Biomedical Engineering: Applications, Basis and Communications, Vol. 25, No. 1 (2013) 1350007 (7 pages)
DOI: 10.1142/S1016237213500075

INTERNAL FIXATION OF RADIAL HEAD FRACTURES WITH AN INTRAMEDULLARY NAIL

Matija Krkovic*, Miha Brojan†,¶, David Bombac‡ and Dejan Hermann§
*Department for Trauma and Orthopaedics
University Hospitals Coventry and Warwickshire
Clifford Bridge Road, Coventry
CV2 2DX, United Kingdom
†Laboratory for Nonlinear Mechanics
Faculty of Mechanical Engineering, University of Ljubljana
Askerceva 6, SI-1000 Ljubljana, Slovenia
‡Department of Materials and Metallurgy
Faculty of Natural Sciences and Engineering
Askerceva 12, SI-1000 Ljubljana, Slovenia
§Department of Traumatology, University Medical Center
Zaloska cesta 7, SI-1525 Ljubljana, Slovenia
¶miha.brojan@fs.uni-lj.si

Accepted 5 June 2012
Published 28 February 2013

ABSTRACT

Comminuted fractures of the radial head still present significant technical and surgical challenges. In this article, we describe a novel fixation of comminuted radial head fractures with the help of an intramedullary nail. Experiments with solid, conventionally machined intramedullary nails showed some major drawbacks in the fixation of radial head fractures. Several design and manufacturing procedures were proposed. The general idea behind the new design was the concept of a nail which would eliminate the need for prefabricated bores. Experiments with a selective laser sintered thin-walled nail, designed with the help of CT images, fulfilled expectations. This thin-walled proximal radius nail thus offers a stable fixation of the radial head fracture fragments, with the ability to preserve the existing vascular supply to the radial head fragments, and therefore not just use the reconstructed radial head as a bioprosthesis.

Keywords: Radial head fracture; Internal fixation; Nail; CT and MRI imaging; Rapid manufacturing; Selective laser sintering.

INTRODUCTION

The most common mechanism of injury for radial head fractures is a fall on an out-stretched and pronated arm, where posterior subluxation of the forearm occurs as far as the ligaments will allow, and the fracture usually involves the most anterior portion of the radial head. An uncomplicated fracture of the radial head is rarely associated with any neurological symptoms.[1] Radial head fractures represent 1.7−5.4% of all fractures, occurring in 17−19% of elbow injuries and in approximately 33%

¶Corresponding author: Miha Brojan, Laboratory for Nonlinear Mechanics, Faculty of Mechanical Engineering, University of Ljubljana, Askerceva 6, SI-1000 Ljubljana, Slovenia. Tel: +386 1 4771 604; Fax: +386 1 2518 567; E-mail: miha.brojan@fs.uni-lj.si

of all fractures of the elbow.[1] In dislocated elbows, radial head fracture can be expected in 19% of patients.[2] Comminuted fractures of the radial head, "Mason" type III and IV,[3,4] usually consist of at least three fragments. Most of these fragments will still have some soft tissue attachment to the shaft, usually where the joint capsule attaches to the radial head. We believe that in these cases it is extremely important to preserve soft tissue bridge, and the associated blood supply running through it. In cases where there is no soft tissue connection between the shaft and the fracture fragments, no significant additional harm can be caused by "on table" reconstruction of the radial head.[5] It should be noted that it is not known whether or not stable fixation of the radial head to the shaft after a comminuted fracture of radial head is absolutely necessary.[6] The literature points out, with slight scepticism, that open reduction and internal fixation only has a slight advantage over radial head resection or radial head replacement.

Using the radial head as a bioprosthesis is always an option in cases where stable fixation cannot be achieved.[5,6] This was also confirmed by our own experiences and personal communications. In our experience it is difficult to anatomically reduce and fix comminuted fractures of the radial head *in situ*, especially when aiming to preserve existing soft tissue attachments of fracture fragments.

The idea of a nail which offers a secure anchoring point for large and small fragments was born out of this experience. The procedure is described in detail below.

