First Experiences with the New Shoulder Prosthesis Promos®

a report by
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Background

The exact restoration of the glenohumeral joint is generally regarded as a prerequisite for normal shoulder function after arthroplasty.[1-3] However, large inter-individual variations remain a challenge for any implant design. Differences in head inclination, collum antetorsion, offset of the centre of rotation and eccentricity of the head, as well as different shapes of the medullary canal of the humerus, require a modular prosthesis design.[4] These findings led to the development from the first monoblock design by Neer[5] to the third generation of modular shoulder prostheses.[6] Although studies with a high evidence level are still missing, it is assumed that better functional results are possible with modular shoulder designs.

However, the possible reconstruction result is still limited by the surgical technique used, especially by the assembling of the prostheses. The restoration of the original height in fracture cases is achieved in most cases by complex aiming devices. After the initial decision for a prosthesis configuration, several parameters, such as inclination or antetorsion, cannot be changed without major effort.

This was the starting point for a completely new approach for the assembling of total shoulder prostheses. The new type should be assembled step by step *in situ* with all possibilities available for changes that might be required intra-operatively. The individual adaptation of the correct height, antetorsion and inclination should be possible, even after the insertion of the definitive shaft. The prosthesis design should allow for correction of all parameters separately, e.g. change of antetorsion without concomitant change in inclination. The full exchangeability of all components should form the basis for alternative treatment options, such as inverse design in the later treatment of the patient.

New Technical Features

The requirements were fulfilled with a unique modular prosthesis design based on a rectangled, non-cemented shaft. The shape prevents rotation around its longitudinal axis without cementing. The body (metaphyseal component) in different heights helps to restore the original length of the humerus and can be fixed in any antetorsion angle. A special inclination set is utilised to determine the exact inclination of the prosthesis head. Different sizes help to achieve the correct offset. The prosthesis head is eccentric and allows for compensation of the exact centre of rotation. The rotation is secured by exact press-fit within the inclination set. A conventional polyethylene glenoid serves as the counterpart of the joint. No aiming device or sawing jig is required due to the high modularity of the system. The system is assembled *in situ* step by step using trial pieces. It is possible to assemble the whole prosthesis, test the function and exchange a certain part in order to achieve a better function. The high modularity also helps to restore shoulder joints with complex anatomy, e.g. in rheumatoid arthritis (RA) or post-

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2. *Cameron B, Galatz L, Williams GR, Jr, "Factors affecting the outcome of total shoulder arthroplasty",* Am J Orthop *(2001);30(8): pp. 613–623.*
3. *Iannotti JP, Williams GR, "Total shoulder arthroplasty. Factors influencing prosthetic design",* Orthop Clin North Am *(1998);29(3): pp. 377–391.*
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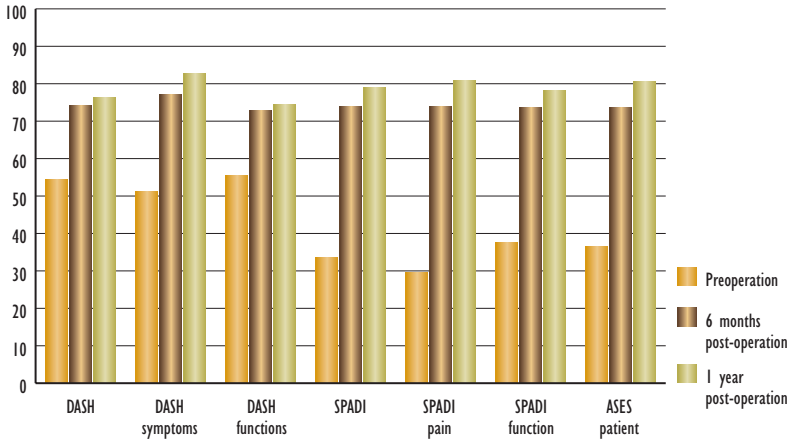
5. *Neer CS 2nd, "Reconstructive surgery and rehabilitation of the shoulder",* Textbook of Rheumatology, *Saunders (1985); pp. 1944–1959.*
6. *Boileau P, Walch G, "The three-dimensional geometry of the proximal humerus. Implications for surgical technique and prosthetic design",* J Bone Joint Surg Br *(1997);79(5): pp. 857–865.*

Figure 1: The Modular Design og the Prosthesis. All Pieces are Available in Different Sizes to Cope with All Anatomical Variations



traumatic cases. Parts of the prosthesis, e.g. the head, can be revised without removal of the whole device. A later conversion to an inverse design is possible, since an adequately fixed shaft may remain *in situ*.

