer or the computerized NK hand evaluation system. The exact procedure and reference point used were described in only 3 (20, 25, 28) of 20 studies. The weighted postoperative means for both elbow flexion and extension and forearm rotation were calculated (Table 3). Greater restriction of ROM was seen in the Link (22) and Katalyst (33) implant groups in the given duration of follow up.. Whether this difference is attributable to specific implant, patient characteristics, or the longer immobilization period post surgery needs to be further evaluated. We performed paired t-test to compare the mean range of motion and found no statistical significant difference in acute and delayed group for flexion ($t(26)=3.25, p>0.001$), extension ($t(26)=1.26$, $p>0.001$s), pronation ($t(26) = 0.625, p>0.001$) or supination ($t(26)=-0.698$, $p>0.001$).

Grip Strength was evaluated in 9 studies (14, 15, 19, 20, 25-29, 31, 32) using either the hydraulic Jamar hand dynamometer or the computerized NK hand evaluation system (Table 4). The decrease in grip strength on the involved side was 12.4% compared to the contra-lateral side. Isometric strength was reported in 5 out of 21 studies (20, 25, 26, 28, 31) and greater average loss was found in supination (19%) and pronation (15.5%) compared to flexion (13%) and extension (14%). Where the non-dominant hand was involved, none of the studies adjusted for

the normative difference in dominant and non-dominant hand. Muhm et al. (19) found no significant difference in the grip strength in short term and mid-term follow up groups.

Stability of elbow joint post RHAP was evaluated in 13 out of 21 studies (13, 14, 17-22, 25-27, 29, 32) on the basis of clinical examination and radiographs. None of the studies reported symptomatic valgus or postero-lateral instability and/or ulnohumeral subluxation. Knight et al. (17) reported one patient with moderate valgus instability but that patient was asymptomatic at mean follow up of 4.5 years.

Mayo elbow performance index (MEPI) is a clinician-based outcome measure that evaluates pain, ulno-humeral motion, stability and ability to perform five functional tasks (35, 36). It was the most frequently used outcome measure, besides the Broberg and Morrey Functional rating system (Table 5). The total MEPI scores can range from 5-100, with higher scores reflecting better outcomes. The cumulative score can then categorised into 4 subsets of poor (0-59), fair (60-74), good (75-89) and excellent (90-100). It has been validated for use in elbow disorders (35, 37). Due to the considerable variability in the method of reporting, a raw score or categorical ranking, the ability to compare results across different studies was limited. The reporting of categorical rankings instead of raw scores would require additional evaluation of the validity and interpretability with respect to other standardised measures.

The American Shoulder and Elbow Surgeons-Elbow Evaluation tool (ASES-e) (38) and Patient Rated Elbow Evaluation (PREE) (39) were the other joint specific outcome measures. ASES-e and PREE both allow patients report on their pain and level of functional impairment and share a similar structure in that they address pain and function in separate subscales. Excellent correlation (>0.90) has been reported in between ASES-e and PREE (40). The ASES has a physician evaluation section that is used to examine physical impairments using a standardized framework.

The disability of arm, shoulder and hand questionnaire (DASH) (41), a region specific outcome measure was reported in 9 out of 21 studies (13-15, 19, 23-25, 29, 33) (Table 6). It evaluates the symptoms, daily activities, sleep and social and work function based on 21 questions rated on a 0-4 Likert scale (41). The higher the DASH score, the greater the level of functional impairment. It has demonstrated excellent psychometric properties in the evaluation of elbow disorders and is the most frequently used outcome measure (35). Use of generic overall health outcome measure (SF-36) was reported in only three studies (25, 27, 28). The SF36 (42) can provide a comprehensive evaluation of quality of life post-surgery but can also be used to rationalize poor outcomes in patients with unexplained causes.

Residual pain as an outcome measure post RHAP was reported in 16 out of 21 studies (13-15, 17, 18, 20-22, 24-29, 32, 33). It was most commonly measured using a 0-10 visual analogue scale (VAS) where 0 stands for no pain and 10 for worst pain ever, or with ASES-e pain subscale. ASES-e pain subscale (38) estimates the intensity of pain based on pain level at night, at rest, when at worst, lifting heavy objects and repetitive elbow movements. Hence, it evaluates the effect of pain on activities of daily living of an individual. One of the reasons for not using a separate pain outcome measure could be that the level of pain intensity measurement is closely integrated in the total raw scores of MEPI and Broberg and Morrey rating system. The

individual scores on pain subscale are more valid rather than the aggregate score due to lack of evidence suggesting concordance between pain score of MEPI or BAM and the VAS pain (43). Overall, the pain level improved post RHAP, with only 9% of participants requiring analgesics on a regular basis. Only 7 cases of wrist pain were reported and it was not associated with radiological evidence of altered ulnar variance (21, 29, 32). In 8 out of 21 studies (13, 19, 21, 22, 25, 29, 32, 33) that reported on patient satisfaction, the outcome was found to be satisfactory (13, 19, 21, 22, 25, 29, 32). It was either measured with a 0-10 visual analogue scale or with ASES-e satisfaction subscale. Wretenberg et al. devised their own satisfaction scale (22).

All of the studies reported radiographic evaluation of RHAP. Most of the studies assessed the presence of peri-prosthetic lucencies, heterotrophic ossification, capitellar erosions or sclerosis and post-traumatic degenerative changes. Significant heterogeneity was found in the classification used for radiolucent lines and the definition of what might be a significant radiological change was not identical across the studies. Evidence of peri-prosthetic loosening and capitellar erosions has been reported with both monoblock and bipolar prosthesis (14, 20, 22). One of the hypotheses might be that the surface area of metal prosthesis is approximately 1/3rd of the native radial head. Hence, excessive loads might be experienced at the radiocapitellar joint with the relatively loose fit of the prosthesis (44, 45). Moreover, silent osteolysis is a well known phenomenon due to the polyethylene wear causing macrophage reaction to the debris. However, this is process occurs over a substantial duration of time and symptoms are not experienced until significant bone loss is apparent (21, 46). Consequently, none of the patients in the review reported symptomatic periprosthetic loosening or implant failure.

Superficial wound infections were reported in 3 out of 391 cases and all resolved completely with oral antibiotics (27, 32). Deep infection was reported in one case of an individual who had the implant removed due to associated contracture (24). Transient neuropathy of ulnar nerve and posterior inter-osseous nerves were most commonly reported neurological complications. In majority of the cases, these symptoms resolved spontaneously with no residual disability. There were only two reported cases where transposition of the ulnar nerve was required (23, 28). In spite of the prevalence of the neurological complications they were inconsistently reported on clinical examination. None of the studies provided survivorship analysis. In this study, we found the incidence of implant removal (3.06%) and revision (2.22%) to be low. This could indicate a high success rate or could be attributed to the deficient reporting of the revision rates.

Discussion

Increased understanding of elbow complex biomechanics and the importance of the radial head in elbow function has led to tremendous progress in the design of the metallic radial head implant over the last decade (47). As most of the patients who need radial head replacement are in the working age group of 20-60 years (35, 48), it is really important to assess the long-term functional outcomes of this surgery. However, previously this has not been adequately analysed in the literature. Hence, in this study we report the results of the systematic review of functional outcomes of patients with metal radial head arthroplasty.

The strengths of this systematic review include that a defined systematic review process was used including a structured critical appraisal. However, some bias may have been introduced

by restricting to studies published in English language and in peer reviewed journals. The possibility of rejecting relevant reports by significantly reduced by having two investigators review all studies for inclusion using criteria agreed to by the two investigators prior to extracting the data and reporting on the study quality. The quality of the studies was assessed using the SEQUES (11) tool; this allows the reader to easily compare the total score with max possible score of 48 points to gain a impression of the study quality.

One of the key features of the study included the heterogeneity of the literature with respect to patient characteristics, type of implant, surgical procedures, outcome measures, follow up times and the lack of an independent evaluator. These factors, combined with the absence of any comparison groups (ORIF/excision/implant designs), limited our ability to perform any meta-analyses that would explain any observed pattern of results or sources of disagreements between the findings. As a result, we were unable to assess superiority of any implant design, surgical technique or post-operative rehabilitation protocol over another. Although we are aware of the word limitations imposed by many peer reviewed journals, the key data elements (methodology, baseline patient information, performance &/or self report outcome measures, radiological outcome and complications) were not reported in a few studies, either in the original article or in the appendix. We did not make any attempt to contact the authors to retrieve any additional information that might be missing in the original article.

Despite the fact that range of motion and strength (isometric and grip) were reported in most of the studies, the style of reporting varied wherein actual value, percent loss or a range was given. Pain and level of satisfaction were not assessed using meticulous and validated methods. The fracture classification system varied and so did the definition of radiographic variables. When the authors used a self-report measure to assess the impact of the surgery on the functional status of the patient, the inability to standardise the categorical rating limited the comparison of outcomes (i.e. good in one was excellent in another) across different studies.

Only a handful of studies collected data prospectively and reported the results at more than one time point. Only one study included multivariate analyses (25) as a result of which the interaction between the patient characteristics and the outcome of the surgery could not be evaluated. Uncertainty persists with respect to the impact of particular factors that may have led to improvement in the post-operative outcome. Similarly, the morbidity and complications data were occasionally reported but these were rarely attributed to any specific patient characteristic.

Also, at present the estimated failure rate of RHAP is very imprecise. Due to lack of standardized reporting of complications and revision rates, it was possible that some complications might have been missed as the care may have occurred at a different centre. However, RHAP is mostly performed in specialized hand centres so this source of error is likely very small. Without regular follow up not all complications or implant failures may be detected; further not all unsatisfied patients undergo revision surgeries. Data on missing patients was reported in very few studies and when reported, its effects or reasons were not given. These factors could contribute to the under-estimation of the rate of failure. Failure is also time dependent and considering the mean follow up of 3.9 years in this review, the results have to be approached with caution.

Overall, the scientific quality of evidence was found to be weak to support the superior outcomes of RHAP with any specific implant for particular patients. However, this study significantly adds to the evidence by appraising the available studies and providing approximate estimates of prognosis. It highlights the shortage of well designed prospective, randomised, multi-centric trials and the need for better reporting standards in radial head arthroplasty.

Future trials must involve meticulously planned studies with prospective, multi-centric data collection using validated outcome measures. Efforts must be made to minimize patient attrition and to follow all the patients enrolled in the beginning of the trial. Authors must pay particular attention to include surgical and implant details along with patient's baseline characteristics including the co-morbidities, occupational and education level and socioeconomic status. An independent evaluator/s must be trained to collect the data, even if it is across different settings. Loss to follow up information must be reported along with suitable analyses to account for its effect. Statistical analyses must be conducted with sufficient power to examine the effect of patient characteristics on the outcomes of radial head arthroplasty.

Conclusion

Given the lack of high quality studies on outcomes of metal radial head arthroplasty, it is ambitious to make any definitive conclusions. However, the available evidence suggests that RHAP may be a reasonable treatment option for patients with complex radial head fractures in short to mid-term follow up.

References

1. Monica JT, Mudgal CS. Radial head arthroplasty. Hand Clin. 2010 vii; Aug;26(3):403-10. doi:10.1016/j.hcl.2010.04.008

2. van Riet RP, van Glabbeek F. History of radial head prosthesis in traumatology. Acta Orthop Belg. 2007 Feb;73(1):12-20.

3. Maghen Y, Leo AJ, Hsu JW, Hausman MR. Is a silastic radial head still a reasonable option?. Clinical Orthopaedics & Related Research. 2011 Apr;469(4):1061-70. doi: 10.1007/s11999-010-1672-2

4. Swanson AB, Jaeger SH, La Rochelle D. Comminuted fractures of the radial head. the role of silicone-implant replacement arthroplasty. J Bone Joint Surg Am. 1981 Sep;63(7):1039-49.