The Idea

Our original idea of how to fix the fracture fragments of the radial head back onto the shaft was focused around the idea of a small nail. This could be inserted through the existing fracture into the radial shaft, with the fragments of the radial head adjusted over the proximal part of the nail, with as much preservation of the soft tissue attachments as possible. Fragments could be then anatomically reduced onto the nail inside radial shaft, and attached with locking screws onto the nail with additional anti-rotational screws through the diaphyseal section of the nail. The nail would offer us a solid base onto which attachment and fixation of the fragments could be done safely and securely, whilst not sacrificing any remaining blood supply.

MATERIALS AND METHODS

A combination of CT, MRI images as well as surface models of the fractures primarily used for diagnosis, were used here to design an intramedullary proximal radial nail. CT and MRI images give a clear picture of the complete bony and soft tissue anatomy and are therefore useful investigations in predicting the best surgical procedures and the design variants of specific (as well as custom-fit) implants.

The basic shape and size of the nail was determined using reconstruction software from a CT image of the human proximal radius. The extrapolated data was then the foundation for a 3D CAD model which was the basis for the design and manufacturing process. The detailed description of similar procedures can be found in many other studies, cf. Refs. 7−11 for more details.

The nail with accompanying surgical instrumentation was manufactured using conventional production methods. The design of the nail includes four locking screws for radial head fragments which need to be inserted into the head of the nail via guiding instruments, and two anti-rotational screws for the diaphyseal part of the nail which are inserted through the stem of the nail, also via guiding instruments which are shown in Fig. 1.

In vitro experiments testing the implantation technique were conducted in the Institute of Anatomy, Faculty of Medicine, University of Ljubljana, on the fresh frozen upper limb of a 65-year old organ donor. The experiment was approved by the Ethical committee, Ministry of Health, Republic of Slovenia.

Kocher's approach was used.[12] The annular ligament was transected and a fracture in the neck of radius was created using an osteotome. The radial head was then removed and a comminuted fracture of the radial head (Mason III) was created again using an osteotome, to represent the most common radial head fracture, as shown in Fig. 2.

Fig. 1 Conventionally manufactured nail and accompanying guiding instrumentation.

Fig. 2 Simulated comminuted fracture of the radial head.

For reduction and fixation purposes, the radial shaft was dislocated, as per our current practices (bone hook was used to pull proximal part of radial shaft laterally to expose medullary canal of radius), to enable access to the proximal radius (the same technique as in a radial head replacement). This enabled introduction of the nail, and more importantly fracture reduction and fixation as shown in Fig. 3. To prepare radius for nail insertion medullary canal was reamed with corresponding reamer removing just the amount of cancellous bone needed for nail insertion. When the nail was introduced, the radial head fracture fragments were reduced and an attempt at fixation of the fragments started. Position of the nail inside of proximal radius is central as in majority of other nailing techniques.

No major difficulties were observed in insertion of the anti-rotation diaphyseal screws, whereas fixation of the radial head fragments with locking screws presented some major challenges, resulting in displacement of the radial head fragments, screw placement in fracture lines and fixation in non-anatomical position.

From a surgical point of view, this design would not be acceptable as a definitive treatment option for radial head fractures, due to the likely suboptimal positioning of the fragments after fixation. At this point, further trials of the device in its current design were stopped and no further cadaveric tests were performed. It was realized that a completely different approach was needed, as minor redesign or attempted optimization of the nail would obviously not give us the desired result which would be general enough for implementation in *in vivo* procedures. This conclusion was a starting point for new, non-conventional solutions and technologies outside the boundaries of common practice.

NEW DESIGN

Designing Process

The decision was made to keep the original shape of the nail, and to improve the fixation procedure for the radial head fragments. The general idea behind the new design

