Alloplastic temporomandibular joint replacement systems: 
The past, the present and the future

Sarah Vandeverre

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Promotor: Prof. M. Mommaerts
Co-promotor: Dr. Dr. M. Büttner
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# Table of content

Abstract...........................................................................................................................................4

I. Introduction....................................................................................................................................5
   I.1 Anatomy of the TMJ..................................................................................................................5

II. Materials and methods................................................................................................................7

III. Results..........................................................................................................................................9
   III.1 History....................................................................................................................................9
      III.1.a TMJ fossa-eminence prostheses and condylar prostheses..............................................9
      III.1.b Total temporomandibular joint replacement.................................................................10
   III.2 Materials used in TMJ prostheses.......................................................................................14
      III.2.a Stainless steel................................................................................................................15
      III.2.b Silicone – Silastic®.........................................................................................................16
      III.2.c Polytetrafluoroethylene – Proplast®...............................................................................16
      III.2.d Polymethylmethacrylate...............................................................................................16
      III.2.e Cobalt – Chrome alloys...............................................................................................17
      III.2.f Titanium..........................................................................................................................17
      III.2.g Ultra high molecular weight polyethylene..................................................................18
   III.3 Design and planning of a custom-made prosthesis.............................................................19
   III.4 Surgical technique................................................................................................................20
   III.5 Post-operative rehabilitation................................................................................................21
   III.6 Complication..........................................................................................................................22
      III.6.a Metal hypersensitivity.....................................................................................................22
      III.6.b Breakdown and corrosion...............................................................................................22
      III.6.c Micromovement and implant loosening.......................................................................23
      III.6.d Foreign body giant cell reaction....................................................................................23
      III.6.e Bacterial contamination and infection..........................................................................24
      III.6.f Facial nerve injuries........................................................................................................26

IV. Discussion..................................................................................................................................26

V. Conclusion....................................................................................................................................30

VI. References..................................................................................................................................31

VII. Addendum..................................................................................................................................36
Abstract

BACKGROUND: There is a long history of temporomandibular joint (TMJ) prostheses development, even though replacement surgery of the TMJ is relatively rare. No systematic review is currently available regarding both the history of developed TMJ prostheses and used materials in these TMJ prostheses. This review will focus on both these subjects.

MATERIALS AND METHOD: The information about TMJ prostheses was gathered by a computerised literature search on the databases of PubMed Central, Elsevier Science Direct, Ovid Lippincott Williams & Wilkins and Willy Online Library Journals. Also relevant article reference sections were studied for additional publications. The search terms used were “TMJ replacement”; “TMJ prosthesis”; “temporomandibular joint replacement” and “temporomandibular joint prosthesis”.

RESULTS: Exclusion criteria applied to the 1783 initial keyword-search retrievals yielded 23 articles. 39 more articles were retrieved from reference sections, for a total of 62 papers were assessed. Quality evaluation was performed using the Level of Evidence (LOE) scale according to the 2011 Oxford Centre for Evidence-Based Medicine LOE recommendations. The quality was categorized from level I to level IV. Level V studies were not included. An overview of all published TMJ replacement systems is presented along with the most common used materials in TMJ prostheses. The problems arising from TMJ reconstruction and inappropriate materials are listed.

CONCLUSIONS: Although there can be found a lot of useful information about the effectiveness of TMJ prostheses in the literature, more long-term follow-up studies with clear-cut outcomes are still needed.
I. Introduction

There is a long history of temporomandibular joint (TMJ) prostheses development, even though replacement surgery of the TMJ is relatively rare. Through many years a lot of different materials were used, ranging from interposition of a wooden block in 1840 by John Carnochan to custom-fitted total TMJ replacement systems composed of titanium alloy, cobalt-chrome-molybdenum alloy and ultra-high molecular weight poly-ethylene (UHMWPE) in 1989 by Techmedica.

As stated by the American Association of Temporomandibular Joint Surgeons and the NICE guidelines, surgical procedures are indicated when pre-surgical imaging studies confirm pathologic and structural changes of the joint that creates significant pain, dysfunction, and impairment. Conditions to be considered are the following:

1) multiply operated TMJ;  
2) previous alloplastic implants;  
3) connective tissue and autoimmune diseases;  
4) inflammatory, infective or reactive diseases;  
5) ankylosis;  
6) deformed or absent structures;  
7) neoplasia.

I.1 Anatomy of the TMJ

The TMJ is a bi-condylar hinge and gliding joint in which the condyles function at the same time (Fig. 1). Between the condyle and fossa is a biconcave disc made out of fibrocartilage that acts as a cushion to absorb stress and allows the condyle to move easily when the mouth opens and closes. The TMJ is a synovial joint and is encapsulated by a fibrous capsule. 

There are three ligaments associated with the TMJ: one major ligament and two accessory ligaments. The temporomandibular ligament is the major ligament reinforcing the joint and is actually a thickening of the joint capsule. It prevents posterior and inferior displacement of the condyle. The two accessory ligaments; sphenomandibular and stylomandibular ligament; are not attached to the joint and do not limit the mandibular movements. Auriculotemporal and masseteric branches (sensory) of the mandibular nerve (V3) innervate the joint.

The muscles of mastication; masseter muscle, temporalis muscle, medial pterygoid muscle and lateral pterygoid muscle; surround the TMJ. Motor branches arising from the mandibular nerve innervate these four muscles. Arterial supply of these muscles is provided by branches of the maxillary artery.
Table 1: function of the muscles of mastication

<table>
<thead>
<tr>
<th></th>
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<th>Temporalis</th>
<th>Lateral pterygoid</th>
<th>Medial pterygoid</th>
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<td>right and left</td>
<td>right and left</td>
<td></td>
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</tr>
<tr>
<td>Protrusion</td>
<td>right and left</td>
<td>right and left</td>
<td>right and left</td>
<td></td>
</tr>
<tr>
<td>Retrusion</td>
<td>right and left</td>
<td>right and left</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right lateral</td>
<td>right</td>
<td>Right</td>
<td>left</td>
<td>left</td>
</tr>
<tr>
<td>Left lateral</td>
<td>left</td>
<td>left</td>
<td>right</td>
<td>right</td>
</tr>
</tbody>
</table>

Figure 1: motions of the jaw by Liebgott [62]. The TMJ is a bi-condylar hinge and gliding joint in which the condyles function at the same time. T: temporalis muscle; M: masseter muscle; MPt: medial pterygoid muscle; LPt: lateral pterygoid muscle; IH: infrahyoid muscles; SH: suprahyoid muscles; sup.: superficial fibers; horiz.: horizontal fibers; Rt: right; Lt: left; A: elevation; B: depression; C: protrusion; D: retraction; E: right lateral excursion; F: left lateral excursion
II. Materials and methods

The information about TMJ prostheses was gathered by a computerised literature search on the databases of PubMed Central, Elsevier Science Direct, Ovid Lippincott Williams & Wilkins and Willy Online Library Journals. The search terms used were “TMJ replacement”; “TMJ prosthesis”; “temporomandibular joint replacement” and “temporomandibular joint prosthesis”. The initial search returned 1783 published articles (1951 – 2014). Articles discussing non-human subjects were excluded further decreasing the potential article numbers to 1617. Inclusion criteria mandated articles in English, French or Dutch; decreasing the number of articles to 1239. Decreasing the search field to title/abstract resulted in 89 potentially relevant articles. These articles were then evaluated for their relevance (evaluation of TMJ prostheses, production of TMJ prostheses, biomaterials used in TMJ prostheses) by reading the abstract resulting in 23 relevant articles. Further articles were retrieved by following the references in the selected literature resulting in 39 articles to be included following the same inclusion criteria, leading to a total of 62 articles. (Fig. 2)

To assess the methodological soundness of each article, a quality evaluation was performed using the Level of Evidence (LOE) scale according to the 2011 Oxford Centre for Evidence-Based Medicine LOE\textsuperscript{65} recommendations. The quality was categorized from level I to level IV. Level V studies were not included.