5. Morrey BF, Askew L, Chao EY. Silastic prosthetic replacement for the radial head. J Bone Joint Surg Am. 1981 Mar;63(3):454-8.

6. Vanderwilde RS, Morrey BF, Melberg MW, Vinh TN. Inflammatory arthritis after failure of silicone rubber replacement of the radial head. J Bone Joint Surg Br. 1994 Jan;76(1):78-81.

7. Trepman E, Ewald FC. Early failure of silicone radial head implants in the rheumatoid elbow. A complication of silicone radial head implant arthroplasty. J Arthroplasty. 1991 Mar;6(1):59-65.

8. Gordon M, Bullough PG. Synovial and osseous inflammation in failed silicone-rubber prostheses. J Bone Joint Surg Am. 1982 Apr;64(4):574-80.

9. Worsing RA,Jr, Engber WD, Lange TA. Reactive synovitis from particulate silastic. J Bone Joint Surg Am. 1982 Apr;64(4):581-5.

10. Moon JG, Southgate RD, Fitzsimmons JS, O'Driscoll SW. Arthroscopic removal of the failed silicone radial head prosthesis. Knee Surgery, Sports Traumatology, Arthroscopy. 2009 Oct;17(10):1243-8. doi: 10.1007/s00167-009-0796-y

11. Muller M, Tsui D, Schnurr R, Biddulph-Deisroth L, Hard J, MacDermid JC. Effectiveness of hand therapy interventions in primary management of carpal tunnel syndrome: A systematic review. Journal of Hand Therapy. 2004 0;17(2):210-28. doi:10.1197/j.jht.2004.02.009

12. Sackett DL, Rosenberg WMC. On the need for evidence-based medicine. J Public Health Med. 1995;17(3):330-4.

13. Celli A, Modena F, Celli L. The acute bipolar radial head replacement for isolated unreconstructable fractures of the radial head. Musculoskeletal Surgery. 2010 May;94(Suppl 1):S3-9. doi: 10.1007/s12306-010-0062-y

14. Dotzis A, Cochu G, Mabit C, Charissoux JL, Arnaud JP. Comminuted fractures of the radial head treated by the judet floating radial head prosthesis. J Bone Joint Surg Br. 2006 Jun;88(6):760-4. doi: 10.1302/0301-620X.88B6.17415

15. Burkhart KJ, Mattyasovszky SG, Runkel M, Schwarz C, Kuchle R, Hessmann MH, et al. Mid- to long-term results after bipolar radial head arthroplasty. Journal of Shoulder & Elbow Surgery. 2010 Oct;19(7):965-72. doi:10.1016/j.jse.2010.05.022

16. Judet T, Garreau de Loubresse C, Piriou P, Charnley G. A floating prosthesis for radial-head fractures. J Bone Joint Surg Br. 1996 Mar;78(2):244-9.

17. Knight DJ, Rymaszewski LA, Amis AA, Miller JH. Primary replacement of the fractured radial head with a metal prosthesis. J Bone Joint Surg Br. 1993 Jul;75(4):572-6.

18. Brinkman JM, Rahusen FT, de Vos MJ, Eygendaal D. Treatment of sequelae of radial head fractures with a bipolar radial head prosthesis: Good outcome after 1-4 years follow-up in 11 patients. Acta Orthop. 2005 Dec;76(6):867-72. doi:10.1080/17453670510045516

19. Muhm M, Castro R, Winkler H. Radial head arthroplasty with an uncemented modular metallic radial head prosthesis: Short- and mid-term results. Eur J Trauma Emerg Surg. 2011;37(1):85-95. doi: 10.1007/s00068-010-0051-8

20. Popovic N, Lemaire R, Georis P, Gillet P. Midterm results with a bipolar radial head prosthesis: Radiographic evidence of loosening at the bone-cement interface. J Bone Joint Surg Am. 2007 Nov;89(11):2469-76. doi: 10.2106/JBJS.F.00723

21. Smets S, Govaers K, Jansen N, Van Riet R, Schaap M, Van Glabbeek F. The floating radial head prosthesis for comminuted radial head fractures: A multicentric study. Acta Orthop Belg. 2000 Oct;66(4):353-8.

22. Wretenberg P, Ericson A, Stark A. Radial head prosthesis after fracture of radial head with associated elbow instability. Arch Orthop Trauma Surg. 2006;126(3):145-9. doi: 10.1007/s00402-005-0032-2

23. Chapman CB, Su BW, Sinicropi SM, Bruno R, Strauch RJ, Rosenwasser MP. Vitallium radial head prosthesis for acute and chronic elbow fractures and fracture-dislocations involving the radial head. J Shoulder Elbow Surg. 2006 Jul-Aug;15(4):463-73. doi:10.1016/j.jse.2005.09.010

24. Doornberg JN, Parisien R, van Duijn PJ, Ring D. Radial head arthroplasty with a modular metal spacer to treat acute traumatic elbow instability. J Bone Joint Surg Am. 2007 May;89(5):1075-80. doi: 10.2106/JBJS.E.01340

25. Grewal R, MacDermid JC, Faber KJ, Drosdowech DS, King GJW. Comminuted radial head fractures treated with a modular metallic radial head ArthroplastyStudy of outcomes. The Journal of Bone & Joint Surgery. 2006 Oct;88(1):2192-200. doi: 10.2106/JBJS.E.00962

26. Harrington IJ, Sekyi-Otu A, Barrington TW, Evans DC, Tuli V. The functional outcome with metallic radial head implants in the treatment of unstable elbow fractures: A long-term review. J Trauma. 2001 Jan;50(1):46-52.

27. Moro JK, Werier J, MacDermid JC, Patterson SD, King GJ. Arthroplasty with a metal radial head for unreconstructible fractures of the radial head. J Bone Joint Surg Am. 2001 Aug;83-A(8):1201-11.

28. Shore BJ, Mozzon JB, MacDermid JC, Faber KJ, King GJ. Chronic posttraumatic elbow disorders treated with metallic radial head arthroplasty. Journal of Bone & Joint Surgery - American Volume. 2008 Feb;90(2):271-80. doi: 10.2106/JBJS.F.01535

29. Lim YJ, Chan BK. Short-term to medium-term outcomes of cemented vitallium radial head prostheses after early excision for radial head fractures. J Shoulder Elbow Surg. 2008 Mar-Apr;17(2):307-12. doi:10.1016/j.jse.2007.07.020

30. Chien HY, Chen AC, Huang JW, Cheng CY, Hsu KY. Short- to medium-term outcomes of radial head replacement arthroplasty in posttraumatic unstable elbows: 20 to 70 months follow-up. Chang Gung Med J. 2010 Nov-Dec;33(6):668-78.

31. Zhao J, Yang S, Hu Y. The early outcomes with titanium radial head implants in the treatment of radial head comminuted fractures. J Huazhong Univ Sci Technolog Med Sci. 2007 Dec;27(6):681-3. doi: 10.1007/s11596-007-0616-x

32. Ashwood N, Bain GI, Unni R. Management of mason type-III radial head fractures with a titanium prosthesis, ligament repair, and early mobilization. J Bone Joint Surg Am. 2004 Feb;86-A(2):274-80. ISSN: 00219355

33. Zunkiewicz MR, Clemente JS, Miller MC, Baratz ME, Wysocki RW, Cohen MS. Radial head replacement with a bipolar system: A minimum 2-year follow-up. J Shoulder Elbow Surg. 2012 Jan;21(1):98-104. doi:10.1016/j.jse.2011.05.012

34. van Riet RPPHD, Morrey BF, O'Driscoll SWPHD, Van Glabbeek FPHD. Associated injuries complicating radial head fractures: A demographic study. Clinical Orthopaedics & Related Research. 2005 December;441:351-5. doi: 10.1097/01.blo.0000180606.30981.78

35. Smith MV, Calfee RP, Baumgarten KM, Brophy RH, Wright RW. Upper extremity-specific measures of disability and outcomes in orthopaedic surgery. J Bone Joint Surg Am. 2012 Feb 1;94(3):277-85. doi: 10.2106/JBJS.J.01744

36. Broberg MA, Morrey BF. Results of delayed excision of the radial head after fracture. J Bone Joint Surg Am. 1986 Jun;68(5):669-74.

37. Dowrick AS, Gabbe BJ, Williamson OD, Cameron PA. Outcome instruments for the assessment of the upper extremity following trauma: A review. Injury. 2005;36(4):468-76. doi:10.1016/j.injury.2004.06.014

38. Research Committee,American Shoulder and Elbow Surgeons, King GJW, Richards RR, Zuckerman JD, Blasier R, Dillman C, et al. A standardized method for assessment of elbow function. Journal of Shoulder and Elbow Surgery. 1999;8(4):351-4.

39. MacDermid JC. Outcome evaluation in patients with elbow pathology: Issues in instrument development and evaluation. Journal of Hand Therapy. 2001 200104/06;14(2):105-14.

40. MacDermid JC, Michlovitz SL. Examination of the elbow: Linking diagnosis, prognosis, and outcomes as a framework for maximizing therapy interventions. J Hand Ther. 2006 Apr-Jun;19(2):82-97. doi:10.1197/j.jht.2006.02.018

41. Hudak PL, Amadio PC, Bombardier C, Beaton D, Cole D, Davis A, et al. Development of an upper extremity outcome measure: The DASH (disabilities of the arm, shoulder, and head). Am J Ind Med. 1996;29(6):602-8.

42. Ware JE,Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. conceptual framework and item selection. Med Care. 1992 Jun;30(6):473-83.

43. Turchin DC, Beaton DE, Richards RR.Validity of observer-based aggregate scoring systems as descriptors of elbow pain, function, and disability. The Journal of Bone & Joint Surgery. 1998 February 1;80(2):154-62.

44. van Riet RP, Van Glabbeek F, Baumfeld JA, Neale PG, Morrey BF, O'Driscoll SW, et al. The effect of the orientation of the radial head on the kinematics of the ulnohumeral joint and force transmission through the radiocapitellar joint. Clin Biomech. 2006 7;21(6):554-9. doi:10.1016/j.clinbiomech.2006.01.006

45. Van Riet RP, Van Glabbeek F, Verborgt O, Gielen J. Capitellar erosion caused by a metal radial head prosthesis. A case report. J Bone Joint Surg Am. 2004 May;86-A(5):1061-4. ISSN 00219355

46. Petscavage JM, Ha AS, Chew FS. Radiologic review of total elbow, radial head, and capitellar resurfacing arthroplasty. Radiographics. 2012 Jan;32(1):129-49. doi 10.1148/rg.321105733

47. Ring D. Displaced, unstable fractures of the radial head: Fixation vs. replacement--what is the evidence? Injury. 2008 Dec;39(12):1329-37. doi:10.1016/j.injury.2008.04.011

48. Kaas L, van Riet RP, Vroemen JP, Eygendaal D. The incidence of associated fractures of the upper limb in fractures of the radial head. Strategies Trauma Limb Reconstr. 2008 Sep;3(2):71-4 doi: 10.1007/s11751-008-0038-8

