The Use of Self-Inflating Soft Tissue Expanders Prior to Bone Augmentation of Atrophied Alveolar Ridges

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ABSTRACT

Background: Extensive bone augmentation procedures are frequently performed prior to implant surgery. To achieve tension-free wound closure at the grafted site and thus avoid dehiscence and exposure or total loss of the bone graft, extensive soft tissue mobilization is required. In vitro studies have shown the potential of self-filling osmotic tissue expanders to optimize the amount of resulting soft tissue and vascularization of the recipient site.

Purpose: The purpose of this prospective clinical study was to evaluate the application and complication rate of osmotic hydrogel expanders inserted subperiosteally prior to bone grafting.

Methods: In this prospective observational study, eight patients were implanted with 11 intraoral osmotic hydrogel expanders prior to bone augmentation procedures. All expanders were placed in subperiosteal positions using the tunnel technique. The occurrence of soft tissue–related complications such as necrosis, perforation, infection, or wound dehiscence leading to expander loss was defined as the primary parameter for analysis and evaluation. Further clinical parameters were soft tissue quality and quantity as well as expansion duration.

Results: The expansion time depended upon defect size and expander dimensions. Complications, that is, perforation of the expanders through the oral mucosa, occurred in two patients (3 expanders) who suffered from extreme preoperative scarring in the treated areas owing to prior trauma in one patient and cleft surgery in the other. Patients were grafted with autologous ($n = 7$) or synthetic ($n = 1$) block grafts. The expanders were removed during bone grafting surgery. No further dehiscence occurred during the observation period, and all patients were treated successfully with dental implants and subsequent prosthetic reconstruction.

Conclusions: Within the limits of this observational clinical study, hydrogel expanders may help to generate additional soft tissue, and they might contribute to the overall improvement of the bone augmentation process by reducing the risk of complications related to the lack of soft tissue. Further randomized controlled studies are necessary.

KEY WORDS: alveolar ridge reconstruction, autogenous bone graft, bone augmentation, bone defects, bone grafting, bone resorption, clinical study

INTRODUCTION

In cases involving severe bone defects of the maxilla or the mandible owing to bone atrophy, trauma, or clefts, large-scale bone augmentation procedures are often performed to replace the missing alveolar bone. The dimensions of such defects usually require the use of extraoral donor sites, owing to the limited availability of intraoral bone. Voluminous horizontal or vertical bone grafting with autologous bone blocks, however, can

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make primary tension-free wound closure difficult. The obligatory extensive soft tissue mobilization combined with periosteal releasing incisions can also lead to a decrease in flap vascularization[1] and increase the risk of wound dehiscence and graft exposure, and these problems in turn commonly lead to complete or partial graft loss. Tension of the covering flap, on the other hand, can also lead to graft exposure, resulting in subsequent graft failure. Accordingly, reported complication rates, especially for vertical bone grafting, are usually described as high.[2,3] Roccuzzo and colleagues described a complication rate of 50% among a group of patients treated with vertical bone grafts using autologous bone blocks. Proussaefs and Lozada reported a complication rate of 25% in patients grafted with intraorally harvested autologous bone grafts. In addition, mandatory periosteal releasing incisions often necessitate subsequent soft tissue surgery, such as vestibuloplasty, in order to recreate a normal intraoral soft tissue situation and achieve long-term stability of the peri-implant soft tissue.

The use of osmotic tissue expanders prior to bone grafting could help to improve soft tissue quality and quantity and thus facilitate bone grafting procedures. In vitro studies have demonstrated constant expansion rates, achieving increases of up to 30 times the original size.[4] Subsequent animal studies have demonstrated that self-inflating expanders can create a surplus of soft tissue, facilitating coverage of bone grafts.[5–7] Additionally, a higher microvessel density in the surrounding soft tissue is described, thus promoting faster osseointegration.[7]

The extraoral use of osmotic tissue expanders is well established in plastic surgery.[8,9] Ronert describes 4 years' experience with hydrogel expanders, used in 58 patients, mainly placed prior to breast reconstruction. A success rate of 81.5% was reported. Berge describes a case series of 10 patients treated with hydrogel expanders prior to radial forearm flap harvesting, permitting simultaneous closure of the donor site after flap raising. In contrast, intraoral application has rarely been described in the literature.[10,11] Kaner and Friedmann report a complication rate of 16.6% during the expansion phase using submucosally placed hydrogel expanders.