For the brief history of TMJ prostheses the designs were then divided in TMJ fossa-eminence prostheses, condylar prostheses; and TMJ total joint prostheses, which replace the glenoid fossa and the condyle, and reviewed in chronologic order. TMJ prostheses that were extended later on to a TMJ total joint prosthesis were mentioned twice. Only the most common used materials in TMJ prostheses are mentioned.
Potentially relevant articles identified with electronic search terms: 1783

Excluded articles: 166
Reason: Non humans

Potentially relevant articles identified: 1617

Excluded articles: 378
Reason: Non English/French/Dutch

Potentially relevant articles identified: 1239

Excluded articles: 1150
Reason: Search field title/abstract

Potentially appropriate articles to be included: 89

Excluded articles: 77
Reason: Not found to be relevant by reading the abstract

Potentially appropriate articles to be included: 105

Excluded articles: 82
Reason: Different topic, no new information

Appropriate articles to be included: 23

Appropriate articles to be included following the references: 39

Final selection: 62 articles

Figure 2: Flow diagram according to QUOROM statement providing information about the number of articles identified, included, and excluded and the reasons for excluding them
III. Results

III.1 History

III.1.a TMJ fossa-eminence prostheses and condylar prostheses

In 1840 John Carnochan was the first to treat an ankylosed TMJ by interpositioning of a block of wood between the raw bony surfaces in gap arthroplasty. In 1890 Gluck described a total joint arthroplasty with an ivory TMJ prosthesis. In 1934 Risdon placed a gold foil in the fossa to prevent re-ankylosis. Eggers (in 1946) and Goodsell (in 1947) used tantalum foil as interposition material. Goodsell tried to fix the foil by placing two stainless steel wires through the foil. Later on the tantalum was abandoned for its complications of fragmentation.

In 1957 Smith and Robinson used custom-made bent plates made out of stainless steel which were placed between de mandible and skull. With this concept they were the first to include the mandibular movement in the TMJ replacement surgery. Three years later Robinson developed a ‘false’ fossa implant out of stainless steel which covered the glenoid fossa and articular eminence. The prosthesis was fixed with two screws to the zygomatic arch to improve stability. In 1968, Robinson changed from stainless steel to Silastic® sponge (polysiloxane).

Inspired by Robinson’s idea, Christensen created in 1963 a 0.5 mm vitallium (an alloy of 60% cobalt, 20% chromium, 5% molybdenum and other substances) plate covering the fossa and articular eminence. The plate was fixed with screws to the zygomatic arch and lateral part of the articular tubercle. Christensen created up to 33 different templates wherefrom the surgeon could choose the best fitting stock fossa-eminence implant for each individual patient. In 1965 Christensen started using a condylar prosthesis, which existed of an acrylic condylar head attached to a vitallium plate. In 1971 Morgan modified Christensen’s prosthesis by only covering the articular eminence with the vitallium plate; in case of degenerative changes of the condyle he caudally elongated the prosthesis with Silastic®.

In 1964 Hahn used in patients who underwent an ablative tumour surgery a ramus prosthesis with an acrylic condyle and a vitallium mesh which could be invaded by fibroblast to stabilise the prosthesis. In 1987 Boyne used the same concept with different materials; the condyle was made of Delrin® (polyoxyymethylene) and attached to a titanium frame work which was screwed to the posterior side of the mandible.

Hahn and Corgill reported in 1970 the use of a ramus-condyle hemiarthroplasty prosthesis for the treatment of ankylosis. The condylar component consisted of polymethylmetacrylate (PMMA) cement whereas the ramus component was made of stainless steel wire mesh.

Between the 70’s and 80’s multiple condylar prostheses were presented. In 1972 Homsy and Kent both reported on the use of a ramus prosthesis made from chrome-cobalt alloy and a condylar head coated with carbon/Teflon® composite (Proplast®) which was expected to facilitate the ingrowth of hard and soft tissue and so improve stability. In the same year Tauras reported the use of custom-made cast-gold ramus-condyle prosthesis for the reconstruction of a TMJ. One year later Morgan described an implant composed of an acrylic condylar head attached to a vitallium ramal mesh. In 1976 Spiessl created a condylar prosthesis (AO/ASIF prosthesis) which was sunk in the condylar stump with a spike and
fixed with five to seven screws to the mandibular ramus for an improved retention. In 1977 Silver used a rectangular vitallium pin which was inserted into the mandibular bone and fixed by PMMA cement.

In 1982 Raveh created the THORP (titanium-coated hollow screw and reconstruction plate) system which used a ball joint and thereby creating a three-dimensional adaptable head. Meaning it was possible to adjust the head in a sagittal and transverse way next to a vertical regulation. In 1984 Flot made a condyle prosthesis that enabled anterior and lateral movement due to the rotating movements of the cap covering the condylar head against the base of the skull; rotational movements of the mandible could be made due to movements between the head and polyethylene surface of the cap. The condylar head was fixed to a stem which was screwed in the mandible. In the beginning the prosthesis was made of a metal alloy and polyethylene, causing particle shedding and wear, therefore in 1987 the cap was made of aluminium oxide ceramics.

**Figure 3: condylar and fossa prostheses by Driemel**. A: (from left to right) Vitek-Kent; Synthes; Delrin-Timesh; Christensen type I, Christensen type II, Biomet Lorenz; B: Vitek-Kent; C: AO/ASIF; D + E: Christensen stock and custom-made; F: TMJ concepts; G: Biomet-Lorenz

**III.1.b Total temporomandibular joint replacement**

In 1974 Kiehn et al. applied principles from total hip joint reconstruction to TMJ prosthesis. The prosthesis consisted of a vitallium mandibular fossa plate, which was fitted and fixed on the temporal side with PMMA cement and a vitallium ramus-condyle prosthesis inspired by Hahn-Corgill. They made several bur holes in the mandibular ramus and the lateral part of the glenoid fossa to improve the retention of the cement to the bone.
In 1976 Morgan designed a condylar prosthesis that formed in combination with his fossa-eminence prosthesis a total TMJ prosthesis. The condylar head existed of acryl fixed to a vitallium plate that could be screwed to the mandible.\textsuperscript{10}

Momma created in 1977 a chrome-cobalt total joint prosthesis.\textsuperscript{1, 10} The fossa component was fixed with screws to the lateral part of the fossa; the condylar component was fixed with screws to the mandible. The head of the condylar part could move in an anterior-posterior direction in the fossa component; mediolateral movements were limited.\textsuperscript{10}

In 1978 Kummoona\textsuperscript{11} designed a new TMJ prosthesis consisting of two parts. The condylar component made of chrome-cobalt alloy, existed of a head fixed on an intramedullary perforated stem or shaft for transferring the load to the mandible, which was inserted in the mandibular ramus and fixed with PMMA cement.\textsuperscript{10} The fossa component was designed to replace the glenoid fossa, the lateral border of the zygomatic arch and zygomatic process of the temporal bone.\textsuperscript{11} The component was fixed with screws or wires to the zygomatic root of the temporal bone.\textsuperscript{10, 11} The head of the condyle and the glenoid fossa were designed to be slightly flattened to allow fibrous tissue penetration from the capsular wall of the joint to prevent wear and tear of the prosthesis.\textsuperscript{10, 11} Kummoona\textsuperscript{11} tested these prostheses in six monkeys. Half of them failed after nine to ten months of functioning due to dislocation of the condylar part, resulting in shortening of the condylar shaft. Only after ten months, the monkeys were killed and the prostheses were examined. After microscopic and microradiography examination he concluded that there was a complete biological acceptance of the implant by the natural tissue. He describes three clinical cases with a maximum of two year post-operative follow-up.

In 1982 the Kent-Vitek prosthesis was created. Originally the system consisted of a bilaminate glenoid fossa implant.\textsuperscript{2} The articulating surface was Teflon®-coated fluoroethylpolyethylene (FEP) and the surface of the tissue-side consisted of polytetrafluoroethylene (PTFE or Proplast®) which could be carved to fit the glenoid fossa; the condylar component was made of chrome-cobalt with a PTFE liner on the inner surface.\textsuperscript{2} In 1986 the composition of the fossa component was modified into an UHMWPE outer layer and a PTFE-hydroxyapatite inner layer because of surface wear of the Teflon® FEP.\textsuperscript{2, 9, 10}Shortly thereafter it had been reported that PTFE caused bony resorption and foreign body reaction with giant cells, therefore in 1992 the American Association of Oral and Maxillofacial Surgeons came to a consensus to discontinue the use of Teflon®-Proplast® interpositional implants and recommend removal of the current implants and to closely follow-up the patients.\textsuperscript{2} In 1969 Charnley, an orthopaedic surgeon reported of massive wear debris causing giant cell reactions and bony erosion in hip prostheses containing PTFE.\textsuperscript{9, 33}

In 1984 Sonnenburg and Fethke compared the stress pattern of an acrylic condylar head with a metallic condylar head and concluded there was no significant difference.\textsuperscript{10} Their condylar prosthesis was made of a spherical head resting on the condylar stump, consisting of forged titanium/palladium alloy and a plate fixed to the mandibular ramus with four to five screws; the fossa component, made out of high-pressure polymerized polyethylene, was fixed to the articular tubercle with a screw and was fitted exactly by putting PMMA cement between the prosthesis and the skull.\textsuperscript{1, 10} Based on this concept, Sonnenburg and Sonnenburg\textsuperscript{45} designed between 1985 and 1990 a new prosthesis with a reduced antero-posterior size of the fossa component, which allowed bending of the plate. This component
was made out of polyethylene and fitted and fixed to the skull with PMMA cement. Additional stabilisation could be achieved with a screw on the zygomatic arch.\textsuperscript{10, 45}

Between 1983 and 1999 the Groningen TMJ prosthesis\textsuperscript{4}, available as stock prosthesis or custom-made prosthesis, was developed and tested in vitro and in vivo.\textsuperscript{42} Both the cranial surface and the condylar ball are composed of zirconium; between these two parts an UHMWPE disc is inserted. The centre of rotation was placed more inferiorly in comparison with other TMJ prostheses, which lead to a closer imitation of the natural opening movements of the joint. After evaluation of an eight-year follow-up of the Groningen TMJ prosthesis they concluded that it was mechanically successful in 87.5\% and in general the patients were satisfied. But the manufacturer decided not to introduce the prosthesis on the market due to a too high financial risk when compared to the possible chance of making profit.

