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Chapter 8

Summary, general discussion and future perspectives

Summary

In this thesis we performed an anatomical evaluation of one of the major passive constraints for shoulder instability, being the labrum and its phylogenetic counterpart at the hip joint. An evaluation of patient outcome measurement scores including a discussion on the Oxford Shoulder Score and the Oxford Shoulder Instability Score has been made (**Appendix Chapter 3**). An evaluation of management of acute first-time anterior shoulder dislocations in the Netherlands by means of a shoulder questionnaire (including treatment of recurrent shoulder instability) is being presented. A detailed clinical and radiological evaluation of the mid- and long term results after a labrum joint capsule (open Bankart) repair is given. And finally, we evaluated a novel technique addressing bony defects of the glenoid.

Chapter 2 mentions evolutionary changes of the shoulder, resulting from the fact that people have evolved to walk upright (e.g. Homo erectus, Homo neanderthalensis, Homo sapiens). One of the advantages of this bipedalism is having free hands, accompanied by new requirements for the shoulder as increased function & mobility. The similarities and differences of the labrum of shoulder (with its well-known Bankart lesion, being highly associated with shoulder instability) and hip joint are analysed with special attention to anatomy, pathology (labrum lesions, feeling of instability and degenerative abnormalities such as osteoarthritis) and therapeutic treatment options.

Chapter 3 evaluates the Dutch translation of the "Oxford Shoulder Score" (OSS), an internationally widely used patient-reported-outcome-measurement (PROM's) for shoulder pathology, including a discussion on the Oxford Shoulder Score and Oxford Shoulder Instability Score (addendum). The OSS-questionnaire assesses the pain and activity level of the affected shoulder in daily life (33% and 66% respectively). Originally, the score was used to assess 111 patients who had undergone shoulder surgery due to chronic shoulder complaints, excluding operations for instability. Later on, the OSS was tested in patients after rotator cuff surgery (surgery for a tear in one or more tendons of the four muscles around the shoulder) and in patients with a frozen shoulder (stiff shoulder capsule) which were being mobilized under general anesthesia. Our study indicates that after translation in Dutch, the measuring instrument proved valid and understandable, comparing with existing clinically validated shoulder questionnaires (namely: the Dutch simple shoulder test and Constant-Murley score) and the generic PROM SF-36 (Short Form 36 Health survey) for shoulder patients at the Reinier de Graaf Gasthuis (Delft, the Netherlands).

Chapter 4 evaluates how orthopaedic surgeons in the Netherlands treat an acute first-time anterior shoulder dislocation (AFASD). Secondly, it evaluates whether this is done according to the (then applicable) CBO-guideline. The effect of the introduction of the national (CBO and Dutch Orthopaedic Association (NOV)) guideline "Acute primary shoulder luxations" in 2005 on general practice is also evaluated. Finally, orthopaedic surgeons were asked how to treat persistent (traumatic) anterior shoulder instability. The outcome of AFASD treatment was different, but surgical treatment options for recurrent instability after AFASD showed even more remarkable variations. The vast majority (93%) used an arthroscopic surgical technique for shoulder instability, the rest an "open" surgical technique. When an open stabilizing operation was carried out, the open (modified) Bankart repair was the most commonly used technique (54%). The Putti-Platt operation was being applied in 16% of the cases as well as the Latarjet procedure. A survey in 2003, prior to the introduction of the before mentioned CBO guideline "acute primary shoulder Luxations" (2005), showed that 65% of the assessed Dutch hospitals had a personalized hospital protocol for the treatment of shoulder luxations (response rate 73%, from 74 Dutch hospitals). The outcome of our study showed that after the introduction of the CBO-guideline, there was only a limited increase of 10% in hospital protocols for the treatment of shoulder luxations (75%). Only 29% of the respondents indicated that their existing hospital protocol had been adapted to reflect the newly introduced guideline.