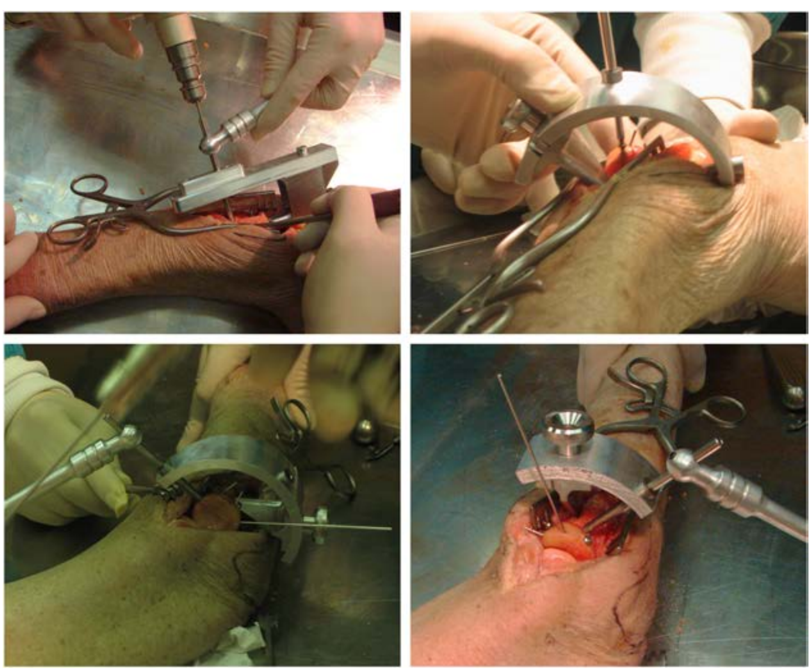

Fig. 3 Surgical procedure using the conventionally manufactured nail.

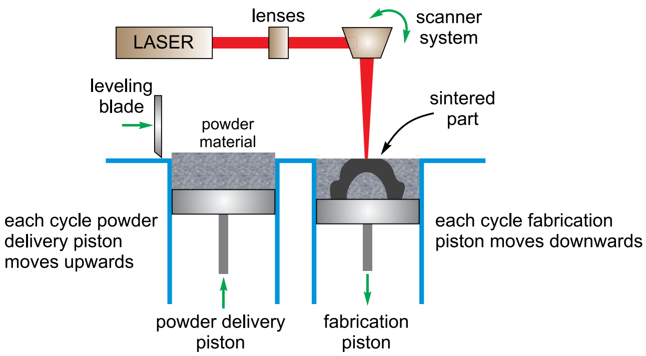

Fig. 4 A schematic diagram of the SLS machine.

was the concept of a nail which eliminates the need for prefabricated bores. The solution for this idea was to use a thin-walled structure, or a solid structure made of a softer material. This would enable a surgeon to drill holes and position the screws in exactly the required positions without the use of special guiding tools. On the other hand, drilling debris should be kept to a minimum.

We chose to create a thin-walled nail using rapid manufacturing (RM) methods, cf. Refs. 13–15 for more details. Products built using RM are usually manufactured directly from 3D CAD models, employing so called layer-by-layer technology. In Figs. 4 and 5 a schematic diagram of the selective lasser sintering (SLS) machine and prototyping procedure are shown, respectively. An extracted surface of the implant model, based on CT images was the foundation for the thin-walled model used in RM. When using RM, one can choose from a variety of different techniques, e.g. SLS, selective laser melting (SLM), selective laser welding (SLW), etc. With these technologies one can immediately generate solid or thin-walled products. SLS is a typical solid free-form fabrication technique, which enables quick production of complex shaped 3D parts directly from powdered materials. The SLS creates parts in a layer-by-layer manner by selectively melting and consolidating thin layers of loose powder using a scanning laser beam. This makes SLS, and other similar processes, ideal for small batch production of customized parts and tools.

For customized medical implants 3D CAD models are prepared from CT or MRI imaging equipment, and sliced into thin layers (see Fig. 5). These layers are later melted and consolidated from metallic, polymeric or ceramic powders to create fully functional products. Surface quality and build time depends on the thickness of the layers.

Several designs of the nail prototypes were made from various materials, such as aluminium, polyethylene, polyamide and polyvinylchloride, of which some were made by conventional and some by RM. The prototype of the thin-walled nail used in the experiment, shown in Fig. 6, was made by RM technology (EOSINT P385, EOS GmbH) from polyamide PA2200 powder, to show the applicability of the idea presented in this study in surgical practice. Thin layers of PA2200 powder with average grain size 56 μm were consolidated with laser to obtain desired shape of the radial nail.

Another approach would be the use of casted polymeric biocompatible materials. They are soft enough to drill in and are more and more often used as a substitute for metal alloys in contemporary trauma and orthopedic implant devices.

