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Replacing temporomandibular joints

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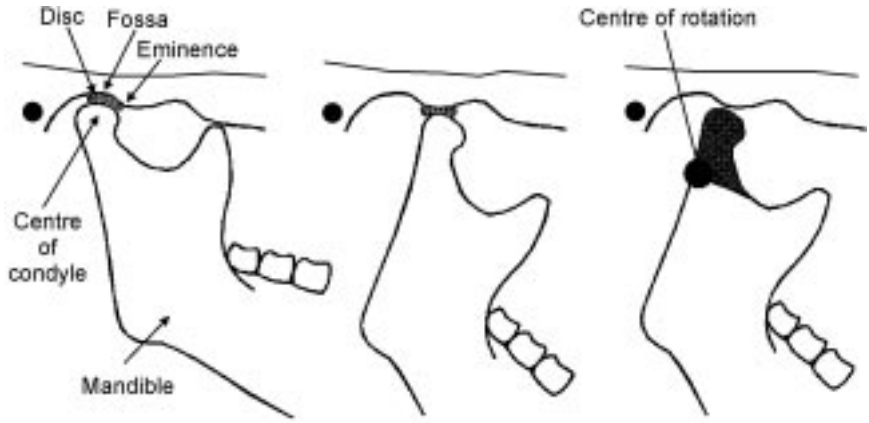
22.1 Introduction

The masticatory system plays an important role during biting, chewing, swallowing, speech, singing and other functions, all directly affecting quality of life. For proper functioning, both temporomandibular joints and the connecting mandible (Fig. 22.1), together with the masticatory muscles and contiguous tissue components, play a major role. In a healthy situation, the masticatory muscles supply the mandible with the required movements and biting and chewing forces, while the left and right mandibular condyles slide smoothly along their articular eminences (Fig. 22.1).

Disturbances of the masticatory system can lead to a wide range of both muscular and temporomandibular joint (TMJ) conditions and pathology, resulting in pain, limited mouth opening, headaches, clicking or popping sounds in the TMJ, and impaired masticatory functioning. Looking more specifically at the TMJ, the conditions affecting this joint most frequently are osteoarthritis, condylar fractures and ankylosis. In addition, TMJ disturbances and muscle problems influence each other and may lead to chronic pain and functional impairment.[1,2] The vast majority of TMJ patients are women in their third and fourth decades.[2]

It has been shown by the Groningen TMJ Research Group and other research groups that TMJ degenerative diseases have a considerable self-limiting behaviour, and non-surgical therapy will reduce the presented signs and symptoms in the majority of TMJ patients.[3–7] Arthroscopic intervention can be considered when non-surgical efforts have failed. Open joint surgery is indicated only when all other methods were unsuccessful, and pain and limitation of movement mean that the patient's quality of life is affected significantly. In clinical practice a small group of TMJ patients with severe pain and TMJ destruction causing a strong limitation of function remains therapy resistant. For these patients, the available treatment modalities do not offer a proper solution, and alloplastic reconstruction of these mutilated TMJs may be the only remaining treatment option.

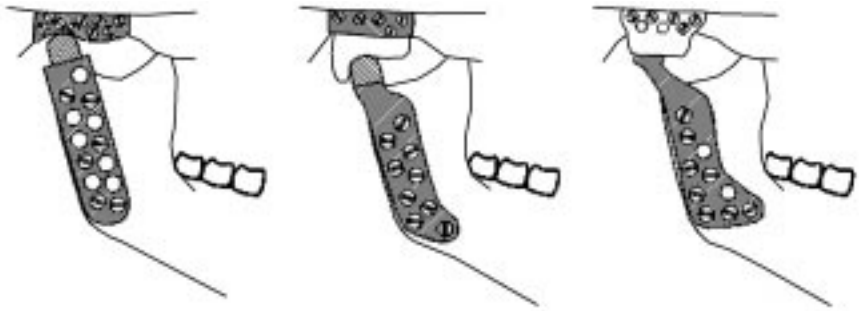


22.1 Lateral view of the temporomandibular joint (TMJ). Left: the condyle at the mandibular side, the articular fossa and eminence at the skull side, and the intervening articular disc. Middle: natural mouth opening, with the condyle translating smoothly along the eminence. Right: imitated condylar translation as a result of the centre of rotation located approximately 15 mm inferiorly of the centre of the condyle. Note that the condyle is removed when a TMJ prosthesis is placed.

The 1980s brought the first commercially available TMJ replacement, the Vitek-Kent prosthesis. This so-called 'anatomical replica' consisted of a metal mandibular (jaw side) part, articulating directly against a poly(tetrafluoroethylene) (PTFE) skull part, thus without an intervening artificial disc. As most previous and later designs, the mandibular part resembled a bone plate with a head, fixed by screws to the lateral side of the mandible. The skull part covered the inferior side of the fossa and articular eminence and was fixated by screws to the lateral side of the articular tubercle.