In 1989 Techmedica developed the TMJ concepts prosthesis as a custom-fitted total TMJ replacement system that is built from data obtained from a CAT scan (computer axial tomography) of the patient’s skull. The prosthetic joint is designed on a CAD/CAM system (computer-aided design/computer-aided manufacturing) and is then fitted to a replica of the patient’s skull. Changes in the patient’s occlusion, jaw position or abnormal anatomy can be adjusted at the design level and can be checked at the construction level. The condylar part of the prosthesis is composed of a titanium alloy shaft and a chrome-cobalt-molybdenum alloy head; the fossa component exists of a titanium mesh coated with UHMWPE.\textsuperscript{1, 2, 10}

In 1993 Falkenström placed the point of rotation of his prosthesis more inferior to the middle of the natural condyle, creating a translation movement when the mouth is opened even if the patient is no longer able to perform real protrusive movements. He calculated that with a unilateral prosthesis like his the normal contralateral joint would no longer be overloaded.\textsuperscript{10}

Between 1992 and 1995 Biomet created the Biomet Microfixation TMJ replacement system as a stock prosthesis. The glenoid fossa component is composed of a grade of UHMWPE (Arcom®); the mandibular part is made of cobalt and chrome alloy; the ramal surface of the condylar implant is coated with titanium plasma spray.\textsuperscript{1, 2} The fossa is available in three different sizes (small, medium and large); the ramal part is available in three different lengths (45, 50 and 55 mm) and styles (standard, narrow and offset).\textsuperscript{2} All sizes and styles of the glenoid fossa component are freely interchangeable with the different sizes of the mandibular component.

In 1965 Christensen added a standardized cast vitallium ramus component with a PMMA condylar head to his vitallium fossa-eminence implant\textsuperscript{2}, thus so creating the first total TMJ prosthesis.\textsuperscript{1, 10} In 1995 Chase reinvented Christensen’s prosthesis by replacing the PMMA condylar head by a chromium-cobalt condylar head.\textsuperscript{7} Then in 1997 Christensen developed a metal-on-metal all cast vitallium custom-made prosthesis, which was designed and manufactured using a stereo-lithographic model.\textsuperscript{1} There were several complications with this implant, including wear of condyle and fossa leading to fossa fracture, wear debris induced metallosis and prosthesis loosening. Nowadays the Christensen prosthesis is no longer available as the company has gone out of business.

At this moment there are only two total TMJ prostheses available: TMJ concepts prosthesis (custom-made prosthesis) and Biomet Microfixation TMJ replacement system (stock and custom-made prosthesis).
Figure 4: total TMJ prostheses (Driemel\textsuperscript{1})
A: Christensen stock prosthesis; B: Christensen custom-made prosthesis; C: Vitek-Kent; D: Hoffman-Pappas; E: Techmedica; F: Groningen; G: Sonnenburg; H: Biomet Microfixation
<table>
<thead>
<tr>
<th>Year</th>
<th>First author / inventor</th>
<th>Type</th>
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<th>Screws</th>
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<td>1840</td>
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<td>Fossa</td>
<td>Gold foil</td>
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<td>Eggers</td>
<td>Fossa</td>
<td>Tantalum foil</td>
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<td>Goodsell</td>
<td>Fossa</td>
<td>Tantalum foil</td>
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<td>Condyle</td>
<td>Acryl – Vitallium</td>
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</tbody>
</table>

PMMA: polymethylmethacrylate; Cr: chrome; Co: cobalt; PTFE: polytetrafluoroethylene; FEP: fluroethytpolyethylene; UHMWPE: ultra-high molecular weight polyethylene; NR: not reported; /: no need for screws

III.2 Materials used in TMJ prostheses

For TMJ prosthesis to be successful, it must meet certain biological and mechanical requirements. There are three major requirements in total TMJ reconstruction: 1) imitation of functional movement; 2) close fit; 3) achieve a long lifetime.10, 22
In context of the first major requirement it is important that the TMJ prosthesis can imitate the translational movement of the condylar during mouth opening, without restriction of the non-replaced contralateral TMJ. The mechanical properties determine the type of material that should be selected. The most important of these properties are: hardness; tensile strength; elastic modulus (the material’s stiffness or rigidity) and elongation. Implants with a higher stiffness than bone prevent stress being transferred to adjacent bone (described as stress shielding) which results in bone resorption around the implant and thus implant loosening. Therefore a material with combination of high strength and low elastic modulus closer to bone has to be used for implantation to avoid loosening of implants and so avoiding revision surgery.

For the second major requirement next to a close fit to the skull and mandible a good osseointegration is desirable. For this goal an appropriate surface which allows formation of new bone cells on the implant, leading to bone cell proliferation and differentiation and thus osseointegration. Surface chemistry, surface roughness and surface topography all play an important role in the development of good osseointegration.

The third major requirement can be classified in biocompatibility, high corrosion and wear resistance. Biocompatible material must be highly non-toxic and should not cause any inflammatory or allergic reactions in the human body. There are two main factors influencing the biocompatibility of the material: being the host response induced by the material and the materials degradation in the body environment. The latter factor can be used to classify the materials in three different categories; 1) bio-tolerant material; 2) bioactive material; 3) bio-resorbable material. Material of the first category leads to rejection and thus failure of the implant, materials out of the last two categories lead to acceptance of the implant and thus success of implantation. Issues with regard to host response induced by the material are thrombosis and fibrous tissue encapsulation. Low wear and corrosion resistance of implants may lead to release of non-compatible metal ions into the body which can cause allergic and toxic reactions. Low wear resistance may also lead to loosening of the implant and the wear debris is found to cause several reactions (e.g. foreign body reaction) in the tissue where they are deposited. So it is important to develop an implant with high corrosion and wear resistance for the longevity of the material in the body.

III.2.a Stainless steel

Stainless steel, in particular SUS316L, has a long history of practical use as a biomaterial; especially due to its lower cost, excellent fabrication properties, good corrosion resistance and availability. It has been used for applications such as bone fixation (bone plates, screw wire, miniplate, etc.), spinal fixation, cardiovascular applications (stent) and catheters (female urinary catheter). The addition of alloying elements such as chromium, molybdenum and nitrogen improve the oxidation resistance and enhance the corrosion resistance respectively. Nickel; next to iron and chromium; is found to be released from stainless steel due to corrosion (pitting, fatigue, fretting and galvanic) in the body environment; skin related diseases such as dermatitis due to nickel toxicity have been reported. Therefore nickel-free stainless steel is being developed by using iron, chrome, molybdenum and a large amount of nitrogen to replace the nickel. The nickel-free stainless steel shows to be more biocompatible than nickel containing stainless steel. Another drawback of stainless steel is its
much higher elastic modulus (210 GPa) than that of bone leading to stress shielding and thus implant loosening.\textsuperscript{23}

\textbf{III.2.b Silicone – Silastic®}

Silastic\textsuperscript{®} is a stable and inert silicone rubber with elastic properties, which is easily carved and doesn’t allow tissue ingrowth.\textsuperscript{21} Fifteen years after introduction of Silastic\textsuperscript{®} to the medical world, several reports were published describing long-term instability of the material, foreign body giant cell reaction around fragmented particles, lymphadenopathy with lymph nodes containing silicone particles and severe reactive synovitis, sometimes resulting in destruction of the condyle.\textsuperscript{1, 21, 41} Therefore in 1992 the American Association of Oral and Maxillofacial Surgery (AAOMS) discontinued to use Silastic\textsuperscript{®} as material for TMJ replacement.\textsuperscript{1, 21}

Animal studies have shown an increased incidence (7\%) of sarcomas due to the presence of silicone implants; especially when implants had a large surface area and a flat and smooth surface morphology; therefore McGregor et al\textsuperscript{38} classified silicone implants prepared as thin smooth films as possibly carcinogenic for humans.