The aim of this study was to evaluate the application of and complication rate associated with the intraoral use of subperiosteally placed osmotic tissue expanders as a precondition for, and prior to, alveolar ridge reconstruction.

MATERIALS AND METHODS

Patients

This study was performed in accordance with the Declarations of Helsinki, and the study protocol was reviewed and approved by the Ethics Committee for Clinical Studies of the Medical Faculty, University of Heidelberg, Germany, prior to the start of the study. All patients were treated in the Department of Oral and Maxillofacial Surgery, University of Heidelberg.

Inclusion criteria were the following: severe bone atrophy of the maxilla or the mandible, need for an implant-retained rehabilitation requiring vertical or horizontal bone augmentation procedures owing to lack of sufficient residual bone.

Exclusion criteria were the following: patients with systemic diseases such as diabetes mellitus and patients receiving intravenous bisphosphonate therapy or systemic corticosteroid treatment. Additionally, patients with periodontitis or inadequate oral hygiene and patients who had undergone radiotherapy were excluded.

Surgical Procedure

After clinical evaluation, preoperative radiological evaluation was performed using panographs and computed tomography to determine the amount of residual bone and the degree of bone atrophy. Further clinical measurements of the defect site were performed preoperatively to determine the required size and dimensions of the expander.

Hydrogel expanders were fitted under local anesthesia. In the vicinity of the atrophied bone area, a small vertical incision, adapted to the diameter of the hydrogel expander, was placed in a position precluding direct interference with the planned final position of the expander. A subperiosteal tunnel then created a pouch permitting expander placement. The dimensions of the pouch were measured using a surgical template corresponding to the expander volume and dimensions. This template permitted measurements of initial expander volume as well as of its dimensions at the end of the expansion phase.

Self-inflating hydrogel expanders (Tissue Expander Cylinder Dental or Tissue Expander Cupola Dental, Osmed GmbH, Ilmenau, Germany) consist of a methyl methacrylate core and a perforated *N*-vinyl pyrrolidone shell. Five different types and sizes of intraoral hydrogel

expander are available, permitting selection of an appropriate expander for each defect size and form (initial volume before swelling 0.045 mL, 0.05 mL, 0.15 mL, 0.25 mL, and 0.42 mL). The duration of the expansion phase depends on the expander size and varies from 20 to 90 days (final volume after swelling 0.24 mL, 0.35 mL, 0.7 mL, 1.3 mL, and 2.1 mL).

The expanders fitted easily, without tension, into the created pouch and were fixed by the use of an osteosynthesis screw to prevent movement and dislocation during the expansion phase. Suture removal was performed after 10 days; no antibiotics were administered. Patients with removable dentures were instructed not to wear them during the expansion phase.

Any postoperative complications such as expander perforations, wound dehiscence, infection, or pain, as well as soft tissue quality, were documented.

Bone Grafting

At the end of the expansion phase, when the expanders reached their final volume, patients were scheduled for bone grafting (Figures 1 and 2). Patients were treated under either local (patients with intraoral bone grafts or bone substitutes) or general (patients with extraoral donor sites) anesthesia.

After midcrestal incision and reflection of the mucoperiosteal flap, expanders were removed and patients were vertically and/or horizontally grafted with block grafts. Owing to the large amount of bone needed, patients were mainly grafted with autologous bone from extraoral donor sites, with bone from either the iliac crest or the calvaria. Smaller defects were treated with intraoral or synthetic block grafts. Bone grafts were fixed with screws, sharp edges were removed, and the transition zones were filled with bone particulate. Tension-free soft tissue coverage of the graft was achieved, avoiding periosteal releasing incisions whenever possible. Sutures were removed after 10 days. All patients received prophylactic antibiotics.

Implant Therapy

After a 3-month healing period, patients with bone grafts from intraoral donor sites or from the iliac crest were scheduled for implant surgery. Patients grafted with calvarial bone or synthetic bone grafts received implants after 4 months of graft healing.

After crestal incision and elevation of a mucoperiosteal flap, the osteosynthesis screws for graft fixation were removed. Implants (Osseospeed, Astra Tech AB, Mölndal, Sweden) were positioned with the implant necks on a level with the surrounding bone. All implants were fitted in a two-stage approach, with second-stage surgery being performed after 3 months of implant healing.