Chapter 5 describes the mid-term clinical and radiological results in terms of stability and the incidence of glenohumeral osteoarthritis of a cohort of 31 patients undergoing modified open Bankart surgery with an average follow-up of 11 years (range 10–15 years) indicated for reasons of post traumatic shoulder instability. We report our surgical technique including the most important steps during this operation procedure. 26 patients (84%) indicated to have a good to very good end result. The recurrence rate varied between 7% and 10% depending on the definition of "recurrent luxation". In 2 patients a redislocation occurred due to a new adequate trauma 1 and 9 years after surgery. The recurrent instability risk (= subluxation sensation and/or dislocations) ranged between 13% and 23%. 32% of the shoulders showed signs of osteoarthritis at time of follow-up, of which 3% were Samilson-Prieto grade 3. The average Rowe score was 90 points (range 66–98) and Constant score 96 points (range 85–100). There were no other complications, such as wound infections.

In **Chapter 6**, the long-term clinical and radiological results in terms of stability and the incidence of glenohumeral osteoarthritis of a cohort of 39 patients undergoing modified open Bankart surgery with an average follow-up of 21 years (range 16–26 years) indicated for reasons of post traumatic shoulder instability is being described. Both studies (Chapter 5 & 6) show that the recurrence rate after an open modified Bankart procedure is low, being 10% at final follow-up. The recurrent instability risk (= subluxation sensation and/or dislocations) 23%. Twenty shoulders (51%) had radiological signs of osteoarthritis at time of final follow-up, of which 10% samilson-prieto grade 2 and 3% samilson-prieto grade 3. The average Rowe score was 85 points (range 25–100) and Constant score 92 points (range 70–100).

Chapter 7 evaluates whether a glenoid defect is to be augmented with a 3D printed scaffold. In A biomechanical cadaver study, several situations were simulated to test the stability of the shoulder. In ten fresh-frozen cadaver shoulders a defect was made in the glenoid, after which a 3D patient specific titanium implant (scaffold) was placed. All shoulders were being scanned before and after the procedure according to 3D CT-protocol (250mAs, 120kV, 0.9 mm coupes). After this, an imaging software package (Mimics Medical 20.0, Materialise, Leuven, Belgium) printed a 3D patient-specific titanium implant (SLM-Titanium printer, ProX DMP320, 3D Systems, Leuven, Belgium) for which a Freeform Plus software package (Geomagic, 3D Systems, Leuven, Belgium) was used. Fixation of the scaffold was being performed by means of two angle stable screws, of which also the screw hole position was optimized using the Freeform Plus software package. Our 3D implants are made of "medical" titanium (Ti6Al4v ELI grade 23). The peak translational force needed to translate the humeral head 10mm anteriorly was measured with a custom-designed shoulder testing device under 5 different conditions, being: (1) the "normal" intact situation, (2) after creation of a controlled anterior bone glenoid defect, (3) after implantation of our 3D Titanium patient specific implant, (4) after a Latarjet procedure with and (5) without 10N attached to mimic the sling effect of the conjoined tendon. The peak translational force needed to translate the humeral head 10mm anteriorly was reduced to 70% after creation of the glenoid bony defect compared to the "normal" intact glenoid. Both the augmentation with a 3D patient specific implant and the classic Latarjet procedure were adequate surgical techniques in restoring the glenohumeral stability in the presence of a bony glenoid defect. The peak translational force needed to translate the humeral head 10mm anteriorly was being restored to 119% ± 16% ($p < 0.01$) and 121% ± 48% ($p = 0.02$), respectively compared to the "normal" intact glenoid situation.

General discussion

The shoulder is the most common joint being prone for developing recurrent instability.[1–5] A traumatic shoulder dislocation is often accompanied by a labral lesion,[6–11] which predisposes the patient to developing chronic shoulder instability.[12–15]

Despite a great diversity in surgical treatment options for the unstable shoulder, there is still no unambiguous policy and the most optimal treatment remains controversial, including conservative management and what and when to do when operative treatment is to be done. This is due, among other things, to the wide variety of possible causes of shoulder instability (varying from functional, proprioceptive problems to anatomical abnormalities that may accompany it). Reasons supporting immediate stabilization over conservative treatment are: there is an unacceptable high risk of recurrence in the young athletic population; recurrent instability causes significant and progressive soft tissue and bony damage and there is a clear improvement in the quality of life conferred by surgery.[16,17]

