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Surface replacing arthroplasty of the proximal interphalangeal joint using the CapFlex-PIP implant: a prospective study with 5-year outcomes

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Abstract

The purpose of this prospective study was to evaluate the 5-year outcomes in patients after proximal interphalangeal joint arthroplasty using the surface replacing implant, CapFlex-PIP. Ninety-two prosthesis were implanted and 65 patients with 68 implants were available for follow-up. The brief Michigan Hand Outcomes Questionnaire score improved significantly from 45 (SD 15) before surgery to 71 (SD 17) at 5 years. On the numeric rating scale, pain during activities decreased significantly from 6.4 (SD 1.9) to 1.8 (SD 1.9). Range of motion of the joints increased significantly from 45° (SD 21) to 54° (SD 24). An axis deviation of more than 5° was found in 65% of the joints before surgery, but only in 25% at 5 years. Soft tissue reoperations were performed on eight patients. Four out of 92 implants underwent revision for stiffness or implant loosening. In three implants, the distal component migrated without needing revision. Overall, the CapFlex-PIP implant demonstrates favourable medium-term results in surface replacing arthroplasty of the proximal interphalangeal joint.

Level of evidence: IV

Keywords

Finger joint, finger implant, joint replacement, osteoarthritis, minimal important change, patient acceptable symptom state

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Introduction

For proximal interphalangeal (PIP) joint arthroplasty, silicone implants are considered the gold standard with respect to functional performance, revision rate and long-term outcomes. However, these can be associated with a higher risk of axial finger joint deviation and instability, as compared with other implants (Bales et al., 2014; Forster et al., 2018; Herren, 2017). To overcome these issues, various surface replacing implants have been developed, although the longer-term efficacy of these remain lacking (Herren, 2017). Revision rates ranging between 2% to 18% have been reported depending on the implant material and surgical approach (Forster et al., 2018; Yamamoto et al., 2017).

The CapFlex-PIP (KLS Martin Group, Tuttlingen, Germany) is a modular surface replacing implant, which had shown good short-term functional results with a relatively low complication rate (Bodmer et al., 2020; Schindele et al., 2015). However, the medium- to long-term results remain unavailable.

While clinical outcomes are important in determining implant efficacy, these should be combined with patient-reported outcome measures to define treatment success (Marks and Rodrigues, 2017).

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Two measurable concepts that consider subjective outcomes from the patients' perspectives are the minimal important change (MIC) and patient acceptable symptom state (PASS). The MIC indicates the smallest change in an outcome score that patients perceive as important (Mokkink et al., 2010), and the PASS is the symptom level beyond which patients consider themselves well (Tubach et al., 2005).

The purpose of this prospective study was to evaluate both the medium-term clinical and patient-reported outcomes, as measured by the brief Michigan Hand Outcomes Questionnaire (brief MHQ) of CapFlex-PIP arthroplasty. We hypothesized that patients would achieve a MIC between surgery and final 5-year follow-up and an acceptable symptom state.

Methods

Patients and setting

All patients receiving a PIP joint arthroplasty with the CapFlex-PIP implant are prospectively documented in a single-centre registry using a REDCap (Research Electronic Data Capture) database (Nashville, TN, USA) (Harris et al., 2009). For this analysis, patients who had a primary arthroplasty of the PIP joint between May 2010 and February 2015 and either a clinical 5-year follow-up or who had completed the study questionnaires 5 years after surgery, were included. Patients who did not sign the consent form or had a shorter follow-up were excluded. The data analysis was approved by the local ethics committee and conducted according to the RECORD (REporting of studies Conducted using Observational Routinely-collected health Data) statement (Benchimol et al., 2015).

Intervention

The PIP arthroplasties were performed by a total of four hand surgeons with varying levels of expertise ranging from non-specialists (level 1) to experts (level 5, 91% of the surgeries) based on the definition of Tang and Giddins (2016). Surgery was performed according to the technique as described by Schindele et al. (2015). We used either a volar (Simmen, 1993), dorsal Chamay (Chamay, 1988) or tendon-splitting approach (Schindele et al., 2017; Swanson, 1973), according to surgeon's preference. All patients followed a standardized rehabilitation protocol, which involved 2 weeks of immobilization and thereafter, active mobilization was commenced. After 6 weeks, they were allowed to fully integrate their hand into daily activities.