The PTFE skull part was less than 1 mm thick, and was coated at the cranial side with Proplast for tissue ingrowth. The same firm also marketed a 'disc implant' to replace the articular disc after discectomy, or to resurface the temporal bone of the skull. The PTFE skull parts and disc implants showed a disastrously high wear rate in combination with deteroriation of the Proplast coating. The resulting particles caused severe soft-tissue irritation and bone resorption.[8,9] As a major consequence of this disaster, several thousands of these prostheses were removed, with the result that in the United States a corresponding number of patients are now waiting for a solution for their mutilated TMJs.[9] Fortunately, in Europe a much more conservative management of TMJ problems was followed, and only few patients received Vitek-Kent products.

Since the Vitek-Kent prosthesis, a small number of new TMJ prostheses have been realised.[10] The major causes of the small numbers are the complex shape and wide range of movements of the TMJ and the small market, in combination with high financial risks in the case of failing devices. Currently, there are three



22.2 The three TMJ prostheses currently available on the market: Left: the TMJ Implants, with a metal–metal articulation; Middle: TMJ Concepts, with a metal head against a metal-backed polyethylene surface; Right: W. Lorentz Surgical, with a metal head against a polyethylene skull part.

TMJ prostheses on the market, namely those from TMJ Implants Inc. (Golden, Colorado), from TMJ Concepts (Ventura, California) and from Walter Lorenz Surgical Inc. (Jacksonville, Florida) (Fig. 22.2).

The TMJ Implants prosthesis was designed in the early 1960s. At that time, the mandibular part had a poly(methylmethacrylate) (PMMA) head, functioning against a chrome–cobalt skull part. At the end of the 1990s, the PMMA head was replaced by a chrome–cobalt head, resulting in a metal-on-metal articulation with a small contact area. For the skull part, a large (33) number of different shapes are available, per side, while for the mandibular side four sizes are available. Interestingly, the commercialisation of this design started only in 1988, after the Vitek-Kent disaster. At that time, the device could be marketed in the United States without any clinical study because it had been used, on a very small scale, prior to 1976.

From the start of its development, the TMJ Concepts prosthesis has been a fully custom-made product. The skull part is made from titanium mesh, with an ultra-high molecular weight polyethylene (UHMWPE) lining underneath. The mandibular part is made of titanium alloy with a cobalt–chrome head.

Just recently, after 15 years of development, the Walter Lorenz (Biomet) prosthesis entered the US market. The design looks similar to the TMJ Concepts, with two important differences. Firstly, the prosthesis consists of a set of standard shapes, both for the skull part as well as for the mandibular part. Secondly, the skull part is made completely out of UHMWPE, without a metal backing. To get a good fit, the articular eminence is flattened and the skull part is placed directly against the bone. Because the articular eminence extends inferiorly, a space remains at the posterior side, between the fossa and the UHMWPE skull part. According to the website of the company, this space may be filled with PMMA bone cement, but there should not be any load on the cement.

With fewer than 1000 patients per year, the number of patient applications of all three of these prostheses is very low compared with hip and knee prostheses.

At the moment only a small number of patients with severe TMJ problems are considered for such a total TMJ replacement. It may be expected, however, that when a clinically proven and properly functioning TMJ prosthesis is available, the indications will broaden considerably.

Athough the Vitek-Kent prosthesis was poorly designed for long-term functioning, it nevertheless showed that a total TMJ replacement can significantly decrease TMJ pain and restriction of movement. Therefore, a project was started at the Department of Oral and Maxillofacial Surgery of the Groningen University Hospital, aiming at the realisation of a TMJ prosthesis that meets all necessary requirements.

During the development of the TMJ prosthesis, three major problems were faced. The first problem was to imitate the large translatory movements of a healthy TMJ. During rest of the mandible, the unloaded condyle and disc are located in the glenoid fossa, on the dorsal slope of the articular eminence (Fig. 22.1). During all mandibular movements, the (loaded) condyle-disc complex is always located more anteriorly, with anterior movements that can exceed 15 mm for maximal opened mouth position (Fig. 22.1).[11] All existing TMJ prostheses lack this anterior condylar movement. Imitation of the anterior movement is especially important because restricted movements of one TMJ cause abnormal deviations of the contralateral TMJ. Although many TMJ patients have symptoms of both TMJs, it is believed that in most cases the problems start on one side, after which malfunctioning affects the contralateral TMJ as well. It is expected that if the symptomatic joint is replaced by a prosthesis that has the ability to imitate condylar translation, the contralateral TMJ can be protected against further damage.

Second, the considerable variation in size and shape of the cranial part of degenerated TMJs complicates the fitting of the prosthesis to the skull. Because the small volume of the cranial part of the TMJ leaves very limited possibilities to adapt the bony structures, it is the TMJ prosthesis that must be adaptable to all variations in size and shape of these structures. In addition, the subtle shape of these bony structures also limits the possibilities for stable fixation to the skull.

Third, the long remaining lifetime of TMJ patients makes that it is essential that a TMJ prosthesis has a similar long lifetime. To be able to guarantee long lifetime, a TMJ prosthesis should be extensively tested prior to patient application. This evaluation should include the expected wear properties of the prosthesis, because wear particles can cause severe adverse tissue reactions. For hip and knee joint prostheses, the formation of large amounts of wear particles is the major cause of long-term failure.[12,13] The results of the Vitek-Kent prosthesis have shown that the TMJ area is also sensitive to wear particles. The necessity of a long lifetime is stressed by the knowledge that the lifetime of hip and knee joint prostheses decreases with every revision surgery.[14] It has been indicated that this will be the case for TMJ prostheses as well.[2]

In this chapter, the requirements for a safe, biocompatible and proper functioning TMJ prosthesis are given. A design that meets these requirements is shown, including the test results and the results of the first clinical application of the developed TMJ prosthesis.