RESULTS

Patients

All eight patients (three male, five female) included in this study received intraoral osmotic hydrogel expanders prior to bone augmentation procedures. The mean age of the patients was 49 years (range 26–74 years). The lack of sufficient bone to retain dental implants was related to bone atrophy in five patients, owing to trauma in two patients, and owing to a cleft in one patient.

Expander Insertion

Eight patients received 11 intraoral osmotic hydrogel expanders prior to bone augmentation procedures (maxilla 7, mandible 4). Nine of the expanders used were 20×7 mm in size, one was 12×6 mm, and one was 24×10.5 mm. The durations of expansion were 40 days, 20 days, and 90 days, respectively. All expanders were placed in subperiosteal positions using the tunnel technique. The expansion time depended on the defect size and expander dimensions. Complications involving perforation of the expanders through the oral mucosa occurred in two patients (three expanders). Both patients showed severe signs of intraoral scarring before insertion of the expanders in the treated areas owing to prior trauma (one expander) and owing to cleft surgery (two expanders). The expanders were lost after 3 weeks and 5 weeks, respectively. The cleft patient had continued to wear his dental prosthesis despite clear postoperative instructions not to do so after surgery.

The exposed expanders were removed and the soft tissue cavities were cleaned and sutured. After soft tissue healing, bone grafting was performed conventionally in a further procedure with periosteal releasing incisions to achieve sufficient soft tissue coverage of the grafted bone sites.

In the expansion phase, all patients stated that they felt a slight pressure in the treated areas, which was described as not painful.

In patients who experienced uneventful healing and no complications, this technique created an expansion of the vestibular mucosa. The volume gained depended