Table 1- Summary of study and patient characteristics

Author	Publication year	Prosthesis	Years of investigation	Duration of follow up in months	No. of Radial heads	Age (years)	Gender	
							Male	Female
Ashwood et al.	2004	Titanium	1996-2001	33.6 (14.4 - 51.6)	16	45 (21-72)	8	8
Brinkman et al.	2005	Judet	1999-2003	24 (12 - 48)	11	43 (26-61)	8	3
Burkhart et al.	2010	Judet	1997-2001	106 (78 - 139)	17	44.1 (25-60)	14	3
Celli et al.	2010	Judet	2000-2007	41.7 (12.3 - 86.3)	16	46.1 (27-74)	11	5
Chapman et al.	2006	Vitallium	1996-2000	A- 30(24-44) D- 37(23-51)	A- 8 D- 8	A- 50 (19-83) D- 50 (40-82)	A- 5 D- 4	A- 3 D- 4
Chien et al.	2010	EVOLVE	2002-2008	38.3 (20-70)	13	37 (16-63)	9	4
Doornberg et al.	2007	EVOLVE	NA	40 (24-55)	27	52 (22-71)	13	14
Dotzis et al.	2006	Judet	1992-2003	63 (12- 144)	14	44.8 (18-85)	10	4
Grewal et al.	2006	EVOLVE	1999-2003	24.5 (12-48)	26	54 (31-80)	9	17
Harrington et al.	2000	Titanium	1961 - 1990	145.2 (72-348)	20	46 (21-75)	7	13
Judet et al.	1996	Judet	1988- 1995	A- 49(24-65) D- 43(24-72)	12	A- 43.4 (25-63) D- 32.7 (18-54)	A- 2 D - 4	A - 3 D- 3
Knight et al.	1993	Vitallium	NA	54 (24- 96)	31	57 (21-83)	12	19
Lim et al.	2008	Vitallium	2001-2005	29.7(13-54)	6	53.3 (21-75)	2	4
Moro et al.	2001	Titanium	NA	39 (26-58)	25	54 (27-84)	11	13
Muhm et al	2011	EVOLVE	2001-2009	ST- 19.2 (12-27) MT- 61.2 (36-86)	ST- 10 MT- 15	ST- 58 (22-81) MT- 59.5 (39-84)	ST- 4 MT- 8	ST- 6 MT- 7

Popovic et al.	2000	Judet	1994-1996	32 (24-56)	11	52.7 (22-68)	6	5
Shore et al.	2008	Titanium/EVOLVE	1993-2004	96 (24-168)	32	54.1 (32-93)	13	19
Smets et al.	2000	Judet	1995-1999	25.2 (5-48)	15	46.4 (20-64)	6	9
Wretenberg et al.	2006	Link	1994-200	44.4 (12- 84)	18	52 (29-82)	11	7
Zhao et al.	2007	Titanium	2003-2004	23.7(18-31)	10	38 (26-54)	8	2
Zunkiewicz et al.	2012	Katalyst	2004-2006	34 (24-48)	30	NA	NA	NA
Total				47.2 ± 29.8 (95% CI, 34.7 - 59.8)	391	48.4 ± 6.9 (95%CI, 45.4 - 51.4)	185	175
				Range: 19.2-145.2			M:F = 1.05:1	

Table 1, Abbreviations: A, acute group; D, Delayed group; ST, short term group; MT, Mid term group; NA, not available; CI, confidence intervals; M, male; F, female

Table 2: Study quality of the included studies based on SEQES criteria

Author	Study Q.	Study Design							Subjects				Intervention			Outcomes			Analysis					Reco.	Total	% of Total score
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24		
Ashwood et al.	1	0	0	0	0	1	1	1	1	1	1	2	2	1	0	1	1	1	0	0	0	1	1	1	18	37.5
Brinkman et al.	1	0	1	1	0	1	1	2	1	1	1	2	2	1	0	1	1	1	0	0	0	1	1	2	22	45.8
Burkhart et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	1	1	1	0	1	2	2	23	47.9
Celli et al.	1	0	0	0	0	1	1	2	1	1	1	2	1	1	0	2	1	1	1	0	0	1	2	2	22	45.8
Chapman et al.	2	0	0	0	0	1	1	0	1	1	2	2	2	1	0	2	1	2	2	1	1	1	2	2	27	56.3
Chien et al.	1	0	0	0	0	1	1	0	1	2	1	2	2	1	0	1	1	1	0	0	0	1	1	2	19	39.6
Doornberg et al.	1	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	1	0	0	0	1	2	2	20	41.7
Dotzis et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	0	0	0	0	1	2	2	20	41.7
Grewal et al.	2	0	2	2	0	1	1	2	1	2	2	2	2	2	0	2	1	2	2	2	2	1	2	2	37	77.1
Harrington et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	1	1	1	0	0	0	1	2	2	20	41.7
Judet et al.	2	1	1	0	0	1	1	0	1	1	1	2	1	1	0	1	1	1	0	0	0	1	2	1	20	41.7
Knight et al.	2	0	0	1	0	1	1	0	1	1	2	2	2	1	0	1	0	1	0	1	0	1	2	2	22	45.8
Lim et al.	2	0	0	0	0	1	1	0	1	1	2	2	2	1	0	2	1	1	0	0	0	1	2	2	22	45.8
Moro et al.	2	0	0	0	0	1	1	2	1	1	2	2	2	1	0	2	1	1	2	2	2	1	2	2	30	62.5
Muhm et al.	1	0	0	0	0	1	1	0	1	2	2	2	2	1	0	2	1	0	2	2	2	1	2	2	27	56.3
Popovic et al.	2	0	2	2	0	1	1	0	1	1	2	2	2	1	0	2	1	1	0	0	0	1	2	2	26	54.2
Shore et al.	2	0	0	0	0	1	1	0	1	2	2	2	2	1	0	2	1	1	2	2	1	1	2	2	28	58.3

Smets et al.	2	0	0	0	0	1	1	0	1	1	1	2	1	1	0	1	1	1	0	0	0	1	1	1	17	35.4
Wretenberg et al.	1	0	0	0	0	1	1	0	1	2	1	2	1	1	0	1	1	1	0	0	0	0	1	2	17	35.4
Zhao et al.	1	0	0	0	0	1	1	0	1	1	1	2	2	1	0	1	1	1	0	0	0	1	2	1	18	37.5
Zunkiewicz et al.	2	0	0	2	0	1	1	2	1	2	2	2	2	1	0	2	1	1	2	1	1	0	2	2	30	62.5

Abbreviations: Reco., Recommendations

Table 3: Elbow range of motion

Implant	Range of motion			
	Flexion	Extension	Pronation	Supination
Vitallium	143.3± 10.8 (139.9-146.5)	18.2 ± 4.1 (16.9-19.4)	70.9 ± 12.1 (67.3-74.5)	72.1 ± 9.2 (69.4 - 74.9)
Titanium	137.9 ± 11.3 (135.2-140.7)	17.8± 9.6 (15.1–20.5)	77.4 ± 2.18 (76.8-77.9)	71.4 ± 5.7 (70 - 72.8)
Judet	131.54 ± 4.8 (130.5-132.58)	16.2± 3.3 (15.3-17.1)	72.4 ± 10.6 (70.1 - 74.7)	74.0 ± 10.9 (71.6 - 76.3)
EVOLVE	129.3 ± 5.7 (128.3-130.4)	17.2± 5.9 (16.1-18.4)	70.6 ± 5.1 (69.7 - 71.6)	62.7 ± 8.3 (61.2 - 64.3)
Katalyst	126	NA	69	74
Link	125	NA	80	75

(Values given are weighted means as per the sample size; values in bracket indicate 95% confidence interval)

Abbreviations: NA, not available

Table 4: Elbow strength

Author	Prosthesis	Strength Parameter	Measured	Impairment
Ashwood et al.	Titanium	Grip Strength	Jamar Dynamomter	Reduced by 12%
Harrington et al.		Grip Strength	Dynamometer	Reduced by 10%
		Isometric strength	NA	Flexion by 10%
				Extension by 13%
				Pronation by 13%
				Supination by 19%
Moro et al.		Grip Strength	NK hand Evaluation System	Reduced by 18%
Zhao et al.		Isometric strength	LIDO work set	Pronation by 17%
				Supination by 18%
Shore et al.		Grip Strength	NK hand Evaluation System	Significantly reduced
		Isometric Strength	LIDO work set	Significantly reduced
Burkhart et al.	Judet	Grip Strength	Jamar Dynamomter	Reduced by 8%
Dotzis et al.		Grip Strength	Jamar Dynamomter	Reduced by 10%
Popovic et al.		Isometric strength	Simple tensiometer	Mild loss (25% of patients)
Lim et al.	Vitallium	Grip Strength		Reduced by 10% .only significant in 2 patients -57% and 75%
Grewal et al.	EVOLVE	Grip Strength	NK hand Evaluation System	14%
		Isometric strength	LIDO work set	Flexion by 20%
				Extension by 19%
				Pronation by 22%
				Supination by 28%
Muhm et al.		Grip strength	Jamar Dynamomter	Reduced by 15%
Shore et al.		Grip Strength	NK hand Evaluation System	Significantly reduced
		Isometric strength	LIDO work set	Significantly reduced

Abbreviations: NA, not available

Table 5: Patient reported functional outcome post RHAP

Author	Follow up (in months)	Outcome measure	Mean Score	Excellent	Good	Fair	Poor
Ashwood et al.	33.6 (14.4 - 51.6)	Mayo Elbow Performance Index Weighted mean = 85.8±4.1 (95%CI, 85.3-86.3)	87 (65-100)	50%	31.3%	18.8%	0
Burkhart et al.	106 (78 - 139)		90.83 (74-100)	35.3%	58.8%	5.9%	
Celli et al.	41.7 (12.3 - 86.3)		89.4(50-100)	75%	12.5%		12.5%
Chapman et al.	A- 30(24-44) D- 37(23-51)		A - 90 ±11.02(75-100) D - 83.75±11.88 (60-100)	A- 50% D- 25%	A- 50% D- 62.5%		D- 12.5%
Chien et al.	38.3 (20-70)		86.92±13.77 (60-100)	61.5%	23.1%	15.9%	
Doornberg et al.	40 (24-55)		85 (30-100)	48.2%	33.3%	11.1%	7.4%
Dotzis et al.	63 (12- 144)		NA	42.9%	28.6%	7.1%	7.1%
Grewal et al.	24.5 (12-48)		80.5±16.7 (9-100)	50%	16.6%	25%	8.3%
Moro et al.	39 (26-58)		80.36 ±16.4 (42-100)	24%	44%	20%	12%
Shore et al.	96 (24-168)		83±19 (32-100)	53.1%	12.5%	21.9%	12.5%
Smets et al.	25.2 (5-48)		85 ± 15.7 (50-100)	46.7%	20%	20%	13.3%
Zhao et al.	23.7(18-31)		NA	50%	40%	10%	
Zunkiewicz et al.	34 (24-48)		92.1 (65-100)				
Harrington et al.	145.2 (72-348)	Broberg and Morrey System Weighted mean = 85.6±3.3 (95%CI, 84.5-86.6)	88 (67-100)	60%	20%	10%	10%
Judet et al.	A- 49(24-65) D- 43(24-72)		NA	25%	58.33%	16.7%	
Lim et al.	29.7(13-54)		78.42±17.13(48.5-100)	16.7%	50%	16.7%	16.7%
Muhm et al.	ST- 19.2 (12-27) MT- 61.2 (36-86)		ST - 82.3 MT - 85.2	ST – 80% MT- 66.6%			
Popovic et al.	32 (24-56)		NA	36.4%	36.4%	18.2%	9.1%
Brinkman et al.	24 (12 - 48)	Elbow functional Assessment	NA	54.5%	45.5%		
		Andrew Elbow Score	NA	72.7%	27.3%		

Abbreviations: NA, not available; A, acute group; D, delayed group; ST, short term group; MT, midterm group