Outcome measures

The patients were assessed before surgery (i.e. baseline) and at 6 weeks, 3 months, and 1, 2 and 5 years thereafter. At each time point, patients completed a set of questionnaires and underwent clinical assessment by a surgeon, usually the one who operated on the patient. The primary outcome was hand function measured with the brief MHQ, which shows good measurement properties for patients with various hand conditions (Knobloch et al., 2012; Waljee et al., 2011; Wehrli et al., 2016). The score ranged from 0 to 100, with higher scores indicating better hand function. Patients rated their pain at rest and during activities on a numeric rating scale (NRS) from 0 to 10, where 0 indicates no pain and 10 maximum pain. Active flexion and extension of the PIP joint were measured with a goniometer and the total range of motion (ROM) was calculated. One measure of maximum grip strength was done in a standardized sitting position using a Jamar dynamometer (SAEHAN Corporation, Masan, South Korea). Standard anteroposterior and lateral radiographs of the PIP joint were obtained and analysed for radiolucent lines and implant migration. Longitudinal finger axis deviations with the centre at the PIP joint were analysed and classified into three groups: no deviation ($<5^\circ$ deviation of the middle phalanx to the longitudinal finger axis), moderate deviation (5°–15°) or severe deviation ($>15^\circ$).

All complications, reoperations and revision procedures were recorded. 'Reoperations' were defined as any subsequent surgical intervention without alteration of the implant, such as tenolysis or arthrolysis. 'Revisions' were defined as any subsequent surgery with implant modifications, such as implant removal or exchange of one or more components.

Statistical analysis

For descriptive statistics, means and standard deviations (SDs) were calculated. Patients were considered to have achieved a relevant improvement if they exceeded the MIC, which was defined as an improvement of at least 1.2, 2.8 and 18 points for pain at rest, pain during activities and the brief MHQ, respectively. Patients were regarded as being in a PASS if pain at rest, pain during activities and the brief MHQ were better than 1.5, 2.5 and 64, respectively (Marks et al., 2019). Within-group changes over the complete study period were analysed using a mixed-effect linear regression model. Due to missing data for follow-up time points in some patients, parameters were estimated with restricted maximum likelihood using the method of Kenward and Roger (1997). Missing data were not replaced. Differences

between the baseline and 5-year deviation measurements from the longitudinal finger axis were analysed with the Wilcoxon signed-rank test.

A linear regression model was generated to detect if the presence of a radiological sign (i.e. radiolucent lines or implant migration) or a reoperation influences the brief MHQ score. Five-year implant survival was estimated using the Kaplan–Meier method. For any patient, censoring occurred either at the time of revision or at the time of drop-out of the registry due to other reasons, such as participation withdrawal.

Results

Between May 2010 and February 2015, a total of 88 patients received 92 CapFlex-PIP arthroplasties. For the analysis of the 5-year outcomes, data from 65 patients with 68 implants were available (Figure 1). At the time of surgery, these patients were, on average, 65 years old (SD 10), with 41 (63%) females and 24 (37%) males. The reasons for surgery were primary osteoarthritis in 55 patients (83%), secondary osteoarthritis in nine (14%) and rheumatoid arthritis in one (2%). The index finger was operated in 33 cases (49%), the middle in 16 (24%), the ring in 15 (22%) and the little in four (6%). The volar approach was utilized in 30 (44%), the dorsal in 32 (47%) and the tendon splitting approach in six (9%) of cases.

