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Groningen temporomandibular total joint prosthesis: An 8-year longitudinal follow-up on function and pain

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ABSTRACT

Total temporomandibular joint replacement is a surgical procedure for patients with severe temporomandibular joint afflictions affecting quality of life, which have not responded beneficially to previous conventional surgery. The aim of this study was to assess the long-term outcome of the Groningen temporomandibular joint (TMJ) prosthesis in patients with chronic pain and mutilated temporomandibular joints following multiple surgical procedures, with respect to prosthesis failure, the patient's postoperative level of satisfaction and longitudinal changes in maximum mouth opening, functional mandibular impairment and pain. Eight female patients were studied in whom Groningen TMJ prostheses were inserted, two unilaterally and six bilaterally.

The Groningen TMJ prosthesis was mechanically successful during 8 years of follow-up in seven out of eight patients with a disc dislocation being seen in one patient (7%). Patients were satisfied, despite the limited improvement of the maximum mouth opening, and pain scores.

Although the decline of MFIQ scores during 8 years of follow-up was significant compared to baseline ($p = 0.027$), the effects of the prosthesis on maximum mouth opening, function and pain were limited. This may be due to persistent chronic pain and the adverse effects of multiple previous surgical procedures.

1. Introduction

Most temporomandibular joint (TMJ) degenerative diseases are self-limiting. In most cases, the natural course of the disease results in pain reduction and normalization of mandibular function. Non-surgical treatment modalities, such as counselling, physiotherapy, and medication tend to support the reduction of symptoms in the majority of patients (de Bont et al., 1997).

If pain and functional impairment persist and can be attributed to a TMJ abnormality, arthrocentesis or arthroscopic intervention may be considered. There is wide consensus that open-joint surgery should only be considered when previous procedures have been unsuccessful, the pain and function impairment are originating from the joint (Laskin et al., 2006), and are affecting the patient's quality of life. Only a very small group of patients do not benefit from any non-surgical and conventional surgical treatments. For these patients alloplastic total joint replacement may be the only treatment option left (van Loon et al., 2002). Different TMJ prostheses have been described over the years, but all have their limitations (Driemel et al., 2009; Guarda-Nardini et al., 2008b). Owing to the prosthesis design, translatory movements of the condyle are often absent or severely restricted (Mercuri and Anspach, 2003). Stock TMJ prostheses are less expensive, but it is often hard to fit a stock prosthesis into a mutilated joint area with disturbed anatomy (Driemel et al., 2009; Mercuri et al., 1995). Custom-made prostheses based on three-dimensional computerized tomography (3D-CT) solve these fitting problems, but these prostheses are more expensive and require more extensive preoperative planning than stock prostheses (Mercuri and Anspach, 2003). The use of adaptable materials in order to ensure a close fit of the prosthesis to the skull leads to micro-motions between the prosthesis and bone once it has been implanted in

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the body, causing secondary bone resorption (Mercuri et al., 1995; van Loon et al., 1995).

Between 1983 and 1999, the Groningen TMJ prosthesis, originally designed as a stock device, was developed in the laboratory and was subsequently tested in vitro and in vivo (Falkenstrom, 1993; van Loon et al., 1999) (Fig. 1). The opening movements of a natural joint are imitated by an inferiorly located centre of rotation (Falkenstrom, 1993). To optimize the mechanical and wear characteristics, an ultra-high molecular weight polyethylene disc is inserted between the zirconium surface of the cranial prosthesis part and the zirconium ball of the condylar part (van Loon et al., 1999). After thorough in vitro and in vivo testing, use of the device in humans was allowed after approval of the Medical Ethical Committee and after written informed consent (van Loon et al., 2002). The aim of this study was to assess the long-term outcome of the Groningen TMJ prosthesis in patients with chronic pain and mutilated temporomandibular joints due to multiple surgical procedures, with respect to prosthesis failure, and also to assess patients' postoperative satisfaction, changes in maximum mouth opening, mandibular function impairment and pain.

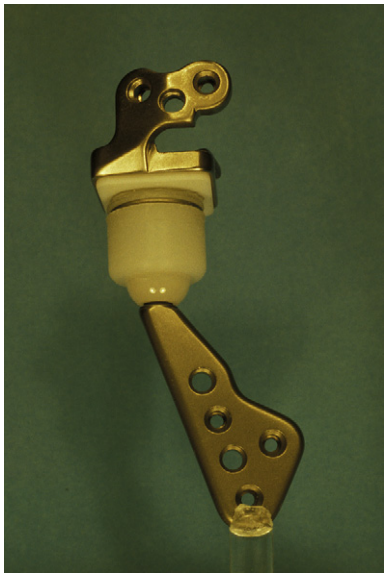

Fig. 1. Groningen TMJ prosthesis consisting of a mandibular part, an intervening disc and a cranial part. The cranial part consists of a fitting member and a basic part. In lateral view.