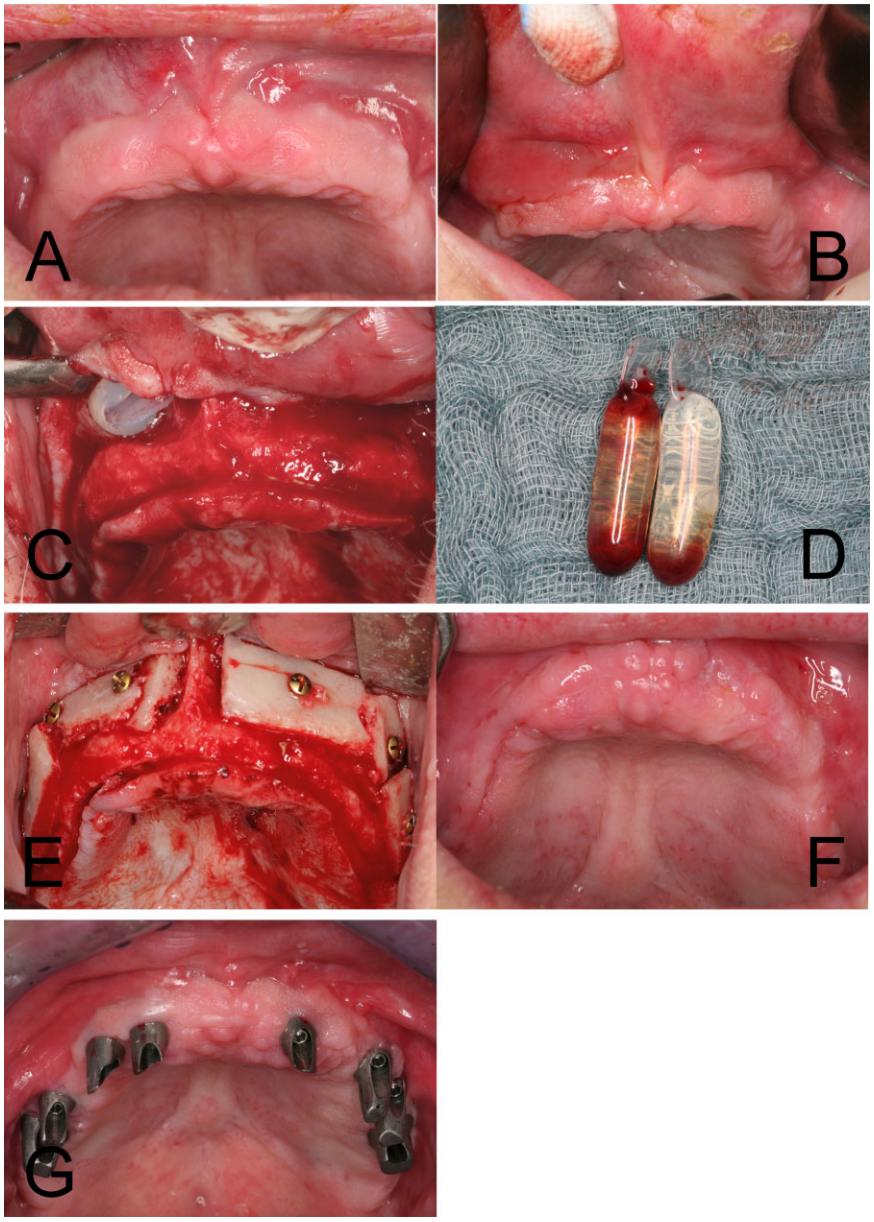

Figure 1 *A*, Clinical situation 1 week after placement of two expanders in the upper maxilla. *B*, Clinical situation after completed expansion phase and prior to bone grafting. *C*, Intraoperative view at expander removal. *D*, Fully expanded hydrogel expanders. *E*, Intraoperative view after lateral bone block grafting with calvarial bone. *F*, Clinical situation 10 days after bone grafting subsequent to suture removal. *G*, Soft tissue prior to cementation of fixed prostheses.

on the final dimensions of the expander. All remaining expanders reached their final size, resulting in a gain of 0.7 mL with six expanders, 0.24 mL with one expander, and 2.1 mL with one expander. The expanded soft tissue was of normal texture, color, and thickness. No signs of inflammation or thinning of the mucosa were visible. No increase in keratinized mucosa was documented after the expansion phase.

Bone Grafting

After the expansion phase, expanders were removed during bone grafting procedures using the same mid-crestal incision as for the simultaneous bone grafting. All expanders were intact and could be completely removed. All were completely surrounded by connective tissue, and no inflammation or granulation was observed in the treated areas. Upon removal, two recipient sites showed

