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Modular endoprosthesis for mandibular body reconstruction: a clinical, micro-CT and histologic evaluation in eight *Macaca fascicularis*

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Abstract. This paper presents the results of an animal experiment, in which a modular endoprosthesis is tested to replace a resected part of the mandible. The prostheses were fixed with polymethacrylate (PMMA) cement into the medullar space of the stumps. Clinical, radiologic, micro-computed tomographic and histologic evaluations were made after 3 and 6 months on four *Macaca fascicularis* for each implantation time. The prosthesis had not loosened but there were some loose screws that had caused fistulas in three animals. The stems of the modules were stably fixed with PMMA cement, surrounded by a fibrous capsule with inflammatory cells. This capsule was thinner in the 6-month group and showed less inflammatory infiltrate compared with the 3-month group; this was not statistically significant. There was an increase in woven bone surrounding the modules after 6 months. After 3 months of implantation, there was a considerable inflammatory reaction in the soft tissues surrounding the module, which subsided over following 3 months. The results are encouraging, but a longer period of follow-up is required to assess its application in a clinical setting, and some design drawbacks need to be addressed.

Keywords: mandibular reconstruction; modular; endoprosthesis; *Macaca fascicularis*.

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The concept of a modular endoprosthesis, fixed with polymethylmethacrylate (PMMA) cement in the medullar space of the mandible, to replace mandibular body segments, has been reported[8,14]. It is based on the use of modular endoprostheses as used in orthopedic surgery[9,11,16]. A modular endoprosthesis for mandibular reconstruction consists of three or more modules, which can be adapted to the size of the defect (Fig. 1). The modules connect both mandibular stumps and have stems that are inserted into the marrow space of the mandible. After fixation of the stems with PMMA cement, the modules

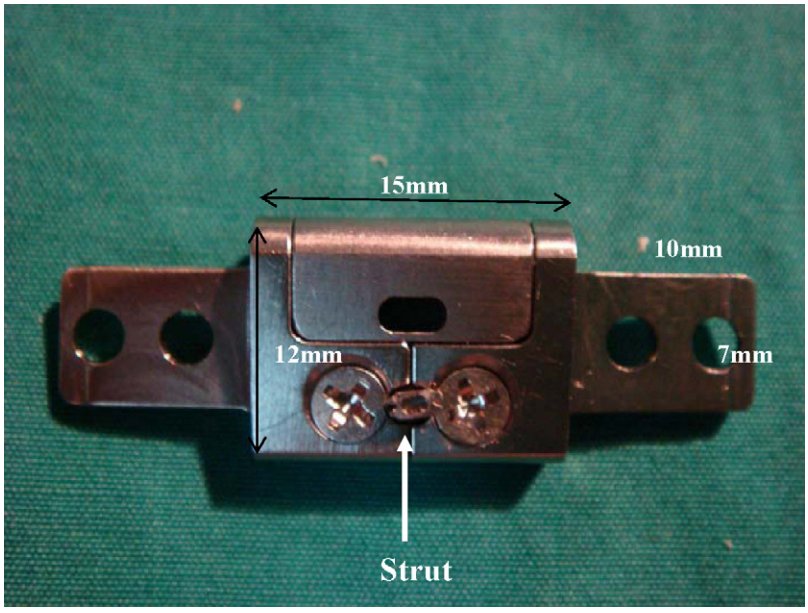

Fig. 1. A modular endoprosthesis with strut.

are tightly connected with a locking system. Using this method, lengthy operation time and hospitalization can be avoided without donor site morbidity. Prosthetic rehabilitation may be less challenging and more cost effective.

Following a preliminary study on the use of a modular endoprosthesis in pigs and monkeys[8], this study presents clinical, micro-computed tomography (micro-CT) and histologic results on 8 *Macaca fascicularis* monkeys. The hypothesis of the current study is that a modular endoprosthesis fixed with PMMA cement in the marrow space of the mandible can be used successfully to reconstruct lost parts of the mandible.