\textbf{III.2.c Polytetrafluoroethylene – Proplast®}

Proplast\textsuperscript{®} is a porous form of polytetrafluoroethylene (PTFE) with an admixture of either graphite (Proplast\textsuperscript{®} I) or aluminium oxide (Proplast\textsuperscript{®} II).\textsuperscript{1, 21} Proplast\textsuperscript{®}/Teflon implants were found to have an enhanced strength, anti-frictional properties and a low elastic modulus resembling that of bone and fibrous tissue.\textsuperscript{21}

In 1991 the US Food and Drug Administration (FDA) recommended removal of all Proplast\textsuperscript{®}/Teflon implants and in 1992 the AAOMS decided to abandon PTFE as material for TMJ prosthesis after it had been recognised to cause foreign body giant cell reactions causing severe cutaneous inflammatory reactions and severe degenerative joint disease, leading to soft and hard tissue destruction and refractory pain syndromes, which continued even after explantation.\textsuperscript{1, 2, 21}

Animal studies have shown an increased incidence of sarcomas due to the presence of implants containing PTFE; especially when implants had a large surface area and a flat and smooth surface morphology; therefore McGregor et al\textsuperscript{38} classified PTFE implants prepared as thin smooth films as possibly carcinogenic for humans.

\textbf{III.2.d Polymethylmethacrylate}

The use of polymethylmethacrylate (PMMA) cement should be done with caution because of the possibility of thermal trauma of the circumjacent tissue and particle shedding which can cause local and systemic reactions. Though the blood flow cools down the surrounding tissue and irrigation of the tissue with water during surgery limits the temperature increase sufficiently decreasing the risk of overheating to a minimum.\textsuperscript{10}

Animal studies have shown an increased incidence of sarcomas at the site of implantation due to the presence of PMMA; especially when the PMMA consisted of a large surface area and a flat and smooth surface morphology; therefore McGregor et al\textsuperscript{38} classified PMMA as possibly carcinogenic for humans.
Cobalt – chrome alloys

Cobalt – chrome alloys are found to have superior strength, hardness, high corrosion resistance and excellent wear resistance. Its corrosion resistance is enhanced by the formation of a protective cobalt – chromium – oxide layer. For biomedical applications a nickel free alloys have been used, such as cobalt – chrome – molybdenum alloy like Vitallium® [60.6% Co; 31.5% Cr; 6% Mo and 1.9% residuum (silicium, manganese and carbon)].

Chrome and cobalt are found to be released from these alloys due to corrosion in the body environment. Animal studies have shown carcinogenicity due to the presence of cobalt; therefore McGregor et al classified cobalt implants as possibly carcinogenic for humans. Another drawback of cobalt – chrome alloys is their much higher elastic modulus (240 GPa) than that of bone leading to stress shielding and thus implant loosening.

Titanium

Combination of outstanding characteristic such as high strength, low density, high immunity to corrosion, complete inertness to body environment, enhanced biocompatibility, low modulus and high capacity to join with bone and other tissue, make of titanium a first choice material. Commercially pure titanium and Ti – 6Al – 4V ELI (Ti 64, Extra Low Interstitial) are the most commonly used titanium materials for implant applications.

Titanium is found to be well tolerated and nearly an inert material in the human body environment. In an optimal situation titanium is capable of osseointegration with bone. Furthermore titanium forms a very stable passive layer of TiO₂ on its surface which provides superior biocompatibility; when the passive layer is damaged, it will be built up immediately due to the high affinity of titanium to oxygen.

Despite of all the outstanding characteristics there are still a few hiccups in the use of titanium as a biomaterial. Due to corrosion titanium, aluminium and vanadium ions are released; the released V and Al ions are found to be associated with long-term health problems (ostéomalacia and neuropathy) due to the toxicity of V and neurotoxicity of Al. Titanium has a restricted use in sliding surfaces due to its low wear resistance and its softness; however surface modification strategies and diamond coating have found to improve the wear resistance of titanium and its alloys.

Though the elastic modulus of titanium is very low (110 -112 GPa), it is still higher than the elastic modulus of bone (around 30 GPa) and therefore there is still the risk of stress shielding and thus implant loosening. Therefore, through the past decade the synthesis of metastable beta titanium alloys has increased substantially. The metastable beta titanium alloys are expected to have a lower elastic modulus, approaching that of bone, and enhanced biocompatibility. The three most common beta-alloys are Ti – 12Mo – 6Zr – 2Fe (TMFZ), Ti – 29Nb – 13Ta – 4.6Zr (TNTZ) and Ti – 35Nb – 7Zr – 5Ta (TNZT) with an elastic modulus of 74-85 GPa, 65 GPa and 55 GPa respectively.

McGregor et al found in animal studies that titanium-aluminium-vanadium alloys produced a high incidence of local tumours, especially when there was implant loosening. For there was inadequate evidence for carcinogenicity for titanium alloys used in orthopaedic implants, the titanium alloys were found to be unclassifiable for their carcinogenicity for humans.
Ultra–high molecular weight polyethylene (UHMWPE) is a polymer of hydrogen and carbon with outstanding physical and mechanical properties. Most noteworthy characteristic are its chemical inertness, lubricity, impact resistance, and abrasion resistance. A wide range of elastic modulus has been reported in literature for UHMWPE depending upon sample size, test configuration and loading rate; when using cylindrical samples of 10mm in diameter, elastic modulus has been measured between 0.85 and 1.10 GPa. Both Kurtz and Edidin et al showed an increase in elastic modulus associated with long-term shelf aging; they found the average elastic modulus increased with 152% after ten years of natural aging. However after ten years of natural aging the surface and subsurface showed signs of ‘brittle’ fracture and cracking; decreasing the material ductility and toughness.

Van Loon et al. developed a wear testing machine that simulated the movements of the mandibular head against the disc, a maximal mouth opening of 28° and lateral deviation of 2° to determine the expected wear rate of UHMWPE disc of their TMJ prosthesis. The constant load was 200N, which is almost twice the expected maximum of in vivo loading; the tests ran for seven million cycles, corresponding to approximately ten years of in vivo functioning. The estimated wear rate of the disc was 0.65 mm$^3$ per year, corresponding to a decrease of thickness of 0.01 mm per year.

**Figure 5: The elastic modulus of biomedical alloys and bone.** This figure shows there is a great difference in elastic modulus between bone and Co-Cr alloys, Vitallium and stainless steel which can lead to stress shielding. The difference between bone and β titanium alloys is smaller and thus the risk of stress shielding is lower.
Table 3: the elastic modulus of biomedical alloys and bone

<table>
<thead>
<tr>
<th>Material</th>
<th>Elastic modulus (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt – Chromium alloy</td>
<td>240</td>
</tr>
<tr>
<td>Vitallium</td>
<td>218</td>
</tr>
<tr>
<td>Stainless steel (316L)</td>
<td>210</td>
</tr>
<tr>
<td>Ti – 6Al – 4V</td>
<td>112</td>
</tr>
<tr>
<td>Commercially pure titanium</td>
<td>110</td>
</tr>
<tr>
<td>Ti – 12Mo – 6Zr – 2Fe (TMFZ)</td>
<td>74 - 85</td>
</tr>
<tr>
<td>Ti – 35Nb – 7Zr – 5Ta – 0.40O (TNZTO)</td>
<td>66</td>
</tr>
<tr>
<td>Ti – 29Nb – 13Ta – 4.6Zr</td>
<td>65</td>
</tr>
<tr>
<td>Ti – 35Nb – 7Zr – 5Ta (TNZT)</td>
<td>55</td>
</tr>
<tr>
<td>Bone</td>
<td>30</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>0.85 - 1.10</td>
</tr>
</tbody>
</table>

III.3 Design and planning of a custom-made prosthesis

A custom-made prosthesis is probably the best solution for the severely damaged joint for example due to juvenile rheumatoid arthritis, multiple operations, severe ankylosis or congenital deformity. Many of these complex TMJ patients have associated jaw and facial deformities. In addition to the placement of the TMJ prosthesis mandibular advancement and/or counter-clockwise rotation of the maxillomandibular complex may be necessary to correct the dentofacial deformity associated with or created by the TMJ condition to obtain optimal functional and esthetic results. Use of a custom-made joint prosthesis allows this correction of the facial deformity and reconstruction of the TMJ’s during the same operation.

