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Treatment of end stage temporomandibular joint disorder using a temporomandibular joint total prosthesis: The Slovenian experience☆

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ABSTRACT

Purpose: The aim of this study was to analyse treatment results after alloplastic temporomandibular joint replacement surgery.
Materials and methods: Twelve patients who met the inclusion criteria underwent operation between the years 2012 and 2016 at the Department of Maxillofacial and Oral Surgery of the University Medical Centre Ljubljana, Slovenia. Seven patients had posttraumatic sequelae, 4 osteoarthritis and 1 psoriatic arthritis. We inserted 12 temporomandibular joint prostheses (Biomet- Lorenz). A retrograde analysis of the patients, subjective assessment of the pre- and postoperative temporomandibular pain, opening the mouth, the ability to chew food, and quality of life (VAS scale, 0–10) was performed. Additionally, we evaluated the inter-incisal distance pre- and postoperatively. Complications that occurred were also included in our evaluation.
Results: During final examinations, at least 15 months after the surgery (on average 39.5 months), we observed an improved ability to open the mouth in all patients. The average preoperative inter-incisal distance was 22 mm (15–30 mm); the average postoperative distance was 37.5 mm (32.3–1.8 mm), ($p < 0.001$). The analysis of pain and other subjective variables (opening the mouth, the ability to chew, quality of life) showed a statistically significant improvement ($p < 0.001$).
Conclusion: According to our initial experience, replacement of the temporomandibular joint with a total prosthesis is a safe and effective treatment method.

1. Introduction

Temporomandibular joint disorder (TMD) is an umbrella term for pain and dysfunction of the temporomandiblar joint (TMJ) and its neighbouring structures, caused by various factors. The prevalence of TMD is 5%; it is more common in women and elderly population (Karlic and Glickman, 2011).

The final stage of the TMD refers to a transformation of the temporomandibular joint to an extent that its function is substantially decreased or even disabled due to disease or injury. In terms of systemic disease, this occurrence is analogous to the end-stage renal disease (ESRD), resulting in dialysis and kidney transplantation.

Possible causes for the end-stage TMD include congenital disorders, tumors, inflammatory diseases, previous surgical procedures, trauma and ankylosis. The most common causes of TMJ ankylosis are TMJ disc damage and prolonged immobilization of the mandible after an intracapsular trauma. Other etiological factors for TMJ ankylosis are systemic infections, myositis ossificans, osteochondroma, rheumatoid arthritis, systemic lupus erytematosus, radiotherapy (Sporniak-Tutak et al., 2011).

Today, various modes of total TMJ reconstruction are available: use of autogenous bone tissue, distraction osteogenesis and TMJ total prosthesis (TP). The goal of the treatment is to restore the form and structure of the joint, eliminate difficulties, restore function and achieve minimal morbidity and duration of the treatment. In end-stage mandibular joint reconstruction, this goal appears to be easily achieved with the use of TMJ TP (Mercuri, 2011a; Machon et al., 2012).

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Following National Institute for Health and Care Excellence (NICE) and British Associations of Oral and Maxillofacial Surgeons (BAOMS) guidelines, a total joint replacement of the TMJ is used after other (i.e., conservative, minimally invasive and surgical) methods have been unsuccessful in restoring normal mouth opening and/or eliminating pain (Nice, 2017; Speculand, 2009). In addition to the clinical picture, magnetic resonance imaging (MRI) and computed tomography (CT) have proved to be helpful in deciding whether to operate, as they can indicate a severely damaged or an ankylosing TMJ (Sidebottom, 2009).