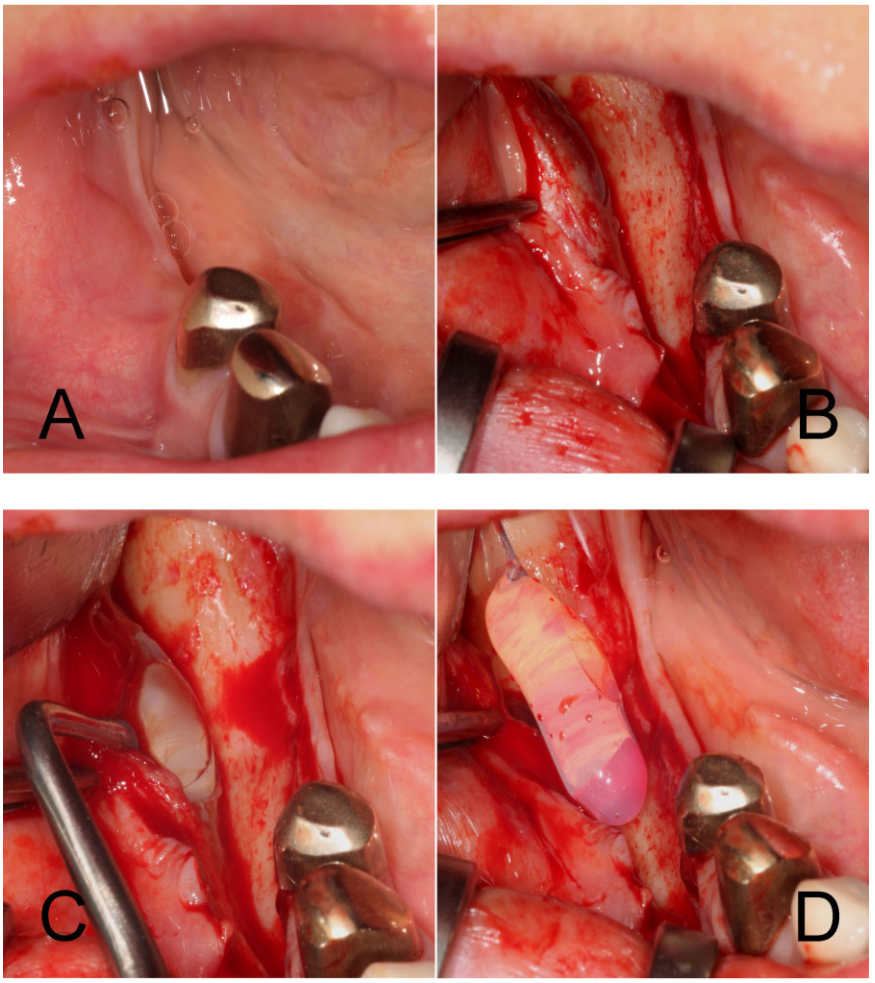

Figure 2 *A*, Clinical situation after expansion. *B* and *C*, Expander fully encapsulated by fibrous tissue at expander removal. *D*, Fully expanded hydrogel expander.

resorption of the underlying bone (Figure 3). In the treated areas, no further periosteal releasing incisions were necessary to achieve tension-free primary wound closure.

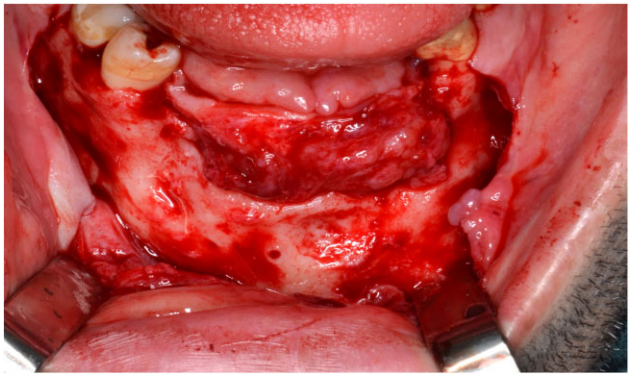

Figure 3 Bone resorption of remaining bone after expander removal and prior to vertical bone grafting.

Of the eight treated patients, five patients received autologous bone from extraoral donor sites (iliac crest 3, calvaria 2), two patients received bone from intraoral donor sites, and one patient received a synthetic block graft. Two patients were treated with vertical block grafts, three patients received horizontal block grafts, and three patients received vertical and horizontal block grafts. Postoperative graft healing was uneventful, with no signs of infection or wound dehiscence.

Implant Treatment

After graft healing all patients were scheduled for implant placement. All patients except one were treated under local anesthesia and received 41 implants in total (maxilla 20 implants, mandible 20). Twenty-eight implants were placed in expanded regions (maxilla 18 implants, mandible 10). According to the success criteria identified by Barone and colleagues,[12] all grafts were

successful at the time of implant placement. No implants had been lost up to the final follow-up. Seven patients received fixed restorations and one patient received a removable restoration.

Soft tissue quantity of all the treated patients had improved, facilitating wound closure. The vestibule could be preserved in all treated patients; however, no increase of keratinized mucosa was achieved. Additional soft tissue surgery in terms of a free gingival graft was necessary in one patient to achieve a stable peri-implant mucosa.

DISCUSSION

Patients with severe bone defects, mainly related to bone atrophy, who desire implant-retained dentures usually need large bone grafts. Extensive grafting procedures, however, require sufficient soft tissue coverage of the underlying bone graft to achieve a successful outcome. Such grafting techniques, especially when involving vertical grafting, are often associated with high complication and failure rates.

Depending upon size and location, some practitioners recommend a more invasive extraoral approach in order to minimize the risk of intraoral dehiscence.[13,14] Others describe the use of free microvascular bone grafts in patients with severe bone atrophy.[15–17] These techniques, however, further increase morbidity and hospitalization of the patient.

In a randomized controlled study in rats, the group with tissue expansion showed increased microvessel density in the tissue above the augmentation material and a more rapid osseointegration 19 days after expander placement.[7] These results suggest that the use of soft tissue expanders may help to reduce morbidity and complication rates for patients. In our trial, however, only 8 out of 11 expanders successfully increased the amount of soft tissue. In the case of three expanders, complications that occurred during wound healing made early expander removal necessary. The affected two patients showed severe fibrous scarring preoperatively in the treated area, causing high pressure at the particular recipient site. Additionally, one patient (two expanders) even continued to wear his prostheses despite clear postoperative instructions, causing exposure of the expander.