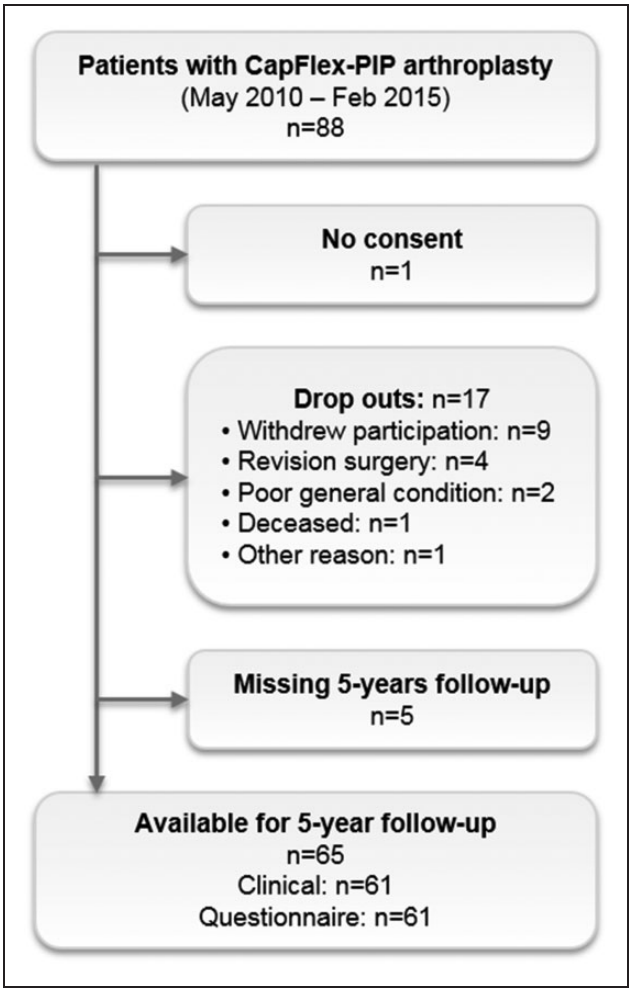

Figure 1. Patient selection flow diagram.

The brief MHQ score increased by 26 points from 45 (SD 15) at baseline to 71 (SD 17) at 5 years ($p < 0.001$; Figure 2(a)). This increase is higher than the defined MIC (18 points) and patients exceeded the PASS threshold, that was defined at a brief MHQ score of 64. Baseline pain at rest (3.5 (SD 2.5)) and during daily activities (6.4 (SD 1.9)) decreased to 1.2 (SD 1.8) and 1.8 (SD 1.9) at 5 years, respectively ($p < 0.001$, Figure 2(b)). Similar to hand function, patients also reached the MIC and PASS for pain at rest and during activities.

Total ROM of the PIP joint (Figure 2(c)) and grip strength of the hand increased from 46° (SD 21) and 19 kg (SD 11) before surgery to 54° (SD 24) and 26 kg (SD 12) at 5 years (both $p < 0.001$).

Radiographic analysis revealed radiolucent lines in eight implants (12%). Radiolucency was found at the proximal component of four implants, at the distal component of another implant and around both components of three further implants. Three events of implant migration of the distal component were observed, each starting after 1, 2 or 5 years, respectively (Figure 3). To date, all these patients did not require subsequent surgery. At baseline, 65% of the fingers had a longitudinal joint axis deviation of more than 5°, whereas only 25% had a residual deviation of more than 5° after 5 years (Table 1; Figure 4; $p < 0.001$). The linear regression model revealed that neither the presence of radiological implant loosening ($p = 0.60$) nor a reoperation ($p = 0.84$) influences the brief MHQ score ($R^2 = 0.01$; $p = 0.85$).

One patient received a steroid injection 12 months after surgery due to persistent swelling around the joint. Eight patients underwent a reoperation involving teno-/arthrolysis/flexor digitorum superficialis tenodesis due to persistent pain, stiffness or swan-neck deformity within the first 5 years (12%). In all these patients, the implants remain in situ and were not removed.

Four of the originally implanted 92 prostheses had to be revised, which resulted in a revision rate of 4.3% for our study cohort. The reason for revision was a stiff PIP joint in two patients, one stiff joint with rupture of the radial collateral ligament and implant loosening in the fourth patient. Revision surgery was performed at a mean time of 32 months (range 17–62) after primary surgery and included