Table 6: Patient reported functional outcome- DASH

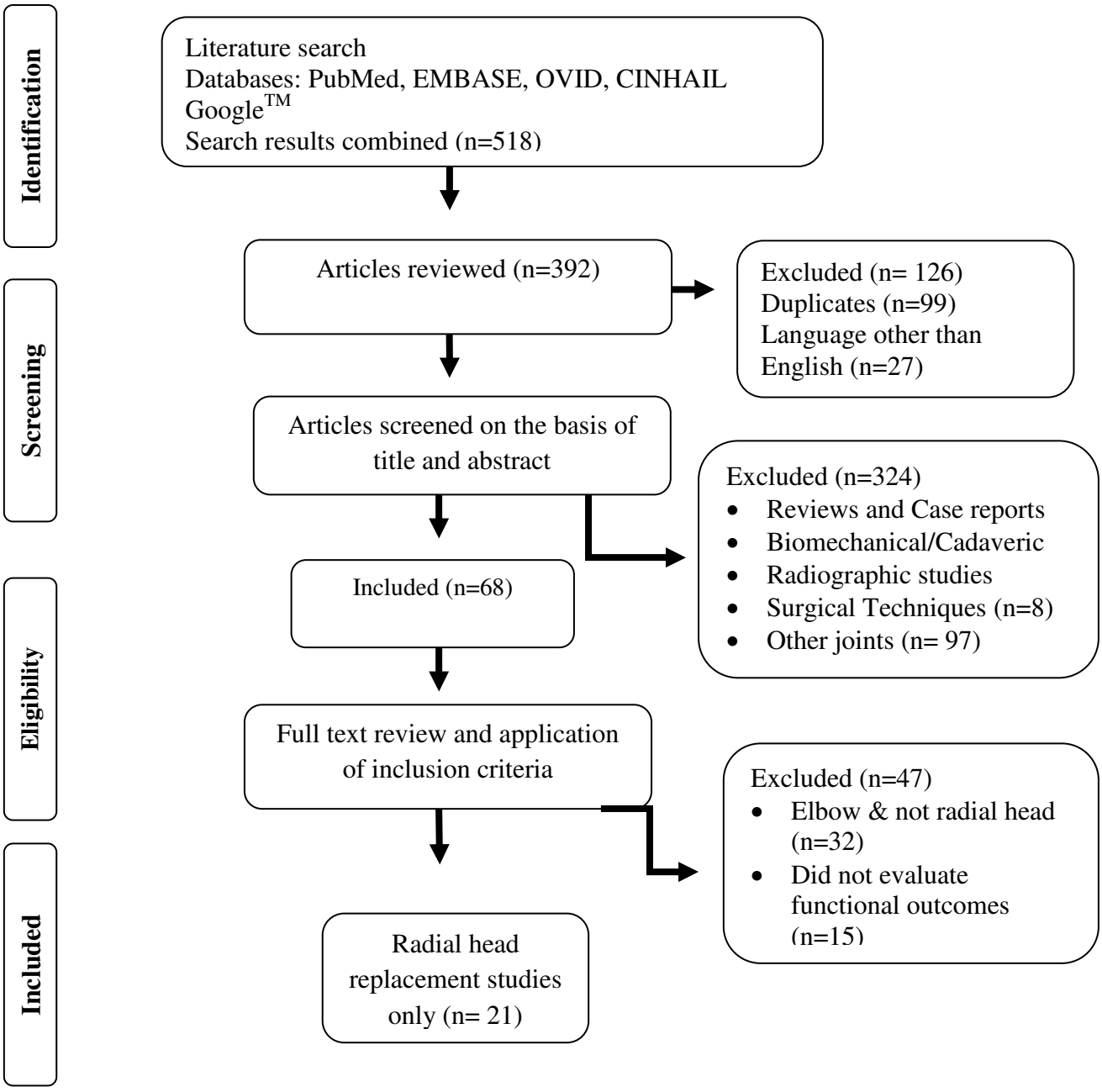
Author	Prosthesis	Mean Dash Score
Chapman et al.	Vitallium	A - 24.18 ± 22.02(5.8-71) D- 30.58 ±20.28 (12.5-75)
Lim et al.		13.62 ± 5.56 (0-65)
Burkhart et al.	Judet	9.8(0-34)
Celli et al.		11.4(0-36.61)
Dotzis et al.		23.9 (0-65.8)
Doornberg et al.	EVOLVE	17(0-82)
Grewal et al.		24.4 ± 21.4 (0-59.2)
Muhm et al.		ST- 27.8 MT- 24.9
Zunkiewicz et al.	Katalyst	13.8 (0-52.5)
Overall	Weighted mean = 18.1 ± 5.9 (95%CI, 17.1 – 18.9)	

Abbreviations: A, acute group; D, delayed group; ST, short term group; MT, midterm group; CI, confidence interval

Table 7: Complications post Radial head arthroplasty

Prosthesis	Removal of Implant	Revision surgery related to implant	Neurologic complications	Periprosthetic lucency	Heterotrophic Ossification	Degenerative changes	Capitellar erosion	Complex regional pain syndrome
Titanium	4 (5.88%)	0 (0%)	4 (5.88%)	34 (50.00%)	17 (25.0%)	14 (20.58%)	18 (26.47%)	2 (2.94%)
Judet	0 (0%)	3 (3.12%)	3 (3.12%)	1 (1.04%)	18 (18.75%)	13 (13.54%)	6 (6.25%)	1 (1.04%)
Vitallium	2 (3.77%)	2(3.77%)	4 (7.55%)	14 (26.42%)	4 (7.55%)	9 (16.98%)	5 (9.43%)	0 (0%)
EVOLVE	0 (0%)	1 (1.09%)	6 (6.59%)	51 (56.04%)	43 (47.25%)	39 (42.85%	18 (19.78%)	1 (1.09%)
Link	5 (27.78)	0 (0%)	0 (0%)	7 (38.89%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Katalyst	0 (0%)	2 (6.67%)	0 (0%)	24 (80%)	13 (43.33%)	22 (73.33%)	0 (0%)	0 (0%)
Overall Rate	11 (3.06%)	8 (2.22%)	17 (4.73%)	131 (36.49%)	95 (26.46%)	97 (27.02%)	47 (13.09%)	4 (1.11%)
Note that Shore et al. is not included in the above table due to confusion over EVOLVE and Titanium								

Figure 1: PRISMA flow diagram for study selection



CHAPTER 3: STUDY TWO

Acute post-operative pain predicts functional outcome post radial head arthroplasty

The following paper has been formatted for submission to Journal of Shoulder and Elbow Surgery.

Acute post-operative pain predicts functional outcome post radial head arthroplasty

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Abstract

Purpose

The purpose of this study was to explore the role of acute pain immediately after surgery in predicting chronic functional impairment (CFI) at 2 years post radial head arthroplasty (RHAP).

Methods
We examined acute post operative pain and functional status at 2 years in 59 patients aged 51.1 years (21-82 years) who underwent radial head arthroplasty (RHAP) with EVOLVE prosthesis. Pain was evaluated by American Shoulder and Elbow Surgeon- Elbow (ASES-e) pain subscale. The functional status at 2 years post surgery was assessed with Disability of Arm Shoulder and Hand questionnaire (DASH). Both the evaluations were conducted by an observer who was independent of surgical care. Regression analyses were conducted to explore the role of acute pain in the functional status at 2 years. Receiver operating curve (ROC) analyses were carried out to assess the discriminative power of acute pain in functional status at 2 years of RHAP.

Results
Acute pain post RHAP was found to be a significant predictor of functional status of 2 years post surgery. The ROC analyses showed that a cut off score of ≥32/50 on ASES-e pain subscale has fair predictive ability (area under the curve, 0.7) to determine the suboptimal outcome post RHAP.

Conclusion
Patients with ASES-e pain subscale score of ≥ 32/50 were found to be more likely to have chronic functional impairment at 2 years post RHAP. Prospective, multi-centric trials with large sample size are required to validate the findings in future.

Background

Radial head fractures (RHF) are the most commonly encountered type of elbow fractures (1). These fractures can occur in isolation or be coupled with other bony or ligamentous injuries (2,3). Radial head arthroplasty (RHAP) is indicated as the treatment of radial head or neck fractures when communition prohibits the stable internal fixation of an unstable forearm or elbow (4). Radial head resection has been proposed as alternate management option for communited RHF; however, it may be associated with delayed complications including reduced strength, persistent pain and instability, increased ulnar variance, and ulnohumeral osteoarthrosis (4-7). Moreover, when lateral ulnar collateral ligament complex injury and possible interosseous membrane injury is suspected, radial head excision is at best avoided (4). In such scenario, RHAP is a reliable management option to restore radiocapitellar contact, which serves as an important stabilizer of elbow and forearm articulations (4,8).

When clinicians and patients need to make decisions about different orthopedic surgery options, prognosis for functional recovery is an important element of the informed consent and shared decision-making process. Many patients who undergo RHAP recover without any complications and resume their normal daily activities within weeks of surgery (9). However, chronic functional impairment (CFI) develops in a striking proportion of patients (10). Clinicians would prefer to identify factors that contribute to greater long-term functional impairment so that they might provide a more accurate prognosis; and in some cases alter the management plan. The ability to do this accurately is limited by the nature of the existing evidence which mainly includes small samples and short to mid-term follow-up.

It is a well known fact that chronic pain is one of the most common reasons for seeking medical attention (11). However, CFI may manifest itself in the form of modifications of task/environment to continue the activities of daily living and hence medical attention is not sought until it is seriously disabling. In the long term, CFI can lead to depression, catastrophizing, reduced self esteem and efficacy, and lost hours of work (12-16) all adding up to increased financial burden on the healthcare and the nation's economy. Therefore, early identification is an important component to management.

Previous studies have identified that age (17), income (17), educational level (18), co-morbidity (18-20) and extent of initial injury (21) are associated with an increased risk of poor functional outcomes post upper limb surgeries. These factors are beyond the control of patient or the healthcare professional. Therefore, they can be used to provide a more accurate prognosis; but are not modifiable as a means of reducing the risk. Acute post operative pain has been proposed as one of the factors that are predictive of chronic pain and disability post surgery (22-24). Acute post operative pain can be assessed in the immediate post operative period when the patient is still in the recovery phase with the help of self report measures. This provides a window of opportunity to alter the management plan and potentially improve outcomes.

The purpose of this study was to explore extent to which acute post surgical pain is predictive of development of CFI in patients with RHAP. We hypothesized that acute pain immediately after RHAP surgery will be able to predict CFI at 2 years post RHAP. Our

secondary purpose was to determine a cut-off score for acute pain that will help us in classifying the patients into high and low risk groups for developing CFI post RHAP at two years.

Methodology

Subjects

A cohort of patients with unreconstructible, communited fracture of radial head treated with EVOLVE metal prosthesis (EVOLVE; Wright Medical Technology, Arlington, Tennessee) from the Hand and Upper Limb Centre (HULC), London, Ontario, Canada between June 2000 and April 2010 were prospectively enrolled. All the participants were skeletally mature and presented with traumatic, acute complex RHF and associated elbow injuries. Patients with RHF that was more than 4 weeks old were excluded, along with patients in whom RHAP was being performed as a secondary or salvage procedure. Subsequent to the surgery, all the patients underwent a tailor made post-operative rehabilitation program supervised by a hand therapist.

Patients completed a baseline questionnaire that included information regarding age, gender, educational and occupational status, co-morbidities and self report questionnaires immediately after surgery and at 2 years. All the assessments were administered by an independent evaluator. Ethics approval for the study was obtained from the institutional review board.