2. Material and methods

2.1. Patients

All patients who had received a Groningen TMJ prosthesis between 1999 and 2001 were included in this study. Patients who were selected had a history of multiple open surgical TMJ procedures, severe TMJ function impairment, persistent nociceptive and/or neuropathic TMJ pain, and reduced quality of life, but no general health afflictions. No standard psychological testing was performed for inclusion, but counselling was available for all study patients. Patients were required to fulfil these criteria in order to receive approval for this study by the Medical Ethical Committee.

All patients gave written informed consent following explicit information on the unknown short and long-term results regarding pain and mandibular function, following insertion of the Groningen TMJ prosthesis.

2.2. Prosthesis selection

In order to be able to use a stock prosthesis, the amount of bone present at the location of screw fixation was assessed on a stereo lithographic model. The best fitting parts of the stock prosthesis were determined by model surgery performed on the stereo lithographic model. When there appeared to be insufficient bone at the location of screw fixation, a custom-made prosthesis was designed and manufactured.

2.3. Surgical procedure

The implantation procedure was based on open-joint surgery principles, following a pre-auricular approach for insertion of the cranial part, and a retro-mandibular approach for insertion of the mandibular part (van Loon et al., 2002; Ellis and Zide, 2006)(Fig. 2). All patients were operated on by the same team of oral & maxillofacial surgeons (LGMdB, FKLS). No postoperative IMF was applied. Jaw-opening exercises were instituted 1 day postoperatively for 3 months. Standard pain medication was prescribed postoperatively according to the WHO pain ladder (Vargas-Schaffer, 2010).

2.4. Assessments

Prosthesis failure was defined as prosthesis removal/re-operation due to material failure (breakage or particulation) or failure of the prosthetic design (poor fit, loosening, and dislocation). Biological failures (infection or immunologic response) or patient failures (patients requesting removal of the prosthesis without any biological indication) (Mercuri et al., 1995) were not considered as prosthesis failure.

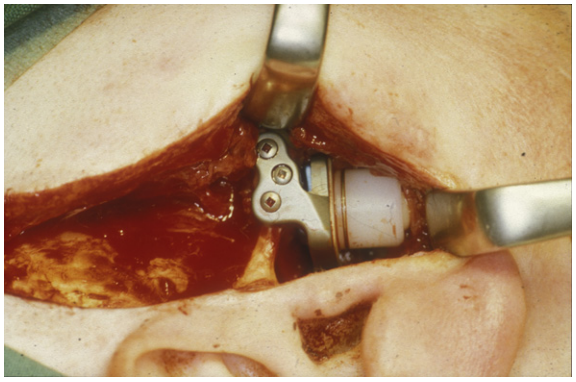

Fig. 2. Preoperative view of the Groningen TMJ prosthesis. A pre-auricular approach is followed for positioning the cranial part. The three screws are placed in the zygomatic arch, and articular eminence area.

Outcomes on patient's satisfaction, maximum mouth opening, mandibular function impairment, and pain were collected by an independent observer. Assessments were performed preoperatively, on the day of hospital discharge, and 6 weeks, 3 and 6 months, 1, 2, and 3 years postoperatively.

Patient satisfaction with the TMJ prosthesis was assessed on a 5-point Likert-scale, 6 weeks postoperatively and at 3 years follow-up.

Maximum mouth opening (MMO) was measured using a vernier caliper. The inter-incisor distance was measured from upper right central incisor to lower right central incisor. The mean of three measurements was used for analysis.

The mandibular function impairment questionnaire' (MFIQ) is a reliable method for assessing the patient's level of function impairment, and was used in this study (Stegenga et al., 1993a,b). A higher score indicates more functional impairment.