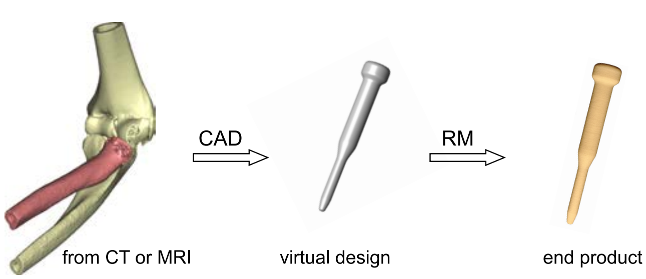

Fig. 5 Prototyping of a thin-walled nail.

Implantation of a Thin-Walled Nail

In vitro experimentation of the implant was conducted on a fresh frozen upper limb taken from an 80-year old male donor with agreement of Ethical committee of Slovenia. Preparation of the limb for the nail implantation was the same as described in the first trial. As the

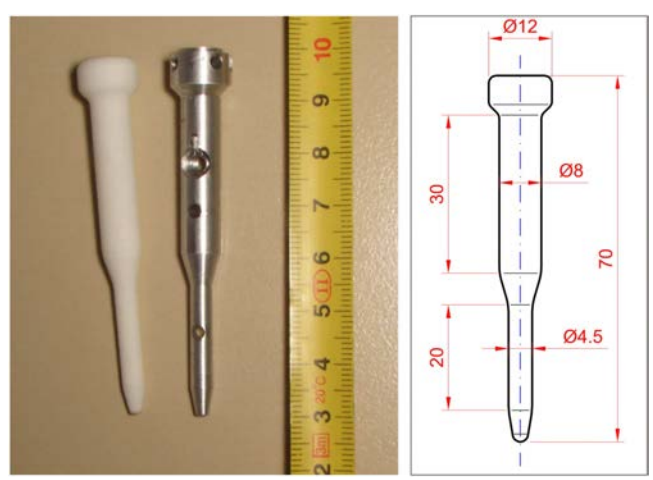

Fig. 6 Two basic designs of the nail made from aluminium and polyamide PA2200, which were used in a first and second experimental surgical procedure, respectively.

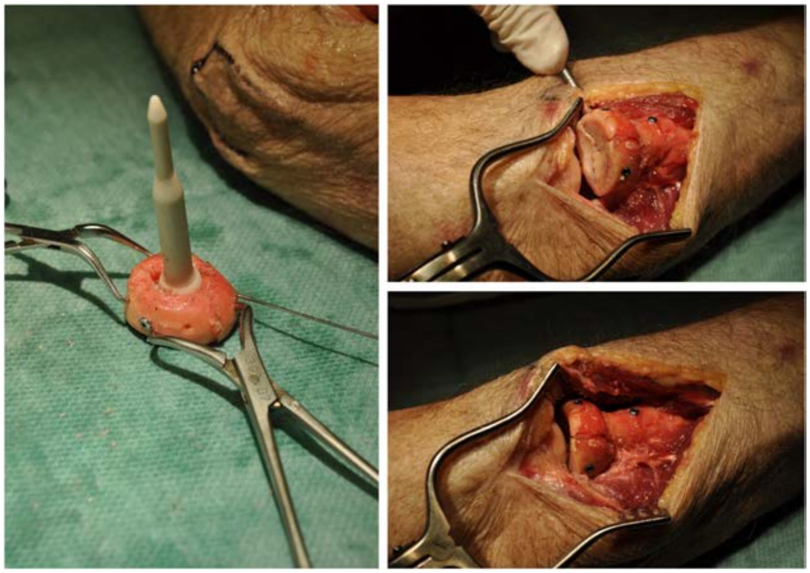

Fig. 7 Implanted nail made by RM technique.