The design of a custom-made prosthesis can either be in one or two stages. If there is any metallic or foreign material in or near the TMJ that needs to be replaced, a two-stage procedure is needed, where in stage one the materials are removed and a spacer is inserted in anticipation of the insertion of the new prosthesis; for the material can interfere with the CT scan. After this step the procedure continues as described below for a one-stage procedure. When a joint is replaced because of ankylosis there is no need for a two-stage procedure.

In case of a one-stage procedure, first a pre-operative CT scan is made. Using the data of the three-dimensional CT scan a stereolithographic model of the TMJ and associated jaw structures is produced. This model is sent to the surgeon for ‘model’ surgery together with a spare fossa model which can be used during surgery as a reference to the pre-operative anatomy. During the model surgery the mandible is spatially repositioned on the model to correct the functional and aesthetic mal-alignment problems. The condyle is removed and any necessary bony contouring of the fossa and mandibular ramus is completed and marked on the plastic model since all the alterations on the model must be accurately duplicated on the patient intra-operatively. Based on this adjusted model the custom-made TMJ prosthesis and acrylic template are developed and sent back to the surgeon. At the operation the ankylosed joint is resected and the glenoid fossa trimmed until the acrylic template fits and the pre-operative bony contours are achieved.
### III.4 Surgical technique

The surgical placement of the TMJ prosthesis is done under general anaesthesia with nasotracheal intubation and complete muscle relaxation. Perioperative antibiotics and anti-inflammatory steroids should be given. The surgical site is infiltrated with local anaesthetics with vasoconstrictor. For the approach of the condyle there are two options; 1) pre-auricular (as described by Rowe or the modified pre-auricular approach as described by Al-Kayat and Bramley) and 2) retrotragal incision (Fig. 6). After the incision a careful dissection of the superficial muscle layers; and identification and preservation of the branches of the facial nerve is necessary. The joint capsule is then incised on the lateral side to expose the condyle and articular fossa. A condylectomy should be performed under continuous irrigation for the removal of the compromised condyle. The mandibular fossa is then flattened and the fossa component template is then adapted and inserted. Intermaxillary fixation (IMF) is temporary performed to preserve or restore the vertical dimension and occlusion. In case of a custom-made prosthesis, prior to surgery all mandibular movements performed on the plastic model are accurately duplicated in dental plaster models from which an intermediate acrylic occlusal splint is constructed for accurate intraoperative repositioning on the mandible. For the approach of the lower ramus of the mandible, several incisions are possible; 1) submandibular, 2) retromandibular or 3) Risdon incision (Fig. 7). The lateral surface of the ramus is flattened and the mandibular component template is placed and secured to articulate with the previously implanted fossa template. The IMF is released and the vertical movement and occlusion is tested. In case of instability of the occlusion or vertical movement, the templates can be repositioned and retested. Further osteotomy or coronoidectomy can be performed in case of restriction of the movement. When the desired position has been reached the templates are replaced for the final prosthetic components. A new evaluation of the occlusion and movements is made. The wounds are carefully rinsed and the deep layers are closed with absorbable sutures, skin is sutured with fine non-absorbable sutures.

Post-operatively patients should receive antibiotics, anti-inflammatories and analgesics for up to three weeks.
Figure 6: Pre-auricular skin incision according to Al-Kayat and Bramley\textsuperscript{26}. In this figure the relation between the underlying structures and skin incision is shown.

Figure 7: Submandibular approach. The red line indicates the skin incision for a submandibular approach.
Table 5: surgical technique

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>preauricular of retroauricular incision right side</td>
</tr>
<tr>
<td>Step 2</td>
<td>exposure of temporomandibular joint</td>
</tr>
<tr>
<td>Step 3</td>
<td>flattening of the fossa using fossa marking guide</td>
</tr>
<tr>
<td>Step 4</td>
<td>mandibular approach</td>
</tr>
<tr>
<td>Step 5</td>
<td>exposure of the ramus</td>
</tr>
<tr>
<td>Step 6</td>
<td>shaping of the ramus using mandibular marking guide</td>
</tr>
<tr>
<td>Step 7</td>
<td>burning using burr guides</td>
</tr>
<tr>
<td>Step 8</td>
<td>placement and testing of fossa and mandible implant templates</td>
</tr>
<tr>
<td>Step 9</td>
<td>placement and screw fixation of definitive fossa and mandible implant</td>
</tr>
<tr>
<td>Step 10</td>
<td>evaluation of movements, checking for dislocation</td>
</tr>
<tr>
<td>Step 11</td>
<td>rinsing with rifampicin</td>
</tr>
<tr>
<td>Step 12</td>
<td>placement of drain and closure of the wound</td>
</tr>
<tr>
<td>Step 13</td>
<td>preauricular of retroauricular incision on the left side</td>
</tr>
<tr>
<td>Step 14</td>
<td>exposure of temporomandibular joint</td>
</tr>
<tr>
<td>Step 15</td>
<td>flattening of the fossa using fossa marking guide</td>
</tr>
<tr>
<td>Step 16</td>
<td>mandibular approach</td>
</tr>
<tr>
<td>Step 17</td>
<td>exposure of the ramus</td>
</tr>
<tr>
<td>Step 18</td>
<td>shaping of the ramus using mandibular marking guide</td>
</tr>
<tr>
<td>Step 19</td>
<td>IMF</td>
</tr>
<tr>
<td>Step 20</td>
<td>burning using burr guides</td>
</tr>
<tr>
<td>Step 21</td>
<td>placement and testing of fossa and mandible implant templates</td>
</tr>
<tr>
<td>Step 22</td>
<td>placement and screw fixation of definitive fossa and mandible implant</td>
</tr>
<tr>
<td>Step 23</td>
<td>evaluation of movements, checking for dislocation</td>
</tr>
<tr>
<td>Step 24</td>
<td>rinsing with rifampicin</td>
</tr>
<tr>
<td>Step 25</td>
<td>placement of drain and closure of the wound</td>
</tr>
<tr>
<td>Step 26</td>
<td>application of light compressive bandages</td>
</tr>
</tbody>
</table>

### III.5 Post-operative rehabilitation

While there is a lot of documentation about the possibilities in the TMJ prosthetic replacement surgery, there are few notes about the post-operative protocols. Guarda-Nardini et al.\textsuperscript{15} made in 2008 a proposal for a post-operative protocol based on the TheraBite® Jaw Motion Rehabilitation System™ protocol for cases of limited jaw mobility. Functional rehabilitation, existing of active and passive exercises was started one week after prosthetic surgery. The treatment regimen used was 7-7-7: the patient opens the mouth with assistance seven times, holds the maximum open position that can be sustained for seven seconds and performs these exercises seven times a day. The patient was advised to perform these passive exercises during three months after surgery, and then intensive physiotherapy was introduced to maintain the mobility. At the same moment a cycle of five injections of hyaluronic acid (1 ml low-molecular weight hyaluronic acid once a week) in the contralateral TMJ was provided on order to improve the function.

In the article mentioned above Guarda-Nardini et al.\textsuperscript{15} did not elaborate on the description of the further given intensive physiotherapy. Lobo Leonardo et al.\textsuperscript{12} used the following intensive physical therapy procedure starting 48 hours post-operative. During the first two post-operative weeks the physical therapy consisted of mandibular opening and closing exercises and stimulation of the maximum mouth opening by keeping the mouth open at the wider range limit for a few seconds. From the third post-operative week on, forced mouth opening exercises were introduced. The proposed therapy was performed at weekly sessions for a minimum period of two months.
III.6 Complications

Many factors contribute to the success or failure of a total joint prosthesis. These factors include: metal hypersensitivity, material wear breakdown and corrosion, prosthesis micro movement, loosening of the prosthetic components, foreign body giant cell reaction, lack of biocompatible and functionally compatible materials, prosthesis failure, bacterial contamination and development of heterotopic/reactive bone apposition around the prostheses.6

III.6.a Metal hypersensitivity

Hypersensitivity to metal is a well-known phenomenon and can lead to premature removal of the prosthesis. Metals found to cause allergic reactions are; nickel, chrome, cobalt, titanium, aluminium and vanadium.27, 28 The most common metal allergies in humans are due to nickel8 (73%),28 Valentine-Thon and Schiwara28 found the second most common reactivity to metal to be due to titanium (42%), however the MELISA (memory lymphocyte immunostimulation assay) test showed weak sensitivity in most reactive patients.