22.2 Temporomandibular joint prosthesis criteria

The three major problems mentioned that should be solved during development of a TMJ prosthesis were elaborated to a complete list of requirements (Table 22.1). A TMJ prosthesis should meet all 11 requirements.

Imitation of functional movement is especially important in case of unilateral TMJ replacement because the movements of the prosthetic side influence the movements of the opposite non-replaced TMJ. While in healthy persons condylar translation exceeds 15 mm during maximal mouth opening, prosthetic condylar translation is known to be less than 2 mm.[15–17] It has been shown that such a limited condylar translation causes unnatural large lateral deviations of the mandible towards the prosthetic side,[18] which will probably adversely affect the non-replaced TMJ. Therefore, a TMJ prosthesis should imitate the condylar translation during mouth opening (requirement 1), without restricting the non-replaced TMJ (requirement 2).

Realisation of a close fit to the skull is complicated by the fact that there is a considerable variation in shape of the skull side of the TMJ, which must fit correctly (requirement 3). In addition, the prosthesis should fit all possible shapes of the mandible (requirement 4), all parts should be of sufficient strength (requirement 5), and the TMJ prosthesis should be stably fixed to the bony structures (requirement 6).

A long lifetime is a normal requirement for a joint prosthesis, but for the TMJ this is even more important because most TMJ patients are relatively young, with a life expectancy of 30–60 years. Because, in general, the expected life of a joint replacement decreases with the number of revision surgeries[19,20] the aim

Table 22.1 Requirements for a TMJ prosthesis

1	Imitation of condylar translation
2	Unrestricted mandibular movements
3	Correct fit to the skull
4	Correct fit to the mandible
5	Sufficient mechanical strength
6	Stable fixation to the bony structures
7	Expected lifetime of more than 20 years
8	Low wear rate
9	Wear particles tolerated by the body
10	Biocompatible
11	Simple and reliable implantation procedures

should be to limit the number of revision surgeries to one, leading to a required lifetime of the prosthesis of a minimum 20 years (requirement 7).

The lifetime of a joint prosthesis, as it is known from hip and knee joint prostheses, is strongly related to the wear rate. It is generally accepted that the constant formation of wear particles leads to bone resorption, which is a major reason for long-term failure of hip- and knee joint prostheses.[13,21] It was assumed that the formation of relatively large amounts of wear particles will also adversely affect the TMJ. Therefore, any TMJ implant should be carefully evaluated with regard to this aspect prior to patient application (requirements 8 and 9).

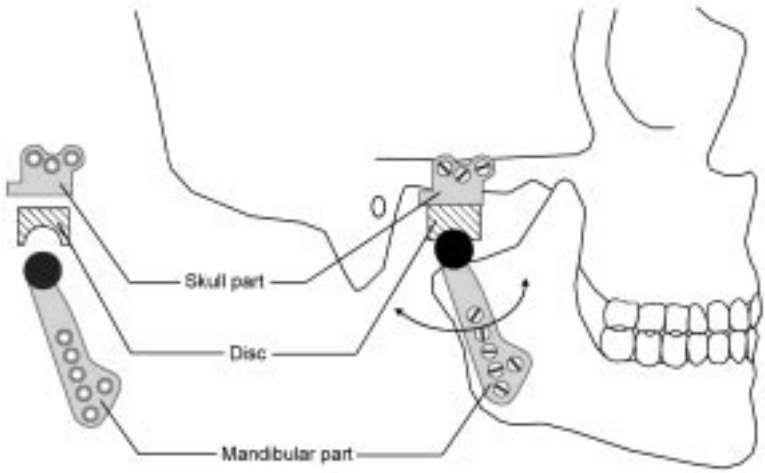
Two additional requirements count for permanent implants in general. The prosthesis should be well tolerated by the patient's body (requirement 10), and the prescribed implantation procedure should allow the surgeon to achieve the intended position of all prosthesis parts (requirement 11).

22.3 Design

In the first part of the research in Groningen, it was found that the natural sliding movement of the condyle can be imitated with a fixed, 'inferiorly located' centre of rotation (Fig. 22.1).[11,18,22,23] The study showed that when the centre of rotation is positioned in the area of the (former) natural condyle, the movements of the non-replaced TMJ exceed the natural movements, while when it is located 15 mm (or more) inferiorly, the movements of the non-replaced TMJ remain within the natural limits.[18] This location was therefore considered the optimal centre of rotation. It has also been demonstrated that an inferiorly located centre of rotation does not increase the loading of the non-replaced TMJ, while the maximum load on the TMJ prosthesis itself will be approximately 100 N.[24]

This inferiorly located centre of rotation had a second advantage, namely that it automatically created space to design a proper, low-wear articulation. For the articulating surfaces of joint prostheses, UHMWPE opposed by a hard counterface seemed a good choice because it is the most frequently applied material, with a history of successful long-term application.[14,25] Although there is also long-term experience with hip joint prostheses that use a ceramic–ceramic or a metal–metal articulation, these combinations are more difficult to apply because they wear slowly only if both parts match each other closely.[26,27] In general, low contact stresses are advantageous for achieving a low wear rate[28,29] and therefore the load was divided over a large contact area by the application of a ball and socket joint. Because the stress in the UHMWPE decreases with increasing thickness,[30,31] and a decrease of the stress results in a decrease of the wear rate,[28,29] the minimum disc thickness was set to 5 mm.