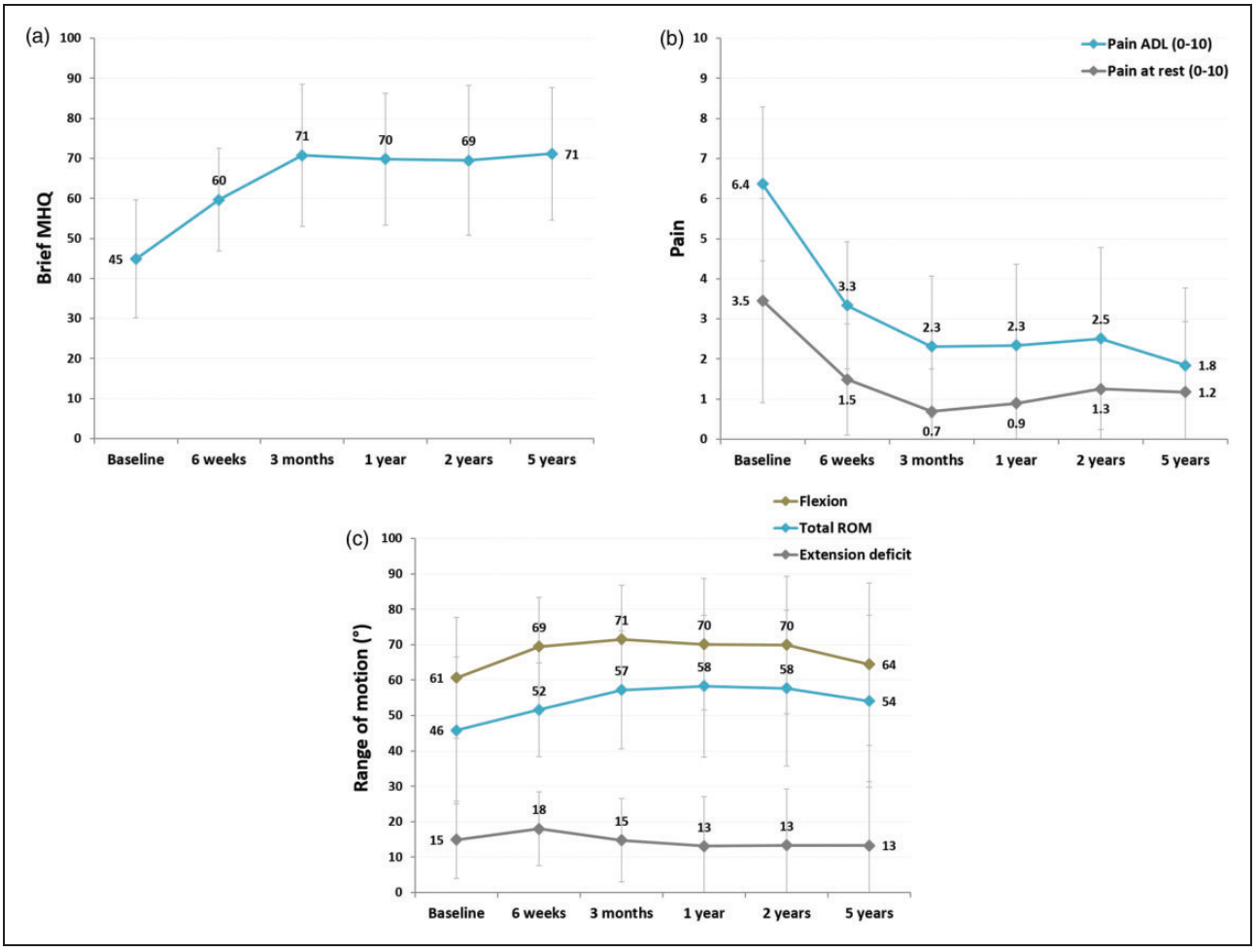

Figure 2. (a) Outcomes for the brief Michigan Hand Outcomes Questionnaire (brief MHQ; score 0–100) over the 5-year postoperative study period. (b) Pain scores at rest and during daily activities (pain ADL; score 0–10) over the 5-year postoperative study period. (c) Total range of motion (ROM), flexion and extension deficit of the affected PIP joint over the 5-year postoperative study period.

two conversions to silicone arthroplasty and arthrodesis in the two other patients. The estimated 5-year survival rate was 87% (95% confidence interval: 57%–97%) (Figure 5).