The hypersensitivity is induced by metal ions and particles which are released from the prosthesis by dissolution, corrosion or wear debris.8, 27 The released metal ions or particles induce an immune response when they bind to proteins or cells and then become an immunogenic antigen or allergen. These allergens are processed by antigen presenting cells which activates the T helper cells. The T helper cells then activate either the B cells which can lead to the production of IgE antibodies (type I or immediate hypersensitivity) or the cytotoxic T cells which leads to releasing of various cytokines and the accumulation and activation of macrophages (type IV or delayed-type hypersensitivity).8

Induction of metal hypersensitivity can occur as reaction to chronic exposure to low levels of toxic metals, exposure to an excessive amount of toxic metals, acute stressors of psychological trauma.8 The hypersensitivity may present itself with local and systemic symptoms. Known local dermatological symptoms are dermatitis, erythema, urticaria; other local manifestations may be TMJ pain, myofascial pain, swelling of the face, muscular spasms, headaches, earaches, tinnitus and vertigo; systemic reactions include chronic fatigue, polyarthralgia, pyrexia, gastro-intestinal problems, neurological reactions, cardiac instability and end-organ failure leading to death.8, 30, 31

Sidebottom et al29, 30 recommend that all patients that are listed for a total TMJ replacement should have routine patch tests for metal to prevent an early rejection due to allergic reactions. Kręcisz et al31 suggest to only do patch tests in case of history of metal dermatitis or dermatitis due to exposure to leather accessories.

III.6.b Breakdown and corrosion

Corrosion is an inevitable reaction when metallic materials come in contact with bodily fluids such as blood and interstitial fluid.52 There are different types of corrosion that have been found in prostheses; including contact corrosion, fretting corrosion, crevice corrosion, galvanic corrosion and pitting corrosion.52

“Contact corrosion” occurs when metals are in contact with biological tissues or fluids such as blood; “fretting corrosion” can occur between the metal component and a hard surface (e.g. bone, metal, UHMWPE); “crevice corrosion” can occur when there is a gap between
Corrosion leads to release of metal ions and particles which are non-biocompatible, which in turn leads to metal hypersensitivity, loosening of implant, foreign body giant cell reaction, implant failure and even carcinogenicity.\textsuperscript{52}

**III.6.c Micromovement and implant loosening**

Use of adaptable materials in order to ensure close fit and the inability of an implant surface to integrate with the adjacent bone and other tissues can lead to micromovements between prosthesis and bone once implanted, causing secondary bone resorption and loosening of the prosthesis.\textsuperscript{4, 10, 23} In order to acquire adaptable materials one must use relatively weak materials. On the other hand when the prosthesis materials have a higher stiffness than bone; they prevent the stress being transferred to the adjacent bone which results in bone resorption around the prosthesis and thus loosening of the prosthesis.\textsuperscript{23} Micromovement of the prostheses can lead to screw loosening, increased wear debris, bone osteolysis, stress fracture of the device, prosthesis failure and thus treatment failure.\textsuperscript{6}

At nonlethal doses, metal particles can stimulate macrophages to release several intercellular mediators, pro-inflammatory and bone-resorbing cytokines (IL-1, IL-6, TNF alpha, PGE\textsubscript{2}) and cobalt-chromium chemokines\textsuperscript{8}; inducing a migration of lymphocytes. These lymphocytes present themselves around the implant; therefore it is likely that metal-induced lymphocyte reactivity may contribute to the cascade of events leading to osteolysis and aseptic loosening. Activated lymphocytes release such as IL-2 (interleukin two), IFN-\gamma (interferon gamma) and RANKL (receptor activated NF-KB ligand), which can stimulate osteoclast activity (directly increasing bone resorption) and inhibit osteoblast activity (decreasing bone production).\textsuperscript{32}

**III.6.d Foreign body giant cell reaction**

From the moment material is implanted in the human body a cascade of inflammatory reactions commences.\textsuperscript{42, 67} This inflammatory cascade includes injury, blood-material interactions, provisional matrix formation, acute and chronic inflammation, granulation tissue development, foreign body reaction and fibrous capsule development (figure 8).\textsuperscript{42}

Foreign body reaction is known to lead to degradation of biomaterials due to an oxidative chain cleavage reaction triggered by macrophages and foreign body giant cells (FBGC) with subsequent device failure. Due to this chemical degradation the surface of the implant becomes brittle and more susceptible to physical damage; as physical damage occurs, cracks open in the material exposing new surfaces to oxidants released by the macrophages and FBGC.\textsuperscript{42}
According to a study by Wolford et al.\textsuperscript{16} postoperative infections involving the TMJ prostheses occurred in 2.5% of the patients and 1.6% of the prostheses. Data from TMJ Implants for both total and partial TMJ replacement prostheses showed an infection rate of 1.6% of the prostheses; Data from Biomet Microfixation system showed that infection occurred in 2.6% of the patients and 1.6% of the joints.\textsuperscript{64}

Bacterial or viral contamination of the prosthesis can occur during surgery or develop at a later time through haematogenous route or localized bacterial sources.\textsuperscript{16} The most common bacteria responsible for prosthesis-related (hip, knee and TMJ) infections are \textit{Staphylococcus epidermidis}, \textit{Staphylococcus aureus}, \textit{Pseudomonas aeruginosa} and \textit{Enterococcus} species.\textsuperscript{14, 34}

It is believed that the majority of the prosthesis-related infections are caused by direct contamination during surgery.\textsuperscript{14} Bacteria come from the CMF region, skin, hair, parotid gland, lymph nodes, bodily fluids like blood and saliva, vascular access sites, or other areas of infection.\textsuperscript{16} At surgery contamination of the prosthesis and/or surgical sites can occur by improper handling and manipulation by medical personnel, inadequate sterilization of
instruments and devices, incomplete skin disinfection, contamination of the air, exposure to unsterile body areas and fluids, and surgical communication of the prostheses to the oral cavity or perforation into the ear canal. Therefore it is important to disinfect the skin of the operating field thoroughly, pay attention to the sterile performance, prevent any direct contamination from the operating staff and treat any distant infection to prevent late haematogenous infections.

Acute infections of the prosthesis can be identified by local (swelling, pain, congestion) and systemic (high leukocyte count, elevated C-reactive protein, fever) symptoms and a positive culture of the joint fluid or biopsies. Delayed prosthesis-related infections or aseptic loosening of the prostheses on the other hand are not as easy diagnosed using the conventional clinical microbiological methods. It has been proven that these infections are often caused by bacterial biofilms which show mild local inflammatory responses and little to no systemic symptoms.

A biofilm is an assemblage of surface-associated microbial cells which are embedded in a self-produced polysaccharide matrix formed on a solid biological (proteinaceous materials in blood, saliva and other bodily fluids) or non-biological (prosthesis) surface. It is believed that prosthesis related infections are biofilm-associated infections which are very resistant to antibiotic treatment. The mechanisms of the high resistance of the biofilm are not completely understood; it is thought that next to the conventional resistance mechanisms (β-lactamase and efflux pumps), poor antimicrobial penetration, limitation of nutrition, slow growth, adaptive stress responses and formation of protected and more persistent cells are involved. Dissemination of microorganisms from the biofilm enables bacteria to colonize new surfaces and begin a new cycle.

There are also several host factors that can contribute to infection susceptibility, including poor tissue quality, diabetes, decreased vascularity, remote infection, sickle cell anaemia, connective tissue or autoimmune disease, immunodeficiency, excessive use of alcohol and/or tobacco, oral diseases, medication, and so on.

To minimize the possibility of prosthesis or wound infections, it is important that patient’s comorbidities are well controlled preoperatively and it is recommended to use broad-spectrum β-lactam antibiotic prophylaxis intravenously before, during and after surgery.

Table 6: Protocol treatment acute and chronic infections proposed by Wolford et al.