This ball and socket joint agreed well with the idea of one centre of rotation, but restricted any horizontal movement of the mandible. Therefore, the UHMWPE disc was given freedom to make small sliding movements against



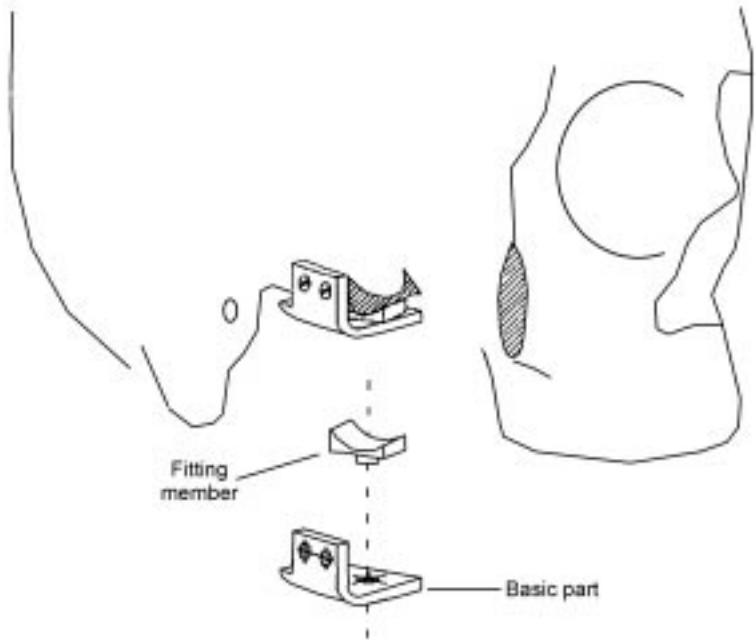
22.3 The basic design of the developed TMJ prosthesis, consisting of a metal–ceramic skull part, a metal–ceramic mandibular part, and an intervening polyethylene disc. The spherical head of the mandibular part rotates in the disc, while the mandibular part together with the disc has freedom to translate against the skull part.

a flat inferior surface of the skull part, resulting in a 'double articulation' with movements at the inferior and superior side of the disc (Fig. 22.3).[32] The sliding movements of the disc were assumed to be small. The centre of the spherical head then became the point of rotation of the prosthesis, located at the optimal centre of rotation.

The shape of the articulating surfaces could be realised only by a total TMJ prosthesis, replacing all components of the joint. This resulted in a primary design, consisting of a skull part, a mandibular part and, similar to the natural TMJ, an intervening disc (Fig. 22.3).

To fit the prosthesis to the skull, three fitting methods were considered, poly(methylmethacrylate) (PMMA) bone-cement, custom-made parts and stock parts. Bone-cement was rejected because of the high temperatures during polymerisation of the cement which may cause necrosis of the supporting bone. Custom-made techniques were rejected because of high costs and doubts about the accuracy of custom-made prostheses. Thus, stock parts were the remaining option.

Looking at the natural, healthy TMJ, it was noticed that the articular eminence is the load-bearing area on the skull side, and therefore the prosthesis is loading this part of the skull only. Because of the considerable differences between patients, the articular eminence and the lateral side of the TMJ were fitted separately. This resulted in a skull part composed of two connected parts, a basic part fixed to the articular tubercle and a cylindrically shaped fitting member facing the articular eminence (Fig. 22.4).[33,34] During implantation, the

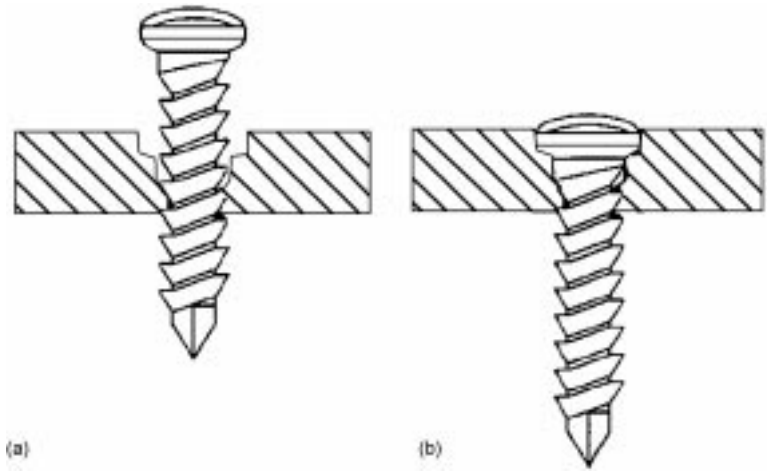


22.4 The skull part consists of a basic part and a fitting member. The basic part is fixed with bone screws to the lateral side of the TMJ, in the region of the articular tubercle. The fitting member fits the articular eminence and can rotate relatively to the basic part, around a vertical axis.

fitting member has the freedom to rotate around a vertical axis relative to the basic part, allowing the fitting member to follow the shape of the articular eminence while the basic part keeps in contact with the articular tubercle. This 'self-adjustment' should result in the best fitting position of both parts.