Material and methods

Eight young, adult male *M. fascicularis*, weighing approximately 3.5 kg, were used in this study. The clinical results of the first 4 monkeys were reported in a previous paper[8]. The monkeys had all molars erupted except for the third molars. Permission was granted by the Institutional Animal Care and Use Committee of SingHealth; the animal laboratory has been certified by the International Association for Assessment of Laboratory Animal Care.

The modular endoprostheses were made with the help of skull models as explained in a previous study[8]. They were made of titanium alloy (Ti-6Al-4V) with a dual acid-etched outer surface (Biomet Microfixation, Florida, USA). The height of the body of the endoprosthesis was 70% of the original height of the mandible, the contour of the buccal and lingual side followed exactly the original contour of the resected mandible. The body of the module had a hole to allow for soft tissue ingrowth. The stems were made to fit as closely as possible the marrow space of the mandible. They were rounded off at the ends to prevent shearing forces generated at the stem–cement interface. The body of the implant was 15 mm long and 12 mm high, and the stem was 10 mm long, 7 mm high and 1 mm thick, with two holes to counteract rotational movements (Fig. 1).

The animals were fasted overnight. The monkeys received 0.05 mg/kg atropine s.c. preoperatively and were sedated with 10 mg/kg ketamine s.c. All animals were weighed prior to surgery and hair from the right mandible region was shaved. Induction of anesthesia was performed by a veterinarian using 3% halothane. Endotracheal intubation was then done using a tube with a diameter of 3.5 mm, which was secured around the central incisor with a ligature wire. Anesthesia was maintained with 1–2% isoflurane. On induction, the monkeys were given 2 mg/kg carprofen (Rimadyl®, Pfizer Inc, New York, USA) for analgesia and 5 mg/kg enrofloxacin (Baytril®, Bayer Health Care, Leverkusen, USA) and 15 mg/kg amoxicillin s.c. (Betamox®, Norbrook Pharmaceuticals World Wide, Ireland).

Preoperative lateral radiographs were taken of all animals, positioned consistently with their right mandible facing the plate. The radiographs were taken using a Siemens POLYMOBIL Plus® machine (Siemens Medical Solutions, Erlangen, Germany) set at 40 kV for 2 ms at a distance of 70 cm.

The resection included a segment containing the first and second permanent molars and the attached gingiva. An intraoral approach was used, beginning with two vertical incisions between the second bicuspid and the first molar as well as behind the second molar. A horizontal incision 2–3 mm below the attached gingiva connected the two vertical incisions. The periosteum was reflected to expose the lower border of the mandible and the planned ostectomy sites. A tapered fissure bur was used to perform the resection and the block was subsequently removed. Bleeding from the inferior mandibular canal was stopped easily.

A 12-mm long tapered fissure burr was used to create a space, 9 mm in height and 11 mm in length, to fit the stems. As a rule, the germs of the third molars were visible in the proximal segment, whereas in the distal segment the contour of the apex of the second biscupid was sometimes visible. The modules containing the stems were fit first and fixation was achieved using PMMA cement Palacos® (Biomet, Florida, USA). The body of the endoprosthesis was then connected using two screws. A problem with the device was the loosening of these screws that connected the modules together[8]. This was addressed by placing a strut between the two screws in the subsequent modules used in the last four animals (Fig. 1).

Before the wounds were closed, the crown of the second premolar was cut off and the alveolar process rounded off to avoid dehiscence of the wound in this critical area. The remaining pulp tissue was extirpated without endodontic sealing. The wounds were closed after the cement had set. The full thickness of the buccinator muscle was dissected from the skin over a length of approximately 5 cm. The mylohyoid muscle was dissected free from the aponeurosis to be pulled over the endoprosthesis and tied to the buccinnator muscle with 3–0 Vicryl® sutures (Ethicon INC, a Johnson and Johnson Company, Somerville, NJ, USA). The mucosa was then closed over this muscle with 4–0 interrupted Vicryl® sutures (Ethicon INC, a Johnson and Johnson Company, Somerville, NJ, USA), which resulted in a two-layer closure. Occlusion was checked after extubation. Radiographs were taken immediately of the operated side of the mandible, with the animals in the same position as before.

The monkeys had an uneventful recovery and were put on a soft diet for the first 2 weeks, after which a normal diet of