2. Materials and methods

In the beginning of 2012, the first TMJ TP was inserted at the Clinical Department of Maxillofacial and Oral Surgery in Ljubljana, Slovenia. Between 2012 and 2016, a total of 12 patients who met the inclusion criteria underwent operation and 12 stock TMJ TP were inserted (Biomet- Lorenz). Two of the patients were male and 10 were female. Seven patients were diagnosed with posttraumatic TMJ sequelae, 4 with osteoarthritis, 1 with psoriatic arthritis. In the first group, 2 patients had posttraumatic bony ankylosis, 2 patients had posttraumatic fibrous ankylosis, and 3 patients had loss of normal TMJ structures due to trauma and bone resorption. The inclusion criterion was TMJ replacement with a TMJ TP for various causes, as per NICE guidelines. The exclusion criteria were previous TMJ conditions (additional oncological treatment, radiation, chemotherapy), for which we predicted a decreased ability to heal and an increased risk of complications compared to the classic TMJ replacement with a TMJ TP. In 1 patient, who underwent operation between 2012 and 2016 and who had previous surgery, radiation and chemotherapy for osteosarcoma on one-half of the lower jaw, we observed an injury of the anterior wall of the acoustic meatus for several months after the insertion of the TMJ TP. The prosthesis was removed and the patient was therefore not included in the study.

Prior to TMJ replacements, the patients had been treated for temporomandibular conditions for 85 months on average. Most of them had already received conservative therapy and had undergone prior surgical procedures (arthrocentesis, arthroplasty; on average 1.5 procedures). Prior to surgery, they received individually targeted radiological diagnostics (orthopantomogram, CT, models, MRI).

The surgeries were performed under general anaesthesia by four experienced surgeons (A.V., A.K., M.K., L.P.) who specialized in maxillofacial surgery. The patients were intubated transnasally, if necessary, with the help of a fibreoptic instrument. The articular process and mandibular ramus were displayed with a preauricular and retromandibular approach and finally connected subperiosteally above the mandibular ramus. The resection of the condylar process was performed next, and, if necessary, resection of the coronoid process as well. Using self-tapping screws and fixation wire, we achieved stable intermaxillary fixation (IMF) in the proper occlusion and positioned the upper and lower jaws in proper correlation. We used a metal bur to re-shape the fossa glenoidalis and mandibular ramus, which enabled us to insert and test different sized models. Once the proper size was chosen, an artificial fossa (ultra-high-molecular-weight polyethylene) was inserted and attached to the zygomatic arch, using titanium screws. Then the artificial condyle (titanium alloy, condylar head made of cobalt-chromium alloy) was attached to the ramus using titanium screws. Finally, we released the IMF fixation and examined the joint mobility. We closed the wound in layers and inserted active drains (Machon et al., 2012; Vesnaver, 2008).

On average, the patients were hospitalized for 6 days. Postoperatively, they underwent orthopantomogram and X-ray examination of the mandible (Towne view). Further imaging examinations were performed after 1 year or sooner, at the surgeon's discretion. Patients received postoperative antibiotic therapy, which was mostly discontinued after 10 days. Analgesic therapy was prescribed when needed. The first day after the surgery, patients started their physical therapy (passive and active excercises) for mouth opening. Postoperatively, we examined the patients after 1 week, 1 month, 2–3 months, 6–12 months, and then once a year. In case of complications, the patients were scheduled for more frequent examinations.

We performed a retrograde analysis of the patients, subjective assessment of the pre- and postoperative temporomandibular pain, opening the mouth, the ability to chew food, and quality of life. Additionally, we evaluated the ability to open the mouth by measuring the inter-incisal distance pre- and postoperatively.

The patients assessed the level of pain on a scale from 0 to 10 (0 meaning no pain and 10 the highest level of pain), the ability to open the mouth on a scale from 0 to 10 (0 meaning normal and 10 no mobility in the mouth), the ability to chew food on a scale from 0 to 10 (0 meaning without limitations and 10 liquid food), and quality of life on a scale from 0 to 10 (0 meaning the largest improvement in the quality of life and 10 the lowest quality of life). Inter-incisal distance was measured in millimetres with an angle ruler, before and after the surgery (Gerbino et al., 2016). We also evaluated postoperative complications (hypoaesthesia, facial paresis, disturbing scars, haemorrhages, inflammations, swelling).