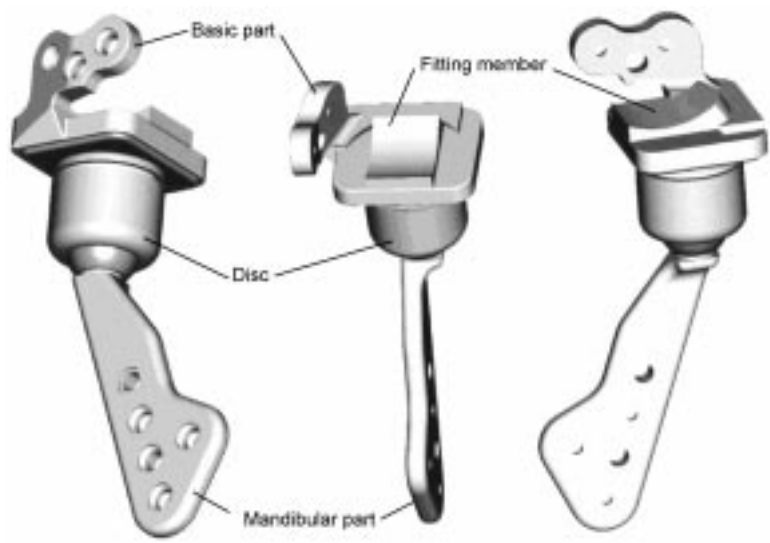
Regarding the mandibular part, the majority of TMJ prostheses uses a flat, non-adaptable mandibular part, positioned against the lateral side of the mandibular ramus.[10] No problems have been reported except when using a small number of screws.[10,35] The mandibular part therefore consists of a flat plate with a spherical head on top.

To ensure an immediate stable fixation, bone screws with sharp thread were selected, similar to self-tapping osteosynthesis screws. The dimensions of the bony structures, especially at the skull side, limited the maximum screw diameter to 2 mm. For extra stability, bicortical fixation was preferred. In addition, to further increase stability, possible movements between screw and prosthesis were eliminated. This 'rigid connection' was achieved by a screw-thread at the inner side of the screw holes (Fig. 22.5).[36] For the insertion of the screws, dental implant techniques were adopted. For the mandibular part, conventional screw fixation is thought to be sufficient, but to increase the stability the rigid connection was also applied.



22.5 The rigid connection between screw and prosthesis is achieved by screwthread of the screw gripping in contra screwthread at the inside of the hole in the prosthesis. During the insertion (a) and in final position (b).

The final design of the TMJ prosthesis (Figs 22.6 and 22.7) was based on the design considerations mentioned above, and the selected materials. For the surfaces opposing the UHMWPE disc, zirconium oxide ceramic was chosen because of its excellent biocompatibility and scratch-resistance, in combination



22.6 The designed TMJ prosthesis, consisting of a skull part, a mandibular part, and an intervening artificial disc, in three views: in latero-caudal view (left), in ventro-cranial view (middle) and in medio-cranial view (right). The skull part consists of a basic part and a fitting member.

22.7 Lateral view of the Groningen TMJ prosthesis on the stereo-lithographic model of the first patient.

with a high strength.[37,38] The other parts, except for the screws, were made from commercially pure titanium (cp-Ti), because of its proven biocompatibility. The screws were made from the stronger Ti alloy (Ti6Al4V), for greater safety.

For composing the 'self-adjusting' skull part, four different basic parts and three different fitting members were designed. The basic parts differed with regard to the caudal-cranial position of the screw holes, the fitting members with regard to the radius of the cylindrical surface facing the articular eminence. The basic part was fixed by three bone screws with the outer two screws rigidly connected to it. Its inferior side was covered by a zirconium oxide inlay. The fitting member could rotate around a pin at its caudal side, while a dovetail joint at its posterior side ensured attachment to the basic part.

The mandibular part came in four versions, differing with regard to the overall length and the latero-medial position of the head. The zirconium oxide head had a diameter of 8 mm. Fixation was achieved with five bone screws, three of them being rigidly connected to the mandibular part. The cylindrically shaped UHMWPE disc had an outer diameter of 12 mm. For initial attachment, the disc was given a 'snap' connection on the spherical head of the mandibular part. A circular cp-Ti wire around the disc provided X-ray visualisation. Templates were provided with the permanent prosthesis parts, to determine the correct position of these parts and to guide the drill in the correct direction. Small canals led the cooling water directly to the drilling site.[39]

22.4 Development and test procedures

Prior to the first clinical application, the above described different parts of the design were evaluated and tested and finally animal tests were performed with the complete TMJ prosthesis. The designed articulation resembles the functional shape of the natural TMJ, with rotation at the inferior side and sliding movements at the superior side of the disc. As previously stated, the translatory movements of the disc will be small and, in contrast to the natural situation, rotation will be the major movement. Condylar translation is therefore imitated by the inferiorly located centre of rotation, located in the middle of the spherical head of the prosthesis, approximately 13 mm below the peak of the articular eminence. It appears that this location agrees well with what is considered the optimal centre of rotation, 15 mm below the centre of the natural condyle. The first requirement, imitation of condylar translation, was therefore met.