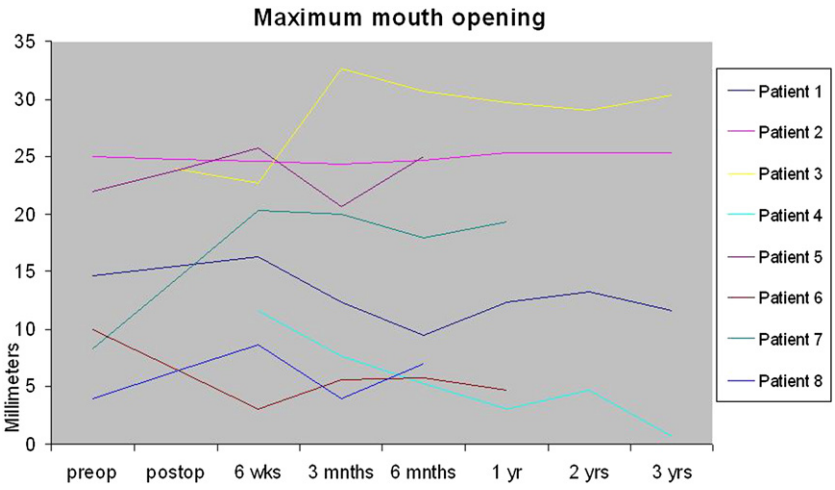

Fig. 3. The maximum mouth opening per patient in time measured preoperatively, 6 weeks, 3 and 6 months, 1 year, 2 and 3 years postoperatively.

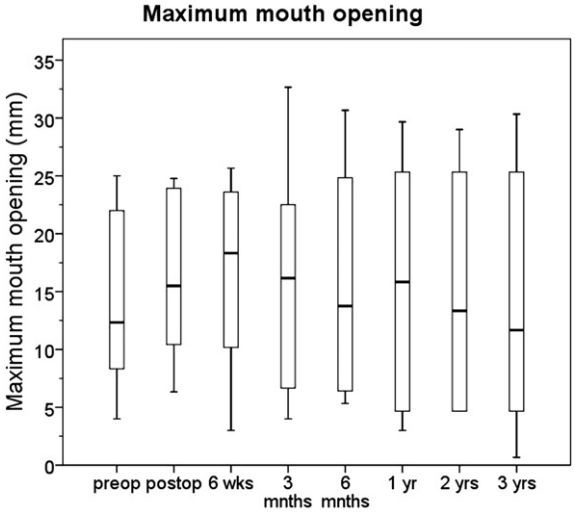

Fig. 4. Box plot of the maximum mouth opening of all patients in time measured preoperatively, 6 weeks, 3 and 6 months, 1 year, 2 and 3 years postoperatively.

Two visual analogue scales (VAS) were used to assess perceived pain: one for pain perceived during the last week before the assessment, and one for current pain at the moment of the assessment.

After 3 years, regular follow-up had ended for most patients. Patients were advised to contact the hospital in case of complaints or problems related to the TMJ prosthesis.

The study patients were contacted by mail and they were requested to fill in the MFIQ and the two VASs for pain at an 8-year follow-up.

2.5. Data analysis

Data were analysed using descriptive statistics and graphs, in SPSS 14.0.1. Missing follow-up data on MMO and VAS were estimated by linear interpolation if data of a previous and a later follow-up were present. The distribution of data, assessed by means of Q–Q plots, appeared to be skewed. Therefore, data are summarized by medians and interquartile ranges. A Wilcoxon signed ranks test was used to test the median difference for MFIQ scores. A p-value ≤ 0.05 is considered to be significant.

3. Results

Between 1999 and 2001, 14 Groningen TMJ prostheses were inserted in eight female patients (two unilateral and six bilateral). The median age of patients at the time of joint replacement was 43 years (39; 52) and the median duration of complaints was 11.5 years (6; 15).

The median preoperative MMO was 12.3 mm (7.3; 22.8). Preoperative data on MFIQ showed a median of 53.5 (47.5; 58). VAS-pain (last week) showed a preoperative median of 7.5 (5.7; 8.5). VAS-pain (current) showed a preoperative median of 8.4 (5.7; 9.2).

In two patients the amount of bone in the zygomatic arch/articular eminence area, and in one patient the amount of bone of the mandibular ascending ramus, was considered inadequate for fixation of the cranial or the mandibular part of the prosthesis. In each of these patients an individual cranial or mandibular part was moulded on the stereo lithographic model and produced in titanium by the manufacturer according to the applicable standards of production.

The median operation time was 3 h per prosthesis (range 2.0–4.5). Initial fixation was uncomplicated for all prosthesis parts. Postoperative recovery was uncomplicated for all patients. One patient with a bilateral prosthesis needed a single sided re-operation for repositioning of a dislocated disc after 5 years of implantation. The reason this occurred is unexplained.