Discussion

The results of our prospective study revealed favourable outcomes for patients 5 years after CapFlex-PIP arthroplasty. Patients achieved a statistically significant and clinically relevant improvement regarding hand function and pain, as well as an acceptable symptom state. The mean active ROM of 54° at 5 years was similar to the ROM achieved with other PIP joint implants, and deviations from the longitudinal joint axis was significantly improved.

The 5-year brief MHQ score of our cohort of 71 points is comparable with published medium-term MHQ scores for other studies using pyrocarbon PIP surface replacements (Mora et al., 2020; Ono et al., 2012). The observed pain levels at rest and during activities, which significantly decreased to scores of 1.2 and 1.8, respectively, are well within the score range of medium-term residual pain levels (i.e. 0.3 to 1.9) expected for silicone implants (Yamamoto et al., 2017). For pyrocarbon implants, medium-term pain scores of between 1.5 and 3.0 had been reported (Dickson et al., 2015; Sweets and Stern, 2011; Vitale et al., 2015) and for the metal–polyethylene SR-PIP implant (Small Bone Innovations™), a NRS score of 3.0 after 8.8 years was published (Murray et al., 2012). Daecke et al. (2012) also reported NRS scores of 0.5 at rest and 2.7 at maximal load for the same implant. From our study, patient-reported outcomes using the CapFlex-PIP arthroplasty are at least comparable with or superior to

Figure 3. (a) Intraoperative lateral radiograph showing the correct positioning of both CapFlex-PIP surface replacement implant components in the middle finger. (b) A 5-year postoperative lateral radiograph reveals migration of the distal component without signs of loosening.

Table 1. Radiological deviation of the longitudinal PIP joint axis before and 5 years post-surgery.

	Axis deviation		
Timing[a]	<5°	5°–15°	>15°
Baseline	23 (34%)[a]	31 (46%)	13 (19%)
5 years	49 (75%)	14 (22%)	2 (3%)

[a]Sixty-seven and 65 radiographs were available at baseline and the 5-year follow-up, respectively.
Percentages may differ from 100% due to rounding errors.

those using silastic or other surface replacing implants.

The mean ROM of 54° achieved by our patient series falls within the functional ROM of 36° to 86° for the PIP joint (Hume et al., 1990), and is similar to that expected of silicone implants (51° to 58°) (Yamamoto et al., 2017). This outcome also corresponds to the medium- and long-term ROM of other metal–polyethylene implants, which range between

Figure 4. (a) Preoperative anteroposterior radiograph showing an axis deviation of greater than 15° at the index finger. The index finger PIP joint underwent a CapFlex-PIP surface-replacing arthroplasty and the middle finger received a silicone arthroplasty. (b) The radiograph taken at follow-up only reveals minimal residual axis deviation at the index finger fitted with the Cap-Flex implant and considerable deviation at the middle finger with the silicone implant.

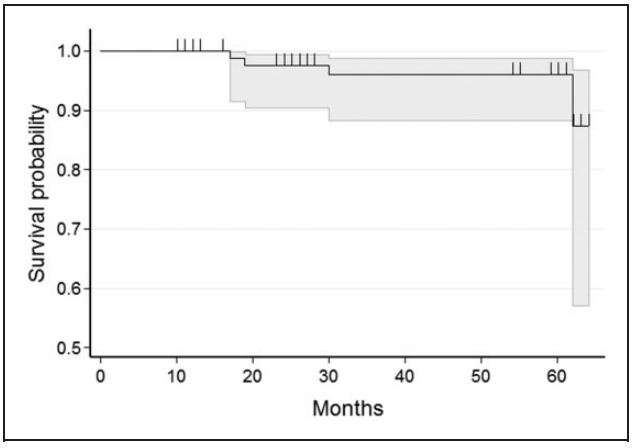

Figure 5. Kaplan–Meier plot showing the estimated 5-year implant survival rate of 87%. The grey area represents the 95% confidence interval (57% to 97%). Vertical marks indicate censored patients, namely patients that completed the study at 5 years or dropped out due to reasons other than revision.

40° and 65° (Daecke et al., 2012; Jennings and Livingstone, 2015; Murray et al., 2012).