The remaining translatory capacities of the articulation, although small, are advantageous for following the cusps of the molars during masticatory movements. Furthermore, they provide freedom of movement in the contralateral non-replaced TMJ. The articulation therefore met the second requirement.

Fitting the skull is a major problem in TMJ reconstruction patients, because of the irregular shape of their TMJs.[10] Therefore, there is a tendency towards custom-made skull parts, which are expensive owing to the complicated and time-consuming procedure. For these reasons a stock-part design was developed. The major invention is the application of two separate parts which fit separate sides of the skull part of the TMJ. This leaves the surgeon more options to achieve a correct fit than with other stock-part designs.

To determine the fit of the designed skull part, prototypes of the basic part (four sizes) and the fitting member (three sizes) were tested on 20 dry skulls.[34] For every skull, the best fitting basic part and fitting member were selected, and the maximum gap between the fitting member and the articular eminence was subsequently determined. All skulls could be fitted well. The average maximum gap between the fitting member and the articular eminence was 0.2 mm, with a range of 0.11–0.43 mm.[34] These results were even better than the accuracy of stereo lithographic models which is in the order of 0.5 mm.[40–42] However, the tested skulls had relatively naturally shaped TMJs and the development of the set of fitting members is not finished yet. The final set should be kept small and needs to be further judged with regard to the third requirement.

The designed mandibular part resembles existing mandibular parts. Therefore, it is expected that there will be no problems with this part, and thus the fourth requirement seemed to be met.

To determine the strength of the skull part and the mandibular part, three-dimensional finite element models were developed. The maximum Von Mises stress in the prosthesis parts and the corresponding loads on the screws were calculated. The load on the TMJ prosthesis was set at 100 N, the expected

maximum load on a TMJ prosthesis.[24] For the skull part, the load was applied at the inferior side by the disc, in a cranial direction. A small contact area (1 mm^2) was assumed between fitting member and skull. All possible positions of the disc, as well as of the contact area between fitting member and skull, were included in the calculations. For the mandibular part, the direction of the load vector was varied to simulate all possible positions of the mandibular part relative to the skull part. Non-rigidly connected screws were assumed to carry no load. The calculations showed that the stresses in the skull part and the mandibular part remained well below the maximum allowed stress for cp-Ti (i.e. 180 N/mm^2), so the fifth requirement was met. For the skull part, the maximum loads on the screws were 150 N in the radial direction and 3 N in the axial direction. For the mandibular part, the maximum loads on the screws were 155 and 11 N in radial and axial directions, respectively.

The *in vitro* strength and stability of the designed rigid connection were tested by static and dynamic loading of rigidly connected screws.[36] In the axial direction, the rigidly connected screws could resist static loads of over 500 N. In a radial direction, the screws could resist static loads of over 200 N when loaded at a distance of 2.5 mm from the prosthesis, increasing to over 500 N when loaded close to the prosthesis. During the dynamic tests, the screws were loaded in the radial direction at a distance of 2.5 mm from the prosthesis, with a load varying between −70 and 70 N, for 5 million cycles. This dynamic shear loading did not induce movements between screw and plate.[36] Therefore the sixth requirement seemed to be met.

The field of TMJ reconstruction has a history of failing TMJ devices, which, among other problems, induced severe bone resorption and degeneration as a result of extreme high numbers of wear particles.[8,43,44] Therefore, the expected wear rate of the UHMWPE disc was determined, using a wear testing machine especially developed for this purpose.[32,45] The testing machine simulated the movements of the mandibular head against the disc, using a maximal mouth opening of 28º and a lateral deviation of 2º. The (constant) load was 200 N, almost twice the expected maximum *in vivo* loading of the prosthesis.[24] The tests ran for 7 million cycles, corresponding to 10 years *in vivo* functioning.[46] From the test results, the expected yearly *in vivo* wear rate was calculated, for both sides of the disc. The expected total disc wear rate was 0.65 mm^3 per year, equivalent to a decrease of thickness of the disc of less than 0.01 mm per year, or 0.2 mm in the required lifetime of 20 years.[32]

Although the tests showed a low wear rate, no data are available on the acceptable amount of UHMWPE wear particles in the TMJ. Therefore, the results were compared with the wear rate of hip joint prostheses. The experiences with hip joint prostheses have shown that the body can tolerate huge amounts of UHMWPE wear particles, in the range of 25–75 mm^3 per year,[47,48] the majority of the particles being of the submicrometre size.[49] Still, the life expectancy of a hip joint prosthesis is 10–15 years.[25] Compared with the yearly

wear volumes for hip joint prostheses, 0.65 mm^3 per year for our TMJ prosthesis is thought to be a sufficiently small amount to ensure a long lifetime. Furthermore, compared with the initial disc thickness of 5 mm, the expected decrease in thickness of 0.2 mm after 20 years of functioning is minimal. From these results it has been concluded that the seventh and eighth requirements were met.