Patient failure was seen in two patients. In one case, the patient could not endure the prostheses in her body and consequently both prostheses were removed (2 years after surgery). The other patient with bilateral prostheses died 1 year after surgery. The cause of death, suicide, was not related to the TMJ prostheses. For follow-up data after 8 years, the remaining six patients returned the questionnaires. Prosthesis failure therefore occurred in one out of 14 prostheses (7%) and patient failure occurred in two out of eight patients (25%).

Six weeks following surgery, four patients reported they were very satisfied and four patients reported being satisfied. At the end of the regular 3-year follow-up patients reported as follows: one patient was very satisfied, four patients were satisfied, and one patient was neither satisfied nor dissatisfied.

Inter-individual and intra-individual differences in MMO during 3 years post surgery are illustrated in Fig. 3. The intra-individual variation in MMO was less than 15 mm. MMO was less than

Table 1
MFIQ scores per patient preoperatively, 6 weeks, 3 and 6 months, 1 year, 2, 3 and 8 years postoperatively.

	Preop	6 weeks	3 months	6 months	1 year	2 years	3 years	8 years
Patient1	54	43	49	46	47	43	48	30
Patient2	53	53	47	29	30		44	40
Patient3	47	42	45	32	36	5	3	43
Patient4	60	42	61	61	61	55	57	57
Patient5	44	52	50	48	54			
Patient6	49	47	46	46	46	46	47	46
Patient7	55	36	47	43	21			51
Patient8	59	53	52	56	64			
Median	53.5	45	48	46	46.5	44.5	47	41.5
IQR[a]25	47.5	42	46.3	34.8	31.5	14.5	23.5	23.3
IQR[a]75	58.0	52.8	51.5	54.0	59.3	52.8	52.5	48.8

[a] IQR = interquartile range.

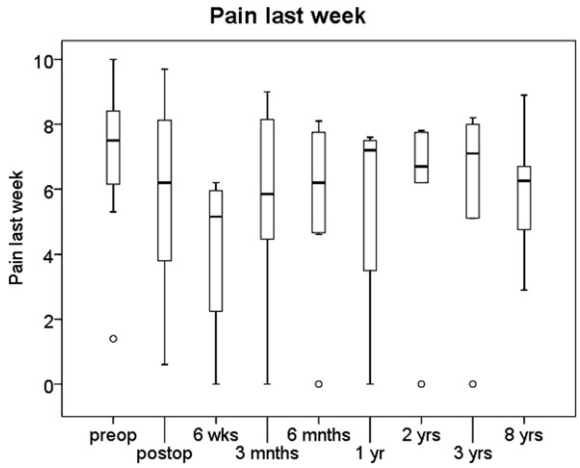

Fig. 5. Box plot of the reported pain during the last week before the assessment measured preoperatively, 6 weeks, 3 and 6 months, 1 year, 2, 3 and 8 years postoperatively. The dot indicates one patient with outlying results.

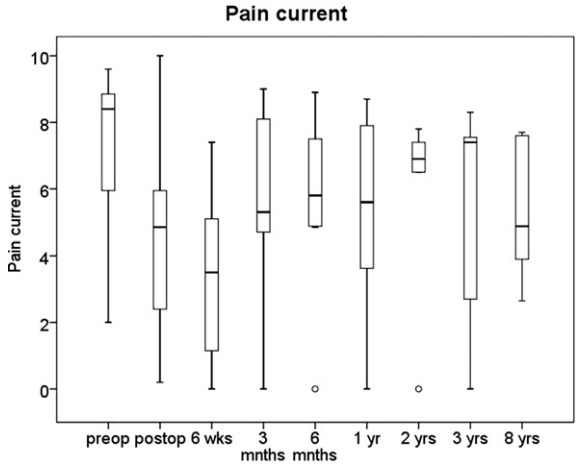

Fig. 6. Box plot of the patient reported pain at the moment of reporting measured preoperatively, 6 weeks, 3 and 6 months, 1 year, 2, 3 and 8 years postoperatively. The dot indicates one patient with outlying results.

35 mm for all patients. In five patients the MMO was smaller than 20 mm during the entire follow-up period. In four patients an initial increase of MMO was seen during the follow-up period. In three patients an initial decrease was seen and in one patient the MMO hardly changed. Fig. 4 shows a postoperative increase of median MMO up until 6 weeks and then a gradual decrease of the median to preoperative level during the 3 years of follow-up.