We compared all pre- and postoperative data acquired at the final regular examinations (at least 15 months and no more than 68 months after the surgery). Additional information was obtained from individual patients by mail or telephone. Based on the data from the literature, we expected a large improvement of the observed parameters. Power analysis for a Wilcoxon signed-rank test was conducted in G*Power software (version 3.1.9) to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, a large effect size ($dz = 0.8$), and one tail (Faul et al., 2009). Based on the aforementioned assumptions, the desired sample size is $n = 12$ patients. Results were expressed as median and interquartile range. A Wilcoxon signed-rank test was used to compare characteristics of pre- and post-operative patients. Statistical analysis was performed using IBM SPSS 23.0 (IBM Corp., Armonk, NY). $P < 0.05$ was considered statistically significant.

3. Results

The data on patients with the inserted TMJ TP are shown in Table 1. The procedures prior to insertion of the TMJ TP are shown in Table 2. Complications after the insertion of the TMJ TP are shown in Table 3. Comparison of the condition before and after the insertion of the TMJ TP is shown in Table 4.

Ten women (83.3%) and 2 men (16.7%) underwent operation. The average age of patients was 49.2 years (minimum 23, maximum 73 years). The average time from the onset of symptoms to joint replacement was 85.9 months (minimum 1, maximum 360 months).

In 7 patients (58.3%), the causes of the condition were mandibular posttraumatic sequelae. Four patients (33.3%) had osteoarthritis, and 1 patient (8.3%) had psoriatic arthritis. In the first group, 2 patients had posttraumatic bony ankylosis, 2 patients had posttraumatic fibrous ankylosis, and 3 patients had loss of normal TMJ structures due to trauma and bone resorption. The first patient with bony ankylosis was classified as type 4 (Sawhney, 1986) and grade 3, according to the classification of Turlington and Durr. The second patient with bony ankylosis was classified as type 2, grade 2. Both patients were symptomatic. Patients with fibrous ankylosis were classified as type 1, grade 0.

The average number of previous procedures (arthrocentesis, arthroplasty) on an individual joint was 1.5 (minimum 0, maximum 4 procedures). The patients were regularly monitored after the surgery. At the final examinations (at least 15 and at most 68 months after the surgery; on average 39.5 months), we observed an improved ability to open the mouth in all patients. The average preoperative inter-incisal distance was 22 mm (15–30 mm) and the average postoperative distance 37.5 mm (32.3–1.8 mm). Postoperative improvement in the ability to open the mouth was statistically significant (Table 4, Fig. 1).

The level of pain decreased in all patients. The average level of preoperative pain was 8.5 (7.3–9), and the postoperative level was 1 (0–3). Five patients were completely pain-free after the surgery. The analysis of pain and other subjective variables (opening the mouth, the ability to chew, quality of life) is shown in Table 4 and Fig. 2. We observed statistically significant improvements in all variables.

All patients developed swelling immediately after the surgery; however, the condition did not require additional surgical procedures. Four patients occasionally described late swelling in the operated area. Only 1 patient experienced a bacterial wound infection.

In 7 patients, a temporary paresis (maximum of 8 months) of the facial nerve (nervus facialis) was observed. The marginal branch was affected in 3 patients, temporal in 5, and zygomatic in 1. We observed a facial paresis as the result of previous procedures in 2 patients.

In 5 patients, a permanent preauricular hypesthesia was observed, in 1 of them in the chin area. Two patients had preauricular hypesthesiae following previous procedures.

Among complications, we did not observe haemorrhages, salivary fistulae, or disturbing scars.