It has been reported that the pressure exerted by the expanders results not only in soft tissue expansion but also in resorption of the underlying bone. Among our patients, two showed signs of resorption. One patient had been fitted with a single expander and the other with two expanders, but the latter showed bone resorption on only one side while the other was unaffected. The situation did not cause problems for these patients, as bone grafting had been performed with an adequate amount of extraoral bone.

In the literature, various bone reactions have been described: some authors report signs of resorption,[18,19] others do not,[5,20] while yet others describe a reduction in bone density.[21] In a rat study of 1998, Sato concluded that osteoclastic bone resorption was dependent upon the pressure applied. With a continuous compressive pressure of <1.96 kPa onto the rat palate, no resorption was noticeable, but under a continuous compressive pressure of >6.86 kPa, significant resorption was observed.[22] Wiese describes a maximum expanding force of 32.4 kPa for the expanders; however, the critical pressure for humans is expected to be higher than for rats.[4]

Analysis of our patients showed that despite the increase in the amount of soft tissue formed, no improvement in soft tissue quality could be achieved. The expanded soft tissue was of normal texture, color, and thickness; however, no increase in keratinized mucosa was achieved in any of the observed cases. This issue may be dependent upon the tissue expansion technique. As all expanders were placed on the vestibular site of the maxilla or mandible, no increase in keratinized tissue is to be expected, as the surrounding tissue is mainly mucosa. Further investigations are needed to examine whether it is possible to improve the expansion technique. In one patient, additional soft tissue surgery, in the form of a free gingival graft, became necessary. None of the patients required vestibuloplasty before prosthetic reconstruction.

Another factor to be considered is that the use of soft tissue expanders prolongs the overall treatment time for the patient. Patients with atrophic alveolar ridges need an additional graft healing period of 3 to 4 months on average. The implant healing period, to which a further soft tissue expansion phase of 20 to 90 days is necessarily added, must also be taken into account. This overall period cannot be shortened because faster expansion rates would cause pressure peaks and increase the risk of expander perforation through the oral mucosa. The earlier hydrogel expanders used in animal studies showed a rapid early

expansion shortly after placement. For this reason, a specific outer silicone shell was added that enabled achievement of a slower and more linear expansion than with the expanders without a shell.[5] Uijlenbroek and colleagues also reported that a higher expansion speed allowed the soft tissue less time to adapt, resulting only in a soft tissue expansion and not in increased soft tissue volume.[20]

The use of soft tissue expanders to increase soft tissue is well documented for extraoral use, as in plastic surgery.[9] Hydrogel expanders that do not require external filling through a valve and that do not exert high pressure peaks resulting in hypoxia of the surrounding soft tissue owing to the absence of a filling process were first described by Wiese in 1993.[4] Additionally, with this type of expander there is no risk of external infections through the filling process. Following extraoral applications,[8,9] these expanders are now available for intraoral application, permitting mucosal expansion, as demonstrated in recent animal studies[7,20] and in one study on humans in which expanders were placed in submucosal positions prior to bone grafting.[10]

Various approaches have been described that aim to avoid soft tissue complications associated with primary wound closure after extensive bone augmentation procedures. Some groups report trying to avoid traditional vertical-ridge augmentation techniques by using interpositional bone grafts, allowing for a large contact zone between graft material and residual bone.[23] Because of the high complication rates related to vertical bone augmentations, a recent review even recommends the use of short implants rather than performing vertical bone grafting.[24] While this is a potential option in the nonvisible lateral areas of the jaw, it is not an acceptable option in the anterior region or in cases of severe atrophy. In such cases, bone grafting often remains the only treatment option.

CONCLUSIONS

In cases of severe intraoral bone atrophy where large alveolar ridge reconstructions are indispensable, primary wound closure and undisturbed and uninterrupted wound healing are essential for successful bone grafting. Hydrogel expanders could help to generate additional intraoral soft tissue supporting tension-free primary wound closure and could thus possibly reduce the risk of complications such as graft exposure and wound healing disturbances; however, randomized controlled trials are necessary to confirm the positive results observed in this small-scale study.

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