In the Netherlands, the arthroscopic Bankart procedure is currently the most performed surgery executed in patients with symptoms of posttraumatic shoulder instability.[18] The open Bankart operation, which was initially described by Bankart in 1923, currently seems to be performed to a lesser extent.[15] However, clear evidence that the arthroscopic version is better than the open surgical procedure, is not obvious.[19–24] The open Bankart operation is even likely to have a better outcome (with less new (sub) luxations) particular in the young (< 25 years) and active (high-demanding) patient who participates in contact or racket sport; physically demanding professions or in patients with bone loss of the glenoid (< 20%) or in patients with clinical signs of having hyperlaxity.[20,25,26] One of the considerable explanations could be the potential re-increase in anterior capsular volume or restretching trait of the anterior capsule over time, even after primary successful arthroscopic Bankart repair and/or capsular shift procedures.[24] In earlier studies, women, elite athletes, and those with frequent dislocations were at highest risk of capsular restretching. An increase in capsular volume was related to positive apprehension and redislocation as well with a lower outcome of the Rowe shoulder score (also known as rating sheet for Bankart repair).[24] These findings possibly correlate with the superior outcome of the open (modified) Bankart repair. This latter open Bankart approach allows surgeons to directly visualize the glenohumeral joint, accomplish a large capsular shift and guarantee a more complete repair of the anteroinferior capsulolabral tissue ending in diminution of elasticity of the anterior shoulder capsule due to conversion in less elastic scar tissue.[22]

Nowadays, identification of bone loss is increasingly emphasized in the optimal treatment of shoulder instability, both before, but even more after a failed initial stabilizing shoulder procedure.[27–32] This is probably partly due to the reports of Zimmerman in 2016 where he documented substantial superiority of the Latarjet procedure and a decreasing effectiveness of the arthroscopic performed Bankart repair over time.[33] Anteroinferior glenoid bone deficiency (even without consideration of presence of humeral bone loss) has been reported in 22% of initial traumatic anterior shoulder dislocations and in up to 90% of recurrent anteroinferior shoulder instability cases.[28,29] This is one of the reasons that some orthopaedic surgeons recommend surgical treatment after a first traumatic anterior shoulder luxation in the young active (male) patient.[16] Among other things because of this, more attention is being placed on bone block stabilization procedures, including even those performed arthroscopically as a definitive treatment for posttraumatic shoulder instability. In the Netherlands, the open Latarjet procedure seems to be the preferred treatment in the presence of glenoid bone loss of > 20%, or in revision casus.[18,34] Because soft-tissue repairs often fail in the presence of significant bone loss or when a deficient capsulabral situation is residual as is often seen after primary surgery.[20,35] Other known bone block augmentational reconstructions include procedures described by Eden (1918), Hybbinette (1917 & 1932) and Bristow and other allografting techniques using (part of) iliac crest bone, femoral head or distal tibia.[36–41] However, one should be aware of the marked increase in complication rate for these bone block procedures over soft tissue arthroscopic surgery but also compared with the open Bankart procedure.[42–44] In this context we evaluated a potential novel treatment technique using a 3D printed scaffold for augmentation to the glenoid bony defect.[45] Usage of such a metallic rim device has been described only once in a preliminary case report in 1947. The surgeon implanted the scaffold anteroinferior to the glenoid in an extra-articular position, identical to our biomechanical cadaver set-up.[46] At that time, the scaffold was being introduced because of the potential technical difficulties to reattach the capsule and/or torn labrum by means of performing three or more drill holes adequately through the (sometimes dysplastic) bony rim of the glenoid.