<table>
<thead>
<tr>
<th>Acute infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Infection identified</td>
</tr>
<tr>
<td>2. Broad-spectrum antibiotics started</td>
</tr>
<tr>
<td>3. Infectious disease consult</td>
</tr>
<tr>
<td>4. Surgery</td>
</tr>
<tr>
<td>a. I/D, C&amp;S, debridement</td>
</tr>
<tr>
<td>b. Prosthesis scrubbed with toothbrush and Betadin solution</td>
</tr>
<tr>
<td>c. Placement of irrigating catheters/drains for 4-5 days</td>
</tr>
<tr>
<td>5. Irrigation of catheters every 4 hours with DAB for 4-5 days, Catheters afterwards removed</td>
</tr>
<tr>
<td>6. PICC line placed</td>
</tr>
<tr>
<td>7. IV antibiotic therapy based on C&amp;S</td>
</tr>
<tr>
<td>8. Outpatient IV antibiotics for 4-6 weeks</td>
</tr>
</tbody>
</table>
**Chronic infection**

1. Infection identified
2. Broad-spectrum antibiotics started
3. Infectious disease consult
4. Surgery stage I
   a. I/D, C&S, debridement, prosthesis removed
   b. Placement of acrylic spacer with or without antibiotic
   c. Placement of irrigating catheters/drains
5. Irrigation of catheters every 4 hours with DAB for 4-5 days, Catheters afterwards removed
6. PICC line placed
7. IV antibiotic therapy based on C&S
8. Outpatient IV antibiotics for 4-6 weeks
9. Surgery stage II
   a. Reconstruction with new prosthesis at 8-10 weeks
   b. Placement of fat graft around articulating area of prosthesis
10. IV antibiotics until discharge
11. Outpatient oral antibiotics for 10 days

I/D: incision and drainage; C&S: culture and sensitivity; DAB: double antibiotic solution (neomycin and polymyxin B); PICC: peripherally inserted central catheter

### III.6.f Facial nerve injuries

During the surgical approach of the temporomandibular joint the surgeon must be very cautious about the facial nerve. Despite skill of the surgeon or the care taken during the approach, the facial nerve stays at risk for damage resulting in injury of the frontal and/or orbicularis oculi muscles. According to Weinberg and Kryshtalskyj the average incidence of facial nerve injury is 10.84%. The incidence of facial nerve injury is greater in patients who had undergone previous TMJ surgery than in patients with previously unoperated joints, with 17.64% and 9% respectively. This increased incidence can be explained by the surgical scarring that leads to fibrosis of the region, thereby causing a distortion of the normal anatomical planes, which makes a precise dissection of these planes more difficult at a second intervention. Dolwick and Kretzschmar found an incidence of facial nerve injury in 32% after their modified preauricular approach. Hall et al. were able to decrease the incidence of facial nerve injury from 25% to 1.7% by altering their dissection technique from a skin-flap dissection to a posterior-superior approach at the level of the temporalis fascia. Nogueira and Vasconcelos found 31% of facial nerve injury in their patients operated for ankylosis of the TMJ.

Nerve injury resulting from surgical approach can be a result of the following: local anaesthesia, electrocoagulation of the vessels adjacent to the facial nerve, crushing by forceps or clamps, excessive traction and retraction, nerve transection, deep ligatures or plication sutures during wound closure, hematoma or edema and inflammation or infection. The temporal branches as well as the zygomatic branches of the facial nerve are particularly vulnerable to injury during TMJ surgery.

### IV. Discussion

TMJ disorders are a common problem in the society, but the diseases necessitating a resection and replacement of the TMJ are comparatively rare. Over the years lot of different TMJ prosthesis were invented, but all had their limitations. So to this day we can only
choose between the two remaining systems; being TMJ concepts prosthesis and Biomet Microfixation TMJ replacement system.

The TMJ is one of the most complex, delicate and highly used joints in the human body.\textsuperscript{20, 43} There are as well as hinge as gliding motions in the TMJ; giving us the possibility to move the joint in different degrees of freedom. Rotation, anterior translation, posterior translation and mediolateral translation are the possible movements of the TMJ.\textsuperscript{43, 67} Another quality of the TMJ is that it cannot function independently but works in tandem with its contralateral joint.\textsuperscript{18, 67} This complexity presents a problem with its reconstruction and many of the movements of the normal TMJ have not been reproduced in the artificial joints available.\textsuperscript{20, 67} Post-implantation loss of translational movements is a great disadvantage in the total TMJ replacement; especially the anterior translation movements are difficult to imitate.\textsuperscript{2, 10, 43}

It has been found that the centre of rotation for an ideal prosthesis is approximately 15 mm below the centre of rotation of the mandibular condyle. If one rotates the mandible about this point, both rotatory and translator movements are made, but it is difficult to produce these translatory movements with the current prosthetic design, unless a disc can be included in the joint.\textsuperscript{20}

Both the AAOMS\textsuperscript{46} and NICE guidelines\textsuperscript{66} recommend nonsurgical management to be considered first for degenerative joint disease; rheumatoid, gouty and infectious arthritis; mandibular dislocation; and ankylosis. The following nonsurgical interventions are recommended: patient education (stress reduction, jaw rest, dietary recommendations), medication (NSAIDS, analgesics, muscle relaxants, steroids), physical medicine, behavioral modification (stress reduction, psychotherapy), orthopedic appliances (splints, and management of dental abnormalities. Surgical intervention for TMJ disorders is indicated when nonsurgical therapy has been ineffective and pain and/or dysfunction are moderate to severe and when pre-surgical imaging studies confirm pathologic and structural changes of the joint that creates significant pain, dysfunction, and impairment. Conditions to be considered are multiply operated TMJ; previous alloplastic implants; connective tissue and autoimmune diseases; inflammatory, infective or reactive diseases; ankylosis; deformed or absent structures and neoplasia. Before considering a total TMJ replacement one must consider other surgical interventions such as arthroplasty; discectomy; discopexy; eminectomy; or condylectomy according to the underlying disease.\textsuperscript{46, 66, 67} Surgery is not indicated for asymptomatic or minimally symptomatic patients, neither for preventive reasons.\textsuperscript{46}

Literature shows that patients in need of a total TMJ replacement are mostly woman with an average age of 40 years\textsuperscript{44}, so implants are expected to serve for a much longer period in comparison with a hip prosthesis (± 15 years); even a lifetime without failure or the need for revision surgery. Therefore it is essential to develop appropriate material with high longevity and excellent biocompatibility.\textsuperscript{23} In order to acquire a high longevity it is necessary that the implants are properly used and placed in the correct manner.\textsuperscript{3} The ideal implant materials features a high strength in combination with a low elastic modulus to avoid stress shielding; high corrosion and wear resistance for a longer service period; and appropriate surface chemistry and topography which allows integration with the adjacent bone to prevent implant loosening and thus failure.\textsuperscript{3, 23, 42}
As stated by Anderson et al.,\textsuperscript{42} the development of novel biomaterials, biomedical devices or tissue-engineered constructs demands a thorough understanding of the biological response to implanted materials. Once a biomaterial is introduced into the body, a sequence of events occurs in the surrounding tissue and ultimately ends in the formation of FBGC at the tissue/material interface. Appropriate surface properties can be achieved while preserving the beneficial properties of the bulk material; high corrosion and wear resistance, excellent biocompatibility and increased bone anchoring can be achieved by surface modification.\textsuperscript{52}

Anderson et al.\textsuperscript{42} also showed that surface chemistry can impact macrophage behaviour such as adhesion, apoptosis, fusion and cytokine secretion. The authors forecast as the fields of tissue engineering and regenerative medicine expands, biomaterials will be combined with cells, proteins, and/or other biological components creating hybrids appropriate for functional regeneration of diseased and damaged tissues. Therefore an in depth understanding of the host response to biomaterials is needed in order to engineer materials that perform suitably in their applications.

Kashi et al.\textsuperscript{67} strive for a multidisciplinary approach for the development of new TMJ prostheses, emphasizing a simultaneous involvement of clinical and non-clinical personnel. They state when developing new TMJ prostheses one should bear in mind important aspects such as safety; efficacy; adverse effects; long-term performance; costs; appropriate selection of the biomaterial in view of the anatomical location and long-term follow-up studies providing evidence of satisfactory clinical performances.

The requirements for TMJ prosthesis as cited by several authors\textsuperscript{10, 22, 23, 44, 56} are listed up in table 7.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Imitation of condylar translation during mouth opening</td>
</tr>
<tr>
<td>2</td>
<td>Unrestricted mandibular movements</td>
</tr>
<tr>
<td>3</td>
<td>Correct fit to skull</td>
</tr>
<tr>
<td>4</td>
<td>Correct fit to mandible</td>
</tr>
<tr>
<td>5</td>
<td>Stable fixation to the bony structures</td>
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<tr>
<td>6</td>
<td>Expected lifetime of more than 20 years</td>
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<tr>
<td>7</td>
<td>Low wear rate</td>
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<tr>
<td>8</td>
<td>Wear particles tolerated by the body</td>
</tr>
<tr>
<td>9</td>
<td>Biocompatible materials</td>
</tr>
<tr>
<td>10</td>
<td>Sufficient mechanical strength</td>
</tr>
<tr>
<td>11</td>
<td>Simple and reliable implantation</td>
</tr>
</tbody>
</table>

We found 15 articles discussing the effectiveness of TMJ prostheses; four of them were classified LOE III b, the rest of them LOE IV. In these articles there is no uniformity about what can be classified as prosthesis failure. Overall failure of TMJ prosthesis can be divided in prosthesis failure, biological failure and patient failure. In their studies Giannakopoulos et al.,\textsuperscript{2}; Speculand et al.,\textsuperscript{5}; Sonnenburg et al.\textsuperscript{45} and Sidebottom et al.\textsuperscript{58} found only biological failures to be the reason of prosthesis failure. The other studies include failure in the three categories in their prosthesis failure rate.