The MFIQ scores for each patient over time are shown in Table 1.

The decline of MFIQ scores after 8 years of follow-up was significant compared to baseline ($p = 0.027$). The two patients showing an increase in MFIQ scores are the patient who committed suicide and the patient who had her prostheses removed.

VAS-pain (last week) for each patient over time is illustrated in Fig. 5. A decline in median reported pain, during the last week before the assessment, was seen during the first 6 weeks after TMJ prosthesis insertion. One patient remained pain free during 3 years of follow-up. In four patients the postoperative pain during the last week before the assessment remained below preoperative levels.

The results for current pain are similar (Fig. 6).

4. Discussion

The design of the Groningen TMJ prosthesis was based on a stock design, but in three out of eight patients custom-made prosthesis parts were required due to lack of available bone. In contrast to our initial design requirements, this shows the need for a stereo lithographic model for the preoperative planning even when using a stock TMJ prosthesis to prevent failure of the prosthetic design. For that reason the application of a custom CAD/CAM technique, seems to be more appropriate.

The outcome of the custom CAD/CAM total TMJ reconstruction system in 215 patients was assessed by Mercuri et al. (1995). Mean follow-up time was 13.6 months. Ten out of the 215 patients (4.7%) were reported to have had prosthesis failure (nine design failure, one material failure). At a comparable follow-up time the Groningen TMJ prosthesis showed promising results. However, after 5 years of functioning prosthesis failure had occurred in one prosthesis (7%). Revision was needed to reposition a dislocated disc. It is assumed that dislocation of the disc may occur more often in patients with less limited mandibular mobility. Maximum mouth opening of all patients in the study did not exceed 34 mm (Fig. 3). The cause of dislocation may have been due to malpositioning of the mandibular part, in this case too far anteriorly. No prosthesis related infection was found in our study.

Patient failure occurred in two patients, i.e. the patient that could not endure the prostheses in her body and had them removed and the patient who committed suicide. Since no standard psychological testing was done, we cannot comment specifically on the psychological condition of these patients. It has been reported in literature that patients suffering from TMJ dysfunction also suffer from increased somatization, stress, anxiety and depression (Pankhurst, 1997). For future research, we advise psychological testing of patients, keeping in mind that previously psychologically healthy patients may turn into anxious and depressed patients after multiple unsuccessful TMJ operations and suffer from chronic pain for years.

Comparative long-term studies investigating the functional benefits of the various prostheses are scarce (Driemel et al., 2009; Guarda-Nardini et al., 2008a). Varying patient groups and different evaluation methods make it hard to compare them. Despite the fact that we tried to avoid major study flaws, we were only able to include eight patients with an initial follow-up of 3 years on post-operative satisfaction, maximum mouth opening, mandibular function impairment, and pain, and an 8-year follow-up in six patients on mandibular function impairment and pain. All our patients were female, which is confirmed in the literature which reports a higher prevalence of females amongst TMJ dysfunction patients (Kim et al., 2011).

Our patients reported being satisfied 3 years after surgery, as evaluated using a 5-point Likert-scale. No other studies measuring patient's satisfaction were available (Mercuri et al., 1995; Quinn, 2000; Wolford et al., 2003). Treatment satisfaction is influenced by individual patient factors such as expectations, age, preferences, duration of disease, and treatment history (Revicki, 2004). Patients eligible for our study were suffering from chronic nociceptive and/or neuropathic pain, severe TMJ function impairment, and reduced quality of life and were likely to have had high expectations of any new treatment regarding their TMJ complaints. In order to reduce the expectations preoperatively, patients were informed not to expect being pain free or to have normalised mandibular function after surgery.

We were surprised by the positive results of patient satisfaction, despite the poor results on MMO and pain. It can be questioned whether the Groningen TMJ prosthesis has contributed to the patients' postoperative satisfaction. Owing to the lack of a control group or other studies to compare with, this answer remains unknown. We assume that the effort made to thoroughly inform patients what to expect has contributed to the fact that our patients were satisfied after surgery.

In this study, objective functioning of the Groningen TMJ prosthesis was evaluated by measuring the maximum mouth opening. In four patients an initial increase of MMO was seen during the follow-up period. In three patients an unexpected initial decrease was seen, and in one patient the MMO hardly changed. These findings are in contrast with the ability of the Groningen TMJ prosthesis to imitate normal TMJ movement. Its sophisticated design provides freedom of movement. It is based on extensive analysis of normal TMJ movement instead of on a copy of the TMJ X-ray configuration.