Future perspectives

Shoulder instability needs a clear definition, which is internationally being accepted. Only then it is possible to carry out comparative (inter-) national studies on interventions (both conservative and operatively). In the presence of a large osseous defect, the patient experiences almost always instability problems of their shoulder. In these situations, provision of a stabilizing shoulder operation in a narrower sense is necessary. In cases with bone loss of more than 20%, a Latarjet operation is commonly being performed. This procedure not only has a high complication rate but also compromises the function of one of the prime movers of the shoulder, the musculus subscapularis. The use of 3D printing techniques in any case does not compromise to this extent the important subscapularis muscle. But "no surgical innovation without evaluation". The development of a new surgical technique should ideally pass through different stages. These stages are described by McCulloch, in its so-called IDEAL-model.[47] (IDEAL Consortium, Lancet see Fig. 1) This model provides a number of easy to implement recommendations for the assessment and implementation of new surgical procedures. After that, the IDEAL-D-model was introduced to evaluate and regulate the use of medical devices and implants in an implant register (e.g. the LROI, www.LROI.nl).[48]

Previously, we have seen that the implementation of guidelines, but also new surgical insights, can be complex, as demonstrated, for example, by the implementation of a new guideline concerning blood management around hip and knee arthroplastics.[49] In development stage 1, also known as the preclinical stage, ex-vitro proof is being provided that safety and reliability is ensured, as in our cadaver study (Chapter 7). At this stage, the surgeon must prove that the concept works (= Proof of concept) and only a few orthopaedic surgeons are involved. In Stage 2a, the new procedure is further developed

	1 Idea	2a Development	2b Exploration	3 Assessment	4 Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Single digit; highly selected	Few; selected	Many; may expand to mixed; broadening indication	Many; expanded indications (well defined)	All eligible
Number and types of surgeons	Very few; innovators	Few; innovators and some early adopters	Many; innovators, early adopters, early majority	Many; early majority	All eligible
Output	Description	Description	Measurement; comparison	Comparison; complete information for non-RCT participants	Description; audit, regional variation; quality assurance; risk adjustment
Intervention	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method	Structured case reports	Prospective development studies	Research database; explanatory or feasibility RCT (efficacy trial); diseased based (diagnostic)	RCT with or without additions/modifications; alternative designs	Registry; routine database (eg, SCOAP, STS, NSQIP); rare case reports
Outcomes	Proof of concept; technical achievement; disasters; dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes	Clinical outcomes (specific and graded); middle-term and long-term outcomes; patient-centred (reported) outcomes; cost-effectiveness	Rare events; long-term outcomes; quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No
Examples	NOTES video	Tissue engineered vessels	Italian D2 gastrectomy study	Swedish obese patients study	UK national adult cardiac surgical database

Fig. 1: IDEAL model including different stages of surgical innovation.
Abbreviations: RCT, randomised controlled trial; SCOAP, Surgical Clinical Outcomes Assessment Programme; STS, Society of Thoracic Surgeons; NSQIP, National Surgical Quality Improvement Program; NOTES, natural orifice transluminal endoscopic surgery.

due to the need for a new solution to a clinical problem (here: shoulder instability with > 20% bone loss). The results must be described in detail. Stage 2b is the exploration and learning phase, in which the surgical procedure is being applied to a larger group of patients to gain experience with the first use and to refine the precise technique or implant. Stage 3 is the assessment phase. At this stage, the aim is to assess the effectiveness of the procedure compared to other procedures. Stage 4 is the last phase, after which the procedure can be used world-wide. The results should be monitored in the long term: does the implant still remains properly fixed in the bone defect? For this late evaluation, micromotion measurements are being needed between implant and bone (such as with RSA or CT) to predict late complications such as implant detachment.[50,51]

In my opinion, 3D printing can be a promising new technology with the potential of offering additional possibilities for orthopaedic surgeons, such as presented in our latest study (Chapter 7) for patients with instability problems of their shoulder due to bone loss. However, to make this specific implant a success, in the end, the titanium implant ideally needs to be replaced by a bioscaffold, in which bone cells can grow. After which incorporation of the implant into the native glenoid bone is possible. This means that the implant is not printed out of titanium, but from material which can be converted into bone by the body itself, such as calcium phosphate. On the other hand, the nanostructure properties of metal are more optimal in strength and stability than those of resorbable bioscaffolds. Ultimately, evaluation is required according to the IDEAL principle: Idea → Development → Exploration → Assessment → Long-term follow-up.[47,52,53] Only with this methodology, a meaningful improvement of quality of patient care can be created.

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