As a final test, the designed TMJ prosthesis was tested in 12 sheep.[50] The shape of the prosthesis was slightly adapted for application in sheep, but the general shape and dimensions differed marginally from the human design. The follow-up period ranged from two weeks to four months. One sheep was excluded because we could not achieve a correct position of the prosthesis parts.

All sheep functioned with their TMJ prosthesis until they were killed. In the majority of the animals, the prosthesis parts were stable with favourable tissue reactions.[50] There was one mechanical failure of a posterior screw of the skull part. This problem could be attributed to an incorrect position of the skull part, resulting in insufficient support of the fitting member and increased loading of the screws. One disc dislocated shortly after the implantation because of an incorrectly positioned skull part in combination with the absence of pre-stress on the disc. A second disc dislocated at a later stage, most likely accidentally. Although 2 out of 11 discs dislocated, these dislocations could be considered accidents and be attributed to lack of surgical experience. Thus, dislocation may be prevented by correct implantation procedures and careful postoperative handling. Furthermore, some weeks postoperatively, fibrous encapsulation will make dislocation virtually impossible. Therefore, there will be little risk of disc dislocation.

The *in vivo* stability of the screws was studied in detail, as this gives an indication of the overall stability. For this purpose, harvested samples were histologically examined and the shear stress between the screws and the bone was calculated from removal torque measurements of the screws. For all mandibular parts, the screws were well incorporated in the bone, with no fibrous tissue layer between the screw and the bone. The average shear stress between the screw and the bone was 3.4 N/mm^2 (standard deviation 1.3 N/mm^2). For the skull part, most screws were well incorporated in the bone, with shear stresses slightly below those for the mandibular part (2.3 N/mm^2, standard deviation 1.2 N/mm^2).

For long-term stability, the screws must be well integrated by the bone, in the same way as dental screw-implants are securely osseo-integrated in the mandible. However, for dental implants an unloaded time period is preferred to allow the implants to heal into the bone, while, in contrast, the screws of the TMJ prosthesis are immediately loaded. In patients who have not been chewing firmly for a long time, the loading will be limited, and can be further reduced by prescribing a soft diet. The animal tests are considered a rough test because the sheep had no initial restrictions and could not be instructed to unload their prosthesis. Even under these severe loading conditions, the removal shear

stresses of the screws were in the same range as has been reported for well-integrated dental implants.[12,51,52] This indicated a good integration of the screws in the bone, and long-term stability can probably be achieved. In combination with the *in vitro* results, the sixth requirement seems to be met.

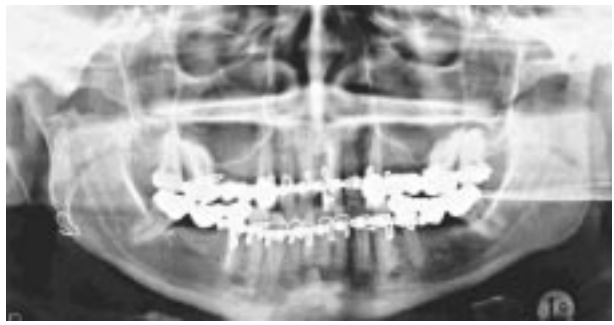
A prosthesis will function properly only when implanted correctly. Therefore, the implantation procedure was included in the development process and refined during the animal tests. Important for the procedure is the rigid connection between screws and prosthesis. After insertion of one rigidly connected screw, the position of the prosthesis parts cannot be changed. This problem was solved by first correctly positioning the prosthesis parts with non-rigidly connected screws, avoiding the need for subsequent positional changes. The usual tightening of the rigidly connected screws does not change the correct position of the prosthesis parts or the position of the screw in the bone, thereby avoiding unfavourable initial stress concentrations in the bone. We therefore found that the rigid screw–prosthesis connection positively influences the implantation procedure. A second important point is the prosthesis articulation, which allows the surgeon positional freedom in all six degrees of freedom and thus facilitates achieving a correct relationship between the mandibular part and the disc. Furthermore, the designed articulation allows the patient to postoperatively reposition the mandibular part in the position that is optimal for the non-replaced TMJ.

From the *in vitro* and the *in vivo* tests, it was concluded that the TMJ prosthesis met the ninth, tenth and eleventh requirements, regarding reactions to wear particles, biocompatible materials and simple and reliable implantation methods. The pre-clinical phase was therefore closed and the first clinical application prepared.

22.5 First clinical application

Application of the device in patients was allowed after approval of the study design by the Medical Ethical Committee, and after written informed consent of the patients. The first patient was a woman, age 43 years. She was referred to our clinic after multiple TMJ surgeries including discectomy, arthroplasties and joint reconstruction of the right TMJ with a rib-graft (Fig. 22.8). At referral the patient had a persistent one-sided (right) ankylosis, with a maximum mouth opening of 5 mm. Because of the severe joint pain the patient was at a high level of pain medication, including morphine 30 mg three times daily (3td), diclophenac 100 mg two times daily (2td), diazepam 5 mg. Owing to the previous surgeries there was a left-sided open-bite. The patient was dentate. It was decided to reconstruct her right TMJ with a TMJ prosthesis.