thin-walled nail is symmetrical, rotational position of the nail is not important, therefore nail can be inserted in any rotation. The fragments were provisionally fixed with K wires, and the head was fitted as a whole fragment to the polyamide PA2200 prototype nail (see Fig. 6) which was already implanted into radial shaft and proximal metaphysis. Reduction of radial head fragments prior to attachment to the radial shaft and thin-walled nail is of limited importance. If possible fragments should be reduced first bearing in mind that existing soft tissue attachment of radial head fragments should be preserved if possible. If provisional reduction with thin K wires is not possible, step by step reduction of fragments onto shaft and thin-walled nail is an option paying a lot of attention to correct orientation of radial head fragments against radial shaft. When appropriate position of fragments is achieved, radial head fragments can be definitively fixed to the thin-walled nail with screws in any chosen direction as consistence of the nail allowing drilling through it with adequate purchase of screw threads. For the fixation of the radial head to the nail, 2.0 mm diameter threaded pegs (TP) from the DVR Anatomic Volar Plating modular tray (Depuy Orthopedics, Warsaw, IN, USA) were used. All the screw heads were sunken below the cartilage surface to prevent possible irritation of the joint. At the final stage of the implantation process an anti-rotational screw was inserted through the nail and the shaft of the radius to provide accurate rotational correction of the fixed radial head, cf. Fig. 7. Thin-walled nail construction allows us to position all screws at the optimal places as there are not predetermined screw holes and no jigs required to possible compromise position of screws. During the procedure only free hand drilling is required and no special guiding instrumentation is used.

Taking into account the cancellous bone loss from radial head only due to reduction of fragments onto the nail, we estimate that approximately $0.33\,\text{cm}^3$ of the bone has to be removed from radial head but placed in fracture gap as a normal bone graft used in every day clinical practice.

The idea behind proximal radial nail is in attempt of achieving stable fixation of Mason 3 and Mason 4 radial head fractures. In these two types of fractures, fragments of radial head are very often used as a structural graft and blood supply does come from radial shaft and reminding soft tissue attachments to the fragments.

DISCUSSION

Open reduction and internal fixation of comminuted fractures of radial head with a thin-walled radial nail inserted through the fracture site, made out of metal or a bioreabsorbable material looks like a viable option according to this pilot study.

All intra-articular and periarticular fractures need anatomical reduction and stable fixation, according to the current recommendations, to enable early motion. Radial head fractures are no different, and also need anatomical reduction. However, whether or not they also require stable fixation is not so clear.[5,6] The advantages which this radial nail can offer to radial head fracture fixation are, preserving existing blood supply to the radial head fragments, and ease of reduction. It can be used as a basic template to aid reduction, and also as an internal support for the fragments once they are reduced.

The literature suggests that the current trend is in favor of open reduction and internal fixation, instead of resection or hemiarthroplasty of the radial head.[16,17] To our knowledge, there is no other similar device described in the current literature. Conventional intramedullary nails are available on the market for the intramedullary nailing of forearm fractures, and the results are comparable to the results of locking plates used in adult patients.[18] Besides preserving the biology of the fracture, we believe that the main objective is, especially in intra-articular fractures, anatomical reduction. Since predrilled holes for the screws in the conventionally machined solid nail offered no such possibility, that concept was abandoned together with the accompanying aiming jig. Another reason for abandoning of the first concept, was that removal of the implant, in the event of complications, would be practically impossible without completely destroying the radial head.

The main advantage of the thin-walled implants and the implants made of biomaterials are the ease of fixation of the implants and fragments to bone or implant without the need for predetermined or predrilled screw holes. This is especially important in cases where there are many small fracture fragments. There is also freedom to choose the exact position of the screws, which is extremely important when trying to achieve stable fracture fixation. The problem of implant removal still exists, except in the case of bioreabsorbable implants.

Through our work on this project, we have realized that creating stable fixation of comminuted radial head fractures is an extremely demanding technique, which would benefit from more engagement from both surgeons and engineers. Anatomical and stable fixation is of paramount importance in all joints. In the method described above, we have consciously sacrificed part of the cancellous bone from the proximal radius and radial head in an attempt not only to achieve easier and more accurate fracture reduction, but also a more stable fracture fixation. Bringing this product into everyday practice will require further optimization, with additional tests and clinical trials.