Assessment of functional status

The Disability of Arm, Shoulder and Hand (DASH) (30) questionnaire (Appendix 3) was used to measure region-specific disability in the study. DASH is the most commonly used composite function evaluation tool in patients with upper extremity musculoskeletal conditions and has been repeatedly included in the assessment of elbow injury patients. It consists of 30 core questions of which 21 assess difficulty with specific tasks, 5 assess symptoms and one each assess social function, work function, sleep and confidence (26,31). Each item is scored in a 5 point numeric rating scale where 1 corresponds to no difficulty, 2 to mild difficulty, 3 to moderate difficulty, 4 to severe difficulty and 5 to unable to perform the task (31,32). The cumulative DASH score is from 0 to 100 where 0 indicates lower disability (33). The validity of DASH in patients with elbow injuries has been examined in the literature (33,34). The test retest reliability of DASH has shown to be exceptionally high (ICC=0.92) for elbow disorders (35).

Pain assessment

We used pain subscale of American Shoulder and Elbow Surgeons Elbow Evaluation instrument (ASES-e) (25) (Appendix 4) to determine the influence of pain on the patient's activities of daily living. The patients rated their pain intensity on five items, 1) when is it at worst, 2) at rest, 3) lifting a heavy object, 4) when doing a task with repeated elbow movements and 5) at night on a 0-10 numeric rating scale where 0 stands for no pain and 10 for worst pain ever. These responses were then added for a total pain score ranging from 0-50 where higher score indicates higher pain (26-29). The ASES-e pain subscale was chosen because it provided an estimate of the pain intensity along with its influence on the elbow function (27). Also, it is easy to administer and requires minimal training (28). The pain subscale has been found to have good construct validity and reliability although minimal clinically important difference has not yet been reported in literature (28,29)

Included variables

We included participants who were followed up for minimum of 2 years from surgery and had no missing data. We extracted data concerning demographics, ASES-e pain subscale score at baseline and DASH score at two years for all the included patients. Previous studies have identify poor functional outcomes of RHAP being related to age (36) and the arm injury being a related to worker's compensation board (WCB) claim (37). Hence, we chose to include these two variables in addition to acute post surgical pain in our analyses.

Statistical Analysis

Descriptive statistics were calculated for all independent variables and DASH at 2 years. Bivariate relationships were calculated between the baseline variables and two year DASH score. The independent variables included, (1) baseline ASES pain score, (2) age, and (3) if the injury to the affected arm was related to work place accident and the patient has WCB claim for the injury. The dependent variable was the total score of DASH at 2 years of RHAP. Pearson's correlation coefficients were used to determine the relationship between age, baseline ASES pain score and WCB status.

The ability of the independent variables to predict the dependent variable was determined using regression. Stepwise regression models were built sequentially was used to test the effect of variables the 2 yr DASH score. The first model included only age. The second included age and WCB status. In the final model, baseline ASES pain score was added to the second model. With each progressive model in regression analyses, the significance of change in the resultant R^2 value was analysed with F-test.

A suboptimal outcome on the DASH score was defined as ≥20/100 at 2 years follow up. There have been no reports of the optimal cut off for poor outcome on DASH post RHAP but the DASH score ranging from 11-17/100 has been defined normative value for the population with upper limb injuries (38,39). Previous studies have used DASH score of 20 to signify functional impairment post distal radial fractures (40). Hence, we chose 20/100 as the cut off for optimal outcome of DASH. This would mean that any patient with a score of DASH ≥20/100 would signify that functional impairment being present. A receiver operating curve (ROC) analyses was used to determine the optimal cut-off of the ASES pain score that best differentiated good versus suboptimal functional outcome in RHAP as determined by the dichotomized DASH rating (i.e. ≥20/100). The optimal cut-off value was defined as the ASES pain score that jointly maximized sensitivity and specificity for predicting the 2-year DASH score.

Positive and negative likelihood ratios were calculated based on the cut off score. The area under the curve (AUC) value was used to determine the accuracy of the acute post surgical pain in predicting the function. The AUC value was interpreted as: AUC = 0.5 is no discrimination, 0.7≤ AUC <0.8 is acceptable discrimination, 0.8 ≤ AUC < 0.9 is excellent and AUC ≥ 0.9 is outstanding discrimination.

All the analyses were performed using SPSS software for Windows (v. 20.0; SPSS Inc., Chicago, IL, USA). An alpha level of 0.05 (two tailed) was used to determine significance.

Results

Data from a total of 59 patients who had complete data at baseline and at 2 year of follow up post RHAP were included in the study. The baseline characteristics of the patients are summarised in Table 1. None of the baseline variables exhibit is a bivariate association to the 2 year DASH score.

No significant correlations were found between any of the independent variables used in the regression analyses ($p>0.05$) (Table 2). The regression models that included age ($\beta= -0.198$, $p>0.05$) and WCB ($\beta= -0.190$, $p>0.05$) status were unable to explain or lacked predictability for the DASH score at 2 years. Inclusion of baseline pain levels caused a significant change ($p<0.001$) in the R^2 value of the predictor model for functional outcome at 2 year post radial head arthroplasty. The final model accounted for 24.4% of variance in the 2 year DASH score (Table 3)

The ROC curve demonstrating the sensitivity and specificity values for range of ASES-e pain scores for predicting CFI post RHAP at 2 years is illustrated in Figure 1. A score of 31.5/50 on ASES-e pain immediately post RHAP surgery had the best combination of sensitivity and specificity, i.e., 76% and 61% respectively. The area under the curve (AUC) was .70 (95% CI, 0.55-0.85) indicating that acute pain in the immediate post operative period was fairly predictive of CFI at two years of RHAP. The positive and negative predictive values were 0.45 (95% CI, 0.27 – 0.64) and 0.87 (95% CI, 0.68 – 0.96) respectively (Table 4).

Discussion

The results of this study indicate that a baseline pain measure can be fairly discriminative in differentiating those with/without chronic functional impairment at two years following RHAP. Patients who exceeded 32/50 on the ASES at baseline were 1.6 times more likely to have suboptimal outcomes. The results of this study are preliminary because the sample size is relatively small and this cut off would need to be cross validated in future studies.

We did not find that age or workers compensation status affected final DASH scores; whereas the addition of the baseline pain score contributed 24% ($R^2=0.244$, $p<0.001$) of variance in the final regression model. This could be interpreted to suggest that the effects of baseline pain are important; and not modified by age or workers compensation status. However, since 76% variability in functional outcomes was not explained in these models, clearly a variety of additional clinical and non-clinical factors must be contributing to the outcomes of surgery. Although the regression model is informative by itself, it may be simpler for clinicians to understand and communicate the relative risk associated with having high baseline pain. Hence the finding that relative risk allows for the clinicians to communicate to patients that if they exceed this threshold they are 1.6 times more likely to have functional problems at two years. In clinical practice, however, it is unclear whether this threshold could be used. Our study illustrates the importance of measuring pain using standardized scales early in the rehabilitation phase of the patients with RHAP.

Previous studies have examined the role of baseline (pre-operative) pain in predicting long term functional outcome post orthopedic surgeries. However, it has been primarily explored in surgeries done to relieve a long standing painful condition like total hip and knee replacements for severe osteoarthritis (41-45) or spinal surgeries to relieve chronic back pain and disability

(15,16). EEG and neurological studies have shown that in these patients, significant changes at neural, psychological and personal level have already occurred prior to the surgical procedure (24,46). These changes have been hypothesised to impact the subsequent outcome of the surgery. Nevertheless the relationship of acute post operative pain and chronic functional impairment in management of traumatic/emergency situations (e.g. fractures) has remained relatively uncertain.

Emerging evidence that early pain experiences in orthopedic surgery are predictive of future outcomes has increased interest in the potential mechanisms behind this finding. Associations merely indicate that two factors tend to occur together and it is unknown whether patients had a pre-existing risk that is reflected in their early postoperative pain ratings; or whether the pain experienced in the early postoperative period is contributing to the outcomes achieved. This is an important distinction since genetics may not be modifiable; but better pain control in the early postoperative period could be affected by clinical interventions. Preclinical studies have shown that genetic basis for neural changes that contribute to sensitization and remodelling of nervous system are altered within 20 minutes of injury (47). Inflammatory mediators are released which carry the nociceptive signals via spinal cord to thalamic, limbic and cortical structures of brain. It is here that the experience and memory of pain is coded (47-49). This process may contribute to the development of chronic pain and suboptimal functional outcomes following surgery. Poor outcomes have been reported in surgeries that last more 3 hours (14,50), low (versus high) volume surgical units (51,52), expertise of the surgeon (53,54) and suspected with intraoperative nerve damage (9,55). How these factors influence the poor outcomes post surgery is not known (54). However, considerable trauma due to initial injury and intra-operative injury, particularly intra-operative nerve damage might be the common element in the above given factors. Nerve damage leads to both acute and chronic modelling of the injured nerves, along with their intact neighbouring nerves, nociceptive pathways in the brain and spinal cord (9,56,57). These alterations might be the probable malefactor in the producing both chronic pain and impairment.

There is also an increasing interest in psychological variables as prognostic variables in predicting chronic functional impairment (58,59) in a variety of other orthopedic conditions. Various psychological prognostic factors have been reported in literature. These include elevated preoperative anxiety (60), less catastrophizing (61), solicitous responding (62,63), fear of surgery (9,14), personality type (59) and social support (64-66). Vlaeyen and Linton's fear avoidance model has been proposed to account for the above cognitive and behavioural manifestations post surgery (13). However, one of the major challenges in studying psychological factors and how they contribute to poor outcomes is that they may be pre-existing or manifest as a result of uncontrolled pain immediately after surgery. In such a scenario, it would be unfortunate to suggest that pre-existing psychological disposition occurs as this may become a situation of blaming the patient for their poor outcomes. Furthermore, it is difficult to have baseline psychological measures for patients that exist prior to the development of orthopedic problems or injuries to appropriately identify pre-existing verses resulting psychological characteristics. It is unclear to what extent these factors would be my modifiable regardless of whether they were pre-existing or not.

Regardless of the reasons for baseline pain being predictive of future outcomes the existence of association has been verified. At present this can be used for prognosis or early identification of patients who might be at risk of poor outcomes. However, clinicians must avoid

being overly prescriptive about this relationship since 76% of the contribution to poor outcomes remains unexplained. Further, since association is not indicative of causation is unclear whether elevated risk can be modified in the early postoperative period.

There are several components to our studies that increase our confidence in our findings. We used validated instruments for both pain and disability. DASH and ASES-e (26,38,67), both have demonstrated superior psychometric properties in this group of patients. The study design was prospective and as such baseline pain was recorded prior to any knowledge about the final functional outcomes; removing some sources of potential bias. Grewal et al. and colleagues (37) have demonstrated that most of the patients recover completely and resume their activities of daily living within 6-8 months post RHAP. Hence, by following patients for 2 years we are confident that we have represented their optimized functional outcomes. Long-term complications such as implant loosening, periprosthetic luceny or degenerative arthritis could alter the long-term functional outcomes following RHAP. Although it will be important to consider these complications, it was beyond the objectives of the study. Finally we considered potential confounding variables that were derived based on the literature pertaining to radial head arthroplasty (age, WCB status).

Our study also had limitations that should be considered when interpreting the findings. We only considered a limited scope of confounding variables and a number of other factors were not considered e.g. effects of the surgeon's skill, different implant designs, patient characteristics, etc. The sample size is relatively small and hence limited the number of predictors we could include in the multivariable regression modeling. The patients were recruited from a single center and the practice styles, patient characteristics and skills of surgeons might have had an effect on the associations, reducing the generalizability of our findings. Finally our decision to include patients who had complete follow-up may have affected our results since those who had incomplete data might have a different prognostic profile. However the characteristics of the patients with complete versus incomplete data were compared and it suggested that these patients did not differ significantly with respect to demographic variables.