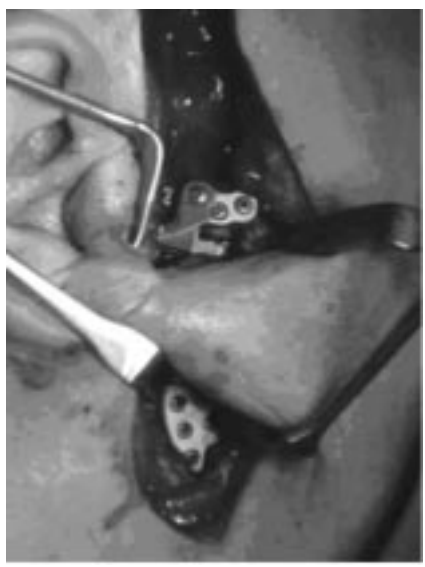
A stereo-lithographic model, based on three-dimensional computed-tomography (CT) data, was used to plan this first operation. The best fitting parts were determined after model surgery. Regarding the skull part, the size of the basic part was determined by the height of the articular tubercle, while the



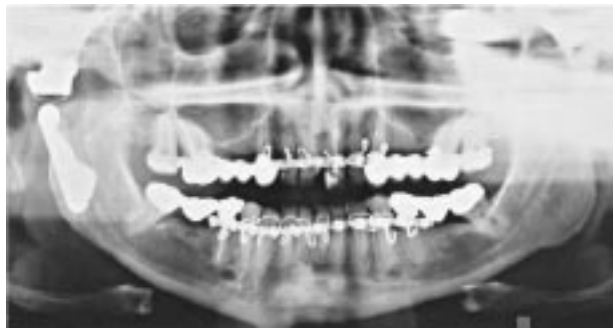
22.8 Preoperative panoramic radiograph of first patient showing a rib graft at the right side and an eroded mandibular condyle at the left side.

shape of the articular eminence determined the curvature of the fitting member. For the mandibular part, its length was determined by the height of the mandibular ramus. The position of the disc, preferably in the middle of the inferior side of the basic part, determined the choice between the mandibular part with medially or with laterally positioned head.

The implantation procedure was based on routine open joint surgery principles, following a pre-auricular approach for the skull part and a retro-mandibular approach for the mandibular part (Fig. 22.9). First a gap-osteotomy was performed at the level of the fossa and the remnants of the rib graft were



22.9 Preoperative view of the Groningen TMJ prosthesis. A pre-auricular approach is followed for positioning the skull part while the mandibular part is placed following a retro-mandibular approach.



22.10 Postoperative panoramic radiograph of first patient showing right-sided prosthesis in place.

removed to create space for the prosthesis. During surgery intermaxillary fixation was applied.

The skull part template was positioned parallel to the cranial edge of the articular tubercle, while it was gently pushed against the articular eminence to make the fitting member rotate into its best fitting position. The screw holes were drilled using a low rotational speed (1500 rpm) and firm pressure, to convert the energy of the drill to cutting and not to frictional heat.[39] To ensure proper distances between the screw holes, the template was kept in position by placing a pin in the drilled hole, for the first two drilled holes. The remaining hole could be drilled without further manipulation. The skull part template was then left in place and the mandibular part template was positioned together with the disc template, with some pre-stress on the disc. The screw holes were drilled following the same procedure as used for the skull part.

After the correct position of all parts had been achieved the templates were replaced by the permanent prosthesis parts, starting at the skull side. For the permanent skull part, the non-rigidly connected middle screw was inserted first, after which the two rigidly connected screws were inserted. For the permanent mandibular part, a similar procedure was followed. The incisions were closed in layers with a mini-redon in place. Peri-operative prophylaxis against infection was performed with cefuroxim 1500 mg i.v. 3td for 24 hours. Post-operative radiographs showed the correct position of all prosthesis parts (Fig. 22.10).

The patient's occlusion was preserved by applying intermaxillary fixation on elastics for the first two days. Thereafter this fixation was intermittent, with only active jaw movements by the patient herself. No physical therapy was prescribed. For pain relief the pre-operative pain medication schedule was continued.

Patient recovery was uneventful except for some persistent swelling of the operated side. The patient was discharged at 10 days postoperatively. The initial mouth-opening had at that time increased from 5 mm to 18 mm. The pain level was at the pre-operative level.

22.6 Conclusions

The presented TMJ prosthesis design is a mixture of well-known and accepted techniques, and new inventions. Among the well-known techniques are screw fixation and the use of proven biocompatible materials. The main new developments are a double articulation, including an inferiorly located centre of rotation, a self-adjusting skull part which is built from stock parts, and a rigid screw–prosthesis connection.

The Groningen TMJ prosthesis successfully made the difficult step from prototype to first patient application. The developed TMJ prosthesis appears to meet 8 of the 11 requirements shown in Table 22.1. The other three requirements, i.e. the fit to the skull (requirement 3), the expected lifetime of the device (requirement 7), and the reliability of the implantation procedure (requirement 11), require further evaluation.

22.7 Sources of further information and advice: useful websites

www.tmj.org
www.tmj.com
www.tmjconcepts.com
www.lorenzsurgical.com

22.8 References

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