Nor there are analogue symptom scales, clarity about how many and which prior surgeries the patients underwent or the duration of the symptoms before total joint replacement. There
| Author          | Year | Prosthesis | Study | LOE | # pts | FU   | Interference symptom | Pain level | MIO (mm) | Prosthesis | Age patient | Duration | Prior χ |
|-----------------|------|------------|-------|-----|-------|------|----------------------|------------|----------|------------|-------------|----------|
| Giannakopoulos³ | 2012 | Biomet     | prosp | III b | 256 442 | 3 y  | 8.2 → 2.5 VAS 69.5% ↓ | 8 → 2.6 VAS 67.5% ↓ | 20.4 → 29.5 44.6% ↑ | 3.2% | 41.1 ± 11.1 | 11.4 ± 6.6 | 4.9 ± 3.9 |
| Mercus³         | 1995 | TMJ concepts | prosp | IV  | 216 363 | 13.6 m | 55% ↑                  | 58% ↓       | 27% ↓     | 4.7% | 40.9 ± 10.3 | 10.3 ± 7.0 | 5.4 ± 4.8 |
| Schuurhuis⁴     | 2012 | Groningen  | prosp | IV  | 8 14 | 8 y  | NR                  | NR          | 12.3 → NR 7% | 43 | 11.5 | NR          |
| Speculand⁵      | 2000 | Kent Vitek | prosp | III b | 17 27 | 14.5 m | NR                  | NR          | min: + 4 max: + 26 | 11% | 44 | NR          | 1.5 |
| Speculand⁵      | 2000 | Christensen | prosp | III b | 45 59 | 14.5 m | NR                  | NR          | min: + 23 max: + 30 | 0% | NR | NR          | 1.5 |
| Wolford³        | 2003 | Christensen | prosp | III b | 23 40 | 20.8 m | 7.2 → 5.4 VAS 25.0% ↓ | 7.8 → 6 VAS 23% ↓ | 23.4 → 30.1 28.6% ↑ | NR | 38.8 | NR          | 3.9 |
| Wolford³        | 2003 | TMJ concepts | prosp | III b | 22 38 | 33.0 m | 5.9 → 3.9 VAS 33.9% ↓ | 7.2 → 4.1 VAS 43.1% ↓ | 27.4 → 37.3 36.1% ↑ | NR | 38.5 | NR          | 2.6 |
| Kent³           | 1993 | Kent Vitek 1 | prosp | III b | 138 | 10 y | 1.8 → 2.6 44.4% ↓ | 8.5 → 7.4 VAS 12.9% ↓ | 20.4 → 26.4 29.4% ↑ | 68.1% | 37.2 | NR          | 3.86 |
| Kent³           | 1993 | Kent Vitek 2 | prosp | III b | 124 | 6 y  | 1.9 → 2.7 4.21% ↓ | 8.4 → 5.8 VAS 30.9% ↓ | 21.7 → 29.5 35.9% ↑ | 17.8% | 37.2 | NR          | 3.86 |
| LoboLeandro¹²   | 2013 | Biomet     | prosp | IV  | 300 399 | 1 y  | 2.16 → 4.96 129.6% ↓ | 1.18 → 0 100% | 11.3 → 38.9 244.2% ↑ | NR | NR | NR          | NR |
| LoboLeandro¹²   | 2013 | Biomet     | prosp | IV  | 7 1 | 10 y | 2.16 → 4.21 94.9% ↓ | 1.18 → 0 100% | 11.3 → 41.8 269.9% ↑ | NR | NR | NR          | NR |
| Wolford³        | 2003 | TMJ concepts | prosp | IV  | 38 68 | 5 y  | NR                  | 7.7 → 3.6 VAS 53.2% ↓ | 27.5 → 32.6 16.5% ↑ | 0% | 36 | NR          | 2.9 |
| Sonnenburg⁶     | 1985 | Biomet     | prosp | IV  | 12 19 | 2-8 (5) y | 7.8 → 0 VAS             | NR          | 16.4 → 33.2 102.4% ↑ | 5.3% | 29 | NR          | NR |
| Mercuri⁴        | 1999 | TMJ concepts | prosp | IV  | 215 363 | 30.7 m | 49.4% ↑                  | 52.7% ↓       | 39.6% ↑     | NR | 40.9 ± 10.3 | 10.3 ± 7.0 | 5.4 ± 4.8 |
| Mercuri⁵        | 2002 | TMJ concepts | prosp | IV  | 58 97 | 107.4 m ±15.5 m | NR                  | 41.4 → 9.8 76.3% ↓ | 25.5 → 33.2 23.2% ↑ | 0% | 39.9 | 10.9 ± 7.8 | 4.2 ± 2.9 |
| Wolford⁶        | 1994 | TMJ concepts | prosp | IV  | 56 100 | 30 m (16-46) | NR                  | 70.2% ↓       | 24.9 → 31.3 25.7↑  | 0.5% | 41.0 | 9.7 ± 4.5 | 4.9 ± 4.5 |
| Mercuri⁷        | 2007 | TMJ concepts | prosp | IV  | 61 102 | 11.4 y | NR                  | 70.2% ↓       | 24.9 → 31.3 25.7↑  | 0.5% | 41.0 | 9.7 ± 4.5 | 4.9 ± 4.5 |
| Sidebottom⁸     | 2013 | TMJ concepts | prosp | IV  | 74 103 | 1 y  | 3.8 → 9.3 144.7% ↑ | 7.2 → 0.8 88.9% ↓ | 22.4 → 33.7 50.4% ↑ | 1.9% | 47.0 | NR          | 2 |
is also a too great of difference in the follow-up period to make a meaningful comparison between the different TMJ prostheses.

V. Conclusion

There is still a long road to go before the ultimate TMJ prosthesis can be invented, for there is still need for a lot of research in the biomaterial domain. Also to confirm good clinical performance of any new TMJ prosthesis, long-term follow-up studies with unambiguous outcomes studied will be necessary.

One must keep in mind as cited by Alfred Stille (1813 – 1900) “Medicine like all knowledge, has a past as well as a present and a future, and in that past is the indispensable soil out of which improvement must grow.”
VI. References


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VII. Addendum

VII.1 NICE indications for total TMJ replacement

Prerequisite:

- Failed conservative management
- CT/MRI as a minimum

Disease process:

- Degenerative joint disease
- Ankylosis
- Post-traumatic/surgical condylar loss
- Previous prosthetic reconstruction
- Previous costo-chondral graft
- Major congenital deformity
- Multiple previous procedures

Indication:

- Dietary score <5/10
- MIO <35mm
- Occlusal collapse/AOB/retrusion
- Excessive condylar resorption
- Pain score >5/10

Contra-indications:

- Ongoing local infective process
- Severe immune compromise
- ASA 3 (relative contra-indication)
VII.2 Process of TMJ prosthesis production

**Step 1:** High resolution CT
Exported to modelling company

**Step 2:** 3D digital model
Anatomically mapped out vital structures

**Step 3:** Web-based teleconference with surgeon and biomedical engineer
Osteotomies performed virtually

**Step 4:** Design of condyle and glenoid fossa prostheses
Placement of screws designed to avoid vital structures

**Step 5:** Osteotomy cutting guides fabricated
Occlusal wafers are made

**Step 6:** 5-axis robotics machines cut material to right size and length
Fossa component milled from UHMWPE
Mandibular component from cobalt-chrome-molybdenum + titanium plasma coating

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**Typical Development Timeline**

- **Week 1:** Send CT Scan
- **Week 2:** Web Conferencing and Surgical Planning
- **Week 3:** Implant Approval
- **Week 4:** Implant Manufactured
- **Week 5:** Implants Shipped

*This time frame will vary based on surgeon response time.*

From Biomet Microfixation; Patient Matched Joint Replacement brochure
VII.3 Surgical procedure

A: incision (M: mandible; V: external jugular vein, arrow: incision marking); B: ankylosed joint; C: flattening of the fossa with marking guide (arrow); D: resected proc. coronoides; E: resection condyle with marking guide (arrow); F: checking of templates (single arrow: fossa template; double arrow: mandibular template); G: placement prosthesis; H: closure of wound