The functional status of the patient was assessed based on the region-specific self report outcome measure (DASH). The DASH is designed as a uni-dimensional measure of upper extremity function (26). However, there have been debates about the dimensionality of the measure and it certainly is apparent that symptoms are included in the measure since a number of the items ask about pain or numbness/tingling (68). We chose to use DASH as it is the most commonly used measure in upper extremity disorders, but agree that a joint specific functional outcome measure might have been more accurate indication of the level of functioning. Furthermore, addition of a performance based test (FIT-HaNSA) (12) would have added an additional dimension to our understanding of functional outcomes.

Conclusion

Acute post operative pain is a significant determinant of the long term suboptimal functional outcome (≥20/100 on DASH) post radial head arthroplasty. A risk score of ≥32 out of 50 on ASES-e pain subscale can be implemented in the clinical practice to differentiate patients who are at high versus low risk of having chronic functional impairment post RHAP. Further longitudinal studies are required to validate these results in independent prospective cohorts and to investigate the clinical application of prognosis or early intervention.

References

(1) Pike JM, Athwal GS, Faber KJ, King GJ. Radial head fractures--an update. Journal of Hand Surgery - American Volume 2009 Mar;34(3):557-565.

(2) Mason ML. Some observations on fractures of the head of the radius with a review of one hundred cases. Br J Surg 1954 Sep;42(172):123-132.

(3) van Riet RPPHD, Morrey BF, O'Driscoll SWPHD, Van Glabbeek FPHD. Associated Injuries Complicating Radial Head Fractures: A Demographic Study. Clinical Orthopaedics & Related Research 2005 December;441:351-355.

(4) Monica JT, Mudgal CS. Radial head arthroplasty. Hand Clin 2010 vii; Aug;26(3):403-410.

(5) Ikeda M, Sugiyama K, Kang C, Takagaki T, Oka Y. Comminuted fractures of the radial head. Comparison of resection and internal fixation. J Bone Joint Surg Am 2005 Jan;87(1):76-84.

(6) Coleman DA, Blair WF, Shurr D. Resection of the radial head for fracture of the radial head. Long-term follow-up of seventeen cases. J Bone Joint Surg Am 1987 Mar;69(3):385-392.

(7) Herbertsson P, Josefsson PO, Hasserius R, Besjakov J, Nyqvist F, Karlsson MK. Fractures of the Radial Head and Neck Treated with Radial Head Excision. The Journal of Bone & Joint Surgery 2004 September 1;86(9):1925-1930.

(8) Ring D, Quintero J, Jupiter JB. Open Reduction and Internal Fixation of Fractures of the Radial Head. The Journal of Bone & Joint Surgery 2002 October 1;84(10):1811-1815.

(9) Katz J, Seltzer Z. Transition from acute to chronic postsurgical pain: risk factors and protective factors. Expert Rev Neurother 2009 May;9(5):723-744.

(10) Sindrup SH, Jensen TS. Efficacy of pharmacological treatments of neuropathic pain: an update and effect related to mechanism of drug action. Pain 1999 Dec;83(3):389-400.

(11) Gureje O, Von Korff M, Simon GE,Gater R. Persistent pain and well-being: A world health organization study in primary care. JAMA: The Journal of the American Medical Association 1998 July 8; 280:147-151.

(12) MacDermid JC, Ghobrial M, Quirion KB, St-Amour M, Tsui T, Humphreys D, et al. Validation of a new test that assesses functional performance of the upper extremity and neck (FIT-HaNSA) in patients with shoulder pathology. BMC Musculoskelet Disord 2007 May 17;8:42.

(13) Elfving B, Andersson T, Grooten WJ. Low levels of physical activity in back pain patients are associated with high levels of fear-avoidance beliefs and pain catastrophizing. Physiotherapy Research International 2007 March;12(1):14-24.

(14) Peters ML, Sommer M, de Rijke JM, Kessels F, Heineman E, Patijn J, et al. Somatic and Psychologic Predictors of Long-term Unfavorable Outcome After Surgical Intervention. Ann Surg 2007 March;245(3):487-494.

(15) Crook J, Milner R, Schultz IZ, Stringer B. Determinants of Occupational Disability Following a Low Back Injury: A Critical Review of the Literature. J Occup Rehabil 2002;12(4):277-295.

(16) Truchon M, Fillion L. Biopsychosocial Determinants of Chronic Disability and Low-Back Pain: A Review. J Occup Rehabil 2000;10(2):117-142.

(17) Chung KC, Kotsis SV, Kim HM. Predictors of functional outcomes after surgical treatment of distal radius fractures. J Hand Surg Am 2007 Jan;32(1):76-83.

(18) Holtslag HR, van Beeck EF, Lindeman EL,Loek P., H. Determinants of Long-Term Functional Consequences After Major Trauma. Journal of Trauma-Injury Infection & Critical Care 2007 April;62(4):919-927.

(19) Brown KR, Jean-Claude J, Seabrook GR, Towne JB, Cambria RA. Determinates of functional disability after complex upper extremity trauma. Ann Vasc Surg 2001 Jan;15(1):43-48.

(20) McCarthy ML, MacKenzie EJ, Bosse MJ, Copeland CE, Hash CS, Burgess AR. Functional Status following Orthopedic Trauma in Young Women. Journal of Trauma-Injury Infection & Critical Care 1995 November;39(5):828-837.

(21) Kamaleri Y, Natvig B, Ihlebaek CM, Bruusgaard D. Does the number of musculoskeletal pain sites predict work disability? A 14-year prospective study. Eur J Pain 2009 Apr;13(4):426-430.

(22) Macrae WA. Chronic post-surgical pain: 10 years on. Br J Anaesth 2008 2008;101(1):77-86.

(23) Weigl M, Cieza A, Cantista P, Reinhardt JD, Stucki G. Determinants of disability in chronic musculoskeletal health conditions: a literature review. Eur J Phys Rehabil Med 2008 Mar;44(1):67-79.

(24) Young Casey C, Greenberg MA, Nicassio PM, Harpin RE, Hubbard D. Transition from acute to chronic pain and disability: a model including cognitive, affective, and trauma factors. Pain 2008 Jan;134(1-2):69-79.

(25) Research Committee,American Shoulder and Elbow Surgeons, King GJW, Richards RR, Zuckerman JD, Blasier R, Dillman C, et al. A standardized method for assessment of elbow function. Journal of Shoulder and Elbow Surgery 1999;8(4):351-354.

(26) Smith MV, Calfee RP, Baumgarten KM, Brophy RH, Wright RW. Upper extremity-specific measures of disability and outcomes in orthopaedic surgery. J Bone Joint Surg Am 2012 Feb 1;94(3):277-285.

(27) Doornberg JN, Ring D, Fabian LM, Malhotra L, Zurakowski D, Jupiter JB. Pain dominates measurements of elbow function and health status. J Bone Joint Surg Am 2005 Aug;87(8):1725-1731.

(28) John M. The American Shoulder and Elbow Surgeons Elbow Questionnaire: Cross-cultural Adaptation into German and Evaluation of Its Psychometric Properties. Journal of Hand Therapy 2010 201007/09;23(3):301-314.

(29) MacDermid JC, Michlovitz SL. Examination of the elbow: linking diagnosis, prognosis, and outcomes as a framework for maximizing therapy interventions. J Hand Ther 2006 Apr-Jun;19(2):82-97.

(30) Hudak PL, Amadio PC, Bombardier C, Beaton D, Cole D, Davis A, et al. Development of an upper extremity outcome measure: The DASH (disabilities of the arm, shoulder, and head). Am J Ind Med 1996;29(6):602-608.

(31) Beaton DE. Measuring the wole or the parts? Journal of Hand Therapy 2001 200104/06;14(2):128-142.

(32) Guyatt GH, Townsend M, Berman LB, Keller JL. A comparison of Likert and visual analogue scales for measuring change in function. J Chronic Dis 1987;40(12):1129-1133.

(33) Atroshi I, Gummesson C, Andersson B, Dahlgren E, Johansson A. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: reliability and validity of the Swedish version evaluated in 176 patients. Acta Orthop Scand 2000 Dec;71(6):613-618.

(34) Dowrick AS, Gabbe BJ, Williamson OD, Cameron PA. Outcome instruments for the assessment of the upper extremity following trauma: a review. Injury 2005;36(4):468-476.

(35) Turchin DC, Beaton DE, Richards RR. Validity of Observer-Based Aggregate Scoring Systems as Descriptors of Elbow Pain, Function, and Disability*. The Journal of Bone & Joint Surgery 1998 February 1;80(2):154-62.

(36) Popovic N, Lemaire R, Georis P, Gillet P. Midterm results with a bipolar radial head prosthesis: radiographic evidence of loosening at the bone-cement interface. J Bone Joint Surg Am 2007 Nov;89(11):2469-2476.

(37) Grewal R, MacDermid JC, Faber KJ, Drosdowech DS, King GJW. Comminuted Radial Head Fractures Treated with a Modular Metallic Radial Head ArthroplastyStudy of Outcomes. The Journal of Bone & Joint Surgery 2006 October 1; 88:2192-2200.

(38) Jester A, Harth A, Germann G. Measuring Levels of Upper-Extremity Disability in Employed Adults Using the DASH Questionnaire. J Hand Surg 2005 9;30(5):1074.e1-1074.e10.

(39) Hunsaker FG, Cioffi DA, Amadio PC, Wright JG, Caughlin B. The American Academy of Orthopaedic Surgeons Outcomes Instruments Normative Values from the General Population. The Journal of Bone & Joint Surgery 2002 February 1;84(2):208-215.

(40) Grewal R, MacDermid JC. The Risk of Adverse Outcomes in Extra-Articular Distal Radius Fractures Is Increased With Malalignment in Patients of All Ages but Mitigated in Older Patients. J Hand Surg 2007 9;32(7):962-970.

(41) Fortin PR, Clarke AE, Joseph L, Liang MH, Tanzer M, Ferland D, et al. Outcomes of total hip and knee replacement: Preoperative functional status predicts outcomes at six months after surgery. Arthritis & Rheumatism 1999;42(8):1722-1728.

(42) Jones CA, Voaklander DC, Suarez-Alma ME. Determinants of function after total knee arthroplasty. Phys Ther 2003 Aug;83(8):696-706.

(43) Jones CA, Voaklander DC, Johnston DW, Suarez-Almazor ME. The effect of age on pain, function, and quality of life after total hip and knee arthroplasty. Arch Intern Med 2001 Feb 12;161(3):454-460.

(44) Morrison RS, Magaziner J, McLaughlin MA, Orosz G, Silberzweig SB, Koval KJ, et al. The impact of post-operative pain on outcomes following hip fracture. Pain 2003;103(3):303-311.

(45) Lingard EA, Katz JN, Wright EA, Sledge CB. Predicting the Outcome of Total Knee Arthroplasty. The Journal of Bone & Joint Surgery 2004 October 1;86(10):2179-2186.

(46) Scholz J, Woolf CJ. Can we conquer pain? Nat Neurosci 2002 Nov;5 Suppl:1062-1067.

(47) Carr DB, Goudas LC. Acute pain. The Lancet 1999 6/12;353(9169):2051-2058.

(48) Besson JM. The neurobiology of pain. Lancet 1999 May 8;353(9164):1610-1615.

(49) Hunt SP, Mantyh PW. The molecular dynamics of pain control. Nat Rev Neurosci 2001 Feb;2(2):83-91.

(50) Kalso E, Mennander S, Tasmuth T, Nilsson E. Chronic post-sternotomy pain. Acta Anaesthesiol Scand 2001;45(8):935-939.

(51) Lavernia CJ, Guzman JF. Relationship of surgical volume to short-term mortality, morbidity, and hospital charges in arthroplasty. J Arthroplasty 1995;10(2):133-140.

(52) Cheng C, Cheng Y, Chen J. A learning curve of total knee arthroplasty (TKA) based on surgical volume analysis. Arch Gerontol Geriatr 2011 201107/08;53(1):e5-e9.

