Osteolysis associated with RegJoint operations: A Summary

30.10.2014/Minna Leppänen

Background

This summary was initiated due to a question from a clinician who has noticed osteolytic changes in radiographs in 6 patients approximately 6-9 months after an operation of the CMC I –joint. The age of the patients varied from 83 to 50 years at the time of the operation, all patients had osteoarthritis in the CMC I joint and all operations were performed arthroscopically. Clinically all patients were pain-free and functionality of the operated joints was very good in the follow-up. Power of the operated finger has increased up to 200%.

Previous published data

In the study of Honkanen and others (2009) 23 patients with rheumatoid arthritis had 80 metacarpophalangeal arthroplasties performed with RegJoint implant. The follow-up time was on average 59 months. In three patients the joint space widened from 4.1 to 7 mm during the follow-up time. These three joints were eroded into the metacarpal and/or in proximal phalangeal bone surfaces and one of these three joints had also developed palmar subluxation. At final follow-up, the joint space thickness was equal to a value measured at 3 months in 24 joints. The joint space decreased from 1 to 3mm in 45 joints and increased from 1 to 2 mm in 11 joints. Altogether in 57 joints (71%), the joint space change was within a range from a 1 mm decrease to a 1 mm increase. Osteolytic changes exceeding 2 mm had developed on the surfaces of the metacarpal and/or proximal phalangeal bone surfaces in 4% of cases between the 3 month and final follow-up.

Honkanen later summarized in her PhD thesis the findings of the above mentioned study and her later work: "Osteolytic changes were minor and confined to joint surface areas, but were not found in the diaphyseal bone. Osteolytic changes exceeding 2 mm had developed on the surfaces of the metacarpal and/or proximal phalangeal bone surfaces in three out of 80 cases between 3-month and final follow-up. In conclusion, implant absorption did not induce any significant osteolysis. None of the implants had to be revised."… (Honkanen, PhD Thesis page 56) and "…An important aspect disclosed by these studies was that no adverse tissue reactions occurred, either in the phase of mechanical strength loss or in the monomer elimination phase. Osteolytic changes were minimal, on average 59 months after surgery in 4% of cases over 2 mm resorption was measured, and never exceeded 4 mm. This indicates indirectly that the degradation rate and volume of the implant were on a par with the clearing capacity of the tissue." (Honkanen, PhD Thesis, page 62).

In the study of Tiihonen and others (2012) 17 patients with rheumatoid arthritis had their CMC I joints operated with RegJoint. During the follow-up time of two years no complications were reported. Radiologically only minor osteolysis was detected in the bone structures around the RegJoint implant.

Non-published data

In the follow-up data from clinical studies in 2000-2006 no osteolysis was reported either as a specific radiological finding or as an adverse event (data on the RegJoint product registration file, 2011). The data consisted of 216 patients who had one or more joints operated with Regjoint.

Dr Burkhard Mai (Vitos Orthopaedische Klinik, Kassel, Germany) has over 10 years' experience with RegJoint. He has not reported any significant osteolysis in his patients with operated MCP or CMC I joints. In his presentation after 5 years' follow-up time in 43 operated MTP joints he has sometimes noticed initial cup shaped bone resorption later then increased calcification. In CMC I operations he had had no complications, but sometimes noticed widened joint space radiologically. When asked he commented that "when you open the surface of bone, e.g. the MT in MTP I joint, same with MCPs, then you observe painless bone resorptions. These resorptions are painless and replaced by strong scar fibrotic tissue. " He has not noticed significant osteolysis in CMC I – operations, but commented that he mostly performs total trapeziectomy. In some congress presentations he has also mentioned "initial cup shaped bone resorption, later increased sclerosis" in bone ends.

Dr Pirjo Honkanen (Tampere University Hospital, Finland) has commented that in her patients with operated MCP -joints some osteolysis has been noticed radiologially during the first year after the operation, but it does not seem to progress further. She supposed that each patient's tissue properties may have role in this phenomenon whether it occur or not. Also osteolysis does not progress to the diaphyseal area. She has also noticed a short period of transient pain in some patients that seems to be connected with the time of the most active resorption of the implant, i.e. a little less than one year after the operation and later between 1.5-2 years after the operation. No specific treatment has been required. Dr Honkanen also commented that this finding was already noticed in some of the very first pilot patients before initiation of clinical studies.

Dr Eero Waris (Helsinki University Hospital) has noticed osteolysis in few of his osteoarthritis patients with operated CMC I joints within a year after the operation. He has also noticed transient pain in some patients that has not required further therapy. He commented that his patients are very active high- demand patients (mostly younger or middle-aged men) whose hands are put on very heavy mechanical stress .Dr Waris has removed two implants due to the pain and osteolysis (one a little less than one year after the operation and another 20 months after the operation), in other patients the finding seem to be clinically non-significant. He is currently collecting 3 years' follow-up data of approximately 30 CMC I-operations with RegJoint. He also supposed that the phenomenon is connected to the active reabsorption period of the implant.

Professor Minna Kellomäki (Tampere University of Technology, Biomaterial Science) commented also that this phenomenon was noticed already in very early pilot studies. It is most likely connected with the active resorption period of the material, but after the complete resorption no further permanent effect of progression remains.

Approximately 300 implants were used during the clinical studies and since the product launch in 2011 approximately 1700 RegJoint's have been implanted. Thus reported occurrence of osteolysis with clinical significance is currently 0.1%. Until today no other inquiries or reports concerning osteolysis as a radiological finding or as a specific adverse event has been received by the manufacturer.

Conclusions

Based on the published studies and non-published information from experienced RegJoint surgeons and biomaterial scientists osteolysis after RegJoint operation is a phenomenon that can be found radiologically in some patients usually 6-12 months after the operation. Osteolysis does not seem to progress and has no or only very limited clinical significance. In rare cases transient, usually mild pain has been reported in the same time period. This phenomenon is supposed to be connected with the active reabsorption period of the implant.

References

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Data on File*: RegJoint product registration dossier 2011.*