4. Discussion

Alloplastic materials have been used for TMJ reconstruction for many years. Until 1980, they were mainly used for partial reconstruction and later for total TMJ reconstruction as well. In 1991 the Food and Drug Administration (FDA) recommended the removal of highly popular Proplast-Teflon fossa hemijoint prostheses because of excessive wear and debris accumulation in the fossa region. This led to foreign body giant–cell reaction and bone resorption. Two years later something similar occurred with Silastic disc prostheses. In 1992 Lindquist et al. concluded that use of condylar prosthesis alone led to resorption of fossa and advocated to use a TMJ TP instead of replacing only the condyle. Vitek- Kent TMJ TP was the first system used extensively in the United States. The fossa component consisted of three layers of Proplast and high density PTFE (Teflon), which showed excessive wear and debris accumulation also in TMJ TP system, so the production was halted.

It was only in the mid-90s, when the use of contemporary TMJ TP with an improved biocompatibility and mechanical resistance showed satisfactory results. The structure of the TMJ TP at the time was equivalent to the contemporary hip prosthesis. Thus, the condylar part of the prosthesis still consists of titanium alloy, condylar head of chrome and cobalt, whereas the fossa component is made of ultra-high-molecular-weight polyethylene (De Meurechy et al., 2018; Mercuri, 2012; Mercuri et al., 2007; Westermark, 2010).

For a TMJ replacement, a stock or custom-made TMJ TP can be used. The advantage of the custom-made prosthesis is its conformity, resulting in reduced micromotion, osteolysis, destabilisation, and surgical duration. Stock prostheses do not offer posterior protection in the prosthetic fossa, which prevents the artificial condyle from being displaced and shifting into the auditory canal. In comparison, stock devices are more affordable than custom-made devices (Mercuri, 2011a, b).

Studies show that postoperative results of custom-made and stock prosthesis are comparable. The use of custom-made prostheses seems most reasonable in the most severe cases, when there is little or poor-quality bone left, usually following unsuccessful previous surgeries (Johnson et al., 2016). Another indication to use custom-made prostheses is on paediatric patients, in whom any removal of the developing bone tissue is undesirable.

At the Department of Maxillofacial Surgery of the University Medical Centre Ljubljana, only stock Biomet-Lorenz prostheses were used. In 8 patients, CT imaging offered assistance in choosing the appropriate dimensions of the prosthesis. For 5 patients, we additionally designed mandibular models to offer a more accurate fitting of the prosthesis.

Our data indicate no instability or loosening of the screw or prosthesis. A statistically significant improvement of mouth opening was noted (interincisal distance in millimeters). In addition, we noted a statistically significant improvement of subjective variables (improved mouth opening, improved chewing ability, improved quality of life and less pain).

Table 1
Data on patients with an inserted TMJ TP.

Age	Gender	Side	Aetiology	Preop open-ID	Postop open- ID	Preop P	Postop P	Preop M open	Postop M open	Preop C	Postop C	QOL Preop	QoL Postop	Dur T	Hosp	Time Postop
49	f	r	psoriatic arthritis	19 mm	41 mm	9	3	9	5	9	4	7	3	63	6	52
28	f	l	pts- fa, t1, g0	25 mm	39 mm	9	3	9	3	7	3	8	3	36	4	24
60	f	l	osteoarthritis	30 mm	31 mm	7	4	7	3	6	4	6	4	97	6	15
59	f	r	osteoarthritis	15 mm	36 mm	8	0	10	2	9	0	10	1	68	6	25
64	f	l	osteoarthritis	15 mm	30 mm	8	1	9	0	8	0	9	0	27	7	51
73	f	l	pts- fa, t1, g0	30 mm	40 mm	9	1	6	0	9	5	9	1	1	6	29
59	m	l	pts- ba, t4, g3	2 mm	30 mm	6	0	10	0	10	1	10	0	360	10	67
33	m	r	pts- ba, t2, g2	10 mm	45 mm	5	0	10	1	9	0	10	0	25	6	37
23	f	l	pts	40 mm	50 mm	10	5	7	0	6	2	8	5	62	8	55
57	f	l	pts	27 mm	36 mm	9	1	9	2	8	0	8	1	149	5	28
27	f	l	pts	33 mm	42 mm	9	0	7	0	10	3	10	2	73	4	68
59	f	l	osteoarthitis	18 mm	36 mm	8	0	10	2	9	0	10	1	70	5	23