(53) Devereaux PJ, Bhandari M, Clarke M, Montori VM, Cook DJ, Yusuf S, et al. Need for expertise based randomised controlled trials. BMJ 2005 Jan 8;330(7482):88.

(54) Perkins FMMD, Kehlet HMD, Ph.D. Chronic Pain as an Outcome of Surgery: A Review of Predictive Factors. Anesthesiology 2000 October;93(4):1123-1133.

(55) Hayes C, Browne S, Lantry G, Burstal R. Neuropathic pain in the acute pain service: a prospective survey. Acute Pain 2002;4(2):45-48.

(56) McDermott AM, Toelle TR, Rowbotham DJ, Schaefer CP, Dukes EM. The burden of neuropathic pain: results from a cross-sectional survey. European Journal of Pain 2006;10(2):127-135.

(57) Dworkin RH, Ph, D. An Overview of Neuropathic Pain: Syndromes, Symptoms, Signs, and Several Mechanisms. Clin J Pain 2002 November/December;18(6):343-349.

(58) Fritz JM, George SZ, Delitto A. The role of fear-avoidance beliefs in acute low back pain: relationships with current and future disability and work status. Pain 2001;94(1):7-15.

(59) Rosenberger PH, Jokl P, Ickovics J. Psychosocial factors and surgical outcomes: an evidence-based literature review. J Am Acad Orthop Surg 2006 Jul;14(7):397-405.

(60) Souer JS, Lozano-Calderon SA, Ring D. Predictors of Wrist Function and Health Status After Operative Treatment of Fractures of the Distal Radius. J Hand Surg 2008;33(2):157-e8.

(61) Woby SR, Watson PJ, Roach NK, Urmston M. Are changes in fear-avoidance beliefs, catastrophizing, and appraisals of control, predictive of changes in chronic low back pain and disability? European Journal of Pain 2004;8(3):201-210.

(62) Turk DC, Kerns RD, Rosenberg R. Effects of marital interaction on chronic pain and disability: Examining the down side of social support. Rehabilitation Psychology 1992;37(4):259-274.

(63) Hanley MA, Jensen MP, Ehde DM, Hoffman AJ, Patterson DR, Robinson LR. Psychosocial predictors of long-term adjustment to lower-limb amputation and phantom limb pain. Disability & Rehabilitation 2004;26(14-15):882-893.

(64) Seeman TE, Crimmins E. Social environment effects on health and aging: integrating epidemiologic and demographic approaches and perspectives. Ann N Y Acad Sci 2001 Dec;954:88-117.

(65) Stansfeld SA, MRCP MRCP, Bosma H, Hemingway H, BChir,, M.R.C.P., M.F.P.H.M., Marmot MGBS, et al. Psychosocial Work Characteristics and Social Support as Predictors of SF-36 Health Functioning: The Whitehall II Study. Psychosom Med 1998 May/June;60(3):247-255.

(66) Revenson TA, Schiaffino KM, Deborah Majerovitz S, Gibofsky A. Social support as a double-edged sword: The relation of positive and problematic support to depression among rheumatoid arthritis patients. Social Science and Medicine 1991;33(7):807-813.

(67) MacDermid JC. Outcome evaluation in patients with elbow pathology: Issues in instrument development and evaluation. Journal of Hand Therapy 2001 200104/06;14(2):105-114.

(68) Lehman LA, Woodbury M, Velozo CA. Examination of the factor structure of the Disabilities of the Arm, Shoulder, and Hand questionnaire. Am J Occup Ther 2011 Mar-Apr;65(2):169-178.

Table 1: Bivariate correlation between the baseline patient characteristics and mean DASH at 2 years

Patient characteristic	Number of patients	Mean 2 year DASH	P value
Gender			
Male	26 (44.1%)	14.48	0.173
Female	33 (55.9%)	20.95	
Age			
Age ≤ 60	41 (69.5%)	19.68	0.311
Age > 60	18 (30.5%)	14.49	
Dominant side involved			
No	32 (54.2%)	15.62	0.253
Yes	27 (45.8%)	21.04	
Smoking History (n=54)			
Never smoked	35 (64.8%)	13.45	0.017
Smoker	4 (7.4%)	21.5	
Quit Smoking	14 (25.9%)	28.86	
Education status			
Incomplete grade school	1 (1.7%)	9.17	0.047
Finished grade school	1 (1.7%)	43.33	
Incomplete high school	6 (10.2%)	37.5	
Finished high school	8 (13.6%)	8.33	
Incomplete college	12 (20.3%)	14.58	
Finished college	18 (30.5%)	19.21	
Incomplete university	4 (6.8%)	24.36	
Finished university	5 (8.5%)	17.83	
Graduate level	4 (6.8%)	4.16	
Employment status			
Retired	13 (22%)	16.34	0.503
Homemaker	8 (13.5%)	19.68	
Unable to work because of injury	19 (32.2%)	13.37	
Unable to work due to other reasons	2 (3.4%)	23.33	
Part time light duties	2 (3.4%)	39.17	
Full time light duties	4 (6.8%)	20.62	
Part time regular duties	2 (3.4%)	9.16	
Full time regular duties	7 (11.9%)	20.35	
Student	2 (3.4%)	37.9	
Arm injury part of WCB claim			
No	55 (93.2%)	17.24	0.022
Yes	3 (5.1%)	17.77	
Pending	1 (1.7%)	66.67	

Co-morbidities			
Heart problems (n=42)			0.742
Yes	4 (9.5%)	22.49	
no	38 (90.5%)	19.16	
Arthritis (n=42)			0.16
Yes	7 (16.7%)	28.68	
No	35 (83.3%)	17.64	
Diabetes (n=42)			0.095
Yes	2 (4.8%)	41.23	
No	40 (95.2%)	18.39	

Abbreviations: DASH, Disability of Arm Shoulder and Hand questionnaire; WCB, Worker Compensation Board;

Table 2: Correlation of independent variables used in regression analysis

	Age	WCB status
WCB status	-0.023 (p = 0.862)	
ASES-e (postsurgical pain)	0.133 (p - 0.317)	-0.124 (p = 0.351)

Abbreviations: WCB, Worker compensation Board claim

Table 3: Comparison of regression models used to predict chronic functional impairment at 2 years post radial head arthroplasty

Model	R	R^2	R^2 change	F change	df	Significant F change
Age	0.156	0.024	0.024	1.427	1,57	0.237
Age + Worker compensation board status	0.312	0.097	0.073	4.51	1,56	0.038
Age + Worker compensation board status+ Acute postsurgical pain	0.494	0.244	0.147	10.687	1,55	<0.001

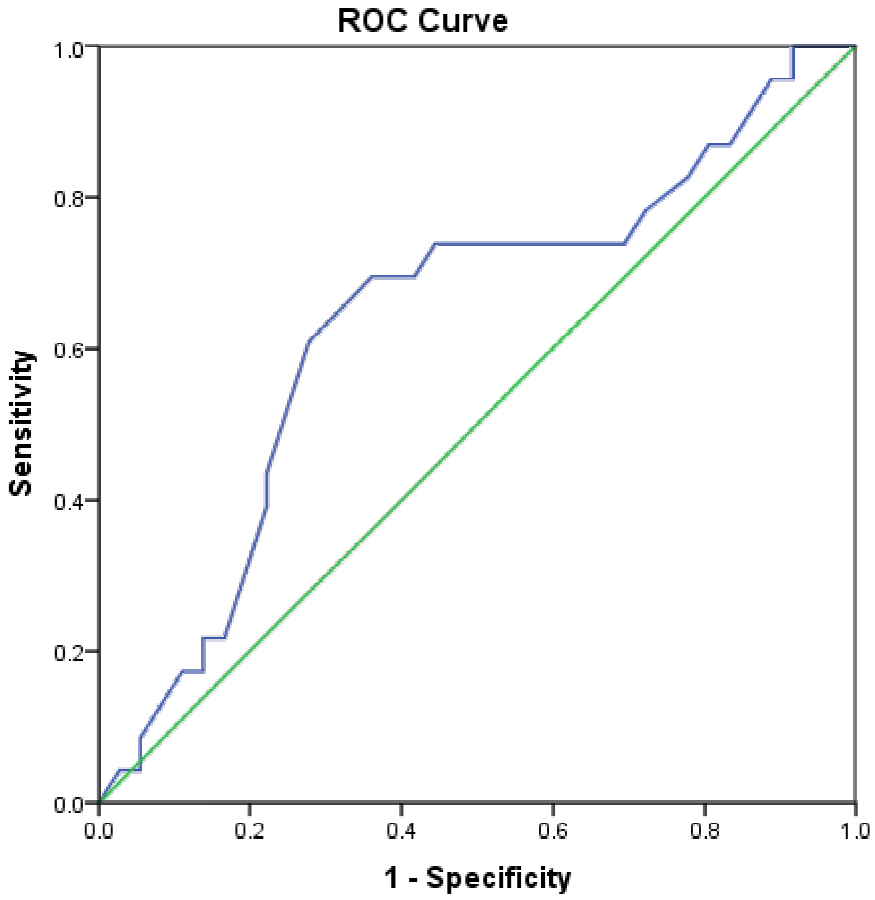
Table 4: Performance of acute post surgical ASES-e pain score in discriminating between patients who have chronic functional impairment at 2 years versus patients who do not with ASES-e pain ≥ 31.5 as an endpoint

Endpoint	AUC	Sensitivity	Specificity	Predicted values	Likelihood ratio
ASES-e pain score ≥ 31.5	0.70 (0.55-0.85)	0.76 (0.49-0.92)	0.61 (0.45-0.76)	PPV = 0.45 (0.27-0.87) NPV = 0.87 (0.68-0.96)	PLR = 2.0 (1.25-3.2) NLR = 0.38 (0.15- 0.92)

Values given in bracket indicate 95% confidence interval

AUC: Area under curve; RR: Relative risk ratio; PPV: Positive predicted value; NPV: Negative predicted value; PLR, positive likelihood ratio; NLR, negative likelihood ratio

Figure 1- Receiver Operative curve showing discriminative properties of acute post surgical ASES-e pain score



In the diagram,
The green line (straight line) is the line of no difference also called as the 'line of equality'. The blue line represents the trade-off between the true positive rate (sensitivity) and false positive rate (one minus specificity). The point at the uppermost left hand corner represents the optimal cut off value of ASES-e pain score that will differentiate good versus suboptimal outcome in RHAP as determined by the dichotomized DASH rating (i.e. ≥20/100).

CHAPTER 4: DISCUSSION/CONCLUDING REMARKS

This sandwich thesis focused on the functional outcomes of radial head arthroplasty (RHAP) in individuals with complex radial head fractures (RHF). It includes two manuscripts that are to be submitted in a peer reviewed journal for publication. The systematic review conducted for this thesis work demonstrated that individuals who undergo metal RHAP following RHF have good to excellent functional outcomes in short to midterm follow up. The second study demonstrated that acute post surgical pain has good discriminative capability in differentiating people with greater intensity pain and functional outcomes at 2 years following RHAP. This work showed that a patient who scored equal to or more than 32 on ASES pain scale would have a 1.6 times increased likelihood of poor functional outcomes.