First Experience

Materials and Methods

All patients were treated with total shoulder arthroplasty using the modular Promos system. Since its introduction, 127 prostheses have been implanted and followed prospectively [at time of writing]. Follow-ups were performed at six (n=97) and 12 months (n=78) after operation. Shoulder function was assessed by objective parameters, such as active and passive range of motion (ROM). Abduction strength was measured using a spring balance as required in the Constant-Murley Score. All X-rays were assessed by an independent observer. Special attention was paid to changes between the different parts of the modular prosthesis and signs of loosening or resorption.

In addition to the so-called objective parameter function of the shoulder, the joint, the complete upper extremity and the subsequent quality of life were assessed by the patient using a validated set of scores.[7] Shoulder specific function was assessed by patients with the Shoulder Pain and Disability Index (SPADI), the American Shoulder and Elbow Surgeons (ASES) questionnaire for the shoulder, function of the whole arm with the Disability of the Arm, Shoulder and Hand (DASH) questionnaire and general health with the Short Form-36 (SF-36). Additionally, the Constant-Murley Score was used to assess shoulder function. All scores were normalised from 0=worst to 100=best for better comparison. All scores were also stratified by the underlying indication. DASH and SF-36 were compared with normative data stratified for age, sex and co-morbidity.

Results

All items of the patient self-assessment improved significantly (see *Figure 1*). The largest changes were noticed for pain (SPADI +172%) and function (SPADI +109%). As expected, passive ROM recovered faster than active ROM. Significant deficits to normative data remained despite the large improvements (DASH norm versus patients $p<0.001$, SF-36 Physical Component Summary (PCS) $p=0.035$).The values of the Constant-Murley Score reached the level of the age-matched control group ($p=0.54$). Small but not significant differences were observed for the different indications. RA patients did not reach the same functional results as osteoarthritis (OA) patients operated on with Promos prostheses (DASH 78.0 in OA versus 67.4 in RA, PCS 74.3 in OA versus 67.6 in RA).

Radiological staging revealed no signs of implant loosening, but radiolucent lines at the glenoid were 25% at the latest follow-up. During the authors' learning curve, four intra-operative fractures were observed during insertion of the shaft. All were fixed with cerclages. Three of them healed uneventfully; one was aggravated by massive obesity and further concomitant diseases. No further intra-operative fractures were observed, due to improvements in the technique and the definition of guidelines regarding the relation between stem size and width of the intramedullary canal. In two cases, rotation of the prosthesis head was observed due to new trauma, and in an additional three cases without new trauma. A thorough biomechanical analysis was performed to explain the failures. The results were used to change the design of one connection in the modular system, as well as an instrument to guarantee the longevity of the prosthesis.

Discussion

The first experiences with the newly developed system met the expectations of the development process. The most striking feature is the full modularity of the prosthesis. Careful choice of all prosthesis components led to adequate restoration of

7. *Angst F, Pap G, Mannion AF et al., "Comprehensive assessment of clinical outcome and quality of life after total shoulder arthroplasty: usefulness and validity of subjective outcome measures",* Arthritis Rheum *(2004);51(5): pp. 819–828.*
8. *Flury M, Goldhahn J, Schwyzer H-K, et al., "Are non-cemented, modular prostheses suitable for total shoulder replacement in rheumatoid arthritis?" 14th European Rheumatoid Arthritis Surgical Society Meeting (ERASS), Pfäffikon/Schweiz, 2006.*

the joint anatomy, even in difficult cases. The perception of the surgeons was proven by the good and very functional results. The objective and subjective parameters are comparable or slightly better than with other types.[8] Large improvements in function of the joint and the arm indicate that the new design leads to better results as assessed by the patients themselves. The detailed analysis clearly shows that patients with complex anatomy especially benefit from the new design. In this group, the largest improvement compared to conventional designs can be expected.

The new design led to some specific problems that could be solved during the learning curve. Cement-free fixation of shoulder prosthesis involves the risk of a fracture. The fractures observed by the authors with a rectangular shaft were simple torsion fractures. They could be prevented with an adaptation of the surgical technique. A separate biomechanical testing was initiated to evaluate whether the rectangled shaft is associated with an increased risk of diaphyseal fracture. Rotation of the head as seen in a few cases can be prevented with a changed interconnection and a torque measurement device for its assembly.

Outlook and Conclusions

The results are comparable with other prosthesis designs; however, the *in situ* assembling of the prosthesis promotes the restoration of complex anatomy, e.g. in RA or post-traumatic cases.

Further development is directed towards the addition of an inverse component. This will allow conversion to an inverse design without the need to exchange the stem and broaden the range of indications that may benefit from the new prosthesis system. ■

Acknowledgement

The development of the patient self-assessment score set, as well as parts of the follow-up, was funded by the Georg and Bertha Schwyzer-Winiker Foundation. The authors thank Susann Drerup for her tremendous work in organising the follow-ups and the data management.