Key: **Age** (years); **Gender** (f – female, m – male); **Side** (r – right, l – left); **Aetiology** (pts-posttraumatic sequelae, ba-bony ankylosis, fa-fibrous ankylosis, t-type (1,2,3,4), g-grade (0,1,2,3); **Preop open- ID** (preoperative opening, ID-interincisal distance in mm); **Postop open- ID** (postoperative opening, ID-interincisal distance in mm); **Preop P** (preoperative pain- VAS scale, 0–10); **Postop P** (postoperative pain- VAS scale, 0–10), **Preop M open** (mouth opening before- VAS scale, 0–10); **Postop M open** (mouth opening after- VAS scale, 0–10); **Preop C** (chewing before- VAS scale, 0–10); **Postop C** (chewing after- VAS scale, 0–10); **QOL Preop** (Quality of Life before- VAS scale, 0–10); **QoL Postop** (Quality of Life after- VAS scale, 0–10); **Dur T** (duration of problems in months); **Hosp** (Duration of hospitalization in days); **Time Postop** (time after surgery in months).

Table 2
Procedures before the insertion of a TMJ TP.

Age	Gender	Side	Aetiology	Artrocentesis	Splint	Artro C	Artro O	Implants	CT b
49	F	r	psoriatic arthritis	1	yes	1	3	yes	no
28	F	l	pts- fa, t1, g0	1	yes	0	2	no	yes, model
60	F	l	osteoarthritis	1	yes	0	2	no	da
59	F	r	osteoarthritis	1	yes	0	1	yes	yes, model
64	F	l	osteoarthritis	0	no	0	2	no	da
73	F	l	pts- fa, t1, g0	0	yes	0	0	no	no
59	M	l	pts- ba, t4, g3	0	yes	0	0	yes	yes, model
33	M	r	pts- ba, t2, g2	0	no	0	0	yes	no
23	F	l	pts	0	no	0	0	no	yes, model
57	F	l	pts	0	no	0	1	no	yes
27	F	l	pts	0	no	0	0	yes	yes
59	F	l	osteoarthritis	1	yes	0	1	yes	yes, model

Key: **Age** (years); **Gender** (f – female, m – male); **Side** (r – right, l – left); **Aetiology** (pts-posttraumatic sequelae, ba-bony ankylosis, fa-fibrous ankylosis, t-type, g-grade); **Arthrocentesis** (No. of procedures prior to surgery); **Splint** (preop use); **Artro C** (closed arthroplasty, No. of procedures prior to surgery); **Artro O** (open arthroplasty, No. of procedures prior to surgery); **Implants** (implant-supported prosthetic rehabilitation); **CT b** (CT prior to surgery, 3D-model use).

Table 3
Complications in patients following the insertion of a TMJ TP.

Age	Gender	Side	Inf	Bleeding	Scarred tissue	Facialis	Hypesthesiae	Swell	Swell later on	Salivary fistula
49	f	r	no	no	common	yes, M	no	ne	no	no
28	f	l	no	no	common	yes, M + T	yes, P	yes	yes	no
60	f	l	no	no	common	No	no, P	yes	yes	no
59	f	r	no	no	common	No	yes, P	yes	no	no
64	f	l	no	no	common	No	no	ne	no	no
73	f	l	no	no	common	yes, T	yes, P	yes	yes	no
59	m	l	no	no	common	yes, M previous, T + Z	no	ne	no	no
33	m	r	no	no	common	yes, T	yes, P	yes	no	no
23	f	l	yes	no	common	No	no	yes	yes	no
57	f	l	no	no	common	yes, M	no	yes	no	no
27	f	l	no	no	common	no, T previous	no, previous P	yes	no	no
59	f	l	no	no	common	yes, T	yes, B + P	yes	no	no