Joint stability and coronal plane deformations are known issues associated with silicone implants following PIP joint arthroplasty (Bales et al., 2014; Forster et al., 2018; Takigawa et al., 2004). The supposed improved joint stability offered by

surface replacement is one of the arguments for using these implants over silicone spacers. Minamikawa et al. (1994) examined the lateral stability of the PIP joint in cadavers before and after arthroplasty with either a silicon or surface replacement implant (titanium–polyethylene) and demonstrated that lateral stability with the surface replacement implant was significantly greater as compared with a silicone spacer. A small series analysing PIP joint stability of healthy people in comparison with patients after PIP surface replacements and silicone arthroplasties revealed that the joint surface replacement arthroplasty tended to achieve better anatomical stability compared with flexible silicone implants (Hensler et al., 2020). In accordance with these studies, we also observed that axial deviation from the longitudinal joint axis was significantly reduced with a surface replacement implant. Therefore, the CapFlex-PIP implant might be more suitable than a silicone implant to ensure lateral stability of the PIP joint and to correct malalignment of the joint axis.

While several authors reported an alarmingly high rate of loosening and migration of pyrocarbon and metal–polyethylene implants of up to 72% (Daecke et al., 2006; Dickson et al., 2015; Jennings and Livingstone, 2015; Reissner et al., 2014; Wagner et al., 2018), only one implant in our series had to be revised due to loosening. Osteointegration was investigated during the course of one CapFlex-PIP implant revision; the bone–implant contact value proved to be sufficient and similar to that observed in hip and knee arthroplasties after micro-cut analysis (Schindele et al., 2016). However, eight implants in our patient collective had radiolucent lines and three prostheses migrated from their original positions. In view of the satisfactory clinical results of the affected patients, however, none of them required further revision surgery, although these could potentially pose a problem during longer follow-ups. In our prospective registry, patients are routinely invited for follow-up consultations up to 10 years after surgery and therefore, longer-term outcomes at 10 years should be available at a later stage for this analysis.

Our rate of soft tissue reoperations (12%) is similar to that as reported for other metal–polyethylene implants (Forster et al., 2018). To reduce soft tissue-related complications, we have adjusted our operative approach, using a preferred tendon splitting approach as this tended to result in better outcomes that were associated with fewer complications, as compared with the volar and Chamay approaches (Bodmer et al., 2020). Furthermore, we adapted the postoperative regime and began early active mobilization after the first dressing change 2–3 days post-surgery.

Of the 92 CapFlex-PIP implants recorded in our registry until February 2015, 4.3% of the implants needed revision. This medium-term revision rate is considerably lower than that of pyrocarbon implants, for which rates of up to 14% to 39% had been reported (Daecke et al., 2012; Dickson et al., 2015; Mora et al., 2019; Wagner et al., 2018) and also when compared with other metal–polyethylene implants with revision rates of up to 27% (Daecke et al., 2012; Jennings and Livingstone, 2015; Komatsu et al., 2018; Luther et al., 2010; Murray et al., 2012).

Our study has several limitations: as we analysed data from a registry used for routine clinical documentation, a significant number of patients (23 patients, 26%) were lost to follow-up and eight patients had either missing clinical or questionnaire data at 5 years. Furthermore, no comparison group, for example patients with silicone arthroplasty, was available. The surgeries were performed by four different surgeons and different approaches were used for implantation. Assessments were also carried out by different surgeons. Therefore, variations in the surgical techniques or assessment can potentially influence the outcomes. Future prospective long-term studies should be standardized regarding the surgical approach and examiner, and should include a control group to gain evidence on whether the CapFlex-PIP surface replacing implant yields superior outcomes over other implants. Another limitation was the use of the brief MHQ, which assesses the function of the entire hand. Because patients often have more than one affected finger or joint, the score might be influenced by symptoms stemming from other parts of the hand. Furthermore, only four revisions were included in the estimation of the 5-year survival rate leading to a large confidence interval. The revealed survival rate of 87% could therefore be unreliable and too low, since the Kaplan–Meier method is known to overestimate the risk of implant revisions (Lacny et al., 2015).

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Ethical approval Ethical approval for this data analysis was obtained from the Cantonal Ethics Committee of Zurich, Switzerland (no. 2014-0546).

Informed consent Written informed consent was obtained from all subjects before the study.

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