CONCLUSION

It can be concluded, not only from the literature review but also from our daily practice with radial head fractures, that restoration of the radial head is important and all possible efforts and resources should be employed to accomplish it. The idea of fixing comminuted radial head fractures with an intramedullary nail is promising. However, treatment with a conventionally machined nail together with accompanying aiming devices proved to be too complicated and time consuming. Furthermore, comparing the nailing of the femur or humerus with the radial head is misleading, because nailing of the radial head requires anatomical reduction of the fragments, which is not the case for most long bone fractures. This was demonstrated by the system used in first experiment, which was inadequate in enabling anatomical reduction. We came to the conclusion that either we stay with the generally accepted fixation technique of screws and plates, or we continue to search for a new augmentation device — a device that would enable us to achieve a stable fixation, with anatomical reduction, especially in cases with major metaphyseal comminution. Fortunately cases like that are rare. The authors believe that SLS production of a thin-walled nail (bioreabsorbable or not) is a big step forward in the search for the ideal fixation tool for comminuted radial head fractures.

Further research in this field is required to prove the efficiency and safety of fixation with thin-walled nails, and their possible uses in other anatomical regions should be explored.

ACKNOWLEDGMENTS

The authors wish to thank Prof. Dr. J. Kopac and Mr. V. Rotar from Laboratory for cutting, Faculty of Mechanical Engineering, University of Ljubljana, for technical assistance.

REFERENCES

1. Morrey BF, Radial head fracture, in Morrey BF (ed.) *The Elbow and its Disorders*, 3rd edn., WB Saunders, Philadelphia, USA, pp. 341–364, 2000.
2. Van Reit RP, Morrey BF, O'Driscoll SW, Van Glabbeek F, Associated injuries complicating radial head fractures: A demographic study, *Clin Orthop Relat Res* **441**:351, 2005.
3. 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* **3**:51, 1962.
4. Mason ML, Some observations on fractures of the head of the radius with a review of one hundred cases, *Br J Surg* **42**:123, 1954.
5. Businge A, Ruedi TP, Sommer C, On-table reconstruction of comminuted fractures of the radial head, *Injury* **41**:583, 2010.
6. Neumann M, Nyffeler R, Beck M, Comminuted fractures of the radial head and neck: Is fixation to the shaft necessary?, *J Bone Joint Surg Br* **93**:223, 2011.

7. Potamianos P, Amis AA, Forester AJ, McGurk M, Bircher M, Rapid prototyping for orthopaedic surgery, *Proc Inst Mech Eng H* **212**:383, 1998.
8. Ma D, Lin F, Chua CK, Rapid prototyping applications in medicine. Part 1: NURBS-Based volume Modelling, *Int J Adv Manuf Tech* **18**:103, 2001.
9. Starly B, Fang Z, Sun W, Shokoufandeh A, Regli W, Three-Dimensional reconstruction for medical-CAD modeling, *Computer Aided Des. Appli.* **2**:431, 2005.
10. Hosni YA, Harrysson O, Design and manufacturing of customized implants, 2002, Available at http://fie.engrng.pitt.edu/iie2002/proceedings/ierc/papers/2250.pdf
11. Mahaisavariya B, Saekee B, Sitthiseripratip K, Oris P, Tongdee T, Bohez EL, Vander Sloten J, Morphology of the radial head: A reverse engineering based evaluation using three-dimensional anatomical data of radial bone, *Proc Inst Mech Eng H* **218**:79, 2004.
12. Catalano III LW, Zlotolow DA, Hitchcock PB, Shah SN, Barron OA, Surgical exposures of the radius and ulna, *J Am Acad Orthop Surg* **19**:430, 2011.
13. McGurk M, Amis AA, Potamianos P, Goodger NM, Rapid prototyping techniques for anatomical modelling in medicine, *Ann R Coll Surg Engl* **79**:169, 1997.
14. Hieu LC, Zlatov N, Vander Sloten J, Bohez E, Khanh L, Binh PH, Oris P, Toshev Y, Medical rapid prototyping applications and methods, *Assembly Autom* **25**:284, 2005.
15. Vandenbroucke B, Kruth JP, Selective laser melting of biocompatible metals for rapid manufacturing of medical parts, *Rapid Prototyping J* **13**:196, 2007.
16. 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* **88**:11, 2006.
17. Lindenhovius AL, Felsch Q, Doornberg JN, Ring D, Kloen P, Open reduction and internal fixation compared with excision for unstable displaced fractures of the radial head, *J Hand Surg Am* **32**:630, 2007.
18. Visna P, Beitl E, Pilny J, Cizmar I, Vlcek M, Kalvach J, Valcha M, Interlocking nailing of forearm fractures, *Acta Chir Belg* **108**:333, 2008.