Key: **Age** (years); **Gender** (f – female, m – male); **Side** (r – right, l – left); **Inf** (infection); **Bleeding** (postop bleeding); **Facialis** (yes – facial paresis temporary, no – no facial paresis, M – marginal branch, T – temporal branch, Z – zygomatic branch, previous – paresis due to previous surgery); H**ypesthesiae** (yes – permanent hypesthesia, no – no hypesthesia, P – preauricular, B – mental, previous – hypesthesia due to previous surgery); **Swell** (facial swelling postop); **Swell later on** (temporary swelling of the postoperative side after several months.).

Table 4
Comparison of the patients, condition before and after TMJ TP (n = 12).

	Before*	After*	p**
Opening (mm)	22.0 (15.0–30.0)	37.5 (32.3–41.8)	<0.001
Pain VAS	8.5 (7.3–9.0)	1.0 (0.0–3.0)	<0.001
Opening VAS	9.0 (7.0–10.0)	1.5 (0.0–2.8)	<0.001
Food/Diet VAS	9.0 (7.3–9.0)	1.5 (0.0–3.8)	<0.001
QoL VAS	9.0 (8.0–10.0)	1.0 (0.3–3.0)	<0.001

Key: * median (interquartile range); ** Wilcoxon signed-rank test; VAS – visual analogue scale, 0–10); Qol- Quality of Life. Statistically significant result, P < 0.05.

When inserting a TMJ TP, complications can occur during or after the surgery. During the surgery, the following complications can occur: haemorrhage, nerve injury, and injury of the auditory canal or salivary glands. Endoprostheses that do not fit completely can result in micromotions, which cause complications. Post-operative complications include haematoma, infections, salivary fistula, pain, malocclusions and hypersensitivity reactions (Machon et al., 2012).

Early postoperative swelling was observed in practically every patient included in our study. Additional treatment was not necessary. Several months after the surgery, swelling occurred in 4 patients and resolved spontaneously. In 1 female patient, an infection was noted and successfully treated with antibiotic therapy. Temporary facial paresis was observed in 7 patients, with a maximum duration of 8 months. In most cases, the temporal branch was affected. Paresis can be attributed to

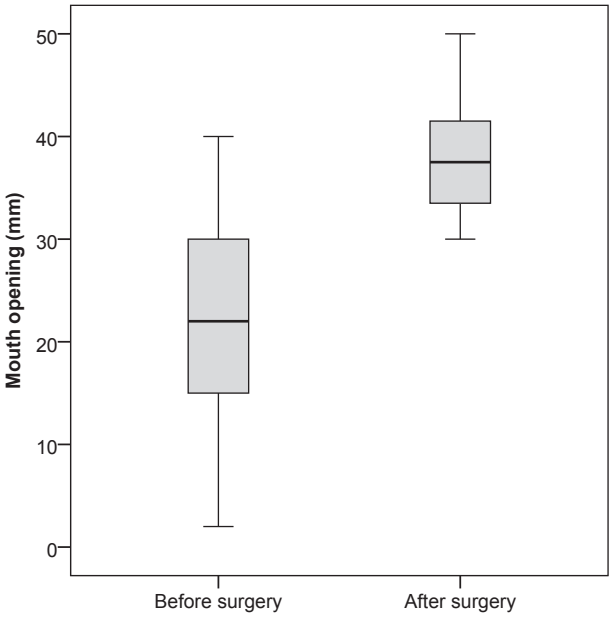

Fig. 1. Mouth opening in patients with the TMJ TP. Key: The chart shows improved mouth opening. Interincisal distance 22.0 (15.0–30.0) (mm) before and interincisal distance 37.5 (32.3–41.8) after surgery. Rectangles show the median and interquartile distance. The upper and lower values are depicted as well.