In our study, measurements were repeated three times to reduce the SDD to 6 mm (Kropmans et al., 2000). Other studies reported significant improvement on mean MMO, but measurements were not repeated in those studies (Mercuri et al., 1995; Wolford et al., 2003; Chase et al., 1995).

In 2007, Mercuri et al showed that preoperative MMO was a significant predictor of postoperative MMO (Mercuri et al., 2007). For every millimetre in preoperative MMO, an increase of 0.48 mm postoperatively was found. Considering the severely limited preoperative MMO (<25 mm) in five out of eight patients only little improvement was expected in our study group, but improvement of MMO was even less than might be predicted by the findings of Mercuri et al. (2007).

All study patients had degenerative joint disease with chronic pain and a history of multiple surgical interventions, severe TMJ function impairment and reduced quality of life. Two patients seemed to be extremely complicated psychologically, resulting in two patient failures, which is a relatively high percentage. Since TMJ disease history influences the results, we cannot compare our results with any other studies available (Quinn, 2000; Wolford et al., 2003; Chase et al., 1995).

In the literature, a VAS is often used to assess mandibular functioning and diet consistency (Mercuri et al., 1995; Wolford et al., 2003; Chase et al., 1995). For assessing multiple mandibular functions the use of the validated MFIQ is advised. Theoretically, a mechanically successful Groningen TMJ prosthesis, providing patients with more freedom of mandibular movement than their own severely damaged TMJ, could result into an improvement of MFIQ scores. In this study, however, patients showed little improvement of MFIQ scores. Apparently, other factors such as chronic pain influence the patient's mandibular performance strongly.

In this study, pain was evaluated using VAS. Patients showed little improvement in pain. Reliability and validity of VAS for chronic pain measurement has been reported previously (Melzack and Torgerson, 1971).

Mercuri et al evaluated pain using VAS, and found that pain was greatest throughout the follow-up period and showed no improvement or even worsening of the pain postoperatively (Mercuri et al., 1995). Although we found little improvement for pain in some of our patients, the trend that chronic pain patients who underwent multiple surgical interventions hardly showed improvement on subjective and objective measurements (Mercuri et al., 1995) was confirmed by our results.

Other studies showed postoperative improvement in mean pain scores (Quinn, 2000; Wolford et al., 2003; Chase et al., 1995; Westermark, 2010). These results for pain are much more favourable than ours, which might be attributed to the differences in patient's TMJ disease history. The insertion of the Groningen TMJ prosthesis does not seem to be the solution for TMJ afflictions in chronic nociceptive and/or neuropathic pain patients with severe TMJ function impairment and reduced quality of life.

During the first 6 weeks postoperatively, median MFIQ scores and median pain scores decreased while median maximum mouth opening increased. The most likely explanation for the decrease in pain scores immediately after surgery is the use of substantial amounts of analgesics during the days and weeks after surgery. Suppression of pain leads to improved mandibular function resulting in a decrease of MFIQ scores. Other explanations for the improvement in pain are the specific effects of surgery and post-operative discomfort that may have distracted the patient's attention from joint pain. Other studies did not report on an initial positive postoperative effect.

The Groningen TMJ prosthesis is not available on the market. The manufacturer has decided that the financial risks (being sued by patients) were higher than the chance of making a profit, especially in the USA, and therefore they decided not to introduce the prosthesis on the market. The TMJ prosthesis systems currently available (Biomet and TMJ Concepts) have a FDA approval, but their wear characteristics are not superior.

5. Conclusion

In conclusion, the Groningen TMJ prosthesis has proven to be mechanically successful in seven out of eight chronic pain patients with mutilated temporomandibular joints due to multiple surgical interventions. Dislocation of the disc was observed in one out of 14 prostheses (7%) during 8 years of follow-up. Patients were generally satisfied, despite the limited improvement of maximum mouth opening, MFIQ scores and pain. The minimal positive effects on mouth opening and pain are attributed to the fact that the TMJ total joint patients eligible for this study are considered extremely difficult to treat due to chronic neuropathic pain and multiple previous operations.

Ethical approval

Application of the device in patients was allowed after approval of the study design by the Medical Ethical Committee and after written informed consent of the patients.

Funding

None.

Conflict of interest

Some authors (LGMdB, FKLS, BS) were directly involved in the design and development of this device.

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