The first study identified that there is a substantial body of mostly low-quality evidence relating to functional outcomes of RHAP. All of the 21 included studies were Sackett's level 4 evidence (1). Consequently, none of the included studies were individually convincing regarding the superiority of a particular implant design and/or material over another. The ability of the findings to inform best practice in evidence based decision making is limited by the significant heterogeneity of RHAP literature concerning health care settings, patient characteristic, implant designs and measurement instruments. Additionally, the reviews of observational studies are more open to random errors and systematic bias due to the confounding, selection of participants and knowledge of prognostic factors causing over-estimation of treatment effects (2,3). Nonetheless, the review addresses the scope and current trajectory of RHAP literature and informs the methodology of future prospective studies i.e. appropriate patient selection, treatment modification, outcome measures. Although it is not possible to have pre-injury upper extremity function scores for most traumatic injuries; we can compare the outcomes achieved to normative scores and other upper extremity injuries and reconstructive procedures. This comparison suggested that RHAP has good to excellent functional outcomes in short to midterm follow up. However, it also noted considerable variation in outcomes that was not explained by implant type. This suggested that studies that would identify ways of differentiating patients who are likely to have suboptimal outcomes were warranted.

Chapter 3 focused on whether it was possible to predict those who would have poorer functional outcomes on the basis of assessment of pain in the post operative period. This study emphasizes the importance of quantifying pain levels in the immediate post operative period and classifying the patient into high or low risk groups for chronic functional impairment based on the pain levels. However, before the results of the study can be interpreted and/or implemented in clinical practice, some of the methodological issues in the study are worth discussing. The results of the study are based on analyses of a pre-existing dataset from a single tertiary centre. Apart from the time saving and economical aspects of using the data, this inferred some other advantages. The data was collected prospectively with the use of well defined, standardised outcome measures by an independent evaluator. This might have reduced the bias associated with knowledge of predictor variables (4). The quality of the dataset was verified with manual checking of all the patient's records and any missing/incorrectly entered information was rectified. Some of the downsides of doing secondary analyses were no control over the aspects of study population, methodology and measurements. Also, factors like accuracy of data collection, missing data and variable could not be explained for. These could have impact the generalizability and validity of these findings.

Another methodological limitation of this study was the sample size. We could extract data for only 59 patients. This limited the number of predictor variables that could be included in the regression model and hence the influence of other confounding variables could not be studied. However, it is also important to note that RHAP is a relatively rare surgery performed mostly in specialised centres. Hand and Upper Limb Centre (HULC), London is the largest surgical unit in Canada specialising in upper extremity disorders. The low sample size reflects the difficulty of recruiting a large sample from a single centre in RHAP trials and stresses the potential for multi-centric trials in future for studying the effectiveness of RHAP.

The pain cut-off score proposed in this study has to be further validated with the help of well designed multi-centric prospective trials. In future RHAP trials, the predictors must be clearly defined and standardised to improve the generalizability of the findings (5). Details pertaining to time points and methods of predictor assessment must be outlined in a transparent manner. An independent blinded evaluator should assess the outcomes in order to prevent the bias (5,6). Further the application of the prediction model given in the second manuscript must be tested in a clinical set up. Guidelines must be proposed to the clinicians in an easy to understand format (7). Until then, the ASES-e pain score of 32/50 can be used by the clinicians with some speculation, combined with their clinical judgement.

This study has important practice and policy implications. The assessment and screening of the patients immediately after surgery will allow the physicians to classify the patients into high or low risk groups for developing functional impairment. Both the clinician and patient will have a better idea of the prognosis and further management. For this model of prognosis based on risk score to be implemented in clinical practice, sufficient empirical evidence linking acute pain and chronic functional impairment, taking into consideration other confounding variables will have to be established. Efforts should be made to ensure that all the decision makers (clinician, patient, hospital management & stakeholder) are involved in all the steps of this process including the designing and testing of the model (8-10). Policy decision making initiatives can then be directed, emphasizing on the distribution of resources to the high risk groups, prolonged hospitalization of patients with inadequate pain control, and improvised access to rehabilitation services. The decision to fund, institutional and organisational barriers, and the potential for misuse and harm of the screening information must be examined. Finally, some amendments in the model might be required to adjust for the variation of the surgical outcome proportional to the volume of the surgical units (11).

There are some limitations of the overall thesis. First, it was impossible to differentiate surgical and rehabilitative components of the functional outcomes following the RHAP. The in depth examination of the different implant designs and materials along with the surgical procedure was beyond the scope of the thesis work. Further, due to the nature of the evidence, we were unable to compare the post operative rehabilitation protocols with the outcomes of RHAP neither could delineate common trends in the rehabilitation protocol. A post-operative rehabilitation protocol was hence not proposed. Subsequent to which, the management of the patients who are at higher risk of developing functional impairment post RHAP will have to rely on the existing evidence concerning acute pain management, post-operative physiotherapy interventions and other rehabilitation alternatives. Recently, a biopsychosocial RACE (Reducing pain, Activating, Cognitive Reshaping, and Empowering) model was proposed for the management of patients with distal radial head fractures (12). The model suggests that the

rehabilitation of the patient with distal radius fracture must be based on their specific injury and psychosocial risk profile to prevent chronic pain post fracture. However, there are no specific studies that demonstrate that functional outcomes of upper extremity trauma can be modified with early identification of patients with high pain levels. A randomized control trial is needed to address this issue and should be based on usual care versus screening plus assignment of a rehabilitative strategy based on risk levels.

The findings of this thesis call attention to next steps that are needed to improve the functional outcomes post RHAP. Prospective, multi-centred randomised control trials must be designed to compare (1) different implant designs and materials used in RHAP, (2) RHAP with other clinically relevant alternative i.e. internal fixation, and (3) usual care versus screening and assignment of rehabilitation strategy based on risk levels. The reporting standards of the effectiveness studies of RHAP must be improved. Alongside, the cost of delivering RHAP and management of the patients with high risk for chronic functional impairment must be assessed with the help of outcomes of cost effectiveness, cost utility and cost benefit. There upon, policies can be adapted to be sensitive to the needs of the patient. Lastly, as RHAP is a specialised surgery, the effect of surgical volume on the outcomes of surgery must be reduced. This can be done by increasing the number of fellowships or providing continued training opportunities for the novice surgeons. This will improve the generalizability and confidence in the findings across different settings.

In conclusion, the study of functional outcomes post radial head arthroplasty unquestionably adds to the existing pool of evidence to understand the outcomes of the surgery. Our findings move towards development of a conceptual framework that informs the evaluation and rehabilitation of patients with RHAP.

References

(1) Sackett DL, Rosenberg WMC. On the need for evidence-based medicine. J Public Health Med 1995;17(3):330-334.

(2) Simunovic N, Sprague S, Bhandari M. Methodological Issues in Systematic Reviews and Meta-Analyses of Observational Studies in Orthopaedic Research. The Journal of Bone & Joint Surgery 2009 May 1;91(Supplement_3):87-94.

(3) Audige LPHD, Bhandari M, Griffin DFRCS, Middleton P, Reeves BCDPHIL. Systematic Reviews of Nonrandomized Clinical Studies in the Orthopaedic Literature. Clinical Orthopaedics & Related Research 2004 October;427:249-257.

(4) Moons KG, Royston P, Vergouwe Y, Grobbee DE, Altman DG. Prognosis and prognostic research: what, why, and how? BMJ 2009 Feb 23;338:b375.

(5) Douglas G Altman, Yvonne Vergouwe, Patrick Royston, Karel G M Moons. Prognosis and prognostic research: validating a prognostic model. BMJ 2009 BMJ Publishing Group Ltd;338.

(6) Karel G M Moons, Douglas G Altman, Yvonne Vergouwe, Patrick Royston. Prognosis and prognostic research: application and impact of prognostic models in clinical practice. BMJ 2009 BMJ Publishing Group Ltd;338.

(7) Douglas G Altman. Systematic reviews of evaluations of prognostic variables. BMJ 2001 BMJ Publishing Group Ltd;323(7306):224-228.

(8) Choi BCK, Pang T, Lin V, Puska P, Sherman G, Goddard M, et al. Can scientists and policy makers work together? Journal of Epidemiology and Community Health 2005 August 01;59(8):632-637.

(9) Knaus WA, Draper EA, Wagner DP. The Use of Intensive Care: New Research Initiatives and Their Implications for National Health Policy. The Milbank Memorial Fund Quarterly.Health and Society 1983 Autumn;61(4):pp. 561-583.

(10) LAVIS JN, ROBERTSON D, WOODSIDE JM, McLEOD CB, ABELSON J. How Can Research Organizations More Effectively Transfer Research Knowledge to Decision Makers? Milbank Q 2003;81(2):221-248.

(11) Phillips KA, Luft HS. The Policy Implications of Using Hospital and Physician Volumes as "Indicators" of Quality of Care in a Changing Health Care Environment. International Journal for Quality in Health Care 1997;9(5):341-348.

(12) Mehta S, MacDermid J, Tremblay M. The implications of chronic pain models for rehabilitation of distal radius fracture. Hand Therapy 2010 November 11.

APPENDIX

APPENDIX 1- The Structured Effectiveness Quality Evaluation Scale (SEQUES)

Evaluation Criteria						Score		
Study question						2	1	0
1. Was the relevant background work cited to establish a foundation for the research question?								
Study design								
2. Was a comparison group used?								
3. Was patient status at more than one time point considered?								
4. Was data collection performed prospectively?								
5. Were patients randomized to groups?								
6. Were patients blinded to the extent possible?								
7. Were treatment providers blinded to the extent possible?								
8. Was an independent evaluator used to administer outcome measures?								
Subjects								
9. Did sampling procedures minimize sample/selection biases?								
10. Were inclusion/exclusion criteria defined?								
11. Was an appropriate enrollment contained?								
12. Was appropriate retention/follow-up obtained?								
Intervention								
13. Was the intervention applied according to established principles?								
14. Were biases due to the treatment provider minimized (ie attention, training)?								
15. Was the intervention compared to appropriate comparator?								
Outcomes								
16. Was an appropriate primary outcome defined?								
17. Were appropriate secondary outcomes considered?								
18. Was an appropriate follow-up period incorporated?								
Analysis								
19. Was an appropriate statistical test(s) performed to indicate differences related to the intervention?								
20. Was it established that the study had significant power to identify treatment effects?								
21. Was the size and significance of the effects reported?								
22. Were missing data accounted for and considered in analyses?								
23. Were clinical and practical significance considered in interpreting results?								
Recommendations								
24. Were the conclusions/clinical recommendations supported by the study objectives, analysis, and results?								
Total quality score (sum of above)=								
Level of Evidence (Sackett)	**1**	**2**	**3**	**4**	**5**			

APPENDIX 2 - Sackett's Grade of Evidence

Level of Evidence	General Criteria for Level of Evidence
1a	Systematic review of homogeneous of randomized, controlled trials (RCTs)
1b	Single high-quality RCT
1c	All or none study
2a	Systematic review of homogeneous cohort studies
2b	Single cohort study (including low-quality RCT; ie less than 80% follow up)
2c	"Outcomes" research; ecological studies
3a	Systematic review of homogeneous case–control studies
3b	Single case–control study
4	Case-series, low-quality cohort and case–control studies
5	Expert opinion without explicit critical appraisal, or based on physiology or "first principles"

Appendix 3 – Disability of the Arm, Shoulder and Hand (DASH) questionnaire

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH

INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\frac{(\text{sum of n responses})}{n} - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may not be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job/work is: _____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you: _____

❒ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may not be calculated if there are any missing items.

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Appendix 4 -American Shoulder and Elbow Evaluation- elbow (ASES-e) pain subscale

PATIENT SELF-EVALUATION: PAIN										
Do you experience pain in your elbow?									Yes	No
Rate your pain:										
1) When it is at its worst	1	2	3	4	5	6	7	8	9	10
2) At rest	1	2	3	4	5	6	7	8	9	10
3) Lifting a heavy object	1	2	3	4	5	6	7	8	9	10
4) When doing a task with repeated elbow movements	1	2	3	4	5	6	7	8	9	10
5) At night	1	2	3	4	5	6	7	8	9	10

0 = no pain; 10 = worst pain ever