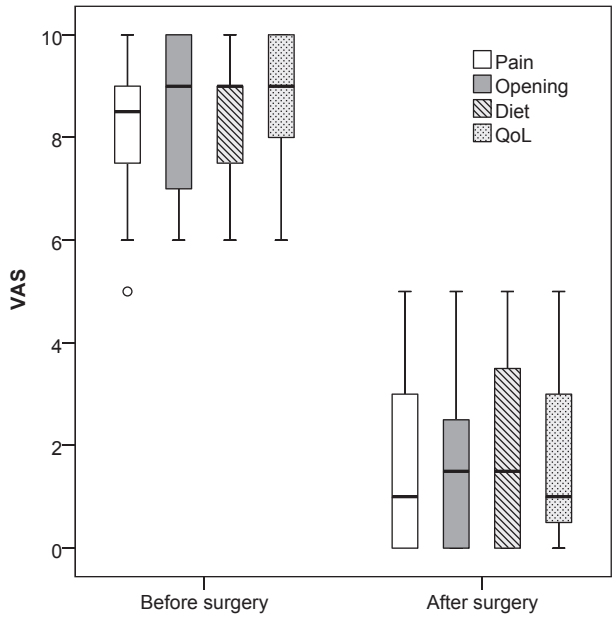

Fig. 2. Pain, mouth opening, diet, quality of life in patients with the inserted TMJ TP. Key: The chart compares subjective variables before and after surgery (VAS scale, 0–10). Assessment of pain intensity decreased from 8.5 (7.3–9.0) to 1.0 (0.0–3.0). Assessment of mouth opening improved from 9.0 (7.0–10.0) to 1.5 (0.0–2.8). Assessment of the ability to chew improved from 9.0 (7.3–9.0) to 1.5 (0.0–3.8). Assessment of the quality of life improved from 9.0 (8.0–10.0) to 1.0 (0.3–3.0). Rectangles show the median and interquartile distance. The upper and lower value are depicted as well.

removing the tissue with the retractor, haematoma, oedema or overly intense electrocoagulations. The incidence is in proportion to the number of previous surgeries (Wolford and Cottrell, 1990). Permanent preauricular hypesthesia was observed in 5 patients. It was a consequence of the auriculotemporal nerve disruption that is necessary if it interferes with our approach to the mandible. A permanent paresthesia around the chin area was reported by 1 female patient, probably due to overly intense electrocoagulations around the mental nerve. Our patients did not state hypoaesthesia as a disturbing factor. Postoperative scars were aesthetically acceptable, as they were well-hidden in skin folds. Other complications were not observed. The long-term results of this study are comparable to the results of other similar studies (Sidebottom and Gruber, 2013; Gonzales-Perez et al., 2015; Giannakopoulis et al., 2012; Leandro et al., 2013).

With the increasing trend of TMJ replacement with the TMJ TP and favourable initial results, a logical next step would be to plan a prospective study featuring additional measurements of propulsion, lateropulsion, deviation, occlusion and function of an unoperated joint (Onoriobe et al., 2016). Treating patients according to their aetiology would deliver more precise data. Based on the described hypersensitivity to cobalt and chromium, preoperative tests seem sensible in order to avoid unnecessary reoperations described in the literature (O'Connor et al., 2016). In addition, further studies will provide answers regarding durability of the TMJ TP.

5. Conclusion

In the light of our initial experience, total replacement of the temporomandibular joint with stock TMJ TP appears to be a safe and efficient treatment method in patients with end-stage TMD. In the future, we will have to analyze the long term postoperative results, and support the research on even better prosthesis design and more durable new materials.

Compliance with ethical standards

The study was approved by the NMEC (Republic of Slovenia National Medical Ethics Committee) on 11.9.2017 (Reference No: 0120–533/2017/3). The patients signed an informed consent.

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Conflicts of interest

The authors declare that they have no conflicts of